Florida-Georgia Vascular Study Group

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Assistant Professor of Surgery
Division of Vascular Surgery
University of Florida
College of Medicine
Vascular Quality Initiative

- **SVS VQI collects:**
  - Pre-operative risk factors
  - Intra-procedural variables
  - Post-procedural outcomes
  - One-year follow-up data

- **SVS PSO**
  - Oversight of data sharing arrangements
  - Oversight of dissemination of information to participating providers
  - Protects data from discovery in federal and state courts
  - Eliminates need for IRB approval and patient consent

- **M2S:**
  - Secure, web-based data collection and analysis system
VQI Regional Groups

• Anonymous pooling of information.

• Increasing power and ability to detect root causes of outcomes.

• Facilitating & initiating quality improvement projects
SVS VQI

Reliable Data Collection

Risk adjusted comparative reports

Quality Improvement Projects

Outcome Assessment
FGVSG

Formed 2010
(FL Vasc Study Group)

19 participating centers

104 Active Surgeons

4645 Procedures to date
(n=4206 at time of analysis)
Regional Meetings

- Spring 2012/Fall 2012: University of Florida
  5/9 Centers
- Spring 2013: Hosted by Emory
  13 Centers
- Fall 2013: Hosted by Florida Hospital
  19 Centers
## Packet Review

### Procedure cumulative summary by August 31, 2013

<table>
<thead>
<tr>
<th>Procedure Name</th>
<th>Number of Procedures</th>
<th>% of Total Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid Artery Stent</td>
<td>216</td>
<td>4.65%</td>
</tr>
<tr>
<td><strong>Carotid Endarterectomy</strong></td>
<td><strong>1169</strong></td>
<td><strong>25.17%</strong></td>
</tr>
<tr>
<td>Endo AAA Repair</td>
<td>577</td>
<td>12.42%</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>299</td>
<td>6.44%</td>
</tr>
<tr>
<td>Infra-inguinal Bypass</td>
<td>578</td>
<td>12.44%</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>189</td>
<td>4.07%</td>
</tr>
<tr>
<td><strong>Peripheral Vascular Intervention</strong></td>
<td><strong>1119</strong></td>
<td><strong>24.09%</strong></td>
</tr>
<tr>
<td>Supra-inguinal Bypass</td>
<td>248</td>
<td>5.34%</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>250</td>
<td>5.38%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4645</strong></td>
<td><strong>100.00%</strong></td>
</tr>
</tbody>
</table>
Open vs. Endovascular Repair of Popliteal Artery Aneurysm (OVERPAR) Trial
An Update

Mohammad H. Eslami, Phil Goodney, and Alik Farber
OVERPAR Trial

A prospective, multicenter randomized trial of open surgical bypass vs. endovascular popliteal artery stent graft repair in asymptomatic patients

Trial sponsored by NESVS and orchestrated through VQI
OVERPAR Trial

Secondary Outcomes

– Clinical
  • Composite MALE - POD (perioperative death)
  • Freedom from secondary interventions
  • Number of interventions
  • Primary, primary-assisted and secondary patency rates
  • Procedure duration
  • 30-day freedom from perioperative MACE
  • Other perioperative complications

– Functional status and quality of life

– Resource utilization (LOS)
Patients with asymptomatic PAA eligible for repair

LE CTA of affected limb
To plan surgery

Informed consent

Open Group
Stent Group

1:1 randomization

4 year study: mean follow-up of 2.5 years
Current VQI Machinery vs. OVERPAR Trial

**Current patients at VQI centers**

- Patients with PAA at the participating VQI centers
  - Data is collected at M2S
  - Time: 1 month and one year

**Current patients at VQI centers Participating in OVERPAR**

- Patients with PAA at participating VQI centers and OVER-PAR Trial
  - 1:1 Randomization
  - Data is collected at M2S
  - Time*: 1 month and annually
Sample Size Calculation

- MALE survival curves estimated using data from the largest series of OPAR and OPG data describing patients with PAD who underwent bypass.
- Assumption: patients will be accrued uniformly over three years and then followed for one additional year past accrual period.
  - 50% loss to follow-up within ten years (~7% after first year and 20% after 3 years).

