DEBATE:
Limitations And Possible Downsides Of VQI Initiatives

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Disclosure

Dr. Kenneth Ouriel is employed by and has equity interests in Syntactx, a Contract Research Organization that receives fees from manufacturers of medical devices, pharmaceutical agents and from diagnostic laboratories.

Syntactx manages clinical trials and has competing services and technology with third party vendor(s) that manage or might potentially manage the VQI and the quality initiatives of other societies.

The Vascular Quality Initiative: A Partnership

PubMed Search of All VQI Articles

<table>
<thead>
<tr>
<th>Lead Author</th>
<th>Title / Journal / Year</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aiello</td>
<td>Outcomes reported by the Vascular Quality Initiative and the National Surgical Quality Improvement Program are not comparable J Vasc Surg, 2014</td>
<td>Original article, comparison of concordance between VQI and NSQIP</td>
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<tr>
<td>Eslami</td>
<td>Using Vascular Quality Initiative (VQI) as a Platform for Organizing Multicenter, Prospective, Randomized Clinical Trials: OVERPAR Trial Ann Vasc Surg 2014</td>
<td>Methods article, announcing use of VQI for pop aneurysm treatment</td>
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<tr>
<td>Kalish</td>
<td>Factors associated with surgical site infection after lower extremity bypass in the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) J Vasc Surg, 2014</td>
<td>Original article, found SSIs differences across regions</td>
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VQI: A laudable initiative for assessing quality

What the VQI does:
A. Provides a data repository for vascular surgical procedural data;
B. “Validates” the cases to assure a 1:1 relationship between hospital & professional claims data and the VQI database; to “eliminate inconsistencies… [and] selection bias… by insuring that each physician is entering the eligible procedures”.

What the VQI does not do:
A. Does not validate outcome (e.g. graft occlusion/stroke/endoleak) – this is left to the physician;
B. Avoids issues of patient consent – ostensibly possible with the PSI structure (although not with the post-market studies that use the VQI);
C. Does not use the SVS itself as a data repository; rather, an outside entity is contracted.

Patient Confidentiality Issues with VQI

Open repair of asymptomatic popliteal artery aneurysm is associated with better outcomes than endovascular repair

Methods:
Vascular Quality Initiative (VQI) databases (2010 to 2013) were queried for patients undergoing asymptomatic PAA repair using OPA and EPAR.

Use of the VQI for Post-Market Studies

After a device approval by FDA, post-market studies are often required. Such post-market studies are useful. The original PMA studies usually have very specific inclusion/exclusion criteria and the study group may differ from the real-world population receiving the device. These studies can be expensive, time-consuming and cumbersome. The VQI has been advocated by many as a more efficient means of post-market study. It is likely that cost can indeed be reduced.

Post-market Studies:

• All is fine if the post-market data is as anticipated.
• If the data is not consistent with safety and effectiveness, however, there are few options available to the device manufacturer go.
• Can a device be withdrawn from the market if the post-market data does not confirm the safety/effectiveness results of the PMS study?

Methodology Can Underestimate Event Rates

<table>
<thead>
<tr>
<th>Study Patient ID</th>
<th>EVAR</th>
<th>1 Month</th>
<th>6 Months</th>
<th>1 Year</th>
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<tbody>
<tr>
<td>001</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Death</td>
</tr>
<tr>
<td>002</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>No Show</td>
</tr>
<tr>
<td>003</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>No Show</td>
</tr>
<tr>
<td>004</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>No Show</td>
</tr>
</tbody>
</table>

Problem: Without pre-specified follow-up visits and required data entry, a “No Show” clinic visit is not recorded in the database - thus is registered as “No Event”.

Is VQI Follow-Up Data Adequate?

Factors associated with surgical site infection after lower extremity bypasses in the Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI)

From the Boston Medical Center, Boston, MA, for the Society for Vascular Surgery, Patient Safety Initiative, Chicago, IL, for the American College of Surgeons, Chicago, IL, for the American Association for Vascular Surgery, Chicago, IL, the University of Miami School of Medicine, Miami, FL, the University of Illinois at Chicago, the University of California, Irvine, and the University of California, Los Angeles, CA. F. Scott Greenberg, MD (Study Chair) and the Executive Committee (available at: https://svsquality.org/vqi).

Points to Consider

• VQI serves a useful purpose. Its organizers/participants should be applauded.
• VQI data can provide accurate estimates of the frequency of procedures performed by practitioners, to the extent that these physicians have volunteered to enter patients into the database.
• But, while procedure entries into the database are validated, their outcomes are not. Without independent data monitoring, VQI outcome data lose reliability. Certain events are missed and others are improperly categorized.
• Importantly, a “registry-design” without pre-specified follow-up visit intervals precludes Kaplan-Meier analyses and other methods that consider censored data to estimate event rates. To assume that “no data” equates with “no event” forces systematic underestimation of the rates of events.
• VQI serves an important role in measuring the volume and some outcomes of patients treated by vascular practitioners. In its present form, VQI is a useful gauge of procedure volume but is not reliable for assessing outcome.