It is a singular honor to be invited by our Society to deliver the John Homans Lecture, for which I am extremely grateful. I am humbled by the 12 previous Society for Vascular Surgery (SVS) members who have given this lecture (Table). It has never been more true that we stand on the shoulders of giants.

In conceiving the Vascular Quality Initiative (VQI), I was inspired by three factors. In his 1994 Presidential Address to our Society, Dr. Norman Hertzer stressed the importance of outcome assessment in vascular surgery, based on his experience with registry reporting in Ohio.1 At the same time, a group of cardiac surgeons from eight hospitals in northern New England had started a regional quality improvement (QI) collaborative to reduce the mortality of coronary artery bypass graft surgery.2 They implemented a shared data registry that provided anonymous benchmarking, held semiannual meetings of physicians, nurses, and researchers to discuss variation in processes of care and outcomes; and developed QI initiatives based on these analyses. By 1996, they demonstrated a 24% reduction in coronary artery bypass graft mortality across the region, with reduced variation and improvement across all centers.3 Finally, in 2000, the Dartmouth Atlas of Vascular Healthcare revealed large regional variation in both the rate and outcome of vascular surgery procedures that could not be explained by patient differences, suggesting a substantial opportunity for QI.4

**VASCULAR STUDY GROUP OF NORTHERN NEW ENGLAND (VSGNNE), 2001-2007**

Influenced by these factors, eight vascular surgeons from six hospitals in Maine, New Hampshire, and Vermont met at Dartmouth in May 2001 to consider forming a regional QI group. In this discussion, we agreed that the mission would focus on improving the quality, safety, effectiveness, and cost of caring for patients with vascular disease. We decided to adopt the same methods that our northern New England cardiac surgery colleagues were using successfully: first, develop a shared data registry for common procedures (carotid endarterectomy [CEA], abdominal aortic aneurysm [AAA] repair, infrainguinal bypass); second, create anonymous reporting based on registry data so that we could compare ourselves with others in terms of processes of care and outcomes; third, hold semiannual meetings to discuss regional variation and develop QI projects. Finally, we decided that in-hospital outcomes were not sufficient, especially for prophylactic procedures, and that we needed at least 1-year follow-up. So, we planned to collect these data when patients came back to the surgeon’s office for follow-up. During 2001-2002, seven in-person working meetings were held, and the group expanded to include surgeons from 12 hospitals, who founded the VSGNNE. Much of the initial work focused on the challenge of what to include in the data collection forms. Details about the patient and disease severity that could be important for risk adjustment, procedure details that might influence outcomes, and of course the outcomes had to be considered. We were concerned about data entry burden, so we committed to limit the data form to one side of one paper sheet (albeit it with a somewhat small font size). The planned mechanism was to submit paper data forms to a study coordinator at Dartmouth for “keypunching” and computer analysis. A startup grant was received from the Centers for Medicare and Medicaid Services (CMS) to cover central data analysis, with each hospital assuming responsibility for data collection. Initially, Institutional Review Board approval and patient consent were required in addition to contracts with each center.

In January 2003, the VSGNNE started collecting data from 12 hospitals. We had our first meeting to review data in April, from the first 529 cases. Based on available data, we decided to initially analyze variation in processes of care, such as appropriate use of preoperative medications, like aspirin and statin. The initial 25 surgeons in VSGNNE were confident that most of their patients were on these medications preoperatively, so they were surprised to learn that only 50% of patients were on a statin, with variation from 20% to 70% among the surgeons. This provoked discussion and sharing of methods to improve this rate, and within 3 years, preoperative statin use increased to 80%, with all 25 surgeons showing substantial improvement. The important learning from this...
early QI project was that if we provided feedback to competitive surgeons about how they compared with others, they would change their practice because everyone wanted to be the best.