<table>
<thead>
<tr>
<th>1-year Rates</th>
<th>OPAR</th>
<th>EPAR</th>
<th>Hazard Ratio</th>
<th>Power</th>
</tr>
</thead>
<tbody>
<tr>
<td>MALE</td>
<td>20%</td>
<td>35%</td>
<td>1.53</td>
<td>80%</td>
</tr>
</tbody>
</table>

- **148** (74 in each group) patients to achieve power of .8 for two-sided test with a type I error bound of .05 using a balanced design.
Randomization

• Participating sites will contact study coordinator at BMC.
• For each center, electronic folders are created by biostatistician.
• Upon receiving the phone call, these electronic folders are accessed and the results (OPAR or EPAR) are relayed to the site study coordinator.
Patient Follow-up

0  1  12  24  36  48

Scheduled post-op visits (months)

History and physical evaluation
Arterial Duplex of the graft/stent
ABI (if possible)
QOL Patient Survey (patients can fill out and send back)

(©Morgan et al. J Vasc Surg 2001; 33: 679-87)
21 VQI sites have agreed to participate.
What is needed from each Center

• **Apply to IRB**
  – Standardized IRB protocol available
  – PI has agreed to assist with IRB questions

• **Enroll patients**
  – Follow-up scheme is similar to standard practice
  – Modified VSGNE forms for PVI and LEB
Dynamic Content: OVER-PAR Data Collection

Admin UI for easy control of center-level dynamic content subscription:

<table>
<thead>
<tr>
<th>CENTER CONTENT PERMISSIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
</tr>
<tr>
<td>Edit</td>
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<tr>
<td>Edit</td>
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<tr>
<td>Edit</td>
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<tr>
<td>Edit</td>
</tr>
</tbody>
</table>

Automatic Patient Screening according to protocol:
- Additional OVER-PAR variables only show for qualifying patients who undergo treatment for **Asymptomatic Popliteal Aneurysm**
OVER-PAR: Infra-inguinal Bypass

Additional History Variables Collected:

<table>
<thead>
<tr>
<th>OVER-PAR Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popliteal Aneurysm Treated?</td>
</tr>
<tr>
<td>Patient Enrolled in OVER-PAR</td>
</tr>
<tr>
<td>Patient Randomized To OPAR</td>
</tr>
<tr>
<td>Max Popliteal Aneurysm Diameter</td>
</tr>
</tbody>
</table>

Additional Procedure Variables Collected:

<table>
<thead>
<tr>
<th>OVER-PAR Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graft Manufacturer</td>
</tr>
<tr>
<td>Graft Type</td>
</tr>
<tr>
<td>Approach</td>
</tr>
<tr>
<td>Max Graft Diameter</td>
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</table>

Additional Follow-Up Variables Collected:

<table>
<thead>
<tr>
<th>Infra OVER-PAR Trial</th>
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<tbody>
<tr>
<td>This patient is a subject in OVER-PAR Trial</td>
</tr>
<tr>
<td>Duplex Stenosis</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
</tr>
<tr>
<td>Date of MI</td>
</tr>
<tr>
<td>Stroke</td>
</tr>
<tr>
<td>Date of Stroke</td>
</tr>
</tbody>
</table>
OVER-PAR: Peripheral Vascular Intervention

Additional **History** Variables Collected:

<table>
<thead>
<tr>
<th>OVER-PAR Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Popliteal Aneurysm Treated?</td>
</tr>
<tr>
<td>Patient Enrolled in OVER-PAR</td>
</tr>
<tr>
<td>Patient Randomized To</td>
</tr>
<tr>
<td>Max Popliteal Aneurysm Diameter</td>
</tr>
</tbody>
</table>

Additional **Procedure Details** Variables Collected:

<table>
<thead>
<tr>
<th>OVER-PAR Trial</th>
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<tbody>
<tr>
<td>Endoleak</td>
</tr>
<tr>
<td>Type of Endoleak</td>
</tr>
<tr>
<td>Number of Stent Grafts Used</td>
</tr>
<tr>
<td>Stent Graft(s) Used</td>
</tr>
<tr>
<td>Overlap Length</td>
</tr>
<tr>
<td>Graft Type(s)</td>
</tr>
</tbody>
</table>
OVER-PAR: Peripheral Vascular Intervention

Additional **Follow-Up** Variables Collected:

