Vascular Study Group of Greater New England (VSGNE)

November 2, 2018
Morning Session
Yale New Haven Hospital
Agenda - Morning

10:00am -10:10am  Welcome by Carlos Mena and Yale-New Haven Hospital

10:10am – 11:10am: National Committee Updates:

- VISION Update
- Regional Reports Review – Philip Goodney / Jens Jorgensen
- LTFU Update / National Quality Initiatives – Jens Jorgensen

11:10am-11:45am: Guest Speaker - Professor Mehran Sadeghi, MD (Yale Medicine)
Molecular imaging for aortic disease (Discussion)
Welcome and Introductions

Baystate Medical Center
Berkshire Medical Center
Beth Israel Deaconess Medical Center
Boston Medical Center
Brigham and Women's Hospital
Cape Cod Hospital
Catholic Medical Center; CTSA NH
Central Maine Medical Center
Charlton Memorial Hospital
Concord Hospital
Danbury Hospital
Dartmouth Hitchcock Medical Center
Diagnostic Imaging of Milford
Eastern Maine Medical Center
Elliot Health System
Good Samaritan Medical Center (Steward)
Hartford Hospital
Hoenig Vascular Center

Lahey Hospital and Medical Center
Lakes Region General Hospital
Maine Medical Center
MaineGeneral Medical Center
Massachusetts General Hospital
Portsmouth Regional Hospital
Rhode Island Hospital
Saint Francis Hospital (Steward)
St. Anne's Hospital
St. Elizabeth's Medical Center
St. Luke's Hospital
The Hospital of Central Connecticut
The Miriam Hospital
Tufts Medical Center
U Mass Memorial
University of Vermont Medical Center
Yale-New Haven Hospital
<table>
<thead>
<tr>
<th>Hospital/Center</th>
<th>City, State</th>
<th>Contact</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trinity Health Network/Springfield</td>
<td>Springfield, MA</td>
<td>Dr. Sandip Maru</td>
<td>Qualified</td>
</tr>
<tr>
<td>John Dempsey Hospital</td>
<td>Farmington, CT</td>
<td>Dr. Bing Shue</td>
<td>Proposal</td>
</tr>
<tr>
<td>Stamford Hospital</td>
<td>Stamford, CT</td>
<td>Dr. Timothy Manoni</td>
<td>Qualified</td>
</tr>
<tr>
<td>Signature HealthCare</td>
<td>Brockton, MA</td>
<td>Dr. Siddiqui</td>
<td>Proposal</td>
</tr>
</tbody>
</table>
2014
NIH U01 (Skinner)

2015
Multi-procedure outcomes
NIH U01 (Skinner)

FDA U01 (Sedrakyan)
Direct Linkages

2017
NIH U01 (Skinner)

FDA U01 (Sedrakyan)
PCORI (O'Malley)
Validation with clinical data

2018
FDA U01 (Sedrakyan)
PCORI (O'Malley)
AHA SFRN (Goodney)
P01 (Skinner)
Device-specific outcomes, cost data, under 65 populations, validation with trials data (multi-site) via EDUCATE

Bekelis et al, BMJ 2016
Hoel et al, JVS 2017
Columbo et al, JAMA Open 2018, JVS 2018
Multiple authors, in preparation
VISION Teams
FDA
Payers
Industry
Goal:
Discuss Ways To Use Real World Evidence to Change Regulatory Practice in Vascular Care
VISION FDA Think Tank, 9/10/18

Where did our Real World Evidence Come From?
VISION: First Steps

Relationships between 2-Year Survival, Costs, and Outcomes following Carotid Endarterectomy in Asymptomatic Patients in the Vascular Quality Initiative

Jessica B. Wallaert,¹ Karina A. Newhall,¹ Bjoern D. Suckow,¹ Benjamin S. Brooke,² Min Zhang,³ Adrienne E. Farber,⁴ Donald Likosky,⁵ and Philip P. Goodney,¹ for the Vascular Quality Initiative Lebanon, and Hanover, New Hampshire; Salt Lake City, Utah; and Ann Arbor, Maryland

VISION: First Steps

**Fig. 1.** Distribution of risk scores for predicting 2-year mortality among asymptomatic patients undergoing CEA.
**VISION is a System in Evolution**

<table>
<thead>
<tr>
<th>Year</th>
<th>Funding</th>
<th>Key Step</th>
<th>Key Publication</th>
</tr>
</thead>
</table>
VISION: First Matching Report

A pilot study for long-term outcome assessment after aortic aneurysm repair using VQI data matched to Medicare claims

Andrew W. Hoel¹, Adrienne E. Faerber², Kayla O. Moore², Niveditta Ramkumar², Benjamin S. Brooke³, Salvatore T. Scali⁴, Art Sedrakyan⁵, and Philip P. Goodney²,⁶

VISION: First Matching Report

[Venn diagram showing the overlap between Medicare, VQL, VQI, VQI-PSO, and internal identifiable data]
VISION: Validation

A comparison of reintervention rates after endovascular aneurysm repair between the Vascular Quality Initiative registry, Medicare claims, and chart review

Jesse A. Columbo, MD, Ravinder Kang, MD, MS, Andrew W. Hoel, MD, Jeanwan Kang, MD, Kathleen A. Leinweber, BA, Karissa S. Tauber, BA, Regis Hila, BA, Niveditta Ramkumar, MPH, Art Sedrakyan, MD, PhD, and Philip P. Goodney, MD, MS. Lebanon and Hanover, NH; White River Junction, Vt; Chicago, Ill; and New York, NY

Journal of Vascular Surgery

2018
96% Sensitive
93% Specific
Accurate Capture of RWD
VISION: Long-Term Survival

Original Investigation | Surgery

Comparing Long-term Mortality After Carotid Endarterectomy vs Carotid Stenting Using a Novel Instrumental Variable Method for Risk Adjustment in Observational Time
Time-to-Event Data

Jesse A. Columbo, MD; Pablo Martinez-Camblor, PhD; Todd A. MacKenzie, PhD; Douglas O. Staiger, PhD; Ravinder Kang, MD, MS; Philip P. Goodney, MD, MS; A. James O'Malley, PhD
VISION: Long-Term Survival

Figure 1. Kaplan-Meier Estimated Mortality, Overall and by Presenting Symptoms

A) All Patients

<table>
<thead>
<tr>
<th>Time, y</th>
<th>CAS (No. at risk)</th>
<th>CEA (No. at risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>12705</td>
<td>73312</td>
</tr>
<tr>
<td>1</td>
<td>10000</td>
<td>60901</td>
</tr>
<tr>
<td>2</td>
<td>6854</td>
<td>44974</td>
</tr>
<tr>
<td>3</td>
<td>4466</td>
<td>30440</td>
</tr>
<tr>
<td>4</td>
<td>2578</td>
<td>19139</td>
</tr>
<tr>
<td>5</td>
<td>1185</td>
<td>11362</td>
</tr>
</tbody>
</table>

Log rank $P < .001$
VISION: Long-Term Survival

Figure 1. Kaplan-Meier Estimated Mortality, Overall and by Presenting Symptoms

Leveraging the Power of Real World Evidence for Long-Term Outcome Assessment

No. at risk
CAS  12705  10000  6854  4466  2578  1185  
CEA  73312  60901  44974  30440  19139  11362

Log rank $P < .001$
VISION: Under 65
Re-Intervention After EVAR, in Non-Medicare Patients

Percent Undergoing Reintervention After EVR

<table>
<thead>
<tr>
<th>Years</th>
<th>At Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not Medicare Eligible</td>
</tr>
<tr>
<td>0</td>
<td>175</td>
</tr>
<tr>
<td>1</td>
<td>129</td>
</tr>
<tr>
<td>2</td>
<td>53</td>
</tr>
<tr>
<td>3</td>
<td>25</td>
</tr>
</tbody>
</table>

log-rank p=.199
Regional Reports:

Philip Goodney, MD

Notes:
1) In all reports, regional data are not shown for regions with <3 centers participating in the applicable registry.
2) In “by Center” bar charts, unless noted, data are not shown for centers with <10 cases.
3) In all graphics, “*” indicates a p-value<.05.
4) This report includes all data that had been entered into the VQI as of June 30, 2017.
Dashboard

The table below summarizes your center’s results as presented in each of the subsequent reports and provides regional and national benchmarks for comparison. In the “Your Center” column, percentages represent the rate of cases with the noted outcome. Numbers in parentheses are the number of cases with the outcome/the total number of cases meeting the exclusion criteria (see the full report for details). In the “Region” and “VQI” columns, the numbers represent the 25th, 50th (median) and 75th percentiles for centers in your region and across all centers in the VQI.

