



2019 Detailed Annual Report



VASCULAR QUALITY INITIATIVE

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1. EXECUTIVE SUMMARY—THE VALUE OF PARTICIPATION IN THE VASCULAR QUALITY INITIATIVE (VQI)

“If you can’t measure it, you can’t improve it.” This management catchphrase has been attributed to Edwards Deming, Peter Drucker, Lord Kelvin and others, but it could serve as the founding principle of the Vascular Quality Initiative. Our mission is to gather data to help hospitals and providers provide better vascular care by assessing their own performance.

VQI’s 12 registries contain demographic, clinical, procedural and outcomes data from more than 600,000 vascular procedures performed nationwide and in Canada, with the addition of Puerto Rico and Singapore this year. Each record includes information from the patient’s initial hospitalization and at one-year follow-up. The wealth of data allows centers and providers to compare their performance to regional and national benchmarks. Each center and provider receive biannual dashboards and regular performance reports, so they can use their data to support 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 VQI data to significantly improve the delivery of vascular care at a local and national level, reducing complications and expenses.

Investigators have used VQI data for risk stratification, outcomes analysis, quality improvement, defining best clinical practices, comparative effectiveness research and improving resource utilization. This work has resulted in more than 225 scientific publications in peer-reviewed journals since 2011. VQI membership also facilitates participation in clinical trials and other medical device evaluation efforts.

The VQI collaborates with multiple organizations, including the American College of Cardiology, Society of Interventional Radiology, American Venous Forum, Society for Vascular Medicine, Vascular Access Society of the Americas, 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 (VQI, NCDR, 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. VQI also works with industry to provide clinically detailed data for device performance, post-market surveillance, and label expansion. 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.



Activities for 2018/2019

1. Center and procedure growth: As of September 2019, VQI had reached two new milestones, with over 600 member centers and more than 600,000 vascular procedures in its registries.

2. Projects and journal articles: In the past year, VQI's Research Advisory Council approved 157 data-analysis projects using VQI data, and 95 articles were published in peer reviewed journals.

3. National quality improvement initiatives: The SVS PSO continues work on two major quality initiatives, working with regional quality groups and centers to develop strategies to 1) increase the prescription of appropriate discharge medications for secondary prevention and 2) increase the use of imaging for long-term follow-up of Endovascular AAA patients.

4. Quality project program: There are 31 VQI centers working on specific quality improvement projects. Results will be presented as posters and abstracts at the VQI@VAM meeting to take place in June 2020.

5. Dashboards and Center Opportunity Profile for Improvement (COPI) reports: The center-level and physician-level dashboard reports are produced quarterly for each VQI registry to report outcomes and provide benchmarks. COPI reports use VQI data to highlight processes of care for improvement.

6. VQI@VAM 2019: Held in Washington, DC, the event was a great success. The SVS PSO hosts this annual meeting in conjunction with the SVS Vascular Annual Meeting. Members present the latest quality activities, including in-depth case reviews, case study presentations, and outcomes analysis as well as presentations from quality experts. VQI@VAM20 will be held in Toronto, Canada on June 15th and June 16th (see VQI website, www.vqi.org, for details).

7. Industry projects: Five post-approval surveillance projects are currently underway in VQI. In addition, the Transcarotid Surveillance Project (TSP) facilitates reimbursement for centers wishing to perform TransCarotid Arterial Revascularization (TCAR). VQI allows data collection for CREST2 participation and works with industry and regulatory agencies in the Registry Assessment of Peripheral Interventional Devices (RAPID) and Superficial Popliteal EvidEnce Development (SPEED) projects.

8. Development: Over the past year SVS PSO has released the new PVI Basic form, which collects 40% less data details than the PVI Comprehensive form to appeal to community-based hospitals and practices. We have also shortened the Varicose Vein Registry Form to decrease data entry burden, and the 30-day data entry forms were added to better document 30-day post-operative outcomes and readmission data. Major clinical changes were made to the Hemodialysis Access registry. The new Venous Stent registry and Vascular Medicine Consult registry will be released in Quarter 4 2019 and Quarter 1 2020 respectively.

9. EU MDR: The European Medical Device Regulation (EU MDR) program has undergone major revision. VQI has supplied data for a number of industry partners to help meet EU MDR requirements.

10. SVS Guidelines: SVS asked VQI to see if registries could be used to document compliance and adoption with AAA guidelines. This was successfully done showing the impact of guideline compliance. A committee led by Dr. Jens Eldrup-Jorgensen is currently reviewing VQI data to support current SVS Claudication Guidelines.

INTRODUCTION TO THE VQI

The Vascular Quality Initiative® (VQI®) is a collaboration of the Society for Vascular Surgery Patient Safety Organization (SVS PSO), 18 regional quality improvement groups organized under the SVS PSO, and Medstreaming/M2S, its commercial technology partner. Other partners include the American Venous Forum (AVF), the Society for Vascular Medicine (SVM), Vascular Access Society of America (VASA) and the Society of Vascular Ultrasound (SVU), along with an additional 16 endorsing societies (see www.vqi.org).

The mission of VQI is to improve the quality, safety, effectiveness and cost of vascular healthcare, by collecting and exchanging information.

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

The SVS PSO is supported by 170 physician volunteers who dedicate their time and effort in support of VQI mission. These physicians provide governance, 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 is funded by annual registry subscription fees from participating hospitals or physician groups, and additional contributions for VQI projects are provided by corporate supporters.



Society for
Vascular Surgery



2. VQI MEMBERS PROFILE

Figure 2.1: Growth of VQI Centers (YTD September 2019)

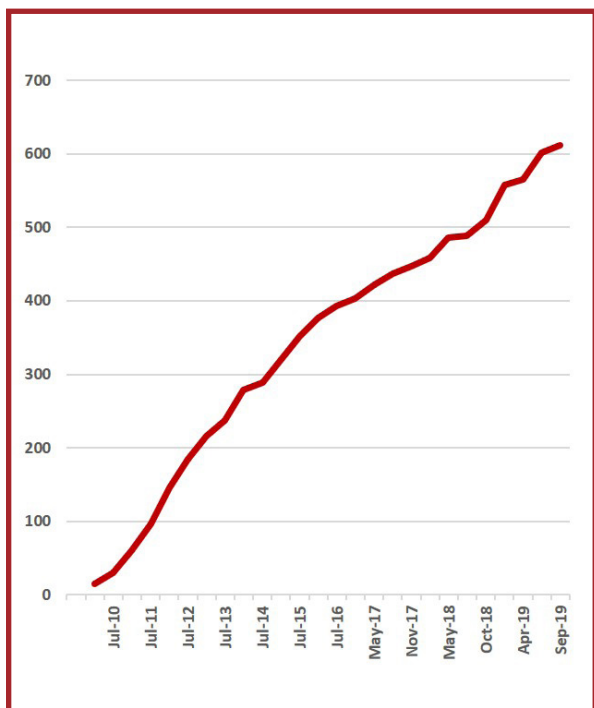


Figure 2.2: VQI Participating Hospital Types

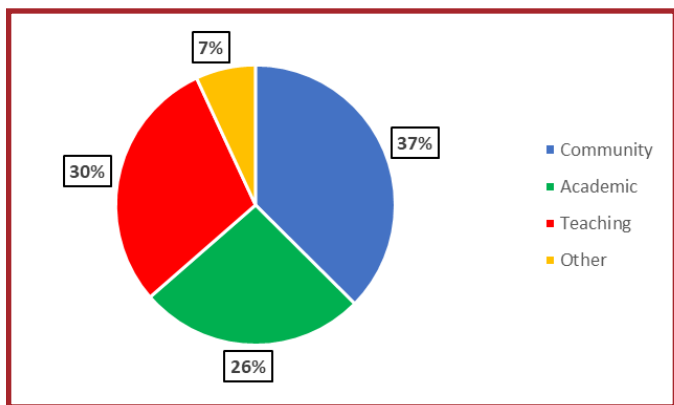
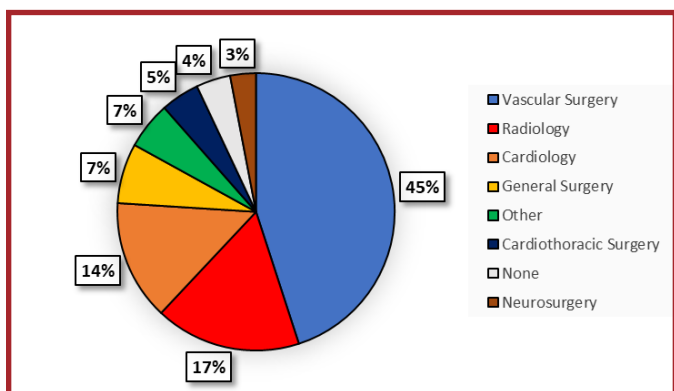


Figure 2.3: Distribution of VQI Physician Specialties



THE VQI REGISTRIES

As of September 2019, there were 12 VQI registries that contained 635,345 vascular procedures. During the past year (October 2018 through September 2019), there were over 110,000 procedures added to the registries.

