



Vascular Quality Initiative



Bylaws Approved by the Carolina's Vascular Study/Quality Group

November 4, 2011

At the 1st Annual Meeting, in Charleston, SC

The mission of the Vascular Quality Initiative (VQI) of the Society of Vascular Surgery[®] is to improve patient safety and the quality of vascular health care delivery by providing web-based collection, aggregation, and analysis of clinical data submitted in registry format for patients undergoing specific vascular treatments. The SVS Patient Safety Organization (SVS PSO) provides outcome analysis intended to be an integral component of each participating health care provider's quality improvement efforts, including the implementation of recommendations, protocols, and best practices developed by the SVS PSO.

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I. Vascular Quality Initiative Overview

The Vascular Quality Initiative (VQI) of the Society for Vascular Surgery® (SVS) is a new program designed to improve vascular health care. It provides an opportunity for individual providers, hospitals and regional quality improvement groups to collect and analyze clinical data in an effort to improve patient care. VQI collects pre-operative risk factors, intra-procedural variables, post-procedural outcomes, and one year follow-up data to assess quality of care and determine best practices in vascular health care under the auspices of the SVS Patient Safety Organization (SVS PSO). The SVS PSO provides oversight of data sharing arrangements, key outcome and quality measure analyses, and dissemination of information to participating providers.

Based on the experience of the Vascular Study Group of New England (VSGNE), it is the belief of SVS PSO that multiple regional study groups provide the optimal unit size for conducting quality improvement projects. Such regional groups promote trust and encourage collaboration among peers which is essential to forming a sustainable quality group. To this end, SVS PSO assists and accredits regional vascular quality groups to participate in the VQI process.

SVS PSO has partnered with M2S, Inc. to provide a secure, web-based data collection and analysis system, with built-in error checking and incomplete record monitoring to ensure data integrity. The system can be used to generate real-time benchmarked reports for major outcomes and complications, as well as longitudinal tracking of center performance compared to a chosen group of centers. These reports permit centers to continuously assess themselves compared to an anonymous group of peers on key performance measures. In addition, participation in the SVS VQI satisfies the requirements for Part IV of the Maintenance of Certification of the American Board of Surgery.

II. Society for Vascular Surgery® Patient Safety Organization

A. Background Information

In response to rising health care costs and increasing concerns about the quality of health care delivery in the United States, the Department of Health and Human Services instituted the Patient Safety and Quality Act of 2005 to encourage healthcare providers to share outcome and patient safety data without fear of reprisal. The Final Rule of this Act, which took effect in November 2008, established an implementation mechanism known as a Patient Safety Organization (PSO), through which the objectives of the Patient Safety Act could be achieved. The Agency for Healthcare Research and Quality (AHRQ) was designated to administer the provisions of the Patient Safety Act and oversee the approval and operations of PSOs. General information about PSOs can be found at <http://pso.ahrq.gov>.

The importance of the Patient Safety Act for providers and hospitals is that it protects all quality work products generated from data entered into a PSO from legal discovery in state and federal court. Quality work products include outcome analyses, benchmarked reports, and other aggregated information intended for quality improvement purposes. The identity of hospitals and providers that are compared in benchmarking and other quality analyses generated through a PSO cannot be disclosed or discovered. Nor can individual patients be identified in any quality reports. There are severe monetary and criminal penalties for any divulgence of confidential patient safety work product by a PSO. Another advantage of a PSO for providers and hospitals is that it permits the collection of patient-identified data for quality improvement purposes without requiring consent from individual patients or prior approval from an Institutional Review Board.

The Society for Vascular Surgery® Patient Safety Organization (SVS PSO) was approved by AHRQ in February 2011 to oversee the data sharing partnerships and patient safety initiatives of customers utilizing M2S's Clinical Data Pathways platform. Directed by a Governing Council of representatives of SVS and regional groups, the mission of the SVS PSO is to improve patient safety and the quality of health care delivery by providing web-based collection, aggregation, and analysis of clinical data submitted in registry format for all patients undergoing specific vascular treatments. Composed of physicians, analysts, and administrative personnel, the SVS PSO staff provides medical expertise, statistical analyses, and oversight of quality improvement activities conducted through the PSO. The Medical Director of the SVS PSO is Jack L. Cronenwett, M.D, who was selected based on his experience with the Vascular Study Group of New England.

The vision of the SVS PSO is a nationally distributed network of regional vascular quality improvement groups, collecting common core datasets to allow anonymous pooling of information. The SVS PSO believes that smaller, regional group meetings to discuss quality improvement foster a sense of ownership, individual responsibility, cooperation, and trust. It is in these meetings where shared data are discussed and quality improvement projects are initiated. For this reason, the SVS PSO encourages providers and hospitals to form quality improvement groups, and to use M2S's web-based data entry and reporting system, to allow sharing of this information. Although it is valuable to collect such data at the individual hospital level, much greater value is achieved by benchmarking clinical data among hospitals. Participation of multiple regions will more rapidly accumulate data that can leverage all the quality improvement initiatives.

B. SVS PSO Governance Policies

ARTICLE I. Name

The organization shall be known as the Society for Vascular Surgery Patient Safety Organization, hereinafter referred to as the “SVS PSO.”

ARTICLE II. Purpose

The purpose of the SVS PSO is to support the objective of the Society for Vascular Surgery to improve the prevention, diagnosis and management of patients with vascular disease, and to position SVS as a national leader in quality control efforts referable to vascular interventions.

The SVS PSO is a Patient Safety Organization, as defined by the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41), implemented to protect the confidentiality of all data and resulting patient safety work product. The SVS PSO engages in patient safety activities focused on vascular and related therapies, including, but not limited to:

- (i) efforts to improve patient safety and the quality of health care delivery;
- (ii) the creation and analysis of patient safety work product (“PSWP”);
- (iii) the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices;
- (iv) the utilization of PSWP for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk;
- (v) activities related to the operation of a patient safety evaluation system (“PSES”) and to the provision of feedback to participants in a PSES;
- (vi) compilation of information regarding patients undergoing certain vascular procedures; and
- (vii) upon the election of an institution obtaining services from the PSO
 - (a) provide for the aggregation and benchmarking of data, as well as comparative data services and/or
 - (b) facilitate and provide administrative services in connection with the formation of study groups consisting of one or more PSO participating institutions for the purpose of answering one or more particular queries by aggregating such participants’ submitted data, and compiling/organizing the results.

ARTICLE III. Participation

Hospitals, individual surgeons or other practice entities contract with the SVS PSO to participate in the quality improvement activities protected under the PSO regulations. The form of the contract between SVS PSO and the participating site must be approved by the SVS PSO Governing Council, including the costs for participation. The contract must affirm the participating sites’ adherence to the SVS PSO policies and procedures. **See exhibit A (below).**

Regional vascular study groups comprised of at least three practice entities that participate in the PSO may be accredited by the SVS PSO and afforded status as a regional quality committee with representation on the Governing Council. Individual physicians or practice entities not part of a regional study group may also participate.