<table>
<thead>
<tr>
<th>OVER-PAR Trial</th>
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</thead>
<tbody>
<tr>
<td>This patient is a subject in OVER-PAR Trial</td>
</tr>
<tr>
<td><strong>Duplex Stenosis</strong></td>
</tr>
<tr>
<td><strong>Endoleak</strong></td>
</tr>
<tr>
<td><strong>Type of Endoleak</strong></td>
</tr>
<tr>
<td><strong>Thrombolysis of Stent Graft</strong></td>
</tr>
<tr>
<td><strong>Date of Thrombolysis</strong></td>
</tr>
<tr>
<td><strong>Thrombectomy of Stent Graft</strong></td>
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<tr>
<td><strong>Date of Thrombectomy</strong></td>
</tr>
<tr>
<td><strong>Access Site Infection</strong></td>
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<tr>
<td><strong>Stent Graft Infection</strong></td>
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<tr>
<td><strong>Myocardial Infarction</strong></td>
</tr>
<tr>
<td><strong>Date of MI</strong></td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
</tr>
<tr>
<td><strong>Date of Stroke</strong></td>
</tr>
</tbody>
</table>
Participating Centers
Why Participate and Enroll?

- Study answers a relevant question
- Will provide level I data
- Uses data collection resources already in place for VQI
- Pilot for running future prospective trials on a modest budget
## Budget

<table>
<thead>
<tr>
<th></th>
<th>Year 1 ($)</th>
<th>Year 2 ($)</th>
<th>Year 3 ($)</th>
<th>Year 4 ($)</th>
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<td>Central Trial Coordinator</td>
<td>2000</td>
<td>4000</td>
<td>4000</td>
<td>0</td>
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<tr>
<td>Statistical Support and</td>
<td>1000</td>
<td>1000</td>
<td>1000</td>
<td>0</td>
</tr>
<tr>
<td>randomization scheme</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Site coordinator support</td>
<td>5000</td>
<td>5000 ($100/pt enrolled)</td>
<td>5000 ($100/pt enrolled)</td>
<td>0</td>
</tr>
<tr>
<td>IRB fees</td>
<td>2000</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Total:</td>
<td>10,000</td>
<td>10,000</td>
<td>10,000</td>
<td>0</td>
</tr>
</tbody>
</table>
A Model for Future Studies using VQI

Comparison of OVERPAR budget with an average RO1 award (2007)

NIH award budget over years.

- **Average NIH RO1 grants**
- **OVERPAR Trial**

Annual amount($)

(Dollars in Bill)

OER: NIH Budget
Contact Mo Eslami at the University of Massachusetts if you are interested in participating in the OVERPAR trial:

(508) 320-7660
Using VQI Data for National Research
A National Level VQI Dataset is a Rich Resource

- Large sample size will permit analyses not possible at single institution or regional level
- Particularly suited to understand regional/geographic/ethnic variation in practice and outcomes

<table>
<thead>
<tr>
<th>Total Procedures Captured (as of May 1st, 2013)</th>
<th>87,226</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid Endarterectomy</td>
<td>24,071</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>3,099</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>8,986</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>3,834</td>
</tr>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>25,554</td>
</tr>
<tr>
<td>Infra-Inguinal Bypass</td>
<td>12,691</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
<td>3,774</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>1,086</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>4,003</td>
</tr>
</tbody>
</table>
Challenges in Using a National Level VQI Dataset

- Large datasets require specialized expertise to properly analyze

- Project completion (analysis, writing, editing) will be done by workgroups representative of the various regions
Two Mechanisms for Analysis of National Level VQI Data

- Initiated within VQI
  - Work commissioned by one of the Quality Committees
  - Analysis done “inside” the PSO by VQI personnel using identifiable data
  - Results are intended to serve as an ongoing quality benchmark
  - Individual centers/providers are informed of their performance relative to national benchmarks
  - E.g. Kalish et al Surgical Site Infection study

- Investigator-initiated
  - Proposal initially submitted to regional group Research Advisory Committee (RAC)
  - If approved by regional RAC, forwarded to national RAC for peer review
  - Upon approval by national RAC:
    - Individual centers given an opportunity to “opt out”
    - Regional groups notified of approved proposal and workgroup membership solicited
    - Non-identified national dataset from participating centers released to investigator who convenes workgroup to conduct analysis and generate report
National Research Advisory Committee (RAC)

• Composition
  – Chair: Philip Goodney, MD
  – Membership: Marc Schermerhorn, Magdiel Trinidad, Britt Tonnessen, Megan Tracci, Adam Beck, Brian Nolan, Andres Schanzer, Karen Woo, Darren Schneider, Grace Wang
National Research Advisory Committee (RAC)

- Review Criteria
  - Study addresses knowledge gap in vascular disease
  - Quality of study design and analytic plan
  - PI expertise and qualifications
  - Need for IRB approval/exemption