**Total Procedures
Captured as of 10/1/2019** **635,345**

Peripheral Vascular Intervention	203,623
Carotid Endarterectomy	128,385
Infra-Inguinal Bypass	55,908
Endovascular AAA Repair	51,971
Hemodialysis Access	51,168
Carotid Artery Stent	34,536
Varicose Vein	33,748
Supra-Inguinal Bypass	18,564
Thoracic & Complex EVAR	15,891
Lower Extremity Amputations	15,637
IVC Filter	13,089
Open AAA Repair	12,825

3. OUTCOMES & DATA QUALITY DASHBOARDS

The VQI dashboards allow physicians and centers to review their performance and compare to regional and national benchmarks. The SVS PSO registry committees selected outcome measures to be reported in the dashboards, which are distributed quarterly to VQI members. The dashboards provide each physician his or her individual results, along with results for the physician's center, region and across all VQI. Results that are in the top 25th percentile are highlighted in green and those in the bottom 25th percentile are highlighted in red.

See below for a Sample Best Practices Physician Dashboards for the PVI registry:

Table 3.1: Sample Physician Dashboard, Peripheral Vascular Intervention (PVI) Registry

Peripheral Vascular Intervention (PVI)

Timeframe: January 1-December 31, 2018

Includes elective admissions only

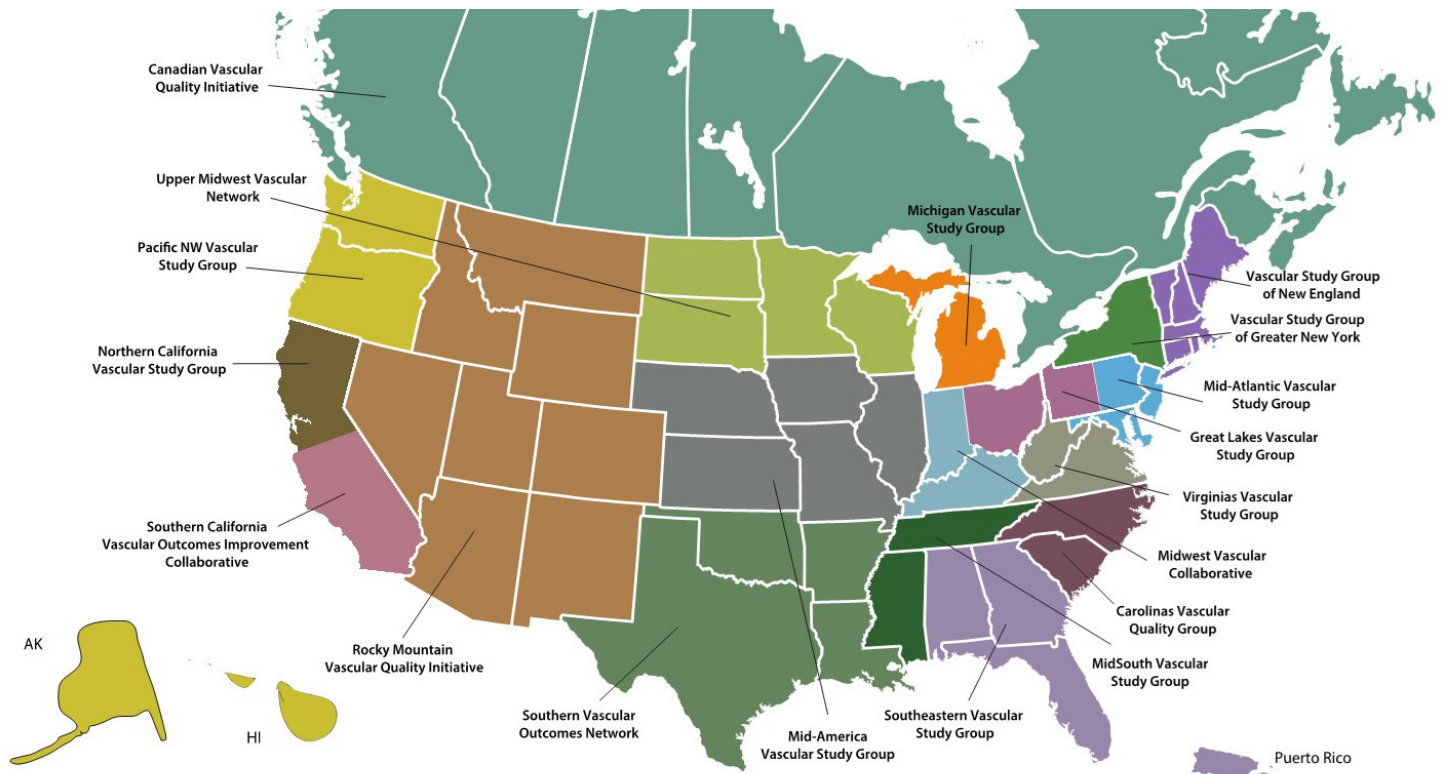
Legend: **Green = Top 25th percentile** **Red = Bottom 25th percentile**

Category	Outcome/Complication	Your Center	Your Region	VQI Overall
Case Data				
	Number of cases reviewed	312	3034	26749
	Median postop LOS (days)	0	0	0
	Median total LOS (days)	0	0	0
Smoking in Claudicants				
	Number of cases	116	1226	12371
	Never	6.9%	10.4%	12.1%
	Prior	62.1%	57.2%	50.1%
	Current	31%	32.4%	37.8%
Preop ABI in Claudicants				
	Preop ABI/Toe Pressure Reported	75%	74.6%	77%
Post op Events				
	MI	0.6%	0.9%	0.4%
	Change in Renal Status	2.9%	1.4%	0.7%
	Thrombosis	0.3%	0.6%	0.5%
	Embolization	0.6%	0.3%	0.6%
	Target Lesion Dissection	1%	1.8%	2.8%
	Artery Perforation	0.3%	0.6%	0.6%
	Access Site Hematoma	6.7%	4.4%	2%
	Access Site Infection	0.3%	0.2%	0%
	Unplanned Amputation	1.6%	1.6%	1.4%
Discharge Medications				
(excludes death in hospital)	Antiplatelet+Statin	92.6%	83.9%	80.2%
Discharge Destination				
	Home	89.7%	87.8%	91.5%
	Rehab Unit	6.1%	7.1%	3.1%
	Nursing Home	3.5%	4.2%	4.4%
	Other Hospital	0%	0.3%	0.5%
	Homeless	0%	0.1%	0.1%
	Dead	0.6%	0.6%	0.4%

4. REGIONAL QUALITY GROUPS

Regional quality groups distinguish VQI from almost all other registries. Each of the 18 groups hold biannual meetings that provide a forum for discussion and work on quality improvement.

Figure 4.1: 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 groups have chosen to focus on include:

- Increased 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
- Increasing statins and antiplatelets at discharge
- In hospital Stroke/Death for CEA and CAS
- Feedback on compliance with SVS EVAR sac size guidelines.

5. QUALITY IMPROVEMENT PROJECTS: LEARNING FROM THE DATA

The QI Community

The SVS PSO encourages centers to submit quality improvement charters on projects using VQI data. This process has helped the SVS PSO identify groups working on similar initiatives and facilitate networking opportunities. All members are encouraged to participate in focused group calls whether or not they have a charter. Also, members who have successfully completed QI projects participate and share their processes and ways they overcame barriers. As the projects reach completion, the SVS PSO will aggregate data and share best practices with the full VQI membership.

The SVS PSO also provides resources to assist VQI centers with their QI projects:

- QI Project Guide and National Initiative Supplement: These booklets provide the foundation and step-by-step guidance to begin and complete a QI project. The QI Project Guide is designed to assist centers that are just beginning a QI project but may be useful at any stage of the QI process. Subsequently, the SVS PSO created a National Initiative Supplement which focused on the progress with the two national QI priorities: Optimal Discharge Medications for Vascular Patients and Endovascular AAA Long-Term Follow-Up with Imaging.
- The “Members Only” area of the VQI website (www.vqi.org) offers access to national QI materials, including presentations and videos, as well as a QI discussion forum to encourage interaction among centers.
- National and regional meetings and quarterly calls help VQI data managers share best practices and QI project ideas.