ARTICLE IV. Governing Council

The Governing Council conducts the business of the PSO and makes all decisions on behalf of the PSO, including oversight of budgets, contracts, policies and procedures, publications, relationships with outside parties, and the general direction of the organization. With the Medical Director, the Governing Council shall assure compliance with federal regulations governing PSOs.

The decisions of the Governing Council are subject to approval by the Board of Directors of the Society for Vascular Surgery (SVS) for the following: adoption of an annual budget, authorization of major changes in the purpose or operations of the SVS PSO or any other action of the Governing Council identified by the chair of the Governing Council as involving a significant legal issue. No action of the Governing Council with respect to any such matter shall be effective and binding until approval by the SVS Board of Directors has been obtained.

The Governing Council consists of representatives appointed by the Society for Vascular Surgery and representatives appointed by each regional vascular study group. The number of representatives shall be determined by the Governing Council. The SVS PSO medical director shall be an ex officio non-voting member of the Governing Council.

The Governing Council may meet in person, by conference call or by email. Meetings may be called by the chair, or at the request of any other two members of the Governing Council.

The duration of the term for Governing Council members is at the discretion of the organization being represented by the individual. In the event of a vacancy in the Governing Council, the remaining members of the Council may exercise the powers of the full Council until the vacancy is filled.

A quorum of the Governing Council consists of at least half the Governing Council members at the time of the vote. A majority vote of the members present at a meeting at which a quorum exists is required to pass resolutions. Minutes of the Governing Council meetings shall be distributed electronically to all Governing Council members.

ARTICLE IV. Officers

The officers of the SVS PSO Governing Council shall consist of chair, secretary and treasurer.

The chair of the Governing Council shall be appointed by the SVS Board of Directors. The chair shall preside at all meetings of the Governing Council and shall, in general, perform all duties customarily incident to the position of president or chair and such other duties as may be prescribed from time to time. The chair shall report regularly to the SVS Board of Directors.

The secretary and treasurer of the SVS PSO Governing Council shall be designated by the Governing Council.

ARTICLE V. Committees

The Governing Council may from time to time establish such committees as it deems advisable. Such committees shall consist of such number of persons, and shall have such powers, as designated by the Governing Council.

SVS PSO standing committees include any Quality Committees established by regional vascular study groups and the SVS PSO Research Advisory Committee.

1) Regional Quality Committees

Each participating regional vascular study group shall designate a Quality Committee consisting of physicians, analysts, and administrative personnel to oversee the quality functions of the regional vascular study group. Each Quality Committee is responsible for all decision making concerning patient safety work product production for its region using shared data within the regional study group, including types of analyses, reports, benchmarking, and risk adjustment. Each regional Quality Committee is technically considered an SVS PSO committee.

2) SVS PSO Research Advisory Committee

The role of the SVS PSO Research Advisory Committee is to set national research priorities, evaluate data analysis requests and initiate studies that use de-identified data from more than one region. The Research Advisory Committee shall include members appointed by the Society for Vascular Surgery, including the chair, plus representatives from each regional vascular study group. The number of representatives shall be determined by the Governing Council. The SVS PSO medical director shall be an ex officio member.

ARTICLE VI. Staff

The SVS PSO shall engage a Medical Director to provide clinical and scientific expertise and to manage the work of the PSO. The Medical Director shall engage such additional staff for the PSO as are needed to fulfill the organizational and analytical needs of the PSO, subject to budget approval by the SVS PSO Governing Council.

The Medical Director shall be an ex officio, non-voting member of the Governing Council and an ex officio member of the SVS PSO Research Advisory Committee.

The Society for Vascular Surgery shall provide administrative support for the PSO, including the Governing Council and the SVS PSO Research Advisory Committee.

ARTICLE VII. Indemnification

To the full extent permitted by, and in accordance with the procedure prescribed in the General Not for Profit Corporation Act of Illinois, the Society for Vascular Surgery shall indemnify any and all of the members of the Governing Council and any and all of the officers, employees, agents and representatives of the SVS PSO for certain expenses and other amounts paid in connection with legal proceedings in which any such persons become involved by reason of their serving in any such capacity for the SVS PSO.

ARTICLE VIII. Amendments

These governance policies may be amended by the Board of Directors of the Society for Vascular Surgery, provided that such amendments are circulated to all SVS PSO participants at least 30 days prior to their consideration.

Exhibit A – Policies to be included in PSO contracts with sites

1. Shared Registry Data Ownership

Each hospital/practice site owns the data that it submits to the SVS PSO, and is entitled to specify and control the use of its data in the manner set forth in the contract. Any use of a site's data by the SVS PSO for purposes other than quality improvement research or any of the standard quality assurance functions performed by the SVS PSO shall require the prior consent of the site, in the manner set forth in the contract.

2. Policies

The following principles guide the function of the SVS PSO and must be adhered to by all participants.

- a. All activities of the SVS PSO must be consistent with the purpose of the PSO, as stated in its governing documents.
- b. Each physician member must submit data for all consecutive procedures in the modules in which they participate that are recorded by the SVS PSO and must agree to submit office claims data on a periodic basis to allow an audit to ensure accurate and complete data entry.
- c. Each member hospital agrees to submit ICD-9 based claims data on a periodic basis to allow an audit to ensure accurate and complete data entry.
- d. Each member hospital and physician must submit complete data forms, including all elements of the SVS PSO registry for all eligible procedures, using a web-based system approved by the SVS PSO, including follow-up data at one year, or other time points established by the SVS PSO.
- e. Each member hospital and physician agrees that comparative data can never be used for competitive marketing. Hospitals and physicians own their own data, and can publish such data with the indication that it is derived from the SVS PSO. However, they may not publish data provided in benchmarking reports that compares their hospital or practice with other groups in the SVS PSO.
- f. Each hospital and physician member must agree to follow the SVS PSO Confidentiality Manual, which is designed to prevent the disclosure of any patient identifiable information, as well as any hospital or physician identifiable information. Further, each SVS PSO hospital and physician member agrees to follow all regulations contained within the Hospital Insurance Portability and Accountability Act (HIPAA) and the Patient Safety Quality Improvement Act (PSQIA).
- g. Failure to adhere to these policies may result in loss of membership in SVS PSO for a hospital or physician, if so determined by a majority vote of the Governing Council.

3. Research

Proposals for research projects using shared regional data or regional data compared to national data may be made by SVS PSO participating hospitals or physicians. Proposals will be reviewed by the SVS PSO Research Advisory Committee, which shall develop criteria for approval and policies about publication. Parties approved for research projects shall agree to abide by all policies for how the SVS PSO or VQI name may be used in publications and presentations.

Regional study groups may publish or present data from their own region without approval by the SVS PSO Research Advisory Committee, but must note that the data are derived from the SVS PSO.