Your center’s results are highlighted in green if your center is at or above the top 25th percentile nationally, in yellow if your center is among the middle 50% of centers, and in red if at or below the bottom 25th percentile.
# Dashboard

| Registry                  | Outcome                        | Your Center % (n/N) | Your Region [25p|50p|75p] | VQI Overall [25p|50p|75p] |
|---------------------------|--------------------------------|---------------------|-----------------------------|---------------------------|
| All                       | Total Procedure Volume         |                     | [57 | 225 | 433]                 | [37 | 134 | 330]                |
| Multiple (July 2015-June 2016) | Long-Term Follow-Up           | [44% | 71% | 84%]                     | [44% | 72% | 86%]                |
| Multiple                  | Discharge Medications          | [82% | 85% | 88%]                     | [75% | 83% | 90%]                |
| AVACCESS                  | Primary AVF vs. Graft          | [80% | 85% | 90%]                     | [74% | 85% | 90%]                |
| CAS                       | In-Hospital Stroke/Death       | [3% | 0% | 0%]                      | [3% | 0% | 0%]                |
| CEA                       | In-Hospital Stroke/Death       | [1% | 0% | 0%]                      | [1% | 0% | 0%]                |
| CEA                       | LOS>1 Day                      | [40% | 28% | 16%]                     | [33% | 22% | 14%]                |
| EVAR                      | LOS>2 Days                     | [15% | 11% | 7%]                      | [18% | 11% | 3%]                 |
| EVAR (July 2015-June 2016) | Sac Diameter at LTFU          | [29% | 58% | 70%]                     | [36% | 56% | 72%]                |
| INFRA                     | Chlorhexidine Skin Prep        | [83% | 96% | 100%]                    | [86% | 98% | 100%]               |
| INFRA                     | Major Complications            | [4% | 1% | 0%]                      | [6% | 0% | 0%]                 |
| IVCF (2017)               | Filter Retrieval               | NA (<3 centers)          | [1% | 27% | 45%]                |
| LEAMP                     | Postop Complications           | [25% | 24% | 23%]                     | [24% | 17% | 10%]                |
| OAAA                      | In-Hospital Mortality          | [0% | 0% | 0%]                      | [2% | 0% | 0%]                 |
| PVI                       | Ultrasound Guidance            | [83% | 93% | 98%]                     | [74% | 93% | 98%]                |
| PVI                       | ABI/TBI Reported               | [69% | 76% | 89%]                     | [65% | 81% | 92%]                |
| SUPRA                     | Postop Complications           | [35% | 28% | 20%]                     | [33% | 23% | 11%]                |
| TEVAR (July 2015-June 2016)| Sac Diameter at LTFU          | [18% | 45% | 67%]                     | [25% | 43% | 56%]                |
| VV (2017)                 | PROMs at LTFU                  | [11% | 21% | 61%]                     | [38% | 97% | 100%]               |
### Total Procedure Volume, All Years

Includes all procedures entered in VQI as of July 16, 2018

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Your Center (N)</th>
<th>Your Region (N)</th>
<th>VQI Overall (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVACCESS</td>
<td>4117</td>
<td>38995</td>
<td></td>
</tr>
<tr>
<td>CAS</td>
<td>2832</td>
<td>21741</td>
<td></td>
</tr>
<tr>
<td>CEA</td>
<td>21636</td>
<td>101836</td>
<td></td>
</tr>
<tr>
<td>EVAR</td>
<td>7219</td>
<td>40276</td>
<td></td>
</tr>
<tr>
<td>INFRA</td>
<td>12231</td>
<td>44904</td>
<td></td>
</tr>
<tr>
<td>IVCF</td>
<td>NA (&lt;3 centers)</td>
<td>9888</td>
<td></td>
</tr>
<tr>
<td>LEAMP</td>
<td>1037</td>
<td>10989</td>
<td></td>
</tr>
<tr>
<td>OAAA</td>
<td>3503</td>
<td>10774</td>
<td></td>
</tr>
<tr>
<td>PVI</td>
<td>24375</td>
<td>149590</td>
<td></td>
</tr>
<tr>
<td>SUPRA</td>
<td>3369</td>
<td>14860</td>
<td></td>
</tr>
<tr>
<td>TEVAR</td>
<td>1322</td>
<td>10904</td>
<td></td>
</tr>
<tr>
<td>Varicose Veins</td>
<td>1285</td>
<td>21136</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>82990</td>
<td>475893</td>
<td></td>
</tr>
</tbody>
</table>
“Others” indicates centers that do not belong to a regional group.
Percentage of Procedures With 9 Months or Greater Follow-Up

Procedures performed between July 1, 2015 and June 30, 2016
Data for this report include all cases with surgery date between July 1, 2015 and June 30, 2016, that had been entered into the VQI as of June 30, 2018.

<table>
<thead>
<tr>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVACCESS</td>
<td>589 (75%)</td>
<td>6740 (70%)</td>
</tr>
<tr>
<td>CAS</td>
<td>348 (44%)</td>
<td>3301 (64%)</td>
</tr>
<tr>
<td>CEA</td>
<td>1858 (66%)</td>
<td>15935 (70%)</td>
</tr>
<tr>
<td>EVAR</td>
<td>689 (69%)</td>
<td>6345 (74%)</td>
</tr>
<tr>
<td>INFRA</td>
<td>1038 (72%)</td>
<td>6504 (75%)</td>
</tr>
<tr>
<td>IVCF</td>
<td>NA (&lt;3 centers)</td>
<td>2086 (69%)</td>
</tr>
<tr>
<td>LEAMP</td>
<td>227 (68%)</td>
<td>2051 (74%)</td>
</tr>
<tr>
<td>OAAA</td>
<td>215 (66%)</td>
<td>1244 (73%)</td>
</tr>
<tr>
<td>PVI</td>
<td>2952 (58%)</td>
<td>23511 (71%)</td>
</tr>
<tr>
<td>SUPRA</td>
<td>381 (68%)</td>
<td>2227 (72%)</td>
</tr>
<tr>
<td>TEVAR</td>
<td>183 (62%)</td>
<td>1976 (69%)</td>
</tr>
<tr>
<td>Overall (July 2015-June 2016)</td>
<td>8494 (64%)</td>
<td>71920 (71%)</td>
</tr>
<tr>
<td>2015</td>
<td>8941 (67%)</td>
<td>70651 (74%)</td>
</tr>
<tr>
<td>2016</td>
<td>8113 (59%)</td>
<td>73127 (60%)</td>
</tr>
</tbody>
</table>
Percentage With Long-Term Follow-Up by Year

- Your Center
- Your Region
- VQI Overall
Long-Term Follow-Up by Center in Your Region (July 2015-June 2016)

"**" indicates center's rate differs significantly from the regional rate.