QUALITY IMPROVEMENT PROJECTS

2019 is the 2nd the year of participating centers submitting QI project charters. The charters include the two national initiatives of D/C Medications and EVAR LTFU Imaging, as well as clinical and documentation topics. Charter projects are listed below:

Table 5.1 – Quality Improvement Projects to Date

TOPICS	PARTICIPATING CENTERS
Discharge Medications (National Initiative)	17
LTFU (including EVAR Imaging, a National Initiative), IVCF Retrieval	9
Clinical	2
Documentation	3
TOTAL	31

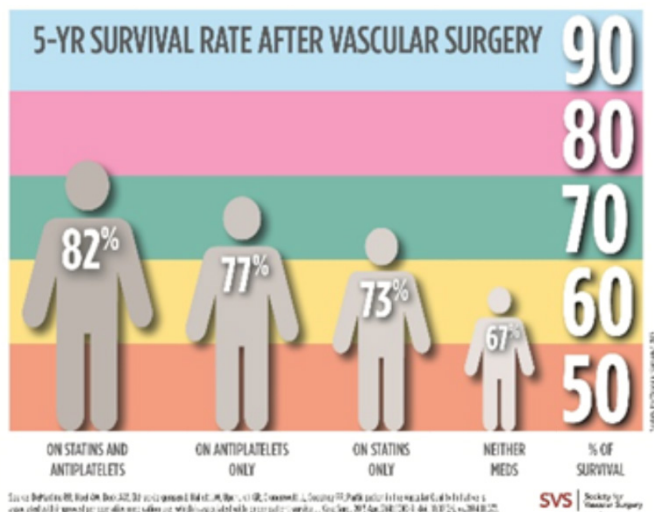
6. NATIONAL QUALITY IMPROVEMENT INITIATIVES—OPTIMAL DISCHARGE MEDICATIONS AND EVAR LONG-TERM FOLLOW-UP IMAGING

Experienced VQI centers have applied registry data and implemented innovative approaches to improve success rates for these initiatives. The SVS PSO seeks to build on these efforts and help these QI initiatives expand from clusters of innovation to coast-to-coast improvements.

Optimal Discharge Medications for Vascular Patients

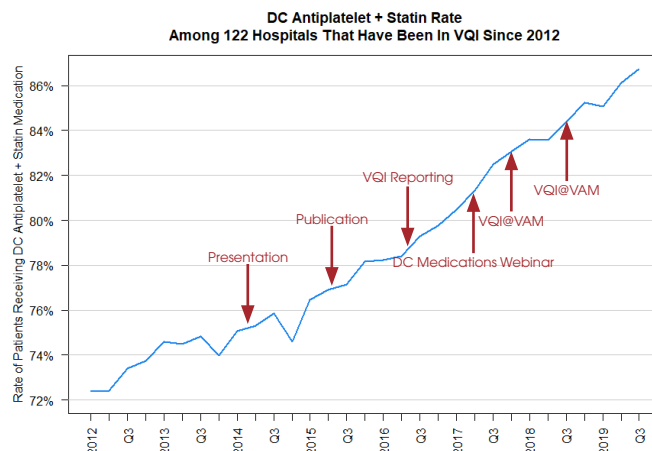
The VQI's first national QI initiative is the prescribing of antiplatelet agents and statins at discharge to improve patients' long-term vascular health. Discharge medications was selected because it is a treatment that affects most vascular surgery patients and is readily actionable.

VQI data has shown that patients undergoing arterial procedures who received a discharge prescription of antiplatelet medications and a statin had significantly better 5-year survival. The VQI provided physicians with individual reports showing their individual prescribing rates for discharge medications and how they compared to their peers. The VQI also disseminated evidence-based information and tools for providers and patients, such as templated communications to primary care physicians, to increase the number of patients receiving optimal medications.



From January 2012 to the present, the prescription of antiplatelets and statins at discharge has risen steadily among VQI members as information about its benefits was disseminated through presentation of the data analysis, publication of the results and sharing of reports with centers and physicians. In addition to the original data analysis and publication led by Randall DeMartino, MD, the SVS PSO added webinars and presentations at the VQI Annual Meeting as part of this National QI Initiative. Individual QI charters and regional presentations continue to reinforce the importance and success of these efforts.

Table 6.1: National QI Dashboard – Discharge Medications



SOURCE: VQI

For example, one participating center used VQI data to show that only 61% of their EVAR patients in 2016 received antiplatelet and statin medications at discharge following a vascular operation. They used a combination of clinical protocols, education and workforce reallocation to increase the rate to 81% in 2017 and 93% in 2018. The SVS PSO is now developing a program designed specifically to help centers with the greatest opportunity for improvement.

EVAR LTFU Imaging

The SVS VQI National Quality Initiative of EVAR LTFU Imaging is in its 5th year. Since EVAR imaging is a long-term follow-up measure, rates are not calculated until two years after the surgery date to allow centers adequate time to capture and enter LTFU. Historically, rates have held nearly constant at 55%. The goal is for 100% of EVAR patients to have imaging at one year. Increased compliance with EVAR LTFU imaging is associated with reduced risk of rupture and improved patient survival.

Many VQI centers are beginning to identify best practices and conduct studies on EVAR LTFU Imaging, but an additional approach needs to take place to reach our goal of 100%. In analyzing data from EVAR LTFU Imaging, the SVS PSO has learned that there are predictive factors in identifying if our patient will return for follow-up. Included in this report are a center's risk factors for not returning for LTFU imaging after EVAR.

VQI Quality Initiative Report

Follow-Up Imaging With AAA Diameter Reported After EVAR (2016 Procedures)

Excludes patients who died within 21 months of surgery. "Imaging" includes CT, CTA, MR, MRA, duplex, and/or angiogram imaging between 9 and 21 months post-surgery, with sac diameter recorded. Time from surgery to imaging=Date of follow-up visit where imaging was recorded - surgery date.

Long-term imaging after EVAR has been an SVS PSO National Quality Initiative for three years, but rates have remained stubbornly low: From 2013 to 2016, respectively, only 54%, 60%, 59% and 60% of EVAR patients received follow-up imaging between 9 and 21 months postop. The goal is for 100% of EVAR patients to have imaging at one year. Increased compliance with EVAR LTFU imaging is associated with reduced risk of rupture and improved patient survival.

Many VQI centers are beginning to identify best practices and conduct studies on EVAR LTFU imaging. To help all centers improve their imaging rates, this report identifies factors associated with loss to follow-up imaging and offers a patient screening tool that might be useful in planning follow-up care.

The table below shows your center's imaging rate for 2016 cases and compares it with your region's rate, the overall VQI rate, and your center's 2015 rate.

Results

Number of 2016 procedures at your center meeting inclusion criteria	36
Number imaged (your center's imaging rate)	32 (89%)
75th percentile for 2016 cases among all VQI centers	79%
Your region's rate for 2016 cases	58%
P-value for comparison of your center's rate to your region's rate	<.01
Overall VQI rate for 2016 cases	60%
P-value for comparison of your center's rate to the overall VQI rate	<.01
Your center's follow-up imaging rate for 2015 cases	76%
P-value for comparison of your center's 2016 rate to its 2015 rate	0.16

The graphic below shows the variation in the rate of follow-up imaging after EVAR among VQI centers. Such variation offers an enormous opportunity for improvement.

Legend: Green: ≤ 25 percentile Red: ≥ 75 percentile

Risk factors for loss to LTFU imaging after EVAR	% with risk factor, 2018 procedures			
	Odds ratio	Your center	Your region	VQI
Age <70 or >79	1.1	57.8%	54.7%	56.7%
Non-white race	1.1	1.6%	5.4%	11.2%
Hispanic ethnicity	1.3	0%	1.9%	3.3%
BMI<24	1.2	20.3%	20%	23.2%
Not discharged home	1.7	4.7%	8.5%	6.1%
Any status, transferred (vs. elective, not trans.)	1.7	14.1%	8.1%	7.9%
Non-elective, not trans. (vs. elective, not trans.)	1.2	1.6%	3.9%	7.1%
Current smoker	1.3	31.2%	32.8%	32.6%
Creatinine>1.8 mg/dL or on dialysis	1.3	6.2%	5%	6.7%
Not living at home	1.3	0%	0.6%	1.3%
No family history of AAA	1.1	92.2%	91.3%	92.9%
No completion endoleak	1.1	85.9%	73.6%	78.1%
Lives >100 miles from home to hospital	1.6	3.1%	1.4%	2.3%
Surgeon has <16 years' experience (vs. 16+ years)	1.1	57.8%	64.7%	53.1%
Frailty index*≥2	1.2	37.5%	38.4%	40.5%

To use the risk score, assign the patient the indicated number of points for each condition listed, then sum the number of points to determine whether the patient is at low, medium or high risk of not being imaged after EVAR. Patients who fall into the moderate or high-risk categories might be noted for special care when planning follow-up.

"Endovascular aortic aneurysm repair (EVAR) is a non-curative treatment of infrarenal abdominal aortic aneurysm disease. When commercially available devices are used within their instructions for use, excellent long-term rupture-free survival can be anticipated. However, due to the persistent presence of the aneurysm and the life-long risk of device related failure and/or endoleak, up to 20% of patients may experience some form of aorta-related re-intervention after EVAR. For this reason, long-term follow-up (LTFU) imaging after EVAR is mandatory, and patients need to be educated about this preoperatively and repeatedly during follow-up. It is the obligation of the operating surgeon to stress the need for life-long imaging surveillance and integrate discussions about LTFU into all stages of AAA EVAR care to ensure that their patients achieve durable outcomes." —Salvatore Scali, MD, Professor of Surgery, University of Florida

—Salvatore Scali, MD, Professor of Surgery, University of Florida

7. VQI DATA ANALYSIS

VQI physicians may request de-identified datasets from each registry for analysis. The SVS PSO Research Advisory Council (RAC) reviews and evaluates requests for datasets by investigators, who provide the RAC a description of their proposed project. These projects have improved clinical care by, for instance, developing practice recommendations for the use of protamine and carotid patching from the Vascular Study Group of New England and for discharge medications from the VQI database. As of the end of September 2019, the RAC has approved 430 projects, and of those, 229 have been published in peer-reviewed journals. In the past year, 157 projects were approved and as of now, 95 have been published.