C. Governing Council and Research Advisory Committee

Governing Council

- Richard Cambria, MD, Chair
- Anton Sidawy, MD, Vice Chair
- Larry Kraiss, MD
- Louis Nguyen, MD
- Michael Stoner, MD
- Regional Representatives TBD
- Jack Cronenwett, MD, Ex Officio

Research Advisory Committee

- Larry Kraiss, MD, Chair
- Philip Goodney, MD
- Jeb Hallett, MD
- Greg Landry, MD
- Andres Schanzer, MD
- Marc Schermerhorn, MD
- Thomas Wakefield, MD
- Regional Representatives TBD
- Jack Cronenwett, MD, Ex Officio

III. Starting a Regional Quality Group

A. Rationale for Starting a Regional Quality Group

Hospitals are interested in length of stay data, and how this is influenced by outcomes and specific complications. Vascular procedures are resource intensive for hospitals, and involve high risk patients. Comparison with other centers in a region provides reassurance as well as ideas for quality improvement. Many physicians do not have an accurate method to tabulate key quality measures, such as stroke and death after carotid endarterectomy, death after AAA repair, and endoleak rate after endovascular AAA repair. Validating the data through a regional registry adds confidence and rigor to this reporting. This can be especially important for excellent but low volume surgeons or interventionists, who may be required to demonstrate good results to continue to perform selected operations. Most importantly, it is only through awareness of these results that quality can be improved. This is the great value of a regional system that fosters group discussion around quality improvement.

Creating a regional group to analyze and share data facilitates the ability to improve quality standards based on outcomes that reflect overall quality challenges faced by multiple institutions. The benefits in forming a Regional Quality Group include the use of anonymous, benchmarked reports for comparison, increasing power and ability to detect root causes of outcomes, facilitating & initiating quality improvement projects, and improving long-term patient surveillance.

B. Practical Guidelines for Starting a Regional Quality Group

Based on the experience of the Vascular Study Group of New England (VSGNE), the following are recommendations for starting a Regional Quality Group.

I. Identify Interested Surgeons

The first step is to identify a few vascular surgeons who would likely be interested in discussing the potential for forming a quality improvement group. They should be in the geographic region that you envision to be appropriate for your group (see below). Initial phone or email conversations will likely identify those who are excited about this possibility, those who are neutral, and those who are skeptical. Focus initially only on those who are excited, and suggest an initial meeting or conference call to discuss.

II. Introductory Meeting

At the first meeting, ideally in person, but potentially by phone, the group needs to discuss the rationale for forming a quality improvement group, to see if everyone is on the same page and has the same intentions. This would be a good time to review the VSGNE experience and Bylaws, as well as the SVS PSO governance policies. The SVS PSO has established requirements for regional groups to join the SVS PSO, which are listed in Section II, B of this packet.

Also at the first meeting, there should be discussion about how to sign up for the SVS PSO through M2S and the costs for each center, depending on how many procedure types the group chooses to collect, and the volume of each center. This information is available from M2S.

III. Size of Region

If the initial group of surgeons agree to establish a regional group, the next question is the appropriate size of the group, in terms of numbers of sites and geographic size. VSGNE decided to limit its size to New England, so that members could drive to a daylong meeting, arriving at 10 am, leaving at 4pm. Further, VSGNE decided that more than 30 centers would probably feel too large at the semi-annual meetings for all members to have an opportunity to participate in discussions, so that enthusiasm and ownership would be maintained. However, geography may determine different solutions for different regions, as might long-term affiliations or lack thereof.

IV. Invite Others

Once a commitment is obtained from at least 3 sites, it is reasonable to extend an invitation to other centers in the region to attend on organizational meeting of the group. It is important to identify key clinicians in each center, and to reach out to invite them. Dividing this task among the initial members based on personal connections or proximity to different sites may be most effective. Ideally each site would send a surgeon or other vascular clinician, a hospital quality officer, and potentially a data manager to the first meeting.

V. Initial Meeting

At the initial meeting it is important to define the mission of the group, and to clearly focus this on regional quality improvement, with regional ownership and responsibility. Bylaws would be the next step after agreeing on a mission statement. VSGNE can provide a model to work from. At this meeting, the details of costs to participate in SVS PSO would need to be described, both for the M2S portion and the SVS PSO portion. This information is available from M2S and SVS.

It is important at this meeting to set appropriate expectations. It takes at least 6 months of data collection to begin to be able to look at data to derive potential quality projects. Really, it takes several years. However, the group can initially focus on variation in process measures, such as variation in pre-op medication usage, like statin or ASA among different centers. It would be appropriate to show examples of benchmark reports that will be available to centers, for key outcome measures for each procedure, and these examples are available from M2S.

It is also important to stress the potential for quality improvement and cost savings to participating hospitals. Hospital quality officers will have good perspective about this, and should be involved early in these discussions. VSGNE examples can be used to indicate future opportunities.

Finally, it is important to describe various options for actually collecting data, and to be sure that each site understands their responsibility in this regard. Data entry has a cost, even if the M2S system has been designed to be user friendly and available to multiple personnel for data entry. Some centers use a nurse to enter data, some use hospital coders, some use physicians, nurses, secretaries, and other personnel. Many models are possible to distribute this work and cost, but data entry does have a cost that cannot be ignored. Unfortunately, there are no EMR systems at this point that contain much of the data elements necessary for vascular quality groups, so data must be abstracted and entered.

VI. Regional Logistics

It is important to designate a regional medical director, and some portion of a project manager, ideally housed in the same center for optimal communication, who will handle the administrative tasks of the group. Initially these tasks are small, but can grow as more data are entered and more work with the data is possible. In the future, the group may want to hire statistical services, or instead, may want to make such analyses the responsibility of academic centers that can do this quality research. Initially, costs in VSGNE were very low, with a part time project manager only. Now we have expanded to include a half-time statistician, and a data coordinator (20%) effort. VSGNE also pays for lunch for attendees at the semi-annual meetings, which are rotated to different member hospitals. For this reason, each regional group should designate a fiscal agent, such as an institution or foundation, which can receive regional fees from participating centers, and pay expenses authorized by the regional group. For governance, an executive committee is needed, and VSGNE uses one representative from each center. Finally, SVS PSO will invite each regional group that it certifies to designate a representative to the SVS PSO Governing Council, which will oversee any data sharing and use between regions.

VII. Next Steps

If your regional group reaches this stage, you will have many ideas for quality projects, research studies, and collaboration with other regional groups. VSGNE is happy to provide members who can serve as resource for any stage of progress.

VQI can assist in forming a regional group by identifying and recruiting institutions, providing informational materials and product demonstrations, drafting data sharing agreements, supplying bylaw templates, and helping to organize regional kick-off meetings as well as annual and/or semi-annual meetings.

For more information on forming a regional study group in your area, contact c.bosela@svspsso.org.

C. Current Regional Quality Groups

There are currently 11 regional quality groups organized or organizing under the SVS PSO. In total, there are more than 85 hospitals participating in this initiative. Contact information for the current regional groups is listed below.