From 2003 to 2007, VSGNNE data collection continued (to 8600 cases), and 1-year follow-up was achieved for 86% of patients by this committed group of surgeons. Fortunately, a waiver for patient consent was granted by Institutional Review Boards because it had proved impossible to obtain consent in all cases, which prevented an all-inclusive registry. A governance structure was created with representation from each center, and new registries for peripheral vascular intervention and carotid artery stenting (CAS) were added. QI projects expanded from optimizing preoperative medications\(^5\) to increasing the use of patching during conventional CEA\(^6\) and developing better cardiac risk prediction models\(^1\) to improve patient selection. As we began to analyze procedural outcomes, it appeared that these were excellent, which raised questions about consecutive case submission vs the potential for “cherry-picking.” As a result, a claims-based audit mechanism was developed, which showed no outcome bias in missing cases and allowed sites to enter missing cases to achieve 99% completeness.\(^8\) Reassured by this audit, the VSGNNE presented its first report at the 2007 SVS annual meeting and published this in the *Journal of Vascular Surgery*.\(^8\)

**VASCULAR STUDY GROUP OF NEW ENGLAND (VSGNE), 2008-2011**

Awareness of the QI work being done in northern New England led to significant interest by others. During 2008-2009, five centers from Massachusetts joined VSGNNE, resulting in its name changing to the VSGNE. Further, guests from other parts of the country began attending VSGNE regional meetings to understand the specific methods involved in this activity. Data collection continued, such that 14,000 cases had been entered by 2010, which provided more opportunity for both research by VSGNE members and QI projects. During a semiannual VSGNE meeting, a question was raised as to whether protamine reversal of heparin was appropriate on completion of CEA. The answer was unknown, but by this time, data from 4,587 CEA\(^9\)s were available, including protamine use and reoperation for bleeding rates. Research by Stone et al\(^9\) demonstrated that surgeon practice pattern was nearly evenly divided (46% of CEA\(^9\)s had protamine used), with individual surgeons nearly always having the same practice, presumably based on their training and experience. Subsequent analysis showed that protamine use was associated with a significant reduction in the rate of reoperation for bleeding (1.7% to 0.6%), without any increase in thrombotic complications.\(^9\) Presentation of these data at VSGNE and SVS meetings, associated publication, led to a rapid increase in protamine use across VSGNE from 52% to 62%, which was associated with a reduction of reoperation for bleeding from 1.4% to 0.6%.\(^10\) This project provided an important illustration of registry research leading to new knowledge that can drive QI. Further, it demonstrated that research can effect rapid practice change by surgeons with an ownership stake in the registry, much more rapidly than has been demonstrated with generic research publication.\(^11\)

By 2010, VSGNE had expanded to 27 participating hospitals, with a nearly equal distribution of 13 academic and 14 community centers (Fig 1). After expiration of the CMS startup grant, all participating hospitals agreed to share the central administrative costs for data analysis and reporting, which continues to be the main funding mechanism for VQI. In addition, centers outside New England expressed interest and were invited to join VSGNE as “Adjunct Members” so they could benchmark their processes and outcomes with VSGNE members. This growth required more infrastructure, with paper data collection no longer feasible. Accordingly, VSGNE partnered with a Dartmouth spinoff company (M2S) to create a web-based infrastructure for data entry and real-time reporting. Further, as more large hospitals began joining the initiative, more concerns arose about data confidentiality and protection from legal discovery. To address these concerns, the Vascular Study Group Patient Safety Organization (VSG PSO) was created by M2S for the VSGNE. PSOs are authorized to collect data for QI purposes without the need for informed consent, protect the data from legal discovery, and allow the use of fully nonidentifiable data for research.\(^12\) This PSO structure not only expedited the expansion of VSGNE but set the stage for the creation of additional regional quality groups. Since 16 centers outside New England had joined the VSG PSO by 2010.

