Vascular Quality Initiative®

2015 ANNUAL REPORT

Vascular Quality Initiative®

SVS PSO Governing Council Report

Larry Kraiss MD, Chair

My predecessor, Dr. Richard Cambria, provided exemplary leadership during the formative years of the PSO, creating an organization with committed physician participants, strong governance, stable finances and excellent staff. Four years after inception, the SVS PSO is no longer a start-up operation. There are now 350 participating centers and 2,500 participating physicians who have contributed over 216,000 procedures to the registries.

Coming into this job last June, I knew that we needed a roadmap to take us to the next level of maturity. To create that roadmap, we held our first strategic planning session last fall. We identified a number of areas for development.

- **Provide reports that inform day-to-day practice.**
  Three Center Opportunity Profile for Improvement (COPI) reports have been released: Surgical Site Infection (SSI), Length of Stay after CEA, Length of Stay after EVAR and many more in development. The SSI COPI report facilitated reduction in SSI among a number of centers identified to have the greatest opportunity for improvement. The VQI has also released a "Current Best Practice" announcement strongly recommending that patients undergoing arterial intervention be discharged home on a statin and antiplatelet agent because we have shown that these patients have 14% improved survival after five years.

- **Make the VQI even more relevant and useful for measuring the quality of vascular care.** We released a new Varicose Vein registry this year with the American Venous Forum and are in the early stages of working with the Society for Vascular Medicine on a Registry for medical management of PAD. We also are actively exploring how to incorporate charge/cost data into our registries.

- **Broaden and deepen the infrastructure of the VQI.** As our PSO has grown and matured, we recognize the need for more staff to work with our highly-effective medical director, Dr. Jack Cronenwett. In addition to Administrative Director Carrie Bosela, three full time staff have been recruited: Nadine Caputo as Quality Director, Dan Neal as Analytic Director, and Megan Mathy for administrative support in the SVS Chicago office. This increase in permanent staff will greatly accelerate new projects in our PSO.

- **Identify distinct revenue streams to support VQI development projects.** We know that to continue improving the VQI, we need to diversify our revenue sources beyond participation fees. There is great interest by vascular device companies for using blinded VQI data to meet regulatory requirements. Several of them have contributed unrestricted grants to help fund VQI development projects. We also anticipate income from companies who want to "lease" the VQI infrastructure to conduct their own studies. We expect these arrangements will provide opportunities for participating VQI centers to defray the costs of participation.

- **Strengthen our relationship with regulatory agencies and other registries.** Maturing as an organization has meant gradually shifting away from an exclusively internal focus to an external focus. We are actively cultivating relationships internationally with other vascular registries, and in the US with the AHRQ, FDA and CMS. These relationships are already bearing fruit, increasing the stature of VQI as a voice for quality and increasing the value of participation.

Finally, I am regularly reminded that VQI’s success depends on the deep commitment to quality of its members who go out of their way to participate. I am honored to work with so many who generously contribute their time in numerous capacities to improve VQI.

Research Advisory Committee Report

Philip Goodney MD, Chair

VQI members can request non-identifiable national datasets for research and quality improvement projects approved by their regional group. These data do not identify patients, centers or providers, but provide a rich source to analyze real world practice and variation in process and outcomes. Data requests are reviewed by the PSO Research Advisory Committee (RAC) to be sure that they are scientifically valid, that they are consistent with the VQI mission, and that they do not overlap existing projects.

The VQI RAC consists of 20 members with broad scientific background and regional representation. To date, the RAC has approved 45 proposals from 37 unique VQI investigators in 17 centers, representing diverse topics across multiple procedures. (For details, see http://www.vascularqualityinitiative.org/vqi-resource-library/).

RAC policies allow investigators to easily request expansion of the scope of their initial project when analyses suggest this. Progress of projects is tracked by the RAC and investigators with similar projects are encouraged to collaborate. With a database of >200,000 procedures, VQI provides a rich opportunity for research that often leads to quality improvement projects based on new scientific evidence.

www.vascularqualityinitiative.org
Vascular Technology Council Report
Fred Weaver MD, Chair

Members of the VTC have met with the FDA and over two dozen manufacturers of arterial and venous devices as well as companies that focus on the medical management of vascular disease.