8. SVS GUIDELINES AND THE VQI

The SVS Document Oversight Committee approached VQI to see if registries could be used to document compliance with SVS AAA guidelines and impact on outcomes. Of the 111 SVS AAA guidelines, 10 could be measured in VQI registries. Compliance with recommendations was associated with improved outcomes and should be encouraged for providers. Participation in the VQI registry provides an objective assessment of performance and compliance with guidelines. VQI provider and center reports may be used as a focus for quality improvement efforts. A manuscript has been accepted by the JVS for publication.

Figure 7.1: VQI Approved Data Analysis Projects

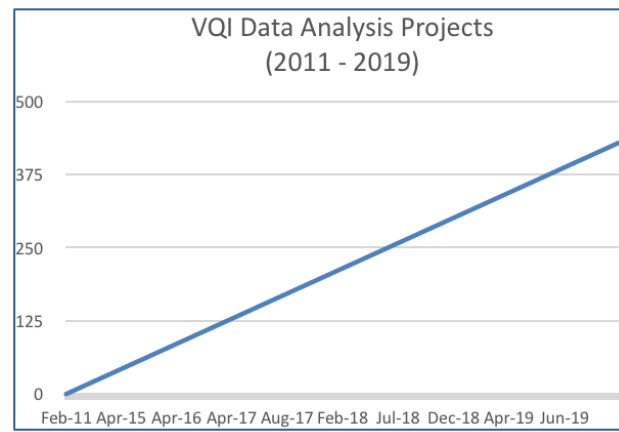
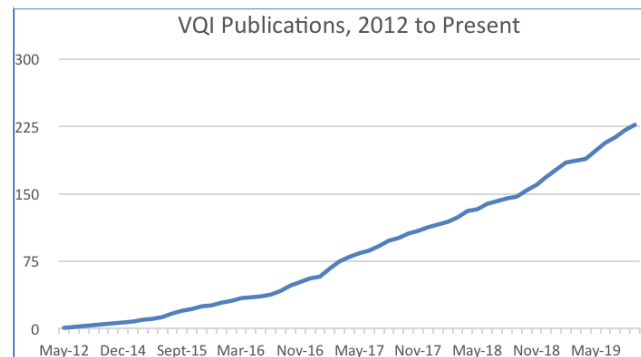


Figure 7.2: VQI Publications



9. PACLITAXEL AND THE VASCULAR COMMUNITY

In December 2018, a meta-analysis published by Katsanos and colleagues identified an association between the use of paclitaxel drug coated balloons (DCB) or drug eluting stents (DES) in the treatment of peripheral arterial disease (PAD) and increased mortality at two and five years after treatment, when compared to patients treated with non paclitaxel-coated or eluting devices. After further investigation of the available data, the FDA advised physicians to inform patients of this reported risk and consider alternatives to paclitaxel devices in the treatment of PAD. The FDA has initiated additional review of the mortality signal and convened an Advisory Panel.

The VQI Peripheral Vascular Intervention registry (PVI) began capturing device identifier information in the fall of 2016 with linkage to the Global Unique Device Identification Database (GUDID). The PVI registry has established a linkage to the Social Security Death Index file in order to ascertain vital status in a longitudinal manner. As such, the VQI-PVI registry may serve as a unique and representative data source for assessing the long-term safety of Paclitaxel DCB and DES.

VQI has developed two proposals to address the paclitaxel mortality signal. VQI VISION proposal 1 is an analysis of mortality of patients with paclitaxel devices leveraging real world evidence from VQI in collaboration with the Vascular Implant and Surveillance Outcomes Network (VISION), Phil Goodney MD, Dartmouth and Art Sedraykan MD, Weill Cornell Medical Center using linkages to claims data allowing retrospective analysis of paclitaxel devices extending the follow up period. VQI DELTA proposal 2 is a retrospective analysis as well as continued surveillance of peripheral paclitaxel coated devices in VQI utilizing Data Extraction and Longitudinal Trend Analysis (DELTA) in collaboration with Fred Resnic, MD, at Lahey Clinic.

10. USING VQI DATA FOR COLLABORATIVE PROJECTS

Medical devices are an integral component of vascular healthcare. 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 labeling indications.

Post-Approval Surveillance Projects

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

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

•Bard LifeStent® Popliteal Artery Stent

Project. A Prospective Registry Surveillance of the clinical use of the Bard® LifeStent® Vascular Stent Systems. The objective of this project is to conduct long term post-market surveillance of the safety and effectiveness of the Bard® LifeStent® Vascular Stent Systems for the treatment of symptomatic de novo or restenotic lesions in the popliteal artery. Enrollment is nearly complete with 64 of the 74 required patients 29 of 30 sites currently in the project.

•Medtronic IN.PACT Admiral DCB ISR

Project. Separate from the expansion of indication project, (see highlighted box right), the objective of this post-market registry surveillance project is to assess the long-term safety and performance of the IN.PACT® Admiral® DCB in a U.S. population for the treatment of ISR lesions in the superficial femoral and popliteal arteries. This project has 263 of the 300 required patients, and 49 of the 50 required sites enrolled.

Medtronic IN.PACT ISR Project

Expansion of Device Indications. Medical devices are approved for specific use cases as outlined in the instructions for use (IFU). However, almost all devices are not infrequently used “off label” for indications not specified in the IFU. Data about such “off-label” use is captured in VQI, offering the potential to provide important information about device performance for non-approved indications. The FDA has indicated that it would consider such data in support of an application for label expansion. Industry projects could combine both historic and prospective VQI data on device performance. This year, VQI demonstrated the ability to supplement already collected procedure and one-year follow-up data with new data added by sites that had performed these procedures, greatly reducing project completion time. Regulators and industry experts see real-world evidence as a critical tool in the future of clinical trials to reduce costs, shorten timelines and improve data accuracy. Real-world evidence is also extremely valuable in the expansion of the indications for use of an approved or cleared device.

Recently, Medtronic realized success in obtaining an expansion of the indication for the IN.PACT Admiral™ paclitaxel-coated percutaneous transluminal angioplasty (PTA) balloon catheter. In 2016, Medtronic used the Society for Vascular Surgery’s Vascular Quality Initiative’s (SVS VQI) data to support the safety and effectiveness of the IN.PACT Admiral drug-coated balloon (DCB) for treating in-stent restenosis (ISR). Medtronic compared data from the ISR cohort of the IN.PACT Global Study with an uncoated PTA ISR group derived from SVS VQI. The IN.PACT Admiral DCB ISR Clinical Evaluation met its success criteria, demonstrating superiority of the DCB ISR Cohort on the 12-month primary effectiveness endpoint of target lesion revascularization.

Using the M2S PATHWAYS platform, SVS VQI data provides flexibility to design new studies, or provide robust mining and tailoring of existing data. With an existing network of over 600 centers and more 600,000 procedures, SVS VQI is uniquely positioned to assist in determining benefits and risks of existing and new devices.

•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. For the Gore and Medtronic cohort, we are currently beginning the 5-year follow-up. This project is re-opening in late 2019 and will include a newly approved Cook Zenith® Dissection Endovascular Stent. TEVAR centers will be invited to participate.

Objective Performance Data

The treatment of infrainguinal occlusive disease is undergoing rapid change with new stents, balloons, and other devices coming on the market with increasing frequency. It has been more than 10 years since the publication of objective performance criteria (OPC) for the treatment of lower extremity occlusive disease. Regulatory approval of new devices often requires comparison with the contemporary performance of existing techniques and devices. OPCs can provide supplemental or historical data for device evaluation in support of approval. VQI is participating in a project to develop contemporary OPCs for the multiple modalities used in the treatment of infrainguinal occlusive disease.

Registry Assessment of Peripheral Interventional Devices (RAPID)

RAPID is a collaboration of professional societies (Society for Vascular Surgery, American College of Cardiology, Society for Interventional Radiology), academia, industry, CMS, private payers and EMRs. The goal is to develop a coordinated registry network (CRN). The FDA, through the Medical Device Epidemiology Network (MDEpiNet), has promoted the concept of CRNs to generate real-world evidence about medical device performance. Data are aggregated from multiple registries to evaluate and monitor endovascular devices and may be used to create an objective performance criterion (OPC). The initial phase (completed) was to develop core data elements and definitions that can be used by all registries and to incorporate unique device identifiers. A registry-based analysis of device performance in the SFA and popliteal artery, Superficial Femoral and Popliteal artery Evidence Development (SPEED), was used to create Objective Performance Criteria (OPC) for infrainguinal occlusive disease. A manuscript has been accepted in *Circulation: Cardiovascular Interventions*.