- Application process outlined in the Resource Library on VQI website [www.vascularqualityinitiative.org](http://www.vascularqualityinitiative.org)
A High Bar for Release of National VQI Datasets

To date, the RAC has received 7 proposals and approved 6

• Variation and intensity of medical therapy in patients undergoing vascular surgery
  • Dr. Randall DeMartino, Dartmouth

• Development of VQI Cardiac Risk Predictor
  • Dr. Daniel Bertges, U Vermont

• Comparison of Open and Endo repair of asymptomatic popliteal aneurysms
  • Dr. Mohammad Eslami, Boston U

• Derivation of risk factor model predicting adverse outcomes after Carotid Endarterectomy (CEA) using Vascular Study Group of New England (VSGNE) carotid dataset and external validation using the remainder of SVS-PSO dataset
  • Dr. Mohammad Eslami, Boston U

• Identifying risk factors for cerebral reperfusion syndrome will permit patients to be better managed and reduce morbidity
  • Dr. Grace Wang, Penn

• Comparison of the efficiency of data collection in VQI vs. NSQIP for predicting post CEA stroke and death
  • Dr. Karen Woo, USC
Arterial Quality Committee (AQC)

Larry Kraiss, MD, chair

Members: Adam Beck, Paul Anain, Fred Beavers, Sabah Butty, Dennis Gable, Mark Glickman, Phil Goodney, Steven Kappes, Jeffrey Prem, Jacob Robison, Andres Schanzer, Marc Schermerhorn, Darren Schneider, Magdiel Trinidad, Grace Wang
Venous Quality Committee (VQC)

Brajesh K Lal, MD, Chair

Members: Faisal Aziz, Antony Comerota, Rob Crawford, Brian DeRubertis, Antonios Gasparis, David Gillespie, Heather Hall, Mark Iafrati, David Kuwayama, Mark Meissner, William Marston, Mark Mewissen, Albeir Mousa, Marc Passman, Eric Peden, Joseph Raffetto, Apostolos Tassiopoulos, Rob Winter
Quality Committee’s Focus

• Chairs and workgroups for each procedure
  – Updating variables/definitions
  – Variable auditing (statistical)
  – Quality Initiatives
  – Report parameters
Use Regional Data to Establish Proof-of-Concept, Expertise or Feasibility

Regional Group Quality Initiatives:

1. VSGNE:
   - Chlorhexidine prep and discharge on statins/antiplatelet agents as practice guidelines
   - Pilot 30 day follow up for Infra to capture SSI and readmission data
   - Smoking cessation

2. Florida/Georgia:
   - Smoking cessation

3. Carolina’s:
   - Pre-op Statin and Antiplatelet
   - LOS CEA and EVAR
   - Smoking Cessation and use of Chantix
   - Trial of Interactive Telephone System (Listen UP) for Pre op and Postop Instruction and Post-procedure Monitoring to Reduce Readmission
Regional Quality Initiatives (VQI data)

8. Sovonet:
   - Statins
   - Use of Chlorhexidine night before surgery

9. Southern California:
   - 30 day readmission

10. Mid Atlantic:
    - EVAR and CEA LOS

11. Illinois:
    - LOS, Claudication, Pre-op medication

12. Virginia’s:
    - Use of Antiplatelet Agents in Patients Receiving Lower Extremity Interventions
Summary

• National level VQI data a valuable but challenging resource
• VQI has an interest in ensuring only the highest quality reports are generated from national level data
• Thus, proposals for national level data are rigorously scrutinized
• Regional data should be used for preliminary analyses to establish feasibility and demonstrate expertise
Request for Non-Identifiable National Datasets

SVS-PSO data, collected in the Vascular Quality Initiative® (VQI®), represents national practice and is a valuable resource. It is the mission of the Society for Vascular Surgery’s Patient Safety Organization Research Advisory Subcommittee (PSO-RAC) to ensure that data collected in the Vascular Quality Initiative is used for projects that meet the following criteria:

- The project is a study that addresses knowledge gaps in the care of patients with vascular disease.
- The project is a study that is well designed, and addresses a topic of interest to VQI participants.
- The project is submitted by study team that can execute and interpret analyses presented in the study proposal.
Request for Non-Identifiable Regional Datasets