New England		
Dr. Jack Cronenwett	Dartmouth-Hitchcock Medical Center	jack.cronenwett@hitchcock.org
Mid-Atlantic		
Dr. Grace Wang	University of Pennsylvania	Grace.Wang@uphs.upenn.edu
Washington, D.C.		
Dr. David Deaton	Georgetown University Hospital	david@deaton.md
Virginias		
Dr. Gilbert Upchurch	University of Virginia	gru6n@virginia.edu
Carolinas		
Dr. Jeb Hallett	Roper St. Francis Heart & Vascular	johnjeb.hallett@ropersaintfrancis.com
Florida		
Dr. Adam Beck	University of Florida - Shands	adam.beck@surgery.ufl.edu
Georgia		
Dr. Ayel Ben-Arie	Piedmont Healthcare	ben_arie@hotmail.com
South (SoVONet)		
Dr. Mark Davies	Methodist Hospital	MDavies@tmhs.org
Southern California		
Dr. Fred Weaver	USC University Hospital	fweaver@surgery.usc.edu
Rocky Mountains		
Dr. Larry Kraiss	University of Utah Hospitals and Clinics	Larry.kraiss@hsc.utah.edu
Michigan		
Dr. Alex Shepard	Henry Ford Hospital	ashepar2@hfhs.org

IV. Regional Group Example



A. Vascular Study Group of New England

History

The Vascular Study Group of New England (VSGNE) was organized in 2002 by surgeons in ME, NH and VT to improve the quality of vascular health care by analyzing and reporting outcomes based on a common registry. It gradually expanded to now include more than 25 hospitals in all 6 New England States. To date, VSGNE has collected in-hospital and one-year data (patient and disease characteristics, processes of clinical care, and outcomes) for more than 19,000 major vascular procedures (carotid endarterectomy, carotid stenting, open and endovascular AAA repair, supra- and infra-inguinal bypass, peripheral vascular intervention, and thoracic and complex EVAR). Such data do not commonly exist within health care organizations. VSGNE uses patient-identified data to be able to match with the Social Security Death Index to determine long-term outcomes and to conduct periodic audits based on hospital billing data to validate complete entry of all appropriate procedures. In this way it differs from the NSQIP database, which currently focuses on a random sampling of procedures with short term follow-up. Different from an institutional database, the registry designed by VSGNE provides anonymous benchmarked reports of key outcomes and quality measures to participating providers and hospitals to allow comparison with peers in a region. Both large and small hospitals have found considerable value in this information to complement their ongoing internal quality assurance and improvement activities. Additionally, participating surgeons satisfy Part IV of the Maintenance of Certification requirements by the American Board of Surgery.

Methods for Regional Quality Improvement

Governance of VSGNE is provided by an Executive Committee, consisting of one representative from each hospital, as well as a Medical Director, Project Manager, and Epidemiologist. Bylaws of the group are included below, but contain the following key principles:

- a) Any physician who performs vascular treatments being monitored in this registry can participate.
- b) Consecutive cases must be entered by each participating physician. Hospital billing data must be submitted periodically to validate entry of all procedures.
- c) One year follow-up data must be collected in the physician's office.
- d) All reporting of outcomes for hospitals and providers must be anonymous.
- e) No hospital or group can use pooled data reports for competitive marketing purposes.

Data collection is done by physicians, nurses, coders, and other personnel at each hospital. VSGNE has evolved from initial paper forms to current web-based data entry. In the past, data analysis and quality report generation was done twice per year by VSGNE staff at Dartmouth-Hitchcock Medical Center, and shared with members at semi-annual meeting which have rotated among participating centers. In 2009, VSGNE teamed up with a medical information company, M2S, Inc. of West Lebanon, NH, to develop an automated and scalable web-based system for data entry and real-time generation of quality reports. This has now been successfully implemented at all VSGNE centers. Each center owns its data and can download it in various formats from the web-based system. In addition, this web-based system provides a real-time reporting system, including the generation of anonymous regional, medical center, and

physician-level quality reports, which can be viewed or printed at any time. This system is immediately applicable to individual hospitals or other regional groups. For more details about this system see <http://www.m2s.com/vascular-quality-initiative>.

Quality Improvement

The goal of VSGNE is to improve the quality of care in all hospitals by providing regionally benchmarked reports of key outcome and quality measures. VSGNE members have already achieved improvements in a number of areas, such as the use of patching during carotid endarterectomy. Further, VSGNE has initiated specific quality improvement projects which have significantly increased the use of important preoperative medications, including antiplatelet agents, beta-blockers and statins. The accumulated data have allowed risk-adjustment algorithms to be developed, which provide more accurate benchmarking between hospitals and also inform better patient selection and decision making. As the VSGNE registry expands, the group will have more power to detect root causes of variations in outcomes across the region, in order to focus future quality improvement efforts. Further, VSGNE can use the registry in the clinical care pathway to ensure appropriate longitudinal follow-up of patients that is important to improve and understand long term results.

VSGNE has demonstrated the ability to use aggregated data to recognize patterns of outcome events and their associated causes that would not be possible in individual practice. This allows VSGNE to define processes of care that can improve outcomes, and it allows individual hospitals and surgeons to understand their results in the context of regional benchmarks. Quality improvement analyses have led to new clinical information which has now been presented at 17 major national or regional vascular society meetings since 2007. Each of these has resulted in a published or in-process scientific article to disseminate the quality improvement work of the group. This productivity has led to considerable recognition of the VSGNE and its participating hospitals. This will most certainly result in other regions as cooperative regional groups are established.

B. Sample Bylaws of the Vascular Study Group of New England

I. Mission Statement

The Vascular Study Group of New England (VSGNE) is a voluntary, cooperative group of clinicians, hospital administrators, and research personnel organized to improve the care of patients with vascular disease. By collecting and exchanging information, the group strives to continuously improve the quality, safety, effectiveness and cost of caring for patients with vascular disease.

II. Membership

Hospitals and physicians performing any of the vascular procedures recorded by VSGNE are eligible for full membership if they are located within the New England states of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont. Full Membership requires that the member hospital or physician follow the policies and procedures established by VSGNE (see Section VII). Hospitals act as the contracting agent for membership in VSGNE, such that physicians who perform vascular procedures in that hospital are eligible to participate. A majority vote of the VSGNE Executive Committee is required to approve full membership of new hospitals. A hospital which is approved for full membership is hereinafter referred to as a “VSGNE Member”.

III. Patient Safety Organization

The VSGNE is an unincorporated association of member hospitals and physicians that use the Society for Vascular Surgery® Patient Safety Organization (SVS PSO) as the vehicle for quality improvement and the M2S, Inc. Pathways product for data collection and quality report generation. Contracts are required between member hospitals and the SVS PSO, M2S, and the Hitchcock Foundation, which acts as the fiduciary agent for VSGNE for regional staff and projects. SVS PSO is a Patient Safety Organization, as defined by The Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41), implemented to protect the confidentiality of all data and resulting patient safety work product. SVS PSO is a limited liability company created for the purpose of satisfying VSGNE’s desire for a patient safety organization by the Society for Vascular Surgery (SVS). M2S, Inc. provides web-based services to SVS PSO related to the VSGNE registry, under an administrative services agreement. Under the relevant agreements with each member hospital, SVS PSO will perform common data management services for member institutions, as determined by the VSGNE Quality Committee of the SVS PSO.