Transcarotid Artery Revascularization (TCAR) Surveillance Project (TSP)

TSP is a unique effort that allows CMS to reimburse centers performing TCAR based on a national coverage determination. Centers participate in the TSP by entering patients into the VQI registry to allow the SVS PSO to assess the safety and efficacy of TCAR in comparison to the standard treatment, carotid endarterectomy.

To date, more than 292 centers have contributed more than 8,108 TCAR cases to the CAS registry. This represents the largest dataset of information on TCAR procedures.

CREST-2 Registry

This randomized, controlled clinical trial compares CEA and CAS to best medical therapy, and the VQI is one of two registries supporting the trial. Investigators must report their carotid artery stent procedures to be qualified for this trial and then report non-randomized procedures during the trial. This year more than 110 interventionists used VQI to report more than 2,350 CAS procedures for the CREST-2 Registry project. VQI participation in the CREST-2 registry facilitates enrollment and participation by leveraging VQI infrastructure.

Corporate Contributions to Ongoing VQI Programs

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 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 for the past year are listed below:

Quality Champions



Quality Partners



Quality Associates



INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES (ICVR)

The mission of the ICVR is to provide a collaborative platform through which registries and other stakeholders around the world can share data to improve vascular health care. The VQI is participating in this effort, along with Vascunet, a sub-committee of the European Society of Vascular Surgeons, among others. The ICVR will provide:

- **Development and testing of innovative methodological approaches**
- **Forums for discussion, workshops, and conferences**
- **Safety studies, surveillance and comparative outcome evaluation**
- **Collaboration/peer reviewed articles and white papers**

Other participants include national device regulators and medical device manufacturers. Current projects include The Vascular Implant Surveillance and Interventional Outcomes Network (VISION) initiative in the US, which aims to develop a national device surveillance network in the vascular device space. There also are two current ICVR prospective AAA device-performance projects, both of which aim to enroll consecutive patients for two years. An evaluation of treatment of ruptured AAA is under development and has the potential to lead to label expansion. Other projects include management of carotid and lower extremity arterial occlusive disease. For more information on the ICVR, please see <http://www.icvr-initiative.org/>.

11. THE VQI AND COMPLIANCE WITH THE EU MDR

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 approach to medical device regulation.

One of the most important but most challenging requirement of EU MDR is the active Post-Market Clinical Follow-up required to establish safety and performance during the total lifecycle of a device. Manufacturers must report such data to maintain their CE mark for each device by May 2020. Medstreaming/M2S and the 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. VQI collects much relevant data to provide real-world evidence needed to meet the new EU MDR.

“Manufacturers face significant challenges in collecting real-world clinical follow-up data about their devices,” said Jack Cronenwett, MD, CMO Medstreaming/M2S. “In fact, some companies are now considering the need to remove some currently CE-marked devices from the European market if they cannot obtain needed data. We are pleased to have supplied data from the SVS VQI to several manufacturers to help them successfully meet EU MDR requirements. Going forward, we believe that the SVS VQI and other quality improvement registries will be a primary data source to address current and future regulatory challenges faced by device manufacturers world-wide.”

POTENTIAL BENEFITS FROM VQI FOR KEY STAKEHOLDERS

For Patients

- Improved care based on VQI data and quality initiatives
- Using benchmarks and best practices to reduce length of stay
- Improved long-term care through emphasis on follow-up and secondary prevention

For Physicians/Providers

- Developing best practices through VQI data analysis
- Identify meaningful benchmarks for QA and QI efforts
- Improve patient selection using VQI risk assessment calculators

For Policy-Makers

- Improve 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 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
- Implement better data for device monitoring

12. FUTURE DEVELOPMENTS

In 2020, the VQI plans to support improved care and promote patient safety in the following areas:

- Launch and begin enrollment in the Vascular Medicine Consult Registry to collect data on medical (or non-operative) management of peripheral arterial disease due to atherosclerosis, atherosclerotic carotid artery occlusive disease and abdominal aortic aneurysm. This new registry is a collaboration between the SVS PSO, the Society for Vascular Medicine (SVM) and the American Heart Association (AHA) to try to define the natural history and best medical management of patients not requiring an operation.
- Launch and begin enrollment in Venous Stent Registry to collect data on the management and outcomes of venous stents placed for lower extremity venous occlusive disease. This new registry is a collaboration among the SVS PSO, American Venous Forum (AVF) and industry partners with input from the FDA. The SVS PSO is very grateful for the contributions from our industry supporters, which made this development possible.
- Continue to pilot the Vascular Ultrasound Registry, to collect and analyze vascular laboratory data, initially focused on diagnosis and treatment of carotid artery disease. This new registry will match ultrasound images with VQI clinical data in the CEA and CAS registries.
- Infra-Inguinal and Supra-Inguinal registries will be revised in 2020, along with the Open AAA registry.
- Enhanced reporting capabilities with ability to drill down to patient level data will also be released in 2020.
- Explore the addition of variables to help better manage the usage of Opioids in vascular procedures.

The background of the page is a light blue gradient. A thick, dark blue curved line starts from the top left corner and sweeps downwards towards the bottom right, creating a dynamic, abstract shape. The word "APPENDICES" is written in a bold, red, sans-serif font, positioned in the lower right quadrant of the page.

APPENDICES

APPENDIX A— VQI SITES LISTED BY STATE OR PROVINCE (AS OF 10/1/2019)