<table>
<thead>
<tr>
<th>Num.</th>
<th>Medical Center Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Central Maine Medical Center</td>
</tr>
<tr>
<td>2</td>
<td>Hoenig Vascular Center</td>
</tr>
<tr>
<td>3</td>
<td>Brigham and Women’s Hospital</td>
</tr>
<tr>
<td>4</td>
<td>Saint Francis Hospital</td>
</tr>
<tr>
<td>5</td>
<td>Beth Israel Deaconess Medical Center</td>
</tr>
<tr>
<td>6</td>
<td>University of Vermont Medical Center</td>
</tr>
<tr>
<td>7</td>
<td>Concord Hospital</td>
</tr>
<tr>
<td>8</td>
<td>Boston Medical Center</td>
</tr>
<tr>
<td>9</td>
<td>Elliot Health System</td>
</tr>
<tr>
<td>10</td>
<td>Baystate Medical Center</td>
</tr>
<tr>
<td>11</td>
<td>MaineGeneral Medical Center</td>
</tr>
<tr>
<td>12</td>
<td>Tufts Medical Center</td>
</tr>
<tr>
<td>13</td>
<td>U Mass Memorial</td>
</tr>
<tr>
<td>14</td>
<td>Hartford Hospital</td>
</tr>
<tr>
<td>15</td>
<td>Danbury Hospital</td>
</tr>
<tr>
<td>16</td>
<td>Maine Medical Center</td>
</tr>
<tr>
<td>17</td>
<td>The Miriam Hospital</td>
</tr>
<tr>
<td>18</td>
<td>St. Elizabeth Medical Center</td>
</tr>
<tr>
<td>19</td>
<td>Rhode Island Hospital</td>
</tr>
<tr>
<td>20</td>
<td>Dartmouth Hitchcock Medical Center</td>
</tr>
<tr>
<td>21</td>
<td>Berkshire Medical Center</td>
</tr>
<tr>
<td>22</td>
<td>Massachusetts General Hospital</td>
</tr>
<tr>
<td>23</td>
<td>Charlton Memorial Hospital</td>
</tr>
<tr>
<td>24</td>
<td>Yale-New Haven Hospital</td>
</tr>
<tr>
<td>25</td>
<td>Eastern Maine Medical Center</td>
</tr>
<tr>
<td>26</td>
<td>Catholic Medical Center; CTSA NH</td>
</tr>
<tr>
<td>27</td>
<td>Lakes Region General Hospital</td>
</tr>
</tbody>
</table>
Long-Term Follow-Up by Region Across VQI (July 2015-June 2016)

“Others” indicates centers that do not belong to a regional group. “*” indicates region’s rate differs significantly from the VQI rate.
Discharge Medications Procedures performed between Procedures performed between June 1, 2017 and May 31, 2018 entered by June 30, 2018
Excludes patients who died in hospital and patients who were not treated for medical reason or non-compliant. “Antiplatelet” is defined as ASA or P2Y12 inhibitor

<table>
<thead>
<tr>
<th></th>
<th>Number of Procedures at Your Center</th>
<th>Antiplatelet+Statin</th>
<th>Antiplatelet Only</th>
<th>Statin Only</th>
<th>Neither</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your Region</td>
<td>7453</td>
<td>85%</td>
<td>10%</td>
<td>3%</td>
<td>2%</td>
</tr>
<tr>
<td>VQI overall</td>
<td>69404</td>
<td>81%</td>
<td>12%</td>
<td>4%</td>
<td>3%</td>
</tr>
</tbody>
</table>
Discharge Antiplatelet+Statin Rate by Center in Your Region (June 2017-May 2018)

Centers (centers with <10 cases not shown)

*** indicates center's rate differs significantly from the regional rate.

Discharge Antiplatelet+Statin Rate by Region Across VQI (June 2017-May 2018)

"Others" indicates centers that do not belong to a regional group. "***" indicates region's rate differs significantly from the VQI rate.
Hemodialysis Access: Percentage of Primary AVF v. Graft Procedures performed between June 1, 2017 and May 31, 2018

Excludes patients with previous access procedure in the same arm

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI. The table below shows the number of access procedures meeting the inclusion criteria for the VQI and the percentage of cases that were AVF v. graft.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of access procedures meeting inclusion criteria</td>
<td>363</td>
<td>5641</td>
<td></td>
</tr>
<tr>
<td>Percentage with primary AVF</td>
<td>85%</td>
<td>82%</td>
<td></td>
</tr>
</tbody>
</table>
Rate of Primary AVF Access in Your Region (June 2017-May 2018)

Centers (centers with <10 cases not shown)

**"" indicates center's rate differs significantly from the regional rate.

Rate of Primary AVF Access by Region Across VQI (June 2017-May 2018)

"Others" indicates centers that do not belong to a regional group. "**" indicates region's rate differs significantly from the VQI rate.
**Carotid Artery Stent: Stroke or Death in Hospital**

Procedures performed between June 1, 2017 and May 31, 2018

Elective procedures, excluding prior ipsilateral CAS, and dissection, trauma and “other” lesion types. The table below shows the number of CAS procedures meeting inclusion criteria that were in the VQI as of June 30, 2018, and the observed and expected rates of in-hospital stroke or death for those cases.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CAS procedures meeting inclusion criteria</td>
<td>383</td>
<td>4000</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among procedures meeting inclusion criteria</td>
<td>2.3%</td>
<td>2.2%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>355</td>
<td>3672</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among cases with complete data</td>
<td>1.4%</td>
<td>2.1%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of stroke or death among cases with complete data*</td>
<td>1.7%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>1</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of In-Hospital Stroke or Death After CAS by Year

- Your Center
- Your Region
- VQI Overall
Rate of In-Hospital Stroke or Death After CAS in Your Region (June 2017-May 2018)

- Other centers in your region
- Your center
- Observed
- Expected

Centers (centers with <10 cases not shown)

*** indicates center’s observed rate differs significantly from its expected rate.

Rate of In-Hospital Stroke or Death After CAS by Region Across VQI (June 2017-May 2018)

- Observed
- Expected

“Others” indicates centers that do not belong to a regional group. "***" indicates region’s observed rate differs significantly from its expected rate.
Carotid Endarterectomy: Stroke or Death in Hospital
Procedures performed between June 1, 2017 and May 31, 2018
Elective procedures, excluding prior ipsilateral CEA and concomitant CABG, endovascular or other arterial procedure

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of CEA procedures meeting the inclusion criteria in the VQI, and the observed and expected rates of in-hospital stroke or death for those cases.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CEA procedures meeting inclusion criteria</td>
<td>1229</td>
<td>13860</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among procedures meeting inclusion criteria</td>
<td>0.8%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>1178</td>
<td>13147</td>
<td></td>
</tr>
<tr>
<td>Observed rate of stroke or death among cases with complete data</td>
<td>0.8%</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of stroke or death among cases with complete data*</td>
<td>1.1%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0.49</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of In-Hospital Stroke or Death After CEA in Your Region (June 2017-May 2018)

Centers (centers with <10 cases not shown)

*** indicates center’s observed rate differs significantly from its expected rate.

Rate of In-Hospital Stroke or Death After CEA by Region Across VQI (June 2017-May 2018)

“Others” indicates centers that do not belong to a regional group. *** indicates region’s observed rate differs significantly from its expected rate.
Carotid Endarterectomy: Percentage of Patients with LOS>1 Day
Procedures performed between June 1, 2017 and May 31, 2018
Elective procedures, excluding prior ipsilateral CEA, concomitant CABG, proximal endovascular or other arterial operation, in-hospital death with LOS<=1 day, procedures done on weekends or not done on admission day.
Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of CEA procedures meeting inclusion criteria in the VQI, and the observed and expected rates of those cases with LOS>1 Day.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CEA procedures meeting inclusion criteria</td>
<td>1118</td>
<td>12452</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;1 day among procedures meeting inclusion criteria</td>
<td>29%</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>1074</td>
<td>11954</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;1 among cases with complete data</td>
<td>29%</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of LOS&gt;1 among cases with complete data*</td>
<td>23%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of CEA Patients With LOS>1 Day in Your Region (June 2017-May 2018)

Other centers in your region  Your center  Observed  Expected

Centers (centers with <10 cases not shown)

"**" indicates center's observed rate differs significantly from its expected rate.