Each member hospital must have contracts with SVS PSO and M2S, Inc. (the Hospital Contracts), which affirms adherence to the VSGNE Bylaws. The form of the Hospital Contracts between SVS PSO and M2S, Inc. and member hospitals must be approved by the VSGNE Executive Committee, including the costs for SVS PSO and M2S services.. The Hospital Contracts shall include annual charges, based on hospital procedure volume or number of participating physicians, to be paid to SVS PSO and M2S for web-based data collection, data management and report generation. In addition, the Executive Committee establishes an annual fee for VSGNE hospitals to fund semiannual meetings and VSGNE staff, which is paid to the Hitchcock Foundation, through an annual contract with each participating hospital.

III. Committees and Staff

a. Executive Committee:

The business of the VSGNE shall be managed by or under the direction of an Executive Committee, which may exercise all the powers of the VSGNE except as otherwise

determined by two-thirds of the VSGNE Member hospitals. The Executive Committee conducts the business of the VSGNE and makes all decisions on behalf of the VSGNE, including oversight of budgets, contracts, publications, relationships with outside parties, requests for membership, and the general direction of the association. In the event of a vacancy in the Executive Committee, the remaining members of the Executive Committee may exercise the powers of the full Executive Committee until the vacancy is filled. The Executive Committee may designate other committees as necessary to conduct the business of VSGNE.

The VSGNE Executive Committee consists of one representative appointed by each VSGNE Member hospital, as well as the Medical Director, Project Manager and Epidemiologist, all of whom are voting members of the Committee. The Executive Committee may meet in person, or by conference call or email. Meetings may be called by the Medical Director, or at the request of any other two members of the Executive Committee. The Executive Committee oversees the interaction of VSGNE with the SVS PSO and M2S, Inc., including costs and contractual details for VSGNE Member hospital participation in the SVS PSO. It approves research studies and publications, relationships with outside parties, requests for membership, de-identified data distribution for research or sale to commercial entities and the general direction of the VSGNE.

A quorum of the Executive Committee consists of representatives of at least two-thirds of the VSGNE Member hospitals, which is necessary to conduct business. A majority vote of the members present at a meeting at which a quorum exists is required to pass resolutions. In the event that an Executive Committee member cannot attend a meeting, the hospital may designate an alternate, who shall have full voting rights. Minutes of the Executive Committee meetings are distributed electronically or via the VSGNE website to all hospital and physician members of the VSGNE.

b. Quality Committee:

The VSGNE Quality Committee consists of physicians, analysts, and administrative personnel appointed by the VSGNE Executive Committee to the VSGNE Quality Committee of the SVS PSO. These individuals represent VSGNE on the SVS PSO, and must sign agreements to abide by all confidentiality rules of the SVS PSO. The VSGNE Quality Committee is responsible for all decision making concerning patient safety work product production using VSGNE regional data within the SVS PSO, including types of analyses, reports, benchmarking, and risk adjustment to be conducted by the SVS PSO. The Quality Committee represents the interests of all member hospitals and physicians on the SVS PSO, and oversees all SVS PSO quality improvement activities for the VSGNE region.

c. Staff:

a) The **Medical Director** is a vascular surgeon nominated by the Executive Committee and elected by a majority vote of the full membership of the Executive Committee to a three year renewable term. The Medical Director chairs the Executive Committee, prepares the agenda for VSGNE meetings, prepares an annual budget and is responsible for the overall operations of the VSGNE between meetings of the Executive Committee.

b) **Staff Members** may be hired by the Executive Committee to meet organizational and analytical needs of VSGNE. Staff members are selected by the Executive Committee and

their percentage effort and associated salary are set by the Executive Committee, consistent with the annual budget. VSGNE Staff shall include but are not restricted to:

- i. A **Project Manager**, who is responsible for day-to-day operation of the VSGNE under the supervision of the Medical Director, including but not limited to support to member hospitals regarding web-based data submission and report generation, as well as preparing for VSGNE meetings, coordinating quality improvement activities and all other operational functions of the group.
- ii. An **Epidemiologist**, who is responsible for oversight of the analytic and statistical functions of the group.
- iii. A **Statistician**, who is responsible for the analyses of data necessary to conduct quality improvement activities.

IV. Shared Registry Data Ownership

Each hospital owns the data that it submits to the VSGNE registry via the SVS PSO, and is entitled to specify and control the use of its data in the manner set forth in the Hospital Contract. Thus, any use of a hospital's data by the VSGNE for purposes other than quality improvement research or any of the standard quality assurance functions performed by the VSGNE shall require the prior consent of the hospital, in the manner set forth in the Hospital Contract.

VII. Policies

The following principles guide the function of the VSGNE and must be adhered to by all members.

- 1) All activities of the VSGNE must be consistent with the mission statement above. All data reports that compare physicians or hospitals must be anonymous, unless identification of specific hospitals or physicians is unanimously approved by the involved hospitals or physicians. Any reports that identify hospitals or physicians are considered quality assurance documents. All members of the VSGNE agree to keep such information strictly confidential.
- 2) Each physician member must submit data for all consecutive procedures that are recorded by VSGNE and must agree to submit office claims data on a periodic basis to allow an audit to ensure accurate and complete data entry.
- 3) Each member hospital agrees to submit ICD-9 based claims data on a periodic basis to allow an audit to ensure accurate and complete data entry.
- 4) Each member hospital and physician must submit complete data forms, including all elements of the VSGNE registry for all eligible procedures, using a web-based system approved by the VSGNE, including follow-up data at one year, or other time points established by the VSGNE.
- 5) Each member hospital and physician agrees that comparative data can never be used for competitive marketing. Hospitals and physicians own their own data, and can publish such data with the indication that it has been audited by the VSGNE. However, they may not publish data provided in benchmarking reports that compares their hospital or practice with other groups in the VSGNE.

- 6) Each hospital and physician member must agree to follow the VSGNE Confidentiality Manual which is available on the VSGNE website (www.vsgne.org), and is designed to prevent the disclosure of any patient identifiable information, as well as any hospital or physician identifiable information. Further, each VSGNE hospital and physician member agrees to follow all regulations contained within the Hospital Insurance Portability and Accountability Act (HIPAA) and the Patient Safety Quality Improvement Act (PSQIA).
- 7) Failure to adhere to these policies may result in loss of membership in VSGNE for a hospital or physician, if so determined by a majority vote of the Executive Committee.