Abington Memorial Hospital (PA)	Catawba Valley Medical Center (NC)	Harborview Medical Center (WA)
Abrazo Arizona Heart Hospital (AZ)	Catholic Health Initiatives-Iowa Corp. dba	Harlingen Medical Center (TX)
Abrazo Arrowhead Campus (AZ)	MercyOne Des Moines Medical Center (IA)	Harrison Medical Center (WA)
Advanced Vascular Therapy, LLC (OR)	Catholic Health Mercy Hospital of Buffalo (NY)	Hartford Hospital (CT)
AdventHealth Celebration (FL)	Catholic Health Sister of Charity Hospital (NY)	Health Central Hospital (FL)
AdventHealth Orlando (FL)	Catholic Medical Center (NH)	Health Park Medical Center (FL)
Advocate Good Samaritan Hospital (IL)	Cedars-Sinai Medical Center (CA)	HealthPartners, Inc. (MN)
Alamance Regional Medical Center (NC)	Centra Health (Lynchburg General Hospital) (VA)	Heart Hospital of Lafayette (LA)
Albany Vascular Specialist Center (GA)	Central Florida Regional Hospital (FL)	Heart Hospital of New Mexico at Lovelace
Alexian Brothers Medical Center (IL)	Central Maine Medical Center (ME)	Medical Center (NM)
Allegheny Clinic Vascular Surgery (PA)	Charleston Area Medical Center (WV)	Henrico Doctors' Hospital (VA)
Allina- Abbott Northwestern Hospital (MN)	Charlton Memorial Hospital (MA)	Henry County Medical Center (TN)
Allina- Mercy Hospital (MN)	Chester County Hospital (PA)	Henry Ford Allegiance (MI)
Allina- United Hospital (MN)	Cheyenne Regional Medical Center (WY)	Henry Ford Hospital (MI)
Allina- Unity Hospital (MN)	CHI Health Nebraska Heart (NE)	Henry Ford Hospital West Bloomfield (MI)
Altru Health System (ND)	Christiana Care Health System (DE)	Hoag Memorial Hospital Presbyterian (CA)
AMITA Health Adventist Medical Center LaGrange (IL)	Christus Highland Medical Center (LA)	Hoenig Vascular Center (MA)
AnMed Health Medical Center (SC)	Christus St. Michael Hospital (TX)	Holmes Regional Medical Center (FL)
Arizona Endovascular Center (AZ)	CHUM (QC, Canada)	Holy Spirit - Geisinger Affiliate (PA)
Arizona Vascular Specialists (AZ)	CISSEO (QC, Canada)	Horizon Vascular Specialists (MD)
Arnot Health (NY)	CJW Medical - Chippenham Hospital (VA)	Hospital of Central Connecticut (CT)
Asante Rogue Regional Medical Center (Asante Health System) (OR)	CJW Medical - Johnston-Willis Hospital (VA)	Hospital of the University of Pennsylvania (PA)
Associates in Vascular Care (NJ)	Cleveland Clinic, Heart and Vascular Institute (OH)	Houston Methodist St. John Hospital- Clear Lake (TX)
AtlantiCare Regional Medical Center (NJ)	Clinton Memorial Hospital (OH)	Huntington Hospital (CA)
Aultman Hospital (OH)	Coastal Vascular & Interventional, PLLC (FL)	Huntsville Hospital (AL)
Aurora Baycare Medical Center (WI)	Coastal Vein and Vascular Specialists (FL)	Inova Alexandria Hospital (VA)
Aurora Lakeland Medical Center (WI)	Cobb Hospital, Inc. (GA)	Inova Fair Oaks Hospital (VA)
Aurora Medical Center in Kenosha (WI)	Columbia St. Mary - Milwaukee (WI)	Inova Fairfax Hospital (VA)
Aurora Medical Center in Manitowoc County (WI)	Columbia St. Mary - Ozaukee (WI)	Inova Gainesville Hospital (VA)
Aurora Medical Center in Oshkosh (WI)	Columbia Surgical Services, Inc. (MO)	Inova Loudoun Hospital (VA)
Aurora Medical Center in Summit (WI)	Columbia University Irving Medical Center (NY)	Inova Mount Vernon Hospital (VA)
Aurora Medical Center in Washington County (WI)	Columbus Regional Hospital (IN)	Integrus Baptist Medical Center, Inc. (OK)
Aurora Medical Center of Grafton (WI)	Community Hospital East (IN)	Intermountain Medical Center (UT)
Aurora Memorial Hospital of Burlington (WI)	Community Hospital Heart & Vascular (IN)	IU Health- Arnett Hospital (IN)
Aurora Sheboygan Memorial Medical Center (WI)	Community Hospital South (IN)	IU Health- Ball Memorial Hospital (IN)
Aurora Sinai Medical Center (WI)	Concord Hospital (NH)	IU Health- Bloomington Hospital (IN)
Aurora St. Luke's Medical Center (WI)	Cone Health Heart & Vascular Center (NC)	IU Health- Methodist Hospital (IN)
Aurora St. Luke's South Shore (WI)	Confluence Health (WA)	IU Health- Saxony Hospital (IN)
Aurora West Allis Medical Center (WI)	Cookeville Regional Medical Center (TN)	Jersey Shore University Medical Center (NJ)
Avera Heart Hospital of South Dakota (SD)	Cooper University Medical Center (NJ)	John Sealy Hospital, UTMB (TX)
Backus Hospital (CT)	Covenant Healthcare (MI)	John T. Mather Hospital (NY)
Baltimore Washington Medical Center (MD)	Danbury Hospital (CT)	Johns Hopkins Bayview Medical Center (MD)
Banner Desert Medical Center (AZ)	Dartmouth Hitchcock Medical Center (NH)	Kadlec (WA)
Banner Heart Hospital (AZ)	Deborah Heart and Lung Center (NJ)	Kaleida- Buffalo General Hospital (NY)
Baptist Health Louisville (KY)	Decatur Memorial Hospital (IL)	Kansas Heart Hospital (KS)
Baptist Health Madisonville- Jack L. Hamman Heart & Vascular Center (KY)	Deer Valley Medical Center (AZ)	Keck Medical Center of USC (CA)
Baptist Hospital of Miami (FL)	Delray Medical Center, Inc. (FL)	Kennedy University Hospital (NJ)
Baptist Memorial Hospital- Memphis (TN)	Diagnostic Imaging of Milford (CT)	Kennestone Hospital, Inc. (GA)
Barnes Jewish Hospital (MO)	Dixie Regional Medical Center (UT)	KentuckyOne Health- Jewish East (KY)
Baton Rouge General Medical Center (LA)	DLP Conemaugh Memorial Medical Center, LLC (PA)	KentuckyOne Health- Jewish Hospital (KY)
Bayfront Health Seven Rivers (FL)	DMC Harper University Hospital (MI)	King's Daughters Medical Center (KY)
Baylor All Saints Medical Center (TX)	Doylestown Hospital (PA)	Lahey Hospital and Medical Center (MA)
Baylor- Jack and Jane Hamilton Heart and Vascular Hospital (TX)	Dr. P. Phillips Hospital (FL)	Lake Health - West Medical Center (OH)
Baylor Scott & White Medical Center - Irving (TX)	Dr. Ricardo Vasquez, MD (IN)	Lakeland Regional Medical Center (FL)
Baylor- The Heart Hospital Denton (TX)	Duke University Medical Center (NC)	Lakes Region General Hospital (NH)
Baylor- The Heart Hospital Plano (TX)	Eastern Maine Medical Center (ME)	Lakeview Regional Medical Center (LA)
Baylor University Medical Center (TX)	Eisenhower Medical Center (CA)	Lancaster General Hospital (PA)
Bayshore Community Hospital (NJ)	Elkhart General Hospital (IN)	Lee Memorial Health System (Gulf Coast Medical Center) (FL)
Baystate Medical Center (MA)	Elliot Hospital (NH)	Legacy Health (OR)
Beaufort Memorial Hospital (SC)	Emanuel Medical Center (CA)	Lehigh Valley Hospital (PA)
Beaumont Royal Oak Hospital (MI)	Emory Healthcare (GA)	Lenox Hill Hospital (NY)
Beebe Healthcare (DE)	Emory St. Joseph's Hospital (GA)	Lifespan- Rhode Island Hospital (RI)
Berkshire Medical Center (MA)	Englewood Hospital and Medical Center (NJ)	Lifespan- The Miriam Hospital (RI)
Beth Israel Deaconess Medical Center (MA)	Evansville Surgical Associates (IN)	Loma Linda University Medical Center (CA)
Beth Israel Medical Center (NY)	Excelsa Health (PA)	Long Island Jewish Medical Center (NY)
Bethesda North Hospital (OH)	Fairlawn Surgery Center (VA)	Los Robles Hospital & Medical Center (CA)
Borgess Hospital (MI)	Fletcher Allen HealthCare (VT)	Loyola University Medical Center (IL)
Boston Medical Center (MA)	Flint Hills Heart, Vascular, and Vein Clinic, LLC (KS)	Lutheran Hospital of Indiana (IOM Health System) (IN)
Brigham and Women's Hospital (MA)	Florida Hospital Memorial Medical Center (FL)	Lyerly Baptist Neurosurgery (FL)
Bronson Battle Creek Hospital (MI)	Florida Hospital Zephyrhills, Inc. (FL)	MacNeal Hospital (Loyola University Health System) (IL)
Bronson Methodist Hospital (MI)	Floyd Medical Center (GA)	Maimonides Medical Center (NY)
Brookwood Baptist Medical Center (AL)	Forsyth Medical Center (NC)	Maine Medical Center (ME)
Bryan Medical Center (NE)	Fox Valley Surgical Associates Ltd. (WI)	MaineGeneral Medical Center (ME)
BSA Hospital (TX)	Franciscan Alliance, Inc. (IN)	Marietta Memorial Hospital (OH)
Camden Clark Medical Center (WV)	Froedtert Memorial Lutheran Hospital (WI)	Marin General Hospital (CA)
Cape Canaveral Hospital (FL)	Geisinger Community Medical Center (PA)	Martin Medical Center (FL)
Cape Cod Hospital (MA)	Geisinger Medical Center (PA)	Mary Washington Hospital (VA)
Capital Health Medical Center - Hopewell (NJ)	Geisinger Wyoming Valley Medical Center (PA)	Massachusetts General Hospital (MA)
Capital Health Regional Medical Center (NJ)	Gilvady's Vein Clinic (IL)	Matthews Medical Center (NC)
CardioThoracic Vascular Surgeons (TX)	Glens Falls Hospital (NY)	Mayo Clinic Arizona (AZ)
Carilion Roanoke Memorial Hospital (VA)	Good Samaritan Hospital (OH)	Mayo Clinic Florida (FL)
Carle Foundation Hospital (IL)	Goshen Hospital (IN)	Mayo Clinic Health System - Northwest Wisconsin Region, Inc. (WI)
Carolinas Healthcare - Pineville (NC)	Gottlieb Memorial Hospital (IL)	Mayo Clinic Hospital - Rochester (MN)
Carson Tahoe Regional Hospital (NV)	Grady Memorial Hospital (GA)	McKay-Dee Hospital (UT)
	Grey Nuns Hospital (AB, Canada)	McLaren Bay Region (MI)
	Guthrie Clinic (PA)	
	Hackensack University Medical Center (NJ)	