Rate of CEA Patients With LOS>1 Day by Region Across VQI (June 2017-May 2018)

Observed  Expected

"Others" indicates centers that do not belong to a regional group. "**" indicates region's observed rate differs significantly from its expected rate.
Endovascular AAA Repair: Percentage of Patients with LOS>2 Days

Procedures performed between June 1, 2017 and May 31, 2018

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of EVAR procedures meeting inclusion criteria</td>
<td>491</td>
<td>5207</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;2 days among procedures meeting inclusion criteria</td>
<td>13%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>474</td>
<td>4936</td>
<td></td>
</tr>
<tr>
<td>Observed rate of LOS&gt;2 among cases with complete data</td>
<td>12%</td>
<td>13%</td>
<td></td>
</tr>
<tr>
<td>Expected rate of LOS&gt;2 among cases with complete data*</td>
<td>14%</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0.29</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of EVAR Patients With LOS > 2 Days in Your Region (June 2017-May 2018)

Centers (centers with <10 cases not shown)

“**” indicates center’s observed rate differs significantly from its expected rate.

Rate of EVAR Patients With LOS > 2 Days by Region Across VQI (June 2017-May 2018)

“Others” indicates centers that do not belong to a regional group. “**” indicates region’s observed rate differs significantly from its expected rate.
EVAR: Rate of Sac Diameter Reporting at Long-Term Follow-Up

Procedures performed between July 1, 2015 and June 30, 2016

Data for this report include all cases with surgery date between July 1, 2015 and June 30, 2016, that had been entered into the VQI as of June 30, 2018. The table below shows the number of EVAR procedures in the VQI, and the percentage of those cases in which the patient had a follow-up visit between 9 and 21 months post-surgery at

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of EVAR procedures</td>
<td></td>
<td>689</td>
<td>6345</td>
</tr>
<tr>
<td>Percentage with sac diameter recorded at follow-up</td>
<td></td>
<td>53%</td>
<td>55%</td>
</tr>
</tbody>
</table>
Rate of LTFU Sac Diameter Reporting in Your Region (July 2015-June 2016)

**Other centers in your region**  **Your center**

80%  70%  60%  50%  40%  30%  20%  10%  0%

Centers (centers with <10 cases not shown)

"**" indicates center's rate differs significantly from the regional rate.

Rate of LTFU Sac Diameter Reporting by Region Across VQI (July 2015-June 2016)


"Others" indicates centers that do not belong to a regional group. "**" indicates region's rate differs significantly from the VQI rate.
Infrainguinal Bypass: Percentage of Procedures with Chlorhexidine or Chlorhexidine+Alcohol Skin Prep

Procedures performed between June 1, 2017 and May 31, 2018

In VQI patients, chlorhexidine and chlorhexidine+alcohol skin preps have been shown to reduce the surgical-site infection rate by 50% compared to iodine-based skin prep. Chlorhexidine+iodine and chlorhexidine+iodine+alcohol skin preps have not been shown to reduce the infection rate, but rates of their use are also reported in the table below. Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of procedures</td>
<td></td>
<td>850</td>
<td>6680</td>
</tr>
<tr>
<td>Rate of chlorhexidine or chlorhexidine+alcohol skin prep</td>
<td>90%</td>
<td>88%</td>
<td></td>
</tr>
<tr>
<td>Rate of chlorhexidine+iodine or chlorhexidine+iodine+alcohol prep</td>
<td>6%</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Rate of in-hospital surgical-site infection</td>
<td>2.6%</td>
<td>2.6%</td>
<td></td>
</tr>
</tbody>
</table>
Percentage With Chlorhexidine or Chlorhexidine+Alcohol Skin Prep in Your Region (June 2017-May 2018)

Other centers in your region • Your center

Centers (centers with <10 cases not shown)

*** indicates center's rate differs significantly from the regional rate.

Percentage With Chlorhexidine or Chlorhexidine+Alcohol Skin Prep by Region (June 2017-May 2018)


"Others" indicates centers that do not belong to a regional group. *** indicates region's rate differs significantly from the VQI rate.
Infrainguinal Bypass: Rate of Major Complications

Procedures performed between June 1, 2017 and May 31, 2018
Includes only patients with indication of rest pain or tissue loss. Major complications are defined as in-hospital death, ipsilateral BK or AK amputation or graft occlusion.

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of INFRA cases with indication of rest pain or tissue loss in the VQI, and the percentage of those cases that resulted in hospital death, ipsilateral amputation or graft occlusion.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of INFRA procedures meeting inclusion criteria</td>
<td>525</td>
<td>4008</td>
<td></td>
</tr>
<tr>
<td>Percentage with major complications after INFRA</td>
<td>2.7%</td>
<td>4.2%</td>
<td></td>
</tr>
</tbody>
</table>
Rate of Major Complications After INFRA in Your Region (June 2017-May 2018)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

*** indicates center's rate differs significantly from the regional rate.

Rate of Major Complications After INFRA by Region Across VQI (June 2017-May 2018)

- Others indicates centers that do not belong to a regional group.
- ** indicates region's rate differs significantly from the VQI rate.
IVCF: Percentage of Temporary Filters With Retrieval or Attempt at Retrieval
Procedures performed between Jan. 1 and Dec. 31, 2017
Excludes patients with permanent filters and patients who have died since discharge
(Your center did not have 3 centers with more than 10 procedures)
Lower-Extremity Amputation: Rate of Postop Complications

Procedures performed between June 1, 2017 and May 31, 2018

Complications are defined as myocardial infarction, dysrhythmia, congestive heart failure, surgical site infection, renal or respiratory complication and/or amputation-related reoperation.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of amputation procedures</td>
<td></td>
<td>229</td>
<td>2947</td>
</tr>
<tr>
<td>Percentage with complications after LEAMP</td>
<td></td>
<td>25%</td>
<td>18%</td>
</tr>
</tbody>
</table>
Rate of Complications After LEAMP in Your Region (June 2017-May 2018)

Centers (centers with <10 cases not shown)

** Indicates center's rate differs significantly from the regional rate.

Rate of Complications After LEAMP by Region Across VQI (June 2017-May 2018)

"Others" indicates centers that do not belong to a regional group. "**" indicates region's rate differs significantly from the VQI rate.
Non-Ruptured Open AAA: In-Hospital Mortality
Procedures performed between June 1, 2017 and May 31, 2018
Excludes ruptured aneurysms

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of OAAA procedures meeting the inclusion criteria in the VQI, and the observed and expected rates of in-hospital death for those cases.

<table>
<thead>
<tr>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of OAAA procedures meeting inclusion criteria</td>
<td>148</td>
<td>988</td>
</tr>
<tr>
<td>Observed rate of in-hospital death among procedures meeting inclusion criteria</td>
<td>1.4%</td>
<td>5%</td>
</tr>
<tr>
<td>Number of procedures with complete data*</td>
<td>142</td>
<td>928</td>
</tr>
<tr>
<td>Observed rate of in-hospital death among cases with complete data</td>
<td>1.4%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Expected rate of in-hospital death among cases with complete data*</td>
<td>3.5%</td>
<td>NA</td>
</tr>
<tr>
<td>P-value for comparison of observed and expected rates</td>
<td>0.25</td>
<td>NA</td>
</tr>
<tr>
<td>Observed rate of in-hospital death among procedures with infrarenal proximal clamp</td>
<td>0%</td>
<td>5%</td>
</tr>
<tr>
<td>Observed rate of in-hospital death among procedures with suprarenal proximal clamp</td>
<td>2.5%</td>
<td>5.2%</td>
</tr>
</tbody>
</table>

*“Expected rate” is the rate estimated by a statistical model that accounts for patient characteristics, including age, gender, race, BMI, comorbidities, medication and stroke and vascular history. “Cases with complete data” include patients who have data on all of those factors.
Rate of In-Hospital Death After OAAA by Year

Rate of In-Hospital Death After OAAA in Your Region (June 2017-May 2018)

"**" indicates center's observed rate differs significantly from its expected rate.
Rate of In-Hospital Death After OAAA by Region Across VQI (June 2017-May 2018)

“Others” indicates centers that do not belong to a regional group. “**” indicates region’s observed rate differs significantly from its expected rate.
PVI: Percentage of Percutaneous Femoral Access Sites Using Ultrasound Guidance

Procedures performed between June 1, 2017 and May 31, 2018
Excludes cut-down access guidance

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of percutaneous femoral PVI access sites in the VQI, the percentage of those cases in which ultrasound access guidance was used, the percentage in which a closure device was used, and the rate of hematoma.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of percutaneous femoral access sites</td>
<td>2241</td>
<td>23903</td>
<td></td>
</tr>
<tr>
<td>Rate of ultrasound access guidance</td>
<td>89%</td>
<td>77%</td>
<td></td>
</tr>
<tr>
<td>Rate of closure device usage</td>
<td>63%</td>
<td>68%</td>
<td></td>
</tr>
<tr>
<td>Rate of any hematoma (minor, moderate or major)</td>
<td>4.3%</td>
<td>2.1%</td>
<td></td>
</tr>
<tr>
<td>Rate of moderate or major hematoma</td>
<td>0.8%</td>
<td>0.6%</td>
<td></td>
</tr>
</tbody>
</table>
Rate of Ultrasound Access Guidance in Your Region (June 2017-May 2018)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

"**" indicates center's rate differs significantly from the regional rate.