Important progress to date:

- Held Corporate Roundtable discussions with industry and FDA for longitudinal evaluation of existing technology, which highlighted the value of the existing VQI data and the benefit of customized data elements and follow-up for evaluation of device efficacy.
- Identified opportunities to use VQI registries to obtain needed data to shorten the approval process for expanded indications. The potential to leverage VQI as a platform for regulatory approval is a critical focus of the VTC.
- Initiated two FDA-required post market surveillance projects using VQI (highlighted below), establishing important efficiency advantages, including rapid site recruitment without IRB costs or individual site contracts, an established network of sites already collecting much of the needed data, and ease of customizing the registries for new projects.
- Established a mechanism for industry to support new initiatives in the VQI, such as new registries and reporting functionality. Corporate support totaled $525,000 this year, provided by Quality Champions and Quality Partners.
- Held Corporate Roundtable discussions with industry and FDA for longitudinal evaluation of existing technology, which highlighted the value of the existing VQI data and the benefit of customized data elements and follow-up for evaluation of device efficacy.
- Initiated two FDA-required post market surveillance projects using VQI (highlighted below), establishing important efficiency advantages, including rapid site recruitment without IRB costs or individual site contracts, an established network of sites already collecting much of the needed data, and ease of customizing the registries for new projects.
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VQI External Projects
Jack Cronenwett MD, SVS PSO Medical Director

DEVEICE POST-APPROVAL SURVEILLANCE
The TEVAR Dissection Surveillance project, begun last year with FDA, Gore and Medtronic, is well underway toward capture of 200 acute and 200 chronic Type B dissection procedures with 5-year follow-up. In fact, 31 sites have already submitted data for 174 cases in < 1 year, which is well ahead of schedule, and demonstrates the efficiency of using an existing data collection mechanism in an established network of sites. The Lombard Aorfix® Surveillance project, launched this year with FDA and Lombard, includes core lab analysis of follow-up CT images, demonstrating another capability of the VQI mechanism. Discussions are currently underway regarding 6 additional projects in the PVI and CAS areas, with FDA and industry, underscoring the value of registry data to efficiently serve multiple stakeholders who are interested in quality improvement.

CREST-2 REGISTRY
Through a collaboration with CREST-2 investigators, VQI members who use the CAS registry can report their data in order to be certified as a C-2 participant, and then use VQI CAS Registry to meet the requirements of C-2 to report data for non-randomized patients during this trial. This is another example of the important use of VQI data for multiple purposes.

INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES
The ICVR was organized this year by VQI and European/Australasian members of VASCUNET to allow international collaboration on vascular quality improvement projects specifically focused on total life cycle vascular device evaluation worldwide. With support from the FDA and the public-private partnership of the Medical Device Epidemiology Network (MDEpNet), this group has held two meetings, solicited participation of 10 national registries, and selected an initial project concerning devices used to treat para-renal AAA.

For the past 7 years, M2S has partnered with VQI to allow VQI member physicians to electronically report PQRS measures based on VQI data submitted via M2S. This has allowed 283 physicians to qualify for PQRS reporting, initially obtaining a 2% bonus of all their Medicare billings, but now transitioning to avoid a 2% penalty for all Medicare billings. This program has relied on 8 quality measures developed by the SVS Quality Performance Measures Committee (QPMC) that were approved by the National Quality Forum and CMS.

This year, M2S successfully applied to become a Qualified Clinical Data Registry (QCDR) by CMS. This allows VQI and QPMC to develop new measures for more flexible PQRS reporting by VQI members with less stringent percent reporting criteria. As a result, 15 new measures are available for PQRS reporting in 2015, across multiple procedures, including PVI, Varicose Vein and IVC.

For more information see www.vascularqualityinitiative.org

PQRS Reporting with VQI and M2S

VQI Member Characteristics

QUALITY CHAMPIONS

QUALITY PARTNERS

www.vascularqualityinitiative.org
Regional Quality Group Activity
Carrie Bosela RN, Administrative Director

VQI has 18 regional vascular quality groups that meet semi-annually to review non-identified regional data provided by the PSO. Each region discusses variation in processes of care, identifies regional opportunities for improvement and then initiates and conducts regional quality projects. Many of these QI projects are now progressing rapidly, examples of which include:

- Increasing use of antiplatelet and statin use pre-operatively and at discharge
- Decreasing myocardial infarction after major arterial procedures
- Determining the role for non-autologous biological grafts versus synthetic grafts for leg bypass
- Enhancing recovery after lower extremity amputation
- Reducing length of stay after CEA, EVAR, oAAA and LEB procedures
- Improving long term follow up of patients in VQI
- Reducing preventable causes of readmissions
- Preventing contrast-induced nephropathy after peripheral arteriography
- Increasing smoking cessation after major arterial procedures (highlighted below).