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McLaren Flint (MI)	NWCH - St. Matthews (KY)	Sanford Clinic Vascular Associates (SD)
McLaren Greater Lansing (MI)	NYU Langone Medical Center (NY)	Sanger Heart & Vascular Institute (NC)
McLaren Macomb (MI)	NYU Winthrop Hospital (NY)	Sarasota Memorial Hospital (FL)
McLaren Northern Michigan (MI)	Ocala Regional Medical Center (FL)	Savannah Health Services, LLC d/b/a Memorial
McLeod Regional Medical Center (SC)	Ocean Medical Center (NJ)	Health University Medical Center (GA)
Medical Center Hospital (TX)	Ochsner Medical Center (LA)	Scott & White Memorial Hospital (TX)
Medical City Dallas (TX)	OhioHealth Doctors Hospital (OH)	Scottsdale Osborn Medical Center (AZ)
Medical City Denton (TX)	OhioHealth Dublin Methodist Hospital (OH)	Scripps Green Hospital (CA)
Medical City Fort Worth (TX)	OhioHealth Grady Memorial Hospital (OH)	Scripps Memorial Hospital La Jolla (CA)
Medical City Plano (TX)	OhioHealth Grant Medical Center (OH)	Seattle Vascular Surgery (WA)
Medical Faculty Associates, Inc. (DC)	OhioHealth Mansfield Hospital (OH)	Self Regional Healthcare (SC)
Medical University of South Carolina Hospital (SC)	OhioHealth Marion General Hospital (OH)	Sentara Careplex Hospital (VA)
MedStar Cardiology Associates (MD)	OhioHealth Riverside Methodist Hospital (OH)	Sentara Leigh Hospital (VA)
MedStar Franklin Square Medical Center (MD)	Oklahoma Heart Hospital South, LLC (OK)	Sentara Martha Jefferson (VA)
MedStar Georgetown University Hospital (DC)	Oklahoma Heart Hospital, LLC (OK)	Sentara Norfolk General Hospital (VA)
MedStar Good Samaritan Hospital (MD)	Oklahoma Heart Institute at Hillcrest Medical	Sentara Northern Virginia (VA)
MedStar Harbor Hospital (MD)	Center (OK)	Sentara Obici Hospital (VA)
MedStar Montgomery Medical Center (MD)	Orange Regional Medical Center (NY)	Sentara Princess Anne Hospital (VA)
MedStar Union Memorial Hospital (MD)	Oregon Health & Sciences University (OR)	Sentara RMH Medical Center (VA)
MedStar Washington Hospital Center (DC)	Oregon Vascular Specialists, LLC (OR)	Sentara Virginia Beach General Hospital (VA)
Memorial Hermann Greater Heights Hospital (TX)	Orlando Regional Medical Center (FL)	Sentara Williamsburg Regional Medical Center (VA)
Memorial Hermann Heart & Vascular Institute- Tex	OU Medical Center (OK)	Sequoia Hospital (CA)
as Medical Center (TX)	Our Lady of Lourdes Regional Medical Center, Inc. (LA)	Sharp Grossmont Hospital (CA)
Memorial Hermann Katy Hospital (TX)	Our Lady of the Lake (LA)	Sharp Memorial Hospital (CA)
Memorial Hermann Memorial City Medical Center (TX)	Overlook Hospital (NJ)	SIH - Memorial Hospital of Carbondale (IL)
Memorial Hermann Northeast Hospital (TX)	Palmetto Health Richland (SC)	Singapore General Hospital Pte Ltd (Singapore)
Memorial Hermann Southeast Hospital (TX)	Palo Alto Medical Foundation (CA)	SIU School of Medicine, Memorial Medical Center (IL)
Memorial Hermann Southwest Hospital (TX)	Parkview Medical Center (CO)	South Miami Hospital (FL)
Memorial Hermann Sugar Land (TX)	Penn Presbyterian Medical Center (PA)	South Seminole Hospital (FL)
Memorial Hermann The Woodlands Hospital (TX)	Penn State Milton S. Hershey Medical Center (PA)	Southdale Hospital (MN)
Memorial Hospital at Gulfport (MS)	Pennsylvania Hospital (PA)	Southern Ocean Medical Center (NJ)
Memorial Hospital of South Bend (IN)	Penrose St. Francis Health Services (CO)	Southside Hospital (NY)
Memorial Hospital Pembroke (FL)	Peripheral Vascular Associates (TX)	Southwest Healthcare System (CA)
Memorial Hospital West (FL)	Piedmont Athens Regional Medical Center, Inc. (GA)	Spartanburg Regional Health Services District, Inc. (SC)
Memorial Medical Center (IL)	Piedmont Hospital Atlanta (GA)	Spectrum Health Hospital (MI)
Memorial Regional Hospital (FL)	Pima Vascular (AZ)	SSM DePaul Health Center (MO)
Memorialcare Long Beach Medical Center (CA)	Pinehurst Surgical (NC)	SSM Health St. Louis University Hospital (MO)
Memorialcare Orange Coast Medical Center (CA)	Porter Adventist Hospital (CO)	SSM St. Anthony Hospital (OK)
Memorialcare Saddleback Medical Center (CA)	Portsmouth Regional Hospital (NH)	SSM St. Clare Health Center (MO)
Menorah Medical Center (KS)	Presbyterian Hospital (NM)	SSM St. Joseph Health Center (MO)
Mercy Hospital Springfield (MO)	Presbyterian Medical Center (NC)	SSM St. Mary's Health Center (MO)
Mercy Hospital St. Louis (MO)	Presbyterian St. Luke's Medical Center (CO)	St. Anthony Lakewood (Centura Health
Mercy Medical Center (OH) (OH)	Prime Healthcare Foundation - Southern Regional	Corporation) (CO)
Mercy Medical Center- Baltimore (MD)	Medical Center (GA)	St. Anthony Medical Center (CHI Franciscan
MercyOne Siouxsland Medical Center (IA)	ProHealth Care (WI)	Health) (WA)
Methodist Dallas Medical Center (TX)	ProMedica Toledo Hospital, Jobst Vascular (OH)	St. Anthony's Hospital (BayCare Health System) (FL)
Miami Vein Center (FL)	Providence Alaska Medical Center (AK)	St. Anthony's Medical Center (MO)
Michigan Vascular Center (MI)	Providence Holy Cross Medical Center (CA)	St. Charles Health System, Inc. (OR)
Middlesex Hospital (CT)	Providence Holy Family Hospital (WA)	St. Charles Hospital (NY)
Midland Memorial Hospital (TX)	Providence Hospital (AL)	St. Clair Hospital (PA)
Midwest Institute Minimally Invasive Therapies (IL)	Providence Little Company of Mary, Torrance (CA)	St. Elizabeth's Medical Center (MA)
Midwest Physician Alliance (IL)	Providence Medford Medical Center (OR)	St. Francis Heart Center (IN)
Mission Hospital (NC)	Providence Portland Medical Center (OR)	St. Francis Medical Center (CHI Franciscan Health) (WA)
Mobile Infirmary (AL)	Providence Regional Medical Center (WA)	St. John's Health Center (CA)
Montefiore Medical Center (NY)	Providence Sacred Heart Medical Center (WA)	St. Joseph Medical Center (MO)
Morton Plant Hospital (FL)	Providence Saint Joseph Medical Center (CA)	St. Joseph Medical Center (IL)
Mount Sinai Hospital (NY)	Providence St. Mary Medical Center (WA)	St. Joseph Medical Center (WA)
Mount Sinai Medical Center (FL)	Providence St. Peter Hospital (WA)	St. Joseph Mercy Health System (MI)
MultiCare Deaconess Hospital (WA)	Providence St. Vincent Medical Center (OR)	St. Joseph's Medical Center of Stockton (Dignity
MultiCare Good Samaritan Hospital (WA)	Providence Tarzana Medical Center (CA)	Health) (CA)
MultiCare Tacoma General Hospital (WA)	Radiology Associates - Fox Valley (WI)	St. Luke's Campus (NY)
Nashville Vascular & Vein Institute (TN)	Redmond Regional Medical Center (GA)	St. Luke's Healthcare- St. Luke's Regional Medical
Nebraska Medical Center (NE)	Regents of the University of New Mexico (NM)	Center (ID)
Nebraska Methodist Hospital (NE)	Regional Medical Center of Orangeburg &	St. Luke's Hospital (MN)
New Hanover Regional Medical Center (NC)	Calhoun Co (SC)	St. Luke's Hospital - Allentown Campus (PA)
New York-Presbyterian/Brooklyn Methodist (NY)	Rex Hospital, Inc. (NC)	St. Luke's Hospital - Anderson Campus (PA)
New York-Presbyterian/Queens (NY)	Riverview Medical Center (NJ)	St. Luke's Hospital - Bethlehem Campus (PA)
Newark Beth Israel Medical Center (NJ)	Roper St. Francis Hospital (SC)	St. Luke's Hospital - Monroe Campus (PA)
North Florida Regional Medical Center (FL)	Rose Medical Center (CO)	St. Luke's Hospital - Quakertown Campus (PA)
North Memorial Health Hospital (MN)	Rush Foundation Hospital (MS)	St. Luke's Hospital - Warren Campus (NJ)
North Okaloosa Medical Center (FL)	Russell C. Lam MD PA (TX)	St. Luke's Hospital (MA)
North Shore University Hospital (NY)	Rutgers Robert Wood Johnson Medical School (NJ)	St. Luke's Hospital (MO)
Northeast Georgia Medical Center (GA)	Saint Anthony Medical Center (IL)	St. Luke's Methodist Hospital (IA)
Northeast Methodist Hospital (TX)	Saint Barnabas Medical Center (NJ)	St. Luke's Roosevelt Hospital Center (NY)
NorthShore Skokie Hospital (IL)	Saint Francis Hospital and Medical Center (CT)	St. Mary Corwin Medical Center (CO)
Northside Hospital Atlanta (GA)	Saint Francis Medical Center (IL)	St. Mary Medical Center (PA)
Northside Hospital Cherokee (GA)	Saint Francis Medical Center (MO)	St. Mary's Hospital (CO)
Northside Hospital Forsyth (GA)	Saint Joseph Hospital (CO)	St. Mary's Hospital (WI)
Northwest Hospital & Medical Center (WA)	Saint Joseph Hospital (KY)	St. Mary's Medical Center (WV)
Northwestern Medicine Central DuPage Hospital (IL)	Saint Joseph Regional Medical Center (IN)	St. Patrick Hospital (MT)
Northwestern Memorial Hospital (IL)	Saint Luke's Hospital of Kansas City (MO)	St. Peter's Hospital (NY)
Norton - Audubon (KY)	Saint Luke's Memorial Hospital, Inc. (PR)	St. Vincent Healthcare (MT)
Norton - Brownsboro (KY)	Saint Thomas Midtown Hospital (TN)	St. Vincent Heart Center of Indiana, LLC (IN)
Norton Healthcare, Inc. - Norton - Downtown (KY)	Saint Thomas Rutherford Hospital (TN)	St. Vincent Hospital & Healthcare Center (IN)
Norwalk Hospital (CT)	Saint Thomas West Hospital (TN)	Stanford Hospital & Clinics (CA)
Nova Scotia Health Authority (Canada)	Salem Health (OR)	Staten Island Hospital- North Site (NY)
	San Diego Vascular Associates (CA)	