<table>
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<tr>
<th>Year</th>
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<tr>
<td>1951</td>
<td>Daniel Elkin</td>
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<td>Juan Parodi</td>
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<td>2016</td>
<td>Frank Veith</td>
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<td>Hazim Safi</td>
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**Table. Society for Vascular Surgery (SVS) John Homans Lecturers**
VASCULAR QUALITY INITIATIVE, 2011-PRESENT

Growth of the VSG PSO beyond New England illustrated the potential for nationwide participation and was recognized as an important initiative by the SVS. Negotiations with M2S led to a transfer of ownership of the VSG PSO to the SVS, creating the SVS PSO and launching VQI in February 2011. The mission of the SVS PSO remained consistent with the original VSGNNE concept: “to improve the quality, safety, effectiveness and cost of vascular healthcare by collecting and exchanging information.”

Also in 2011, four SVS members who had participated in VSGNE meetings organized four new regional quality groups under the SVS PSO umbrella: Carolinas Vascular Quality Group (Jeb Hallett, MD), Southeastern Vascular Study Group (Adam Beck, MD), Southern Vascular Outcomes Network (Mark Davies, MD), and Southern California Vascular Outcomes Improvement Collaborative (Fred Weaver, MD). The key concept of regional QI groups was that semiannual meetings of physicians, nurses, researchers, and data managers would more likely translate data into QI when organized into smaller groups that would promote trust, collegiality, and collaboration.

Since 2011, VQI has grown rapidly. There are now 18 regional quality groups encompassing the United States and Canada that each meet semiannually to review regional data and to plan QI projects. As of September 1, 2019, there are 602 participating centers and >3200 multispecialty physicians participating in VQI. More than 635,000 procedures have been entered in 12 registries. Long-term follow-up data have been reported for 70% of patients at a mean time of 1 year postoperatively. The principal value of VQI for physicians and centers continues to be the anonymous benchmark reporting of data that they cannot otherwise access. The granular clinical data contained in the trusted VQI registries allows accurate comparison across similar patient, disease, and treatment profiles and is stimulating for all who want to improve their processes and outcomes.

QUALITY IMPROVEMENT IN THE VASCULAR QUALITY INITIATIVE

The SVS PSO has created significant infrastructure to support national, regional, and local QI projects. Quality Councils oversee national projects, the Research Advisory Committee reviews and promotes quality research projects, and PSO staff assist individual centers with QI projects. The VQI@VAM annual meeting promotes and recognizes regional and local QI projects, and the VQI website provides QI resources, including a detailed, step-by-step project guide. As a result of these activities, 55 VQI centers submitted individual QI project proposals to the SVS PSO in 2018 and participated in monthly calls of project coordinators to share learnings and solutions. There are now many examples at the
national, regional, and local level of QI projects, such as reduction of surgical site action, access site hematomas, postoperative myocardial infarction, and length of stay (LOS) as well as improving smoking cessation, long-term follow-up, and late imaging after endovascular aneurysm repair (EVAR).

An important innovation by the SVS PSO was the creation of reports for each center that identify center-specific opportunities for improvement (Center Opportunity Profile for Improvement [COPI] reports). To do this, a multivariable model is developed to identify risk factors that are independently associated with a particular outcome. A COPI report is then prepared to illustrate how each center compares with all others for the main outcome but also for each associated risk factor. Centers can then focus on improving factors most responsible for a poor outcome in their center, such as increased LOS after CEA due to a high frequency of specific postoperative complications (Fig 3). After distribution of COPI reports for LOS after CEA, the percentage of patients with LOS >1 day significantly decreased from 42.9% to 35.3% (P < .001) in VQI centers.

**VARIATION OF CARE IN VQI**

An important goal for QI registries is to identify variation in processes of care or outcomes across participating physicians and centers because variation implies opportunity for improvement. For example, across current VQI centers, the use of peripheral vascular intervention treatment (vs bypass) of claudication or critical limb ischemia varies from 0% to 100% (Fig 4, A). This implies lack of agreement about optimal treatment selection and need for additional research or practice guidelines to optimize care. Similarly, the mean internal carotid artery peak systolic velocity before CEA or stenting in asymptomatic patients varies from 100 to 600 cm/s across VQI centers (Fig 4, B). This large variation indicates lack of agreement about the duplex ultrasound definition of severe carotid stenosis, resulting in different patient selection and the potential to move outlier centers toward the mean through awareness from registry feedback.