VIII. Research

Analyses will be regularly performed by the VSGNE to provide feedback to member hospitals and physicians for purposes of quality improvement within the SVS PSO. These may yield useful information that could benefit the medical community at large, and warrant scientific publication or presentation. Proposals for specific research projects using shared regional data may be made by any VSGNE Member hospital or physician, and shall be considered by the Executive Committee. If approved by the Executive Committee such projects may proceed. All VSGNE Members conducting such research agree to abide by all VSGNE confidentiality rules, all HIPAA regulations, and all PSQIA regulations that are relevant to protecting the privacy of both patients and the member hospitals and physicians, none of whom shall be identified in any publication. All resulting publications and presentations shall be authored by the specific participating individuals from the VSGNE and carry the author byline “on behalf of the Vascular Study Group of New England.” Each participant in such research must sign a statement that attests to these agreements.

VIII. Amendments

Bylaws may be amended by a vote of two-thirds of the full membership of the Executive Committee, provided that such amendments are circulated electronically and on the VSGNE website at least 30 days prior to their consideration. Any amendments published on the VSGNE website shall be deemed incorporated herein by reference.

C. Publications from the Vascular Study Group of New England

1. Goodney PP, Eldrup-Jorgensen J, Nolan BW, Bertges DJ, Likosky DS, Cronenwett JL. A Regional Quality Improvement Effort to Increase Beta Blocker Administration Before Vascular Surgery. *J Vasc Surg* (in press).
2. Bertges DJ, Goodney PP, Zhao Y, Schanzer A, Nolan BW, Likosky DS, Eldrup-Jorgensen J, Cronenwett JL. The Vascular Study Group of New England Cardiac Risk Index (VSG-CRI) predicts cardiac complications more accurately than the Revised Cardiac Risk. *J Vasc Surg*. 2010 Sep; 52(3):674-83.
3. Simons JP, Goodney PP, Nolan BW, Cronenwett JL, Messina LM, Schanzer A. Failure to achieve clinical improvement despite graft patency in patients undergoing infrainguinal lower extremity bypass for critical limb ischemia. *J Vasc Surg*. 2010 Jun; 51 (6):1419-24.
4. De Martino RR, Nolan BW, Goodney PP, Chang CK, Schanzer A, Cambria R, Bertges DL, and Cronenwett JL. Outcomes of Symptomatic Abdominal Aortic Aneurysm Repair: A Multicenter Review from the Vascular Surgery Study Group of Northern New England. *J Vasc Surg* 2010; 51 (2) 530.
5. Goodney PP, Nolan BW, Schanzer A, Eldrup-Jorgensen J, Stanley AC, Stone DH, Likosky DS, Cronenwett JL and the Vascular Study Group of Northern New England. Factors Associated with Death 1 Year After Lower Extremity Bypass in Northern New England. *J Vasc Surg* 2010; 51 (1) 71-78.
6. Goodney PP, Nolan BW, Schanzer A, Eldrup-Jorgensen J, Bertges DJ, Stanley AC, Stone DH, Walsh DB, Powell RJ, Likosky DS, Cronenwett JL; Vascular Study Group of Northern New England. Factors Associated with Amputation or Graft Occlusion One Year after Lower Extremity Bypass in Northern New England. *Ann Vasc Surg*. 2010 Jan; 24(1):57-68.
7. Goodney PP, Nolan BW, Eldrup-Jorgensen J, Stanley AC, Likosky DS, Cronenwett JL. Restenosis Following Carotid Endarterectomy in a Multicenter Regional Registry. *J Vasc Surg* 2009; 50 (6) 1531
8. Schanzer A, Goodney PP, Li Y, Eslami M, Cronenwett J, Messina L, Conte MS; Vascular Study Group of Northern New England Validation of the PIII CLI risk score for the prediction of amputation-free survival in patients undergoing infrainguinal autogenous vein bypass for critical limb ischemia. *J Vasc Surg*. 2009 Oct;50(4):769-75; discussion 775. Epub 2009 Jul 22.
9. Goodney PP, Likosky DS, Cronenwett JL and the Vascular Study Group of Northern New England. Predicting Ambulation Status One Year after Lower Extremity Bypass. *J Vasc Surg* 2009; 49 (6) 1431-1439.
10. Stone DH, Nolan BW, Schanzer A, Goodney PP, Cambria R, Likosky DL, Walsh DB, Cronenwett JL and Vascular Study Group of Northern New England (VSGNNE). Protamine Reduces Bleeding Complications Associated with Carotid Endarterectomy Without Increasing the Risk of Stroke. *J Vasc Surg* 2009; 49 (5) S11.
11. Beck AW, Goodney PP, Likosky DL, Eldrup-Jorgensen J, Cronenwett JL and the Vascular Study Group of Northern New England. Predicting 1-year mortality after elective abdominal aortic aneurysm repair. *J Vasc Surg* 2009 49 (4) 838-844.
12. Goodney PP, Likosky DS, Cronenwett JL and the Vascular Study Group of Northern New England. Factors Associated with Stroke or Death After Carotid Endarterectomy in Northern New England. *J Vasc Surg* 2008; 48 (5) 1139-1145.
13. Cronenwett JL, Likosky DS, Russell MT, Eldrup-Jorgensen J, Stanley AC, Nolan BW. A regional registry for quality assurance and improvement: The Vascular Study Group of Northern New England (VSGNNE). *J Vasc Surg* 2007; 46:1093-1101.

D. Sample Quality Reports from the Vascular Study Group of New England

In the past, semi-annual quality reports for each hospital and provider have been prepared and distributed prior to each VSGNE meeting (November and May). These have been used as the basis for quality improvement discussions at the meetings.

Key quality indicators that are tracked over time for each type of procedure are displayed in a 12 charts per page format. Each chart shows the rate of events in each center (red line) compared with the region average (blue line). Each center receives its own report. The variation across centers at each time point is displayed by small circles which show the maximum and minimum. An example of such a report for carotid endarterectomy is provided.

Risk-adjusted comparisons of key outcomes of each center for each procedure may be generated from the data. An example of stroke or death after carotid endarterectomy follows. Risk-adjusted benchmark reports compare the outcome at each hospital after controlling for different patient factors that can influence outcome, and show standard deviation estimates to ascertain significant variations.

Benchmark information regarding the use of important pre-operative medications, such as beta blockers compares providers and hospitals over time.

Bar graphs that display a comparison of key outcomes and complication rates among centers and providers are available in real-time. These are not risk-adjusted, but provide an estimate for each center and provider of their results in comparison to others in the region, including a ranking of annual volume per procedure. An example for endovascular AAA repair and open AAA repair is provided.

V. Clinical Data Pathways

What is Clinical Data Pathways?

Clinical Data Pathways provides physicians, clinical researchers, and institutions the power to assess outcomes, enhance clinical quality, and improve practice standards, quickly and efficiently through benchmark reporting and data sharing under the protection of the SVS PSO. With ten years of experience in vascular outcome analysis and expert guidance from the Vascular Study Group of New England (VSGNE), M2S has built a secure, web-based clinical data platform solution that is customizable to meet an institution's unique workflow needs while adhering to the requirements of collaborative medical registry protocol.