APPENDIX A— VQI SITES LISTED BY STATE OR PROVINCE (AS OF 10/1/2019)

Steward Good Samaritan Medical Center, Inc. (MA)
 Steward St. Anne's Hospital Corporation (MA)
 Steward Trumbull Memorial Hospital, Inc. (OH)
 Stockton Cardiothoracic Surgical Medical Group (CA)
 Stony Brook University Medical Center (NY)
 Straub Medical Center (HI)
 Strong Memorial Hospital, University of Rochester Medical Center (NY)
 Summa Health System (OH)
 Sunnybrook Health Sciences Centre (ON, Canada)
 SUNY Upstate- University Hospital Medical Center (NY)
 Superior Vein Care, PLLP (ID)
 Surgical Specialists of Central Florida (FL)
 Swedish Cherry Hill (WA)
 Swedish Edmonds (WA)
 Swedish First Hill (WA)
 Tampa General Hospital (FL)
 Tenet Florida Physicians Services, LLC (FL)
 The Johns Hopkins Hospital (MD)
 The Medical Center, Navicent Health (GA)
 The Methodist Medical Center of Illinois (IL)
 The MetroHealth System (OH)
 The Ohio State University, Wexner Medical Center (OH)
 The Practice of John F. Lucas III, M.D. (MS)
 The Reading Hospital and Medical Center (PA)
 The University of Arizona Medical Center- University Campus (AZ)
 The University of California Irvine Medical Center (CA)
 The University of Texas M.D. Anderson Cancer Center (TX)
 The University of Texas Southwestern Medical Center (TX)
 The Valley Hospital (NJ)
 The Vascular Group (NY)
 The Vein and Vascular Institute of Tampa Bay (FL)
 Thomas Jefferson University Hospitals, Inc. (PA)
 Thompson Peak Medical Center (AZ)
 Thunder Bay Regional Health Sciences Centre (ON, Canada)
 Tift Regional Medical Center (GA)
 Toronto General Hospital (ON, Canada)
 Tradition Medical Center (Martin Memorial Medical Center, Inc.) (FL)
 Trident Medical Center (SC)
 Tucson Medical Center (AZ)
 Tufts Medical Center (MA)
 UC Davis Health System (CA)
 UCHA- Memorial Hospital Central (CO)
 UCLA- Harbor Medical Center, Los Angeles County (CA)
 UCLA- Ronald Reagan Medical Center (CA)
 UCSD Medical Center (CA)
 UCSF Medical Center (CA)
 UF Health- Shands Hospital (FL)
 UNC Hospitals (NC)
 United Health Services Hospitals, Inc. (NY)
 United Hospital Center (WV)
 UnityPoint Health- Des Moines (IA)
 UnityPoint Health- Meriter Hospital (WI)
 University of Washington Medical Center (WA)
 University Hospitals Ahuja Medical Center (OH)
 University Hospitals Cleveland Medical Center (OH)
 University of Alabama (AL)
 University of Arkansas Medical Sciences (AR)
 University of Chicago Medical Center (IL)
 University of Colorado - Denver (CO)
 University of Colorado - North Vascular Services (CO)
 University of Iowa (IA)
 University of Kansas Medical Center (KA)
 University of Kentucky (KY)
 University of Maryland Medical Center (MD)
 University of Massachusetts Memorial Hospital (MA)
 University of Michigan (MI)
 University of Minnesota Medical Center (MN)
 University of Mississippi Medical Center (MS)
 University of Missouri Medical Center (MO)
 University of Tennessee Medical Center (TN)
 University of Texas Health Science Center, San Antonio (TX)
 University of Utah Hospital and Clinics (UT)
 University of Wisconsin Hospitals and Clinics Authority (WI)
 University Surgical Associates (TN)
 UPMC Altoona (PA)
 UPMC/ UPP Vascular Surgery (PA)
 UPMC/Hamot Hospital (PA)
 Utah Valley Hospital (UT)
 UVA Medical Center (VA)
 Vanderbilt University Medical Center (TN)
 Vanguard Vascular & Vein (TX)
 Vascular & General Surgical Specialists of SWFL (FL)
 Vascular Associates of South Alabama (AL)
 Vascular Institute of Chattanooga (TN)
 Vascular Institute of Michigan (MI)
 Vascular Surgery Associates (FL)
 Vein Nevada (NV)
 Vidant Medical Center (NC)
 Virginia Commonwealth University Hospital Authority (VA)
 Virginia Mason (WA)
 Wadley Regional Medical Center (TX)
 Wake Forest Baptist Health (NC)
 WakeMed Health & Hospitals -- Cary Campus (NC)
 WakeMed Health & Hospitals -- Raleigh Campus (NC)
 Washington Hospital Health System (CA)
 Weill Cornell Medical College (NY)
 Weiss Memorial Hospital (IL)
 West Jefferson Medical Center (LA)
 West Tennessee Heart and Vascular Center (TN)
 West Virginia University Hospitals, Inc. (WV)
 Westchester Medical Center (NY)
 Western Maryland Health System (MD)
 White Plains Hospital (NY)
 White Square Vascular Surgery (MD)
 Willis-Knighton North (LA)
 Winchester Medical Center (VA)
 Yale-New Haven Hospital (CT)
 Yavapai 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 (PSOs) 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 and providers cannot be disclosed by a PSO, although non-identifiable data can be published for quality improvement research, adhering to both PSO and HIPAA requirements. VQI embraced the use of a PSO to house its activities, because it provides substantially more security and protection than most registries.

VQI ENDORSING SOCIETIES

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 of Interventional Radiology*
Society for Vascular Ultrasound*
Southern Association for Vascular Surgery
Southern California Vascular Surgical Society
Vascular Access Society of America*
Western Vascular Society

**Members of SVS PSO Governing Council*

APPENDIX C— MEDSTREAMING/ M2S CLINICAL PLATFORM

M2S PATHWAYS™ is a secure, cloud-based solution which enables physicians, institutions, clinical data managers, and researchers to collect, manage, analyze, and disseminate their clinical data to achieve optimal outcomes. Accessible by any computer with a compatible browser, PATHWAYS is designed to easily integrate into a variety of workflows by allowing multiple users to access and enter data on a single procedure form, and to spread the responsibilities of data entry to more than one individual. Authentication identifies users' roles and permissions to ensure appropriate access to content within PATHWAYS. Real-time data validation through error-trapping and alerts ensure that only high-quality data is populated into the system. PATHWAYS has been designed to support large-scale quality improvement and research projects as dynamic content within registries can easily be added and/or modified.

Medstreaming-M2S is a medical informatics company specializing in workflow productivity technology, registry development and support services. To address challenges created by fragmentation of clinical data, Medstreaming created specialty-based workflow applications, which improves data workflow in electronic medical records (EMR) systems. Using this clinical workflow expertise, Medstreaming has also developed an integrated platform application that runs as an outpatient EMR, image management and reporting, and practice management workflow solution. All Medstreaming solutions act as aggregators for structuring clinical data which in turn creates powerful data service offerings for multi-purpose, web based, data mining and data analytics. Medstreaming is headquartered in Redmond, WA. M2S, a division of Medstreaming, is a healthcare performance management solutions company that provides innovative technology and services for the healthcare industry to manage clinical information and utilize that information to improve the quality of patient care and reduce costs. The Vascular Quality Initiative is built on M2S's PATHWAYS clinical data performance platform, allowing users to track, measure, and analyze clinical information, promote collaboration, objectively drive decisions, and optimize performance. For more information, visit www.m2s.com.