Rate of Ultrasound Access Guidance by Region Across VQI (June 2017-May 2018)

- Mid-America*
- G. Lakes*
- Midwest*
- Southeast*
- Up. Midwest*
- VQI
- So. Cal.*
- Carolinas*
- Mid-Atlantic
- Virginias*
- New England*
- New York*
- Rocky Mtns.*
- Pacific NW
- MidSouth*
- Canada*
- Nor. Cal.*
- SOVONET*

"Others" indicates centers that do not belong to a regional group. "**" indicates region's rate differs significantly from the VQI rate.
PVI: Percentage of Claudicants With ABI or Toe Pressure Reported Before Procedure

Procedures performed between June 1, 2017 and May 31, 2018

“ABI or toe pressure reported” indicates at least one measure was recorded for the side of the operation, or on both sides for bilateral and aortic procedures.

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of PVI procedures with indication of claudication in the VQI, and the percentage of those cases in which ABI or toe pressure was recorded.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PVI procedures with indication of claudication</td>
<td>1231</td>
<td>11807</td>
<td></td>
</tr>
<tr>
<td>Percentage with ABI/TBI recorded before procedure</td>
<td>75%</td>
<td>77%</td>
<td></td>
</tr>
</tbody>
</table>
Rate of ABI/TBI Assessment Before PVI in Your Region (June 2017-May 2018)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

"*" indicates center's rate differs significantly from the regional rate.

Rate of ABI/TBI Assessment Before PVI by Region Across VQI (June 2017-May 2018)

-Midwest
-New York
-Nor. Cal.
-Southeast
-Canada
-Rocky Mtns.
-New England
-Up.
-Midwest
-Pacific NW
-So. Cal.
-MidSouth
-Carolinas
-VQI
-Mid-Atlantic
-Virginias
-Mid-America
-Michigan
-G. Lakes
-SOVONET

"*" indicates centers that do not belong to a regional group. "**" indicates region's rate differs significantly from the VQI rate.
Supra-Inguinal Bypass: Rate of Postop Complications
Procedures performed between June 1, 2017 and May 31, 2018

Complications are defined as myocardial infarction, dysrhythmia, congestive heart failure, respiratory complications, renal complications, surgical site infection, graft infection, leg ischemia/emboli, reoperation, amputation and/or stroke.

Data for this report include all cases with surgery date between June 1, 2017 and May 31, 2018, that had been entered into the VQI as of June 30, 2018. The table below shows the number of SUPRA cases in the VQI, and the percentage of those cases that resulted in complication.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of SUPRA procedures</td>
<td></td>
<td>285</td>
<td>2124</td>
</tr>
<tr>
<td>Percentage with complications after SUPRA</td>
<td></td>
<td>28%</td>
<td>24%</td>
</tr>
</tbody>
</table>
Rate of Complications After SUPRA in Your Region (June 2017-May 2018)

Centers (centers with <10 cases not shown)

"***" indicates center’s rate differs significantly from the regional rate.

Rate of Complications After SUPRA by Region Across VQI (June 2017-May 2018)

"Others" indicates centers that do not belong to a regional group. "***" indicates region’s rate differs significantly from the VQI rate.
TEVAR: Rate of Sac Diameter Reporting at Long-Term Follow-Up
Procedures performed between July 1, 2015 and June 30, 2016
Data for this report include all cases with surgery date between July 1, 2015 and June 30, 2016, that had been entered into the VQI as of June 30, 2018.

<table>
<thead>
<tr>
<th></th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of TEVAR procedures</td>
<td></td>
<td>183</td>
<td>1976</td>
</tr>
<tr>
<td>Percentage with sac diameter recorded at follow-up</td>
<td>44%</td>
<td>42%</td>
<td></td>
</tr>
</tbody>
</table>
Rate of LTFU Sac Diameter Reporting by Year

Your Center  Your Region  VQI Overall
Rate of LTFU Sac Diameter Reporting in Your Region (July 2015-June 2016)

- Other centers in your region
- Your center

Centers (centers with <10 cases not shown)

“***” indicates center’s rate differs significantly from the regional rate.

Rate of LTFU Sac Diameter Reporting by Region Across VQI (July 2015-June 2016)

“Others” indicates centers that do not belong to a regional group. “***” indicates region’s rate differs significantly from the VQI rate.
Varicose Veins: Percentage of Procedures With Complete Patient-Reported Outcome Measures Recorded at Follow-Up
Includes only patients with any follow-up visit recorded.
All regional data omitted because most regions have <3 centers.

PROMs by Center Across VQI (Jan-Dec 2017)

"***" indicates center's rate differs significantly from the overall VQI rate.
LTFU/National VQI Update:
Jens Jorgensen, SVS PSO
VSGNE

Two unique aspects of our registry

• Regional Study Groups
• Long Term Follow Up
# VSGNE - LTFU

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Your Center</th>
<th>Your Region</th>
<th>VQI Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVACCESS</td>
<td>589 (75%)</td>
<td>6740 (70%)</td>
<td></td>
</tr>
<tr>
<td>CAS</td>
<td>348 (44%)</td>
<td>3301 (64%)</td>
<td></td>
</tr>
<tr>
<td>CEA</td>
<td>1856 (66%)</td>
<td>15935 (70%)</td>
<td></td>
</tr>
<tr>
<td>EVAR</td>
<td>689 (69%)</td>
<td>6345 (74%)</td>
<td></td>
</tr>
<tr>
<td>INFRA</td>
<td>1038 (72%)</td>
<td>6504 (75%)</td>
<td></td>
</tr>
</tbody>
</table>
# VSGNE - LTFU

<table>
<thead>
<tr>
<th>YEAR</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall (July 2015-June 2016)</td>
<td>8941 (67%)</td>
<td>8113 (59%)</td>
</tr>
<tr>
<td>2015</td>
<td>8941 (67%)</td>
<td>70651 (74%)</td>
</tr>
<tr>
<td>2016</td>
<td>8113 (59%)</td>
<td>73127 (60%)</td>
</tr>
</tbody>
</table>
VSGNE - LTFU
VSGNE - LTFU

Long-Term Follow-Up by Center in Your Region  (July 2015-June 2016)

Other centers in your region  Your center

Centers (centers with <10 cases not shown)
# VSGNE – LTFU

## Top Ten

<table>
<thead>
<tr>
<th>Num.</th>
<th>Medical Center Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Central Maine Medical Center</td>
</tr>
<tr>
<td>2</td>
<td>Hoenig Vascular Center</td>
</tr>
<tr>
<td>3</td>
<td>Brigham and Women’s Hospital</td>
</tr>
<tr>
<td>4</td>
<td>Saint Francis Hospital</td>
</tr>
<tr>
<td>5</td>
<td>Beth Israel Deaconess Medical Center</td>
</tr>
<tr>
<td>6</td>
<td>University of Vermont Medical Center</td>
</tr>
<tr>
<td>7</td>
<td>Concord Hospital</td>
</tr>
<tr>
<td>8</td>
<td>Boston Medical Center</td>
</tr>
<tr>
<td>9</td>
<td>Elliot Health System</td>
</tr>
<tr>
<td>10</td>
<td>Baystate Medical Center</td>
</tr>
</tbody>
</table>
Opportunity for Improvement