What is included?

Currently, Clinical Data Pathways captures data for the following procedures: Carotid Endarterectomy, Carotid Artery Stent, Infra-Inguinal Bypass, Supra-Inguinal Bypass, Open AAA Repair, Endovascular AAA Repair, Peripheral Vascular Intervention, Thoracic and Complex Endovascular Aortic Repair, and Hemodialysis Access. Data input forms designed by vascular surgeons contain sufficient clinical detail to allow analyses of root causes for different outcomes, including patient case mix, pre-operative management, and details of surgical technique. All data can be downloaded and saved.

Clinical Data Pathways combines experience with superior technology, making it an optimal platform for quality improvement and data management. Gaining accurate quality outcomes depends on both data integrity and the ability to share results. Pathways maintains data integrity with its functions of error trapping, help text, and incomplete data alerts. Pathways also allows institutions to combine data and view their performance compared to another institution or group.

M2S provides online training sessions prior to set-up to ensure user familiarity with the data entry and report generation features. Participating providers and their data management staff also receive ongoing customer service and technical support via telephone and email.

What are the benefits?

- Detection of specific areas for quality improvement
- Comparison of providers and centers in support of performance improvement initiatives
- National platform for benchmarking
- Identification of best practices
- Demonstration of center's dedication to improving patient care
- Potential to increase physician reimbursement through PQRI
- Data collection to meet CMS's Carotid Artery Stent Facility Recertification requirements

Real-time Reports

- Status reports – Tools for improving data entry efficiency
- Longitudinal benchmarking – Compares center data with an entire region's data over time
- Major Outcomes Reports for Surgeon and Center
- Major Complication Reports for Surgeon and Center
- Pre- and Post-Operative Medication Usage
- Ad-hoc reports – Permit investigation of possible associations within the dataset

B. Data Entry Requirements

Hospitals are fast-paced environments with limited data entry resources. However, the rewards of data collection can influence many areas, from reducing morbidity to improving surgeon and center performance results. To reduce the burden of participating in the Vascular Quality Initiative, SVS PSO has adopted Clinical Data Pathways, a system designed to easily integrate into a variety of workflows, allowing multiple users to access and enter data on a single form, and to spread the responsibilities of data entry to more than one individual. Designed by physicians for physicians, this system captures important demographic and risk factor information as well as major outcome and complication data in order to provide comprehensive outcome analysis and inform performance improvement. The following data entry information and guidance is based on the experience of our current customers.

Sites vary in the number of participants involved in the data entry process. In some institutions, physicians enter the majority of the procedure data and other qualified staff enters the history, demographic, and post-operative information. At other institutions, RNs and/or data entry personnel are responsible for entering all data. These diverse settings make it difficult to ascertain staffing needs. In general, data managers have reported that it takes on average 30-45 minutes to enter each procedure, including time to abstract data from their departmental clinical systems. Performing data entry at the point of patient care may reduce the time requirements to 10-20 minutes per procedure. Physicians have responded that their portion, normally the procedure details, takes only 2-3 minutes.

To assist you in determining your data entry needs, we have compiled several examples detailing the workflows and estimated data entry commitments from centers currently participating in a regional group.

Sample 1: High Volume Institution

An institution performing 750 procedures per year invests approximately 10-15 hours per week collecting and entering data from a combination of electronic and paper medical records. The workflow at this institution has been designed to accommodate physician entry of procedure details followed by the data coordinator completing the remainder of the data elements.

Sample 2: Medium Volume Institution

An institution performing 250 procedures per year reported averaging 5 hours per week on data collection and entry from a combination of electronic and paper medical records. A registered nurse is responsible for extracting data from the medical record and entering it into the Clinical Data Pathways system. This same RN works on multiple registries in which the institution participates.

Sample: Low Volume Institution

An institution performing 110 procedures per year devotes an average of 1-2 hours per week collecting and entering data from a paper medical record. To reduce the burden and improve efficiency of data entry, this institution has split the data entry responsibilities between three main individuals. Once the office has generated a list of the schedule patients, a data entry clerk creates the patient and enters the demographic data. After the operation, the physician or registered nurse completes the procedure and post-operative information. All participants are involved in multiple registries.

C. Pricing

A key feature of the Vascular Quality Initiative is its affordability. SVS PSO and M2S are committed to providing this service at a price that promotes widespread adoption, facilitating its mission of quality improvement through benchmarking. The cost per institution for start-up and annual fees can range from \$3,000-\$25,000; the annual fees are \$2,200-\$18,000 thereafter. Included in these prices are the following procedure forms and associated outcome and complication reports: Open AAA Repair, Endovascular AAA Repair, Carotid Artery Stent, Carotid Endarterectomy, Infra-Inguinal Bypass, Supra-Inguinal Bypass, Peripheral Vascular Intervention, Thoracic and Complex Endovascular Aortic Repair, and Hemodialysis Access. Institutions will be able to purchase new modules as they become available. Additionally, individual regional quality improvement groups may charge a membership fee for participation. For information on the cost of VQI for your institution, contact vqi@m2s.com.

The VQI service cost includes:

One-time Set-up Fee

- Optimal workflow consultation
- Institutional configuration
- Permissions set-up
- Data sharing implementation
- Training of physicians and data managers on application usage

Annual PSO Fee

- Oversight of benchmarking
- New data form design
- Quality analysis
- Development of risk-adjustment algorithms by dedicated statistician and epidemiologist

Annual Database Subscription Fee (based on procedure volume)

- 24/7 Web-based data interface
- Real-time reporting of major outcomes and complications
- Ability to download institutional data sets
- Maintenance and upgrades to purchased forms
- Customer Service and Technical Support

Annual Procedure Volume	Cost Per Form
1-5	\$400
6-15	\$800
16-30	\$1,300
31-60	\$1,800
61+	\$2,300

D. Additional Services from M2S

Automated Data Import - M2S has identified a need for institutions to seamlessly link data from clinical systems and/or electronic medical records (EMR) directly into Clinical Data Pathways, increasing data entry efficiencies. Integration of general and demographic information from your institution's clinical system into Pathways is available upon request for an additional cost which is based on the design and development work needed.

Historical Data Import - Import of historical data is available to institutions that have collected all or a subset of the data elements captured in Clinical Data Pathways. To perform a one-time import of historical data, M2S's development team will work with your site to map fields from your existing database to corresponding fields in Pathways. Once the transfer has been performed, M2S will work with the site to ensure the accuracy of the data transfer.

Customization - Customization of forms, fields, and reports is available to institutions upon request. M2S's engineering and development team will work with your site to understand your institution's unique needs, determine the appropriate design, and test the new features to ensure that they meet your exact specifications.