QI registries can also be used to inform and to monitor adherence to practice guidelines. The SVS has published multiple practice guidelines based on research and expert consensus. VQI now provides the opportunity to monitor real-world practice in comparison with such guidelines and to use these data to identify a need for either education or refinement of guidelines. As an example, SVS guidelines suggest avoiding elective treatment of small-diameter AAAs (<5.5 cm in men, <5 cm in women).

However, across current VQI centers, adherence to this guideline varies from 50% to 100% for EVAR and open AAA repair (Fig 5). This could reflect additional appropriate indications for AAA treatment...
beyond diameter but likely also represents an opportunity for standardization of practice through registry feedback. Importantly, the effectiveness of QI projects or educational efforts can be monitored in real time through the VQI registry.

**VASCULAR QUALITY INITIATIVE RESEARCH AND QUALITY IMPROVEMENT**

With now >600,000 procedures collected, the VQI registry provides Big Data for research, which has resulted in >230 peer-reviewed publications, with exponential growth in recent years as more centers participate. This has created new academic opportunities and the potential to translate research learnings into QI. This was well illustrated by a study of >50,000 patients undergoing arterial treatment in VQI, which demonstrated a 24% improvement in absolute 5-year survival when such patients were discharged on antiplatelet and statin therapy. The opportunity for QI was clear because this optimal medical treatment varied from 30% to 100% across VQI centers and improved with more years of participation in VQI. As a result, a national quality initiative was launched by the SVS PSO, which has resulted in a significant increase in the rate of antiplatelet and statin prescription at discharge (Fig 6). Future analyses will likely demonstrate improved survival based on this initiative.

**Fig 3.** Sample Center Opportunity Profile for Improvement (COPI) report demonstrating factors associated with length of stay (LOS) after elective carotid endarterectomy >1 day for this center. In this example, a high frequency of postoperative complications (highest 25th percentile shown in pink highlighted cells) was associated with prolonged LOS and allowed focus for quality improvement (QI) efforts. CHF, Congestive heart failure; COPD, chronic obstructive pulmonary disease; EVAR, endovascular aneurysm repair; OR, operating room; VQI, Vascular Quality Initiative.
The opportunity for VQI research to drive QI has also been demonstrated through the creation of multiple risk prediction algorithms that enable better selection of treatment for patients with vascular disease. Registry data are used to create multivariable models that can then be populated with individual patient data to predict outcomes. Currently, VQI risk prediction models including postoperative myocardial infarction risk,\textsuperscript{19} 5-year survival after elective AAA repair,\textsuperscript{20} and asymptomatic carotid treatment appropriateness\textsuperscript{21} are available on the website or smart phone application “Calculate” by QxMD.\textsuperscript{22} In future years, with more direct linkage between electronic medical record (EMR) systems and registries, patient-specific practice guidelines derived from registry-based models will likely be immediately available during the process of care, without the requirement for dual data entry.

**DEVICE EVALUATION IN THE VASCULAR QUALITY INITIATIVE**

Vascular treatment requires many devices that are captured in the VQI registry. Proper performance of these devices is important for successful outcomes and thus a central component of quality assessment by the SVS PSO. After initial premarket approval of vascular
devices, they are often used off-label or in different patient populations than tested in the initial, selective device trials. Thus, postmarket assessment of device safety and effectiveness using real-world data from registries is important and has been recommended by both the Food and Drug Administration (FDA) and the European Commission. To date, VQI data have been used for FDA-required postapproval surveillance of six devices and for modification of labeling for two devices. Recently, VQI data have also been used to generate contemporary objective performance goals for superficial femoral and popliteal artery interventional treatment as part of the FDA-sponsored Medical Device Epidemiology Network (MDEpiNet) Registry Assessment of Peripheral Interventional Devices (RAPID) project. These performance goals for balloon angioplasty, stenting, and atherectomy based on >20,000 procedures with long-term follow-up in VQI are a substantial improvement in current, outdated performance goals based on far fewer procedures. Such information is critically important for physicians who need to recommend the optimal device for each patient in their practice.

Most recently, VQI data have been used to provide additional evidence at the FDA panel concerning the appropriate use of paclitaxel-coated balloons and stents, organized because of the meta-analysis suggesting a higher mortality rate of such devices after more than 2 years. The analysis by Bertges et al of >4000 propensity-matched patients from VQI showed no difference in 2-year survival for drug-eluting vs bare-metal stents or drug-coated vs plain balloon angioplasty. Importantly, longer follow-up of survival in these patients in VQI is planned through both Medicare claims and Social Security Death Index matching, which will help inform ultimate decisions about the risk-benefit of such devices. Because of patient identifiers collected by the SVS PSO, it is possible to match the granular procedural information in the VQI registry with long-term outcomes derived from Medicare claims data to potentially extend follow-up beyond the standard 1-year follow-up in VQI. The feasibility and value of this technique have been demonstrated by the Vascular Implant Surveillance and Interventional Outcomes Network (VISION), a collaboration of VQI with the MDEpiNet Analytic Center at Cornell. Initial work has demonstrated the ability to match Medicare claims with 95% of Medicare-eligible patients in VQI plus the accuracy of the claims data to identify important long-term outcomes, such as mortality and reintervention rate. This process is now being applied to long-term patient and device evaluation in VQI to reduce the cost and burden of long-term follow-up and to maintain the advantages of detailed procedural data from the registry.

An additional opportunity to use the VQI registry for device evaluation is illustrated by the ongoing Transcarotid Artery Revascularization (TCAR) Surveillance Project (TSP). Data from the Silk Road Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure (ROADSTER) TCAR study showed lower stroke risk than expected compared with prior transfemoral CAS trials, leading to FDA approval of this device. Both FDA and CMS concluded that additional data about the TCAR approach would be valuable before a future national coverage decision is made regarding CAS in general because the preponderance of available data relate to transfemoral procedures. To ensure data collection, CMS agreed to reimburse centers for TCAR procedures in both symptomatic and asymptomatic high-risk patients, provided that procedural and follow-up data were entered into the VQI registry for subsequent analysis. This has resulted in >5000 TCAR procedures entered into the VQI registry to date.

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**Fig 5.** Percentage of patients undergoing elective abdominal aortic aneurysm (AAA) repair (open and endovascular aneurysm repair [EVAR]) whose AAA diameter met the Society for Vascular Surgery (SVS) practice guidelines of ≥5 cm for women and ≥5.5 cm for men. Each dot represents one center. VQI, Vascular Quality Initiative.

**Fig 6.** Percentage of patients discharged on antiplatelet agent and statin after arterial treatment in the Vascular Quality Initiative (VQI) over time and in relation to the national quality initiative. SVS VAM, Society for Vascular Surgery Vascular Annual Meeting.
with initial analyses suggesting a reduced stroke rate of TCAR vs transfemoral CAS and comparable performance to CEA. This project demonstrates the potential for registry use to establish the effectiveness of emerging technologies and to provide reimbursement of such for participating centers.

**VASCULAR QUALITY INITIATIVE INTERNATIONAL COLLABORATION**

The potential to learn from other national registries stimulated the formation of the International Consortium of Vascular Registries (ICVR) in 2014, an MDEpiNet-sponsored collaboration of VQI and VASCUNET registries. Designed to compare patient, procedure, and device selection and outcomes across multiple countries, the ICVR currently involves 16 national registries sharing core data for combined analysis. Semiannual meetings of stakeholders from each registry have led to initial studies demonstrating substantial variation in the treatment of AAA and carotid disease across these countries. Interestingly, health care financing differences between countries appear to have an important role because many more asymptomatic carotid stenoses and smaller AAAs are electively treated in countries with fee-for-service reimbursement compared with countries with population-based coverage. Combination of data from multiple registries requires harmonization of variables, which is currently being done by ICVR. Recommendations of appropriate registry variables to monitor peripheral arterial disease treatment have been developed, including different levels of detail for different registries that can be collapsed into core definitions for analysis.

**VASCULAR QUALITY INITIATIVE AND COST REDUCTION**

Included in the mission of VQI is health care cost reduction. The potential to combine detailed clinical registry data with cost data has the potential to allow more accurate comparison of costs for comparable patients and procedures than can be derived from heterogeneous diagnosis-related group codes and claims data. To demonstrate this potential benefit, a pilot study across 18 VQI centers was conducted to analyze the variation in costs (derived from charges) for EVAR treatment. VQI clinical data were used to create cohorts of standard vs more complex procedures and those with and without complications to allow accurate, anonymous comparisons among centers. This demonstrated that for standard EVAR procedures without complications, hospital costs varied from $22,000 to $54,000 per admission, with the largest variation due to the implantable device cost. This pilot study provided all centers with more accurate and trusted cost benchmarking, due to the granular clinical data, and allowed Stanford surgeons to significantly reduce the costs of implants, bed utilization, inpatient imaging, and medications.

Ultimately, the combination of clinical outcomes with cost data allows calculation of value. One method to define quality is the avoidance of major adverse event rates, which can be adjusted for severity based on the associated, prolonged LOS. Applying this technique to the EVAR cost pilot study showed variation in value from high quality, low cost to high quality, high cost across the initial 18 centers. This approach provides a model for future engagement of more VQI centers, which is currently being evaluated in a pilot study. This project incorporates detailed, line item-specific hospital cost data into an interactive web-based SVS PSO report to provide centers with the ability to understand detailed costs of different types of procedures and to compare different providers. Beta testing of this system is currently under way and is expected to be available to VQI centers in 2020. Ultimately, the goal is to provide VQI centers with anonymous benchmarking of quality, cost, and value under the SVS PSO.

**ADDITIONAL BENEFITS OF THE VASCULAR QUALITY INITIATIVE**

Over the past 10 years, increased emphasis has been placed on linking levels of reimbursement with hospital and physician performance. CMS established the physician Merit-based Incentive Payment System as a requirement for full Medicare reimbursement, and payers have established preferred provider lists based on outcome measurement. Further, reimbursement for new procedures is more often being linked to a requirement for registry reporting, such as for TCAR and transcatheter valve replacement. Accurate outcome data are important in negotiations for bundled or capitated payments. Finally,
quality registry participation is required for board certification and will soon be required for the SVS Vascular Center Verification program. Fortunately, participation in the VQI registry can meet all of these needs.

In the future, most believe that registry data will become increasingly important and powerful. The current burden of dual data entry will be solved by direct linkage of registry data with EMR systems will allow patient-specific practice guidelines, derived from registry data, to be delivered at the point of care. It is most likely that payments will be more directly based on performance measures going forward. VQI is ideally situated to have a central role in this process because it is multispecialty, multi-stakeholder, and patient focused.

WHY SHOULD I JOIN THE VASCULAR QUALITY INITIATIVE?

In conclusion, you should join VQI if you want to anonymously compare yourself and your center with others in order to understand and improve processes and outcomes, to select the most appropriate treatment for the right patients, to reduce costs, and to select the best devices and monitor their performance. You should join VQI if you want to use the data and reports to perform research, develop and monitor practice guidelines, obtain reimbursement for new procedures, negotiate with payers, and maintain Board and upcoming SVS Vascular Center Verification. Finally, you should join VQI if you want to actively participate in QI, in your center, your region, your country, and internationally. I would like to close by emphasizing that the success of VQI is not due to a few individuals but rather to its distributed nature, exemplified by more than 200 members who volunteer on various committees to drive this effort. Their dedication and that of the SVS PSO staff underscores the aphorism that if you want to go far, go together. Thank you.

REFERENCES