18  St. Elizabeth Medical Center
19  Rhode Island Hospital
20  Dartmouth Hitchcock Medical Center
21  Berkshire Medical Center
22  Massachusetts General Hospital
23  Charlton Memorial Hospital
24  Yale-New Haven Hospital
25  Eastern Maine Medical Center
26  Catholic Medical Center; CTSA NH
27  Lakes Region General Hospital
VSGNE – Discharge Meds

Percentage Receiving Discharge Antiplatelet+Statin by Year

VSGNE – Discharge Meds

Discharge Antiplatelet+Statin Rate by Center in Your Region (June 2017-May 2018)

Other centers in your region  Your center
Number of Participating Centers

Location of VQI Participating Centers

502 Centers, 46 States + Canada
### Total Procedures Captured (as of 10/1/2018)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>164,793</td>
</tr>
<tr>
<td>Carotid Endarterectomy</td>
<td>108,485</td>
</tr>
<tr>
<td>Infra-Inguinal Bypass</td>
<td>48,350</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>43,773</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>42,967</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>24,077</td>
</tr>
<tr>
<td>Varicose Vein</td>
<td>23,526</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
<td>16,197</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>12,665</td>
</tr>
<tr>
<td>Lower Extremity Amputations</td>
<td>12,098</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>11,377</td>
</tr>
<tr>
<td>IVC Filter</td>
<td>10,870</td>
</tr>
</tbody>
</table>

### VQI Total Procedure Volume

Total Procedure Volume tab reflects net procedures added to the registry for the month.
Data Audits starting in 2018!!

- **Inter-rater reliability exercise:** We asked for volunteers to abstract identical cases for selected registries to see how often they agree/disagree. This will let us identify problem data elements that we can improve with better help text and/or training.

- **Random Center Audits:** we plan to audit random cases at selected centers in order to 1) estimate the overall VQI data-element error rate, and 2) identify areas for improvement. Details to come!

- **New PSO-Center Communication Tool for Data Cleanup:** We will use our new web-based “Audit Tool” to ask centers to verify/correct suspicious data entries (out of range, improbable or impossible values in specific records).
August: TEVAR case abstraction
   30 day follow up
September: Validation Case Study! ROI
   Failure modes and effects analysis
October: LTFU required fields
November: Wrapping up a QI project, 2019
   Participation Award information
December: Hemodialysis Registry Changes
2018 reporting schedule

- **July**: Fall Regional Reports
- **July**: Pilot System-Level Fall Reports for Inova and Ohio Health *(new!)*
- **August**: COPI Report: INFRA LOS/Physician Dashboards *(new!)*
- **September**: COPI Report: INFRA SSI *(new!)*
- **October**: QI Initiative Update
- **November**: Cumulative Physician Dashboards *(new!)*

Enhanced Reporting from the PSO
Registry Updates:

- **Hemodialysis Access:** Under major revision with release in 2018 (TBD)
- **Vascular Medicine Registry:** Finalizing changes for release in 2018 (TBD)
- **30-day Follow-up Measures**
- **Varicose Vein:** Under revisions to only collect data on treated leg (shorten the form)
- **Venous Stent Registry:** Under development
- **PVI short form:** Under development
Social Security Numbers

Having the SSN in the record allows us to:

- Match patients with the Social Security Death Index which allows accurate assessment of mortality following vascular procedures.
- Match patients in VQI to their respective Medicare claims to assess long term outcomes which greatly enhances the length of follow up without requiring data entry.
- M2S has designed its security and privacy protocols to ensure PHI is safeguarded in accordance with HIPAA and HITECH. PHI is encrypted both while being transmitted and when data is at rest.

VQI is organized under the legal structure of a patient safety organization (PSO) which has greater data protection than most!!
## VQI Registry Projects

<table>
<thead>
<tr>
<th>Title</th>
<th>Registry</th>
<th>Enrolling</th>
<th>Targets</th>
<th>Follow-Up</th>
<th>Typical $ Per Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>TCAR Surveillance Project</td>
<td>CAS</td>
<td>Yes</td>
<td>-</td>
<td>1 yr</td>
<td>NCD</td>
</tr>
<tr>
<td>Bard® LifeStent® Popliteal Artery Stent Project</td>
<td>PVI</td>
<td>Yes</td>
<td>74 pts 30 sites</td>
<td>1, 2 yr</td>
<td>$1400</td>
</tr>
<tr>
<td>Medtronic IN.PACT® Admiral® DCB ISR Project</td>
<td>PVI</td>
<td>Yes</td>
<td>300 pts 50 sites</td>
<td>1, 2, 3 yr</td>
<td>$1950</td>
</tr>
<tr>
<td>CREST 2 Registry</td>
<td>CAS</td>
<td>Yes</td>
<td>-</td>
<td>1 yr</td>
<td>-</td>
</tr>
<tr>
<td>TEVAR Dissection Surveillance Project</td>
<td>TEVAR</td>
<td>No*</td>
<td>600 pts 50 sites</td>
<td>30 day</td>
<td>$4000</td>
</tr>
<tr>
<td>Lombard Aorfix Surveillance Project</td>
<td>EVAR</td>
<td>No</td>
<td>234 pts 50 sites</td>
<td>30 day</td>
<td>$4000</td>
</tr>
</tbody>
</table>

*Expect enrollment to re-open in late 2018

For more information, contact PATHWAYSsupport@m2s.com
Who attended?

Feedback?
VQI@VAM Highlights:

- **Introduction to the New Member Guide**
  By: Nancy Heatley, Education and Research Projects Manager

- **Tools and Resources of the Vascular Quality Initiative**
  By: Cheryl Jackson, Director of Quality

Links to the new Member Guide and the new QI Project Guide Supplement can be found on the Members Only section of the VQI website in the National Section:

[https://www.vqi.org/national-data/](https://www.vqi.org/national-data/)
Tools and Resources of the Vascular Quality Initiative
Data – Now What

- Open your reports
- Analyze your data
- Use your data
- We all have areas of improvement
- Don’t be afraid

Putting Data into Action
VQI RESOURCES
VQI Resources

- Use your VQI reports
  - Bi-annual reports (Spring and Fall)
  - Dashboards
    - Physician level
    - Center level
  - Center Opportunity Profile for Improvement (COPI) reports
    - Center level
    - Physician level
  - National QI reports
  - D/C medications
  - EVAR LTFU Imaging
  - Analytics engine reports
  - SVS guidelines and recommendations
VQI Resources

- Analyze your data
  - QI Project Guide
    - Original – released in 2016
    - National Quality Initiatives Supplement
  - Tools
    - Case studies
    - Charters
    - PDCA/PDSA
    - DMAIC
VQI Resources

- Webinars
  - February 2018
    - “Starting a QI project”
      - PDCA/PDSA
  - May 2018
    - EVAR LTFU Imaging
    - How to sustain progress
    - DMAIC
  - September 2018
    - Case study from an audit
    - Failure modes and effects analysis (FMEA)
  - November 2018
    - Wrapping up a QI project, 2019 Participation Award information
## Fifty five charters

<table>
<thead>
<tr>
<th>Topics</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge Medications (National Initiative)</td>
<td>20</td>
</tr>
<tr>
<td>LTFU (including EVAR Imaging a National Initiative), IVCF Retrieval</td>
<td>8</td>
</tr>
<tr>
<td>LOS (CEA and EVAR)</td>
<td>11</td>
</tr>
<tr>
<td>Smoking Cessation</td>
<td>5</td>
</tr>
<tr>
<td>Documentation: Epic Workflow, Preop ABI, PVI Documentation,</td>
<td>5</td>
</tr>
<tr>
<td>Clinical: Blood Transfusion, AAA Processes, Limb Salvage, SSI</td>
<td>6</td>
</tr>
</tbody>
</table>
Charters

- Focused group calls
  - Interactive discussion sharing barriers and successes
  - Sharing of charters
  - Networking
  - Checking in – where are you in the process
  - Celebrating success
Newsletters

- The VQI News
  - Distributed every other month
  - Provides updates on regulatory issues, technical updates, and crossover news from the SVS

- VQI Quality Improvement Newsletter
  - Distributed every other month
  - Focusing on QI processes, tools, and definitions
Members Only Website

- Protected area on the VQI website
- Registry forums
  - All registries listed
  - QI forum
Next Steps

- Where are you?
- Wrapping up a QI project
- Sharing outcomes
  - Internally
  - Externally
How to increase regional meeting attendance and participation?