PQRS - Physicians who adopt Clinical Data Pathways may receive an additional benefit through participation in the Physician Quality Reporting System (PQRS). M2S is accredited by CMS to report quality measures on behalf of physicians as part of PQRS for an annual fee of \$350. Such reporting on quality measures within the Pathways system on pre-operative antibiotic usage and carotid patch usage entitles reporting physicians to receive a supplement from CMS of up to 1% of their allowable Medicare billing for the reporting period. For a vascular practice submitting between \$400,000 and \$800,000 claims annually to CMS for Medicare Part B, this reimbursement would be in the range of \$4,000 to \$8,000.

For additional information on these services, contact vqi@m2s.com.

Frequently Asked Questions

1. What is the Vascular Quality Initiative (VQI)?

The Vascular Quality Initiative (VQI) includes two parts:

- a. A Patient Safety Organization (SVS PSO) that collects and analyzes patient data to improve the quality of vascular health care. Composed of regional quality groups, SVS PSO employs the successfully quality improvement methods developed by the Vascular Study Group of New England.
- b. A secure, web-based outcomes data collection tool, M2S's Clinical Data Pathways, which provides a common data collection format for the regional study groups. Clinical Data Pathways collects data on major vascular procedures and provides real-time reports on outcomes and processes of care.

2. What is the relationship between SVS and M2S Inc.?

SVS is the sole owner of the SVS Patient Safety Organization, LLC and controls all aspects of the PSO function, including the selection of PSO staff. M2S is the owner and service provider of the Clinical Data Pathways registry product that has been selected by SVS PSO as the data management services vendor.

3. What is a Patient Safety Organization (PSO) and what role does it play in the VQI?

VQI data analysis activities fall under the protection of the SVS Patient Safety Organization (SVS PSO), which provides an infrastructure for sharing and analyzing data. Patient safety organizations are approved by the federal Agency for Healthcare Research and Quality (AHRQ) for analyzing data for quality improvement purposes. Data analyses done under the auspices of a PSO allow the use of patient-identified data for quality improvement projects, without requiring IRB approval or specific patient consent. Further, such patient safety work product is protected from legal discovery in state or federal court. The purpose of the Patient Safety Act was to allow providers to honestly report outcomes without fear of reprisal for bad outcomes. Identified Patient Safety Work Product (PSWP) cannot be disclosed outside of the PSO. In February, 2011, SVS PSO was accredited by AHRQ.

4. Who runs the PSO?

Oversight for the SVS PSO is provided by a Governing Council that includes representatives from SVS and from regional study groups. The Governing Council sets policies for the SVS PSO; the SVS Board of Directors approves the SVS PSO budget and any major changes proposed by the Governing Council.

The SVS PSO also has a Research Advisory Committee that oversees and approves any research done with de-identified data from the PSO that involves multiple regions.

The Medical Director of the SVS PSO is Jack Cronenwett, M.D., with Carrie Bosela as the Administrative Director.

The Governing Council committee members can be viewed at

<http://www.vascularweb.org/about/Pages/Vascular-Quality-Initiative.aspx>

The Research Advisory Committee members can be viewed at <http://www.vascularweb.org/about/Pages/Vascular-Quality-Initiative-Committees.aspx>

5. Who can participate in the VQI?

Any physician performing procedures included in the VQI can participate, as an individual, a physician group, or a hospital. Participation is not limited to the US and Canada; international participation is welcomed.

6. What is the role of the regional study groups?

Centers participating in the VQI are encouraged to form regional study groups as a way to improve the quality of vascular care by analyzing and reporting outcomes based on use of a common registry. Each regional study group that is approved by SVS PSO for participation has a Quality Committee under the umbrella of the SVS PSO to oversee the protected patient safety work performed on regional data.

Regional study groups have their own governing structure, usually including an executive committee and a research advisory committee to review and approve distribution of regional de-identified data for research.

Currently more than 85 centers in the United States and Canada participate in VQI. Regional groups have been established in New England, the Mid-Atlantic, the Carolinas, Florida, the South (SoVONet), and Southern California. Additional groups in varying stages of development are in Washington, D.C., the Virginias, Georgia, the Rocky Mountains, and Michigan.

SVS and M2S can assist with the formation of a regional group by identifying and recruiting interested institutions, providing informational materials and product demonstrations, and helping organize initial meetings. For more information on forming a regional group in your area, contact c.bosela@svspsso.org.

7. Why is the VQI good for vascular surgery and SVS members?

VQI positions the SVS as a leader in vascular outcomes tracking by providing a common platform for physicians to analyze outcomes, reinforce best practices and share quality improvement efforts regionally and nationally. VQI will provide an opportunity for long-term data collection that is critical to meaningful outcomes assessment of treatment options for vascular disease.

Individual physicians benefit by receiving individual benchmarked quality reports, and this activity is approved as meeting the requirements for Part IV of Maintenance of Certification by the American Board of Surgery. Also, the M2S database collects data to meet the requirements for the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting System (PQRS) and Carotid Artery Stent Facility Recertification.

8. What are the plans for the SVS Vascular Registry?

SVS will continue the SVS Vascular Registry for CEA and CAS during VQI implementation. Subsequently, all SVS Vascular Registry participants are encouraged to utilize the VQI database for their CEA and CAS data collection efforts.

For information about the current incentives for Vascular Registry participants to join VQI, contact c.bosela@svspsso.org.

9. Can I have access to de-identified data for research, and if so, how do I gain access to the data?

You must be participating in VQI to have access to de-identified data for research.

- If you want to access de-identified research data from participating centers within your regional group, you need to gain approval through your regional group research advisory committee of the SVS PSO.
- If you would like to do a cross-regional or national research project, you will need to gain approval through the research advisory committee of SVS PSO, and each regional group contributing data must approve the project and be represented on the study design and writing committee.

10. Can I integrate with my EMR/Clinical System?

For an additional fee, M2S provides integration of general and demographic information from your clinical system into the Clinical Data Pathways system. In the future, SVS PSO plans to work with EMR providers to encourage them to incorporate VQI data elements into the EMR so that all data could be transferred from the EMR to SVS PSO.

11. How much does it cost to participate in VQI?

The VQI registry includes several modules based on type of procedure. The cost to participate in VQI is determined by the number of modules selected and by the annual procedure volume. This approach is intended to encourage institutions of all sizes and practice profiles to participate. Pricing includes a one-time set-up fee, an annual data management subscription fee for M2S's data management services, and an annual fee to participate in the SVS PSO.

Some regional study groups may decide to charge a membership fee for participation in their regional group activities, such as semi-annual meetings and/or regional group research analyses.

12. How does contracting work with SVS PSO and M2S?

There are two contracts, one with the SVS PSO and one with M2S for the Clinical Data Pathways management services. All contracting is facilitated through M2S and both agreements are required in order to participate in VQI.

13. How does contracting and pricing work for hospitals with more than one participating centers?

There will be one contract per hospital or health system. Fees are calculated per institution's annual procedure volume regardless of whether the contract is with an individual institution or multi-center health system.



Vascular Quality Initiative

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For more information on the Vascular Quality Initiative
or for a demonstration of
the Clinical Data Pathways database
Email: vqi@m2s.com or
Call: (603) 298-5509