Non-identifiable datasets for regional or national quality research may be prepared by the Society for Vascular Surgery® Patient Safety Organization (SVS PSO), with permission of the involved Centers (the hospitals or physician groups that have contracted with the SVS PSO). Each regional quality group must specify a mechanism for review and approval of such requests, normally through a Research Advisory Committee (RAC). Only SVS PSO members who are members of a regional quality group may request non-identifiable datasets for regional or national quality research. Each participating Center whose data would be included in a non-identifiable dataset must approve this, as outlined below. Independent Centers not part of a regional quality group only have access to their own clinical data. Procedures vary slightly for requesting non-identifiable data from a single regional quality group versus multiple regional quality groups.
Overview

• VQI national database allows analysis of:
  – Processes of care, in-hospital and one year outcomes
  – Center and regional variation in patient selection, procedure selection and outcomes
  – Comparative effectiveness of alternative procedures

• Examples from:
  – Over 40,000 elective procedures performed 2011-2012
  – CEA and CAS, Leg bypass and PVI, oAAA and EVAR
Vascular Quality Initiative® 2011-2012

**CEA** (n=10,188)
- 77% Asymptomatic

**CAS** (n=1,103)
- 70% Asymptomatic
Vascular Quality Initiative® 2011-2012

Percentage of CEA done for Asymptomatic Stenosis

All VQI Centers Mean = 77%

Patient Selection Variation

29% Asymptomatic

Centers with ≥ 10 Procedures
Percentage of CAS done for Asymptomatic Stenosis

All VQI Centers Mean = 70%

Patient Selection Variation

10% Asymptomatic

Centers with > 10 Procedures

VQI Centers
Vascular Quality Initiative® 2011-2012

**CEA** (n=10,188)
- 77% Asymptomatic
- 90% General anesthesia
  - 50% EEG, stump pressure
- 86% Conventional
  - 95% Patched
- 25% Completion duplex
- 25% IV Meds for BP

**CAS** (n=1,103)
- 70% Asymptomatic
- 95% Patched
- 25% Completion duplex

(Elective only, excludes combined CABG)
Vascular Quality Initiative® 2011-2012

**CEA (n=10,188)**
- 77% Asymptomatic
- 90% General anesthesia
  - 50% EEG, stump pressure
- 86% Conventional
  - 95% Patched
- 25% Completion duplex
- 25% IV Meds for BP

**CAS (n=1,103 )**
- 70% Asymptomatic
- 26% Prior CEA
- 40% Medical high risk
- 49% Anatomic high risk
- 98% Embolic protection
  - 4% Retrograde flow
- 24% IV Meds for BP
## Carotid Treatment Outcomes

<table>
<thead>
<tr>
<th></th>
<th>CEA</th>
<th>CAS</th>
<th>P&lt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asymptomatic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hosp. Stroke-Death</td>
<td>0.8%</td>
<td>1.7%</td>
<td>.01</td>
</tr>
<tr>
<td>Hosp. MI</td>
<td>1.0%</td>
<td>0.6%</td>
<td>ns</td>
</tr>
<tr>
<td>1 Yr Stroke-Death</td>
<td>4.7%</td>
<td>9.4%</td>
<td>.001</td>
</tr>
<tr>
<td><strong>Symptomatic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hosp. Stroke-Death</td>
<td>1.6%</td>
<td>3.9%</td>
<td>.001</td>
</tr>
<tr>
<td>Hosp. MI</td>
<td>1.1%</td>
<td>0.7%</td>
<td>ns</td>
</tr>
<tr>
<td>1 Yr Stroke-Death</td>
<td>6.7%</td>
<td>13.5%</td>
<td>.01</td>
</tr>
</tbody>
</table>
Vascular Quality Initiative® 2011-2012

% Carotid Treatment by CAS (vs. CEA)

All VQI Centers Mean = 13%

Procedure Selection Variation

Centers with ≥ 10 Procedures

1% CAS

47% CAS

VQI Centers
In-hospital Stroke/Death Rate after Elective CEA

14,182 Procedures
(Excludes: previous ipsilateral CEA, concomitant CABG)

Adjusted for: Hypertension, CABG/PTCA, ASA/Plavix, contralateral and ipsilateral ICA stenosis, ipsilateral cortical symptoms

Significantly lower or higher than expected:
* p<0.05
Vascular Quality Initiative®

8,000 Procedures, 2011 to 2012
(Excludes in-hospital deaths, previous ipsilateral CEA, concomitant CABG)

% Patients with Length of Stay > 1 Day after Elective Carