VQI – Past, Present and Future

My View – Jens Eldrup-Jorgensen

INTRODUCTION

At the request of VQI and SVS leadership, I have prepared this summary document on VQI, my activities and my thoughts about the future. If there is any interest in further clarification, documentation or details, I would be pleased to try to provide.

Since its inception in 2011, VQI[1] has had significant growth. As you are familiar with the organization, I will not go into detail here (Attachment – Annual Report 2017/2018). In summary, over this time period, we have expanded from 4 to 12 registries, have over 3000 participating centers, over 500 participating providers (multiple different specialties – less than half vascular surgeons), and over one half million patients in the registry. One of the unique aspects of VQI is the biannual regional meetings emphasizing quality improvement engaging physicians, nurses, data managers, quality officers, and administrators. Last year, over 50 quality project charters were submitted to VQI. The registry has been used for evaluation of resource utilization and supported initiatives to decrease length of stay and increase operational efficiency. The VQI registry has been a robust source for data analysis. There are 10,000 procedures being entered into VQI monthly. The database has been used as the basis for greater than 100 presentations at regional and national meetings and publications in peer reviewed journals. In the March issue of JVS, there were 6 articles based on VQI registry data. The registry has been used by industry partners for label expansion, post-market surveillance and performance and benchmark reports.

The VQI is organized under the governance of a Patient Safety Organization[2] (Agency for Healthcare Research and Quality) which provides confidentiality of patient safety work products and eliminates the need for IRB approval and informed consent for standard clinical care. VQI works on multiple quality improvement projects with external collaborators. Registry Assessment of Peripheral Interventional Devices (RAPID)[3-5] is a collaboration of SVS VQI, ACC NCDR, FDA, other governmental agencies, multiple industry partners and stakeholders under the framework of the Medical Device Epidemiology Network (MDEpiNet)[6] to create a coordinated registry network. The goal is to create a strategic alliance of registries and interested parties to enhance the evaluation of medical devices for lower extremity arterial disease. The International Collaboration of Vascular Registries[7] consists of SVS VQI, multiple European and Asian vascular registries, FDA, other international governmental agencies, industry partners under the guidance of MDEpiNet working to provide an international perspective on device regulation and evaluation. The Transcarotid Surveillance Project (TSP) uses the VQI registry to compare the outcomes of TransCarotid Arterial Revascularization with the gold standard, CEA.[8] The TSP methodology has been reviewed by the FDA and allowed CMS to issue a National Coverage Determination based on VQI registry participation.

ACCOMPLISHMENTS

For many reasons it is a little awkward to list one's accomplishments as there is a natural tendency towards modesty. When told a certain gentleman was very modest, Winston Churchill responded, "*He has much to be modest about*."[9] But the primary reason for any hesitation is that successes or accomplishments are rarely the result of any single person's effort. This is very true for my role in VQI which has enjoyed the major contributions of Jim Wadzinksi, Carrie Bosela, and Dan Neal as well as the rest of the PSO staff along with expert guidance from the Chair of the Executive Council, Fred Weaver. Jim, Carrie and Dan are outstanding performers who have made major contributions to my efforts. In the list below, it is my opinion that the "accomplishments" were a team effort, but I have chosen those where I think I played a substantive role (others may disagree).

VQI has enjoyed great success under the team led by Jack Cronenwett who is responsible for the foundation that we have built on.[10] I would also be remiss if I didn't mention that the incredible success (yes, that is the correct adjective since we started with 8 hospitals and 32 surgeons in Northern New England in 2002[10]) of VQI is due to the huge efforts of hundreds of physician volunteers who have contributed countless hours and provided valuable input and guidance. Quality improvement has been a major interest of mine since being a founding member of VSGNNE in 2002.[11-18]

REGIONAL MEETINGS - Regional quality meetings are an important and unique aspect of VQI.[14] Although other quality registries such as NSQIP and NCDR have annual meetings, the VQI biannual regional meetings (18 in US and Canada) are a unique concept and format. The regional groups allows providers, nurses, data managers, quality officers and administrators to meet together in a town hall format to engage in multi-center quality initiatives. This shared learning environment has initiated successful projects such as antiplatelet agents, statins, tobacco cessation, resource utilization, and minimization of complications.[19] Although some regions have good attendance with engaged members, other regions struggle with attendance and participation. Since becoming director, I have tried to attend at least one different regional meeting every spring and fall to meet the membership, learn from successful agendas, and share what I have learned with other regions. One major focus of the PSO staff is to support and optimize the value of all regional group meetings.

APPROPRIATENESS COMMITTEE - Egregious and unnecessary overuse of arterial and venous procedures is a too common problem in vascular surgery. We thought that VQI data could be used to help inform and monitor the appropriate use of vascular procedures. I started a committee whose membership included experts such as Peter Lawrence, Jose Almeida, Karen Woo, Krishna Jain, and others. We engaged the SVS Clinical Practice Committee to ensure there was no duplication of efforts. The Appropriateness committee met regularly in person and by conference call over two years. We focused our efforts on 3 approaches - 1). using the VQI registry to create Clinical Appropriate Performance Indicators (CAPI) reports, 2). adopting the RAND/UCLA Appropriateness Methodology and 3). learning from other societies in their approach to addressing appropriateness. The committee work was recognized by SVS and made a standing committee under the Quality Council maintaining much of the original membership. This might be in the section labeled promising start.

ACC COLLABORATION - Many institutions are reluctant to participate in VQI due to the expense mostly related to data entry. Many of these institutions already participate in NSQIP and/or NCDR and they are reluctant to join VQI. When data is entered into different registries, the data is resistant to pooling and combined analysis. We believe that VQI is a superior registry compared to NSQIP and NCDR as the variables and outcomes are more focused on vascular surgery. In addition, neither NSQIP nor NCDR have regional meetings to focus on quality improvement and do not collect long term follow up. As any vascular surgeon or provider knows, the success of a vascular procedure is not clearly known for at least one year not 30 days. The NCDR has a high degree of penetrance with many of their registries and considerable resources and infrastructure. I meet regularly with Ralph Brindis, Senior Medical Director, NCDR, and past-president ACC and we have discussed collaborative efforts with our registries. After consultation with Ken Slaw and SVS EB leadership, VQI has begun exploratory discussions with ACC/NCDR. We performed a gap analysis of our registries assessing weakness, strengths, and commonality. Both parties believe there may be advantages in joint efforts and plan to continue our discussions towards further collaboration.

Along similar lines, I have met a few times with David Shahian, Medical Director, STS, who shares the sentiment of a collaborative effort to improve efficiency and enhance the strength of registry data. *If you want to go fast, go alone; if you want to go far, go together – African proverb.*

AUDIT - All large, complex datasets are subject to inaccuracies and data errors. There are many reasons for inaccurate data including simple unavoidable events such as keystroke errors and transcription. Inaccurate data may also result from misunderstanding of definitions, e.g. CHF vs COPD, or poorly phrased data elements. Clinical registries such as NCDR and STS spend hundreds of thousands of dollars annually on audits and ensuring data integrity.[20] In 2016 and 2017, VQI discovered systematic errors in our "blinded data sets (BDS)" that are released to investigators. Our technology vendor creates BDS from the registry that has been entered by sites. In accordance with our status as a Patient Safety Organization (PSO), all Protected Health Information (PHI) must be removed. The BDS is an anonymized and de-identified data set that has been extirpated of all PHI which allows VQI to share it with investigators for analysis. In a couple of the VQI registries, there were coding errors that created inaccurate data. As soon as we realized the scope of this error, we recommended and the Executive Council endorsed a moratorium on the release of BDS until this issue was addressed. We then embarked on a comprehensive effort to ensure the validity and internal consistency of VQI data. The data audit was an enormous effort by VQI and M2S which required thousands of hours of personnel time and hundreds of conference calls due to the complex nature of the coding. It was a lengthy (over a year) and tedious process. A manuscript has been prepared reviewing this internal audit and submitted for peer review and publication (attached – Data Validity). As a result of this effort, VQI is confident of the quality of our data and M2S has created multiple new quality control checks that have been instituted.

Data integrity is not dependent on internal consistency and validity alone. The cornerstone of data integrity is completeness and source data accuracy. As such, VQI has begun a number or Inter Rater Reliability (IRR) exercises. A test case is submitted to multiple coders and evaluated for agreement. The IRR is very helpful in defining poorly worded data variables or choices, lack

of clarity in definitions and poor understanding by the coders (which usually raises one of the previous issues - unclear variable or definition). Source data accuracy is best validated by an external audit. During the past year, VQI has engaged an external consultant, Q-Centrix, to perform random audits on all registries. We plan to audit 1/3 of all centers annually such that every center will be evaluated every 3 years.

GUIDELINES - The SVS Document Oversight Committee engaged the VQI to help assess the compliance with and impact of the AAA guidelines. In January, 2018, the SVS published Clinical Practice Guidelines on the management of AAA.[21] Data from the VQI AAA and EVAR registries was used to measure the compliance with specific guidelines and the impact on outcomes. Separate abstracts have been submitted and accepted for presentation at Charing Cross, April, 2019 and VAM, June 2019. Pertinent findings and the implications of guideline compliance will be incorporated into regional reports and presented at regional meetings. VQI registry committees will review SVS CPG guidelines to see if specific guideline elements should be incorporated into the registry. Similarly, using the findings from VQI on the impact on outcomes of guideline compliance may help inform future guideline writing committees.

COORDINATED REGISTRY NETWORK (CRN)[22] - VENOUS - During the past couple years, the American Venous Forum (AVF) has been integrated into the SVS. During the merger, the AVF agreed to transfer their registry and adopt the VQI registries - varicose vein and IVC filter. There is another widely used venous registry maintained by the American Venous and Lymphatic Society (formerly the American College of Phlebology) - known as the ACP PRO (patient reported outcomes). For the reasons outlined previously, there are disadvantages to having two registries - competition, lack of "poolability" of data, and different variables and definitions. We are working with the AVF and have recently entered into discussions with the ACP PRO about the possibility of joint efforts under the framework of a CRN - Venous.

VISION

MEDICAL DEVICE EVALUATION - Big data is said to be the wave of the future allowing us to extract and analyze data and provide information that would otherwise be undetectable or inaccessible. VQI combines the value of big data with a format (dashboards, COPI reports, peer reviewed publications, and regional meetings) that allow translation of the data into action - quality improvement. Previous findings such as the impact of protamine reversal of heparin[23] and carotid patching[24] could not have been identified without large clinical registry data and VQI promoted adoption of these practices. The VQI Research Advisory Council meets every other month and the last cycle received 53 applications for data analysis.

FDA believes that registry-based trials are the future of device approval and post-market surveillance throughout the total product life cycle.[25] Randomized clinical trials (RCT) are felt to be of decreasing value as they are performed by selected providers at selected centers on selected patients and may not be generalizable and reflect real world outcomes.[26] In addition, RCT are becoming increasingly complex with increasing regulatory challenges and increasing expense resulting in delay to market. Registry-based RCT are felt to provide real world evidence that can support regulatory decision making in a cost effective manner.[27]

MARKET PENETRANCE – The value of any registry is muchly dependent on its participants including both volume and variety. Both NCDR CathPCI and the STS CABG registry have very high penetrance due to requirements for public reporting. The NCDR CathPCI and the STS CABG registries capture over 95% of patients and should be the aspirational goal for VQI. VQI has had steady increased growth since inception without signs of waning. VQI has an excellent distribution of providers from all specialties and institutions including single provider vein centers, office-based laboratories, small community hospitals, teaching hospitals, urban safety net hospitals, large academic medical centers and health systems. Increasing our market penetrance will provide a larger n for analysis as well as enhanced benchmarking for all varieties of practice settings. It is important not only to have centers participate but also to participate in the "core" registries. For arterial disease, that would include CEA, CAS, EVAR, OAAA (although has less and less are done, there is diminishing interest), INFRA, and PVI. For venous disease, the core would be VV and possibly IVC or Venous stent (to be released soon). For an Office-Based Laboratory (OBL), the core would be VV and PVI.

Given the burden of data entry, attracting new members can be challenging especially if they already participate in NSQIP or NCDR. The VQI needs to demonstrate value to potential customers including 1). QA - scorecards and benchmarks, 2). QI - focus and support for projects, 3). decreased resource utilization, and/or 4). a source of academic engagement and productivity. As the Accreditation and Certification Program progresses, it should provide another reason (value) for centers to participate. Certification of programs (e.g. Trauma centers, Commission on Cancer) provides clear demonstration of value to hospital administrators. If the VQI registry is a requirement for certification, it can be an impetus for increased growth and could encourage participation in the core registries.

REGISTRIES – VQI currently has 12 registries consisting of the common arterial and venous procedures. Like all surgical registries, VQI has been a procedure-based registry since inception. This year, the VQI Medical Management registry is being introduced. The Vascular Medicine registry will follow patients with claudication, abdominal aortic aneurysm, and carotid stenosis that are managed non-operatively. We will again have the opportunity to learn from big data the impact of medications, tobacco and other factors. This registry is a collaboration with the American Heart Association (AHA) is endorsed by them. AHA has thousands of field workers who support their "Get With the Guidelines" program and can help promote the Vascular Medicine Registry to help define the natural history of lower extremity arterial occlusive disease, AAA and carotid stenosis. In addition to the planned release of the medical management registry, VQI is releasing a venous stent registry in 2019. There is great interest from industry in the venous stent registry as devices receive FDA approval (slated for 2019). As a side note, one year follow up is clearly a starting point for the medicine registry as much greater value will be provided by a longer period of follow up.

Future plans – There has been interest expressed in registries for pulmonary embolism, open thoracoabdominal aortic aneurysm, visceral artery disease, thoracic outlet syndrome and others. Future registry development will be dependent on resources and the estimated market.

DATA ACCURACY - VQI is all about the data. The foundation of any clinical registry is data accuracy. Unless there is absolute confidence in the data integrity, any analysis or conclusions based upon the registry is suspect. Even small degrees of error can significantly impact outcomes or analyses. Our output and value is entirely based on providing accurate information. Data accuracy has 3 components – completeness, correctness and consistency. The claims validation process ensures completeness. Our previous audit focused on internal consistency and resulted in new and enhanced quality control measures. Our currents efforts (IRR exercises and external consultant) focus on correctness, i.e. source data accuracy.

Both the STS and NCDR have systematic audit processes.[20] VQI needs to upgrade audit capabilities which will be partly dependent on resource availability. In summary, we need to enhance current efforts and have the highest standards for data integrity.

VQI RESOURCES – When given the chance, I emphasize that VQI is understaffed and under resourced. This is not to diminish the outstanding performance of Jim, Carrie, Dan and the rest of the PSO staff but compared to STS or NCDR, VQI has an order of magnitude less revenue and personnel. STS and NCDR are more established with a much larger subscription base and data sales which supports their infrastructure. VQI needs to grow and mature so that a sustainable revenue stream can allow staff and program development.

As our membership increases, so will the revenue. We plan to enhance sales and marketing efforts with M2S. As our output is scalable, increased participation has a disproportionate increase in margin.

Device trials, industry collaboration and data sales are profitable ventures. As the value of VQI data becomes more apparent to FDA and device manufacturers, we anticipate these activities will increase. The TSP and EUMDR changes both highlight the importance of device specific analysis that is available within VQI. Renewed emphasis on industry collaboration is planned for the coming years.

VQI REPORTS – VQI sends out a multitude of reports including Regional Reports, Scorecards (on many different procedures), COPI Reports, and QI Initiatives. Due to membership response and comment, most would benefit from some degree of revision and upgrade. The reports are intended to provide meaningful and actionable information. We also plan CAPI reports to help address appropriateness. *To improve is to change; to be perfect is to change often – WC.*[9]

LONG TERM FOLLOW UP – One of the unique aspects of VQI is our requirement for long term follow up (9-21 months). This provides valuable information about durability of procedures. Of course, 9-21 months is not really long term in the life of a vascular procedure or device. One year follow up of an EVAR is hardly meaningful. At the outset, I thought that we would solve the one year follow up issue quickly and then move on to 2 or 5 year or longer follow up. However follow up and data collection has been more challenging than anticipated. The solution to the issue of (really) long term follow up is automated data integration (see following section) or claims linkage. A number of investigators have done promising work with claims linkage using the CMS data base within the Vascular Implant Surveillance and Interventional Outcomes Network (VISION) a component of MDEpiNet. Claims linkage has the

potential to provide complete, accurate and relatively inexpensive long term follow up for VQI. VQI works closely with VISION investigators.

ASSOCIATE MEDICAL DIRECTOR (AMD) - In the final section, I will outline my view on the medical director work effort. An AMD could help fill the need for clinical guidance. The 12 (soon to be 14) registries need frequent oversight re questions, definitions, and operational issues. I suspect there will be a semi-continuous line of registries in development and requiring revision. It would be advantageous to have an AMD involved in the development and roll out as well as addressing post-release and other ongoing issues. An AMD would also be a natural liaison to other society registries, e.g. NCDR, ACP, and STS. Furthermore, it takes at least a year or more to develop relationships with FDA personnel, industry and other key stakeholders. Having an AMD would allow these personal relationships to develop over time and be advantageous and expedite efficiency for VQI.

AUTOMATED DATA INTEGRATION – One of the major obstacles to VQI membership is the cost and cumbersome nature of data collection. These factors limit the ability of a center to join VQI especially when they currently bear the cost and burden of entering data into NSQIP and NCDR. We have been hearing for years that automated data integration is under development and would allow minimal personnel to accurately and completely transcribe pertinent clinical data from the EHR into the VQI registry. Savings from automated data integration is estimated at a minimum of $40/patient or $20,000 annually for a medium sized center and would be calculated at $4,000,000 annually for all of the centers. That is correct – there are over 100,000 procedures being entered annually into VQI at a minimum cost of $40 per registry and often much more. There are formidable obstacles to automated data integration but M2S continues to work diligently on it and there are promising efforts underway with Cerner. *The pessimist sees difficulty in every opportunity. The optimist sees opportunity in every difficulty. - WC*[9]

VASCULAR RESIDENTS AND FELLOWS – VQI needs to focus more on vascular trainees. Many residency and fellowship programs have requirements for engagement in quality improvement projects or scholarly activity. VQI is the logical choice to support either of these activities. We plan to work with the APDVS to further trainee engagement in VQI.

REGISTRY ASSESSMENT OF PERIPHERAL ARTERIAL DEVICES (RAPID) - RAPID is a Public Private Partnership between the FDA, professional societies (SVS, ACC, SIR), academia, industry, payers, and others to support a national medical device evaluation system.[5] Phase 1 developed a minimum core dataset (100 common data elements - CDE with agreed upon definitions). Phase 1 also recommended incorporation of the global unique device identification database (GUDID) into the registries. In Phase 2, the CDE's were incorporated into VQI, September, 2016. VQI data was used to develop objective performance goals (OPG) for contemporary interventional treatment of SFA-popliteal arteries. A manuscript on **S**uperficial **P**opliteal **E**videnc**E** **D**evelopment (SPEED)[28] is in preparation with the goal of providing historical controls and OPG's for the treatment of occlusive disease of the superficial femoral and popliteal artery using balloon angioplasty, stents, and atherectomy. In phase 3, RAPID plans to use a registry for a device evaluation project such as a registry-based observational project, safety surveillance project, or a registry-based randomized clinical trial. These projects could demonstrate the value of a registry for regulatory decision making.[29]

INTERNATIONAL CONSORTIUM OF VASCULAR REGISTRIES (ICVR)[7] - VQI and 11 other national vascular registries from Europe and Australasia combine data to analyze variation in treatment of carotid and aortic aneurysm disease across countries. Current projects are analyzing volume-outcome relationships and variations between countries for carotid and AAA treatment, as well as developing a core dataset for future PAD projects.[30, 31] A project to evaluate EVAR devices used to treat ruptured AAA is underway. The fall 2018 ICVR meeting was used for an in depth discussion of the new EU data privacy rules and medical device reporting which may have international implications for industry and regulatory agencies.

SELF-SERVING, SELF-PROMOTING AND UNSUBSTANTIATED VIEWS – The previous medical director, Jack Cronenwett, is one of the wisest, most experienced and hardest working vascular surgeons on the planet. When he was VQI medical director, he was being compensated at 0.8 or so FTE by M2S and SVS while working 6 or 7 days per week (I know because I still get his emails Saturday and Sunday). When Jack left, the VQI medical director position was posted as 0.2 FTE (SVS alone) which, with all due respect, is not realistic – see job description (Attached – PSO Medical Director). The medical director is responsible for contacts with SVS PSO chairs – Quality, Research, Arterial, Venous, Executive Committee, Technology, Scientific, SVS PSO staff – General Manager, Administrative Director, Analytic Staff, the leaders of 16 Regional Study Groups, the International Consortium of Vascular Registries, Medical Device Epidemiology Network, FDA, CMS, industry representatives (Gore, Cook, Medtronics), AHRQ, CREST2, and industry trials – TransCarotid Surveillance Project, TEVAR dissection trial, Bard Lifestent Popliteal Artery and Medtronic IN.PACT Admiral DCB ISR project. The medical director position plays a key role in the functioning and future of the PSO. There is also significant travel – RAPID X 2, MDEpiNet, VISION, ICVR, CMS, AHRQ, AVF, VQI strategic retreat, 2 regional meetings, a couple ad hoc meetings, VEITH, VAM, VQI@VAM, and I have my own 2 regional meetings (but they don't require an airplane). In my view the medical director position is pretty much a full time work effort. Initially I was working 0.8 FTE clinically (which was unrealistic and not sustainable for a mortal like me) and have cut back to 0.6 clinical FTE and plan to continue to decrease my clinical activity to allow me to pay adequate attention to PSO responsibilities. The medical director is a constant interface and resource between Jim, Carrie and Dan and clinical activities, RAPID, ICVR, industry trials, M2S, etc. I dedicate 2 full days per week to VQI and it is rare on other days that I don't spend at least a couple hours on VQI related activities. If 2 days in a row are completely clinical, there is a difficult and prolonged catch up. An associate medical director would help assume some of the responsibilities and could decrease the daily responsibilities and urgent issues but there is a continuous stream of potential projects that don't get the attention they deserve. I would recommend that when the position is reposted that it be listed as 0.5-0.6 FTE. I am aware that like many SVS positions, it is honorific and as such the work effort is mostly voluntary and not compensated equivalent to clinical productivity. It may be my lack of knowledge, efficiency or slow learning curve but I consider 0.5-0.6 FTE to be the minimum appropriate work effort.

THE END – The future is very bright. Yes, I have been reading a biography of Winston Churchill (highly recommended).[9]

VISION SUMMARY – including BHAG

1. VQI for device evaluation – solidify relationships with manufacturers and FDA
2. Need to increase market penetrance
    a. Continue to provide and promote value
    b. Accreditation/Certification program
    c. APDVS
3. Registries
    a. Collaboration with NCDR and possibly STS
    b. CRN – Venous – continue work with ACP
    c. Venous stent and medical management to be released 2019
    d. More (registries) to follow
4. MIT Sloan School project – may try again. They also have an Analytics Lab course aimed at analyzing large data sets which may have potential.
5. Audit program for data accuracy
6. VQI resources
    a. Increase revenue – clinical trials, post-market surveillance, data sales
    b. Increase staffing
7. VQI reports
    a. review and revise
    b. create CAPI reports
8. Long term follow up – ideally should be life long
9. RAPID - Continue active participation and support
10. ICVR – Continue active participation and support
11. Hire AMD
12. Automated data integration is a game changer
13. Enhance trainee engagement
14. Bottom line – Bigger and Better
15. VQI strives to be the premier clinical registry with high penetrance that provides high value to members, governmental regulatory agencies, medical device manufacturers, and most importantly allows us to improve the care for our vascular patients

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