- Lead physicians agreed to personally call centers that do not regularly attend.
- Created a script of standardized questions (willing to share with other regions).
- Plan to publish results.
Winner of the Poster Competition:

"Implementation of a Structured Protocol to Improve Rates of VQI Registry Vascular Patient Follow Up" from NY Presbyterian - Weill Cornell Medicine

Authors: Melissa R. Katzman, PA-C, Katherine E. Greger, PA-C, Ashley Graham, BS, Andrew J. Meltzer, MD, and Darren B. Schneider, MD
Research Advisory Council Update
Phil Goodney, MD
Dropping the need to avoid overlap as a criteria for SVS PSO RAC approval.

- Research protocols now need only to demonstrate feasibility that the research can be accomplished using data available in the VQI dataset.

- Overlap with an existing project will not be used as grounds for rejection of a research protocol application.
Check Approved Project List:

https://www.vqi.org/vqi-resource-library/quality-research/rac-approved-project-search/

To submit a proposal to be considered for the National RAC, please follow the link below:

http://abstracts123.com/svs1/meetinglogin
National Research Process

Medicare Matched Datasets:

https://www.vqi.org/vqi-resource-library/quality-research/blinded-datasets/

VQI Medicare Matched Blinded Datasets

Please review the Overview, Datasets and Flowcharts on this page before you start a National RAC project submission to ensure that the data will be suitable for Medicare-matching as the process has changed.

As the Medicare individual level data are subject to Data Use Agreements (DUAs) with the Centers for Medicare and Medicaid Services (CMS), no individual level data can be shared, but TDI will share CMS data that meets aggregated data release guidelines outlined in our DUA. While prior user agreements suggested that blinded datasets could be disseminated, the new DUA requires that no patient-level data be shared.

Overview for Use of VQI-Medicare Matched Datasets

Dataset Profiles

Dataset Profile CAS 3.19.18
Dataset Profile CEA 3.19.18
Dataset Profile EVAR 3.19.18
Dataset Profile HEMO 3.19.18
Dataset Profile INFRA 3.19.18
Dataset Profile OPEN 3.19.18
Dataset Profile PVI 3.19.18
Dataset Profile SUPRA 3.19.18
Dataset Profile TEVAR 3.19.18
National Research Process

Proposal Submissions
December 2018
• Call for Proposals: October 9, 2018
• Due Date: November 19, 2018
• Meeting: December 10, 2018
• Notification Sent: December 11, 2018

February 2019
• Call for Proposals: December 11, 2018
• Due Date: January 28, 2019
• Meeting: February 11, 2019
• Notification Sent: February 12, 2019
Molecular Imaging for Aortic Disease
Professor Mehran Sadeghi, MD
Yale Medicine
(placeholder)
Molecular imaging for aortic disease

Mehran M. Sadeghi, MD
Professor of Medicine
Yale University

New Haven, November 2, 2018
Presenter Disclosure Information

Consultant for Bracco Research USA

None of the agents discussed here is FDA-approved for the proposed indications.
Increasing incidence of TAA: 16.3 per 100,000 per year for men in 2002 in a Swedish study.

High mortality complications: dissection and rupture.

Predictors of outcome: Size, genetics

Aortic Aneurysms

• AAA alone, is responsible for ~10,000 deaths annually in the US (mainly due to rupture).

• The only consistent predictor of expansion is the initial aortic diameter.

• Indications for AAA repair:
  – diameter > 55 mm,
  – increase in size by >10 mm/year,
  – Symptomatic AAA.
Risk of Rupture in Small AAA

• In Multi-center Aneurysm Screening Study 23% of ruptures occurred in those AAA not meeting the criteria for surgery

• Rupture rate 0.6-1% in AAA of 40-54 mm diameter

• The risk of rupture is even higher in women, smokers, and those with a family history of AAA

Golestani R and Sadeghi, JNC, 2014:251-67
Risk stratification in aortic aneurysm

- Genetics:
  - Marfan syndrome and Loeys–Dietz syndrome (TAA)
  - 9p21 region and LRP1 (AAA)

- Biomarkers:
  - MMP-9
  - IL-6
  - CRP

- Biomechanics:
Risk stratification in aortic aneurysm

• Genetics: Role in aneurysm expansion and rupture unknown
  • Marfan syndrome and Loeys–Dietz syndrome (TAA)
  • 9p21 region and LRP1 (AAA)

• Biomarkers: Susceptibility to interference by external factors
  • MMP-9
  • IL-6
  • CRP

• Biomechanics: Labor intensive and complex
In vivo visualization, characterization, and measurement of biological processes at the molecular and cellular level
Molecular Imaging Probe Administration

Biodistribution and Clearance of the Probe

In Vivo Imaging

Image Analysis and Quantification

Image Reconstruction

Toczek J, et al. JNC 2016: in press
Spatial Scale in the Cardiovascular System

- Molecules
- Capillaries
- Endothelium
- Coronaries
- Heart

Logarithmic scale from $10^{-10}$ to $10^0$ meters.
Potential molecular imaging targets in aortic aneurysm

- Inflammation
  - Phagocytosis
  - Cell metabolism
  - Integrin expression and activation
  - Chemokine receptors

- Matrix remodeling
  - Protease activation
  - Elastin turnover
Molecular imaging in aortic aneurysm: USPIO-enhanced MRI and risk of rupture in AAA

Richards et al, Circ Cardiovasc Imaging 2011;4:274-81
• 342 patients with AAA ≥40 mm
• > 2 year follow up
• Primary endpoint: AAA rupture or repair

Addition of USPIO enhancement did not improve event prediction

**18F-Fluorodeoxyglucose**

- 18F-labeled glucose homolog
- Phosphorylated by hexokinase and retained in metabolically active cells
- Commonly used for imaging cancer and infection/inflammation
FDG PET in Large Vessel Aortitis

73 y/o F with giant cell arteritis

72 y/o M with giant cell arteritis, under long-term steroid treatment

Papathanasiou ND et al, Br J Radiol. 2012: e188–e194
FDG PET in Large Vessel Aortitis
(imaging at 3 hours)

TBR cut-off of 1.34: sensitivity of 100 % and specificity of 94.4 %

Martínez-Rodríguez I, et al, EJNMMI, 2014:2863
FDG PET in AAA Risk Assessment

Structural stress and FDG uptake in AAA

FDG PET in acute and chronic aortic dissection

Molecular imaging in aortic aneurysm: FDG PET and outcome in thoracic aortic dissection

$^{18}$F-NaF Imaging

hydroxyapatite crystals

$\text{Ca}_5(\text{OH})(\text{PO}_4)_3$
Prospective case-control (n = 20 per group) and longitudinal cohort (n = 72) study
\(^{18}\text{F-NaF Imaging of Abdominal Aortic Aneurysms [SoFIA\(^3\)]}\)

Predictor of growth independent of age, sex, baseline diameter, smoking, or PAD

Forsythe R, et al. JACC, 2018, 513-23
OTHER EMERGING TRACERS
Imaging of Chemokine Receptors in Vascular Injury

\(^{64}\text{Cu-DOTA-vMIP-II}\)

- Chemokines are a family of chemotactic cytokines (can guide and activate leukocytes).