Regional Smoking Cessation Project
Philip Goodney MD

The VSGNE developed a QI project to improve smoking cessation after a 2013 VSGNE study by Dr. Andrew Hoel et al showed that the one year quit rate after vascular surgery procedures varied from 28%-62% across centers. With input from national experts and further analysis and discussion, we recognized the opportunity for vascular physicians to improve patients’ smoking cessation by providing (1) brief advice, (2) nicotine replacement and (3) referral to existing smoking quit lines. This QI project was initiated in VSGNE and then led to an SVS-funded multicenter randomized trial which has already enrolled 108 patients across 8 centers. The trial is expected to demonstrate the potential for us to improve smoking cessation with organized but minimal effort. This is an example of how regional variation, identified through VQI data, can lead to an important QI project and even a multi-centered clinical trial.

Quality Committee Reports
The Quality Committees have a representative from each of our 18 regional quality groups and have workgroups that oversee each registry.

Arterial Quality Committee, Adam Beck MD, Chair
REGISTRY REVISIONS. This year, the TEVAR and EVAR Registries were substantially updated, including the ability to record device details and to be used for physician-sponsored IDE studies. Currently, both the CAS and PVI Registries are being updated, which will allow collaboration with the CREST-2 Study and future PVI projects.

LONG-TERM FOLLOW-UP. The importance of LTFU for assessing outcomes in VQI has been reiterated by the AQC with a requirement for at least 80% one-year follow-up reporting. Unfortunately, LTFU reporting has decreased as VQI has grown, so a special committee has been tasked to improve this, with discussions at all regional meetings this spring, leading to recommendations that will include recognition of centers with best performance, and other incentives to insure capture of LTFU data.

QUALITY PROJECTS. Work by AQC committees led to important scientific contributions using national VQI data this year. Dr. Jeff Kalish et al reported that chlorhexidine skin prep reduced surgical site infection after infrainguinal bypass. Dr. Randy De Martino et al reported that antiplatelet agent and statin prescribed pre-operatively and at discharge after major arterial procedures improved 5 year survival by 14%. Dr. Sal Scali et al found that prophylactic beta-blockers initiated before major arterial operations did not reduce mortality or myocardial infarction rate, and might be detrimental. This work has led to Current Best Practice announcements by the AQC to VQI members which should improve patient outcomes.

Venous Quality Committee, Jose Almeida MD, Chair
VARICOSE VEIN REGISTRY. A workgroup comprised of PSO and American Venous Forum members developed and released the new VVR in January, which tracks treatment by radiofrequency, laser, chemical, embolic adhesive and surgical ablation. Quality of life data are collected pre-treatment and at follow-up. Within three months of launch, 21 centers entered data for 272 procedures. This registry allows surgeons who restrict their practice to venous treatment to meet maintenance of certification requirements of the American Board of Surgery and will likely facilitate future requirements for vein center accreditation. Currently, integration with vein-specific EMR vendors is being pursued by M2S to allow transfer of VVR data from these EMR systems directly to M2S to eliminate double data entry.

IVC FILTER REGISTRY. Since its launch two years ago, 56 VQI centers have joined the IVC registry, and have now contributed over 2500 procedures. This database allows surgeons who restrict their practice to venous treatment to meet maintenance of certification requirements of the American Board of Surgery and will likely facilitate future requirements for vein center accreditation. Currently, integration with vein-specific EMR vendors is being pursued by M2S to allow transfer of VVR data from these EMR systems directly to M2S, to eliminate double data entry.

FUTURE PROJECTS. The VQC plans to develop a patient portal that will allow QOL data to be collected long term after venous treatment. Quality improvement projects will be driven by data collected in the VV and IVC registries, and a potential future registry to track venous stenting is being considered.

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