- At least four structural groups:
  - c
  - cc
  - cx3c
  - cxc

Liu, et al, JNM, 2013:1135-41

Blocking percentage for individual chemokine receptors

Murine femoral artery wire injury
Imaging of Chemokine Receptors in Vascular Pathology

($^{68}$Ga-pentixafor, a CXCR4 ligand)

Arterial uptake in all 51 patients who underwent $^{68}$Ga-pentixafor PET/CT for noncardiovascular indications

Matrix Metalloproteinases

- A family of ~25 related enzymes that degrade different components of extracellular matrix (and other proteins).

- MMP activity is increased in vascular remodeling, and plays a key role in aneurysm rupture and atherosclerotic plaque vulnerability.

MMP-targeted imaging of carotid aneurysm

Razavian, et al, JNM, 2010:1107-15
MMP-targeted imaging of carotid aneurysm

RP782

Razavian, et al, JNM, 2010
RP782 Uptake Specificity

RP782

RP782 + excess non-labeled tracer

Razavian, et al, JNM, 2010:1107-15
Predicting aneurysm expansion: 
Tracer uptake at 2 weeks vs aneurysm size at 4 weeks

Razavian, et al, JNM 2010
Murine model of AAA with potential for spontaneous rupture

- In vivo RP805 microSPECT/CT
- Ex vivo planar imaging
- Tissue analysis

Minipump implantation

0 4 weeks

Angiotensin II or normal saline

Survival (%)

100 90 80 70 60 50 40 30 20 10 0

Time (days)

0 4 8 12 16 20 24 28

Saline-infused

AngII-infused

Maximum external diameter (mm)

0.5 1.0 1.5 2.0 2.5

Saline-infused AngII-infused

Golestani, et al, Circulation CVI, 2015; 8: e002471
MMP-targeted imaging of AAA

$^{99m}$Tc-RP805

Golestani, et al, Circulation CVI, 2015; 8: e002471
Correlates of MMP tracer uptake in the aorta

- **RP805 uptake**:
  - MMP activity
    - $r = 0.83$, $p < 0.001$
  - CD68 expression
    - $r = 0.89$, $p < 0.0001$
  - Diameter at 4 weeks

Graphs showing the correlation between MMP uptake and other parameters.
Predictive value of MMP imaging in murine AAA

Minipump Implantation (n=25) → RP805 microSPECT/CT → Morphometry

Golestani, et al, Circulation CVI, 2015; 8: e002471
$^{99m}$Tc-RYM1 imaging in aneurysm

$^{64}$Cu-RYM2 PET/CT imaging of AAA
Imaging phagocytic activity in aneurysm
Imaging phagocytic activity in aneurysm

4 weeks Ang II infusion

24 h post-contrast CT

TEM
Conclusions

• Inflammation and protease activation are key mediators of aneurysm expansion and rupture.

• USPIO MRI and NaF PET may predict AAA expansion. Additive value unknown.

• MMP-targeted imaging is emerging as an alternative for AAA risk stratification.

• If validated in humans, these techniques may lead to a new paradigm for management of patients with aortic aneurysms.
Cardiovascular Molecular Imaging Laboratory
Parnaz Boodagh
Arvene Golbazi
Kiran Gona
Jae Joon Jung
Gunjan Kukreja
Jakub Toczek
Jiasheng Zhang
Past members:
Masood Ahmed
Abolfazl Asadi
Azariyas Challa
Leila Esmailzadeh
Amir A. Gharaei
Reza Golestani
Xiaojia Guo
Jinah Han
Svetlana Krassilnikova
Xuan Li
Gaoxing Luo
Ravi Marfatia
Lei Nie
Hooman R. Fassaei
Mahmoud Razavian
Teresa Silva
Sina Tavakoli
Yunpeng Ye

Yale Experimental Nuclear Cardiology Laboratory/Y-TRIC
Albert Sinusas
Yi-Hwa Liu
Yale PET Center
Henry Huang
Chi Liu
Richard Carson
Yale Surgery
George Tellides
Kristine Orion
Yale West Campus Analytical Core
Mousumi Ghosh
Terence Wu
University of Iowa
Donald Heistad
Service d'Ingénierie Moléculaire des Protéines, CEA-Saclay, France
Vincent Dive
Laurent Devel
Lantheus Medical Imaging
Simon Robinson

Thank you!

Funding
NIH, VA, DOD
Arterial Quality Council Update: Jessica Simons, MD
Finalizing Common Variable select options and helptext amongst registries where applicable
Completing all “missing helptext”
Clinically reviewing all helptext to site scientific support where applicable
LTFU **required** fields are complete and M2S is in the process of development for 2018 release
Physician and Center Dashboards: Physician and center stats on critical outcomes by registry over the past year, including regional and VQI benchmarks. First physician reports delivered in February and will be updated in fall. Center-level dashboards planned for June.

Comparative COPI Reports: We will update prior COPI reports with new data to check centers’ improvement. EVAR LOS planned for May, INFRA LOS for August and INFRA SSI in September.

National QI Initiative Updates: Reports will be issued quarterly starting in March tracking centers’ progress on Discharge Medications and Follow-Up Imaging After EVAR.
Venous Quality Council Update
Mark Iafrati, MD
First Bi-Annual Varicose Vein Meeting at VAM!!!

Plan to meet at AVF every year and hold a conference call every Fall
(October 29, 2018 10am -12:00pm ET)
Significant participation in first 3 years
- 130 Physicians entering consecutive VV cases
VVR Participation:

- Total Procedures entered: 20,536
- Entered by 36 sites in 20 states
Effects of age, gender, race and other patient factors on outcome of GSV ablation

Incidence and impact of EHIT after GSV ablation

Clinical and patient reported outcomes after different types of GSV ablation

Impact of truncal vein diameter on ablation outcomes

Factors associated with need for repeat treatment after GSV ablation

Increased opportunity with increasing data

Research drives Quality Improvement!!!
C2 Disease Treatment Data:

- 874 total perforator treatments reported, 332 (38%) for C2 disease
- 332 veins were treated as part of 279 total procedures
- **279 procedures, 124 (44%) were performed at one center**
- 2 other centers have 30 such procedures each
- The remaining 95 such procedures are scattered across 20 other centers
Venous Stent Registry: release 2018

Clinical Workgroup:
Marc Passman, MD (chair), William Marston MD, Tony Gasparis MD, Rabith Chaer MD, BK Lal MD, Lowell Kabnick MD

Industry and FDA Collaboration:
Bard, Boston Scientific, Cook, Gore, Medtronic, Veniti
Governing Council Update
Philip Goodney, MD
Addition of members from the Society for Vascular Ultrasound

- Dr. David Dawson; SVU Physician Director
- Kelly Byrnes, BS, RTV, FSVU; NortonHealthcare; SVU Treasurer

Vote on new Executive Committee Members

- Dr. Leila Mureebe, Duke
- Dr. Randy DeMartino, Mayo
SVS Guidelines & VQI

SVS Guidelines

- Are they being followed?
- Are they adopted over time?
- Do they influence outcomes?
- Can VQI help answer these questions?
SVS Guidelines & VQI

- AAA Guidelines published in January JVS
- 119 recommendations/suggestions
- 15 guidelines potentially measurable in VQI

Compliance with guideline
- Quit smoking > 2 weeks before OAAA – 44%
- EVAR size threshold – 58%
- Preservation of IIA during EVAR – 98%
SVS Guidelines and VQI

Preop Stress Test

Size guideline for AAA repair

OAAA: Compliance with Stress Testing Guideline by Center

EVAR: Compliance with AAA Diameter Guideline by Center

Centers (centers with <10 cases omitted)
Using Cell Saver by Center

OAAA: Compliance with Cell Salvage Guideline by Center

% Procedures Meeting Guideline

Centers (centers with <10 cases omitted)
Adherence to use of cell saver had decreased inpatient and one year mortality following open AAA repair

Guideline compliance improves outcomes
Next Steps:

– Consideration of creation of center level reports for OAAA in Spring of 2019
– Dr. Forbes authoring a manuscript on initial findings
– VQI using the Guidelines to inform registry variables
– Potential to expand this exercise to other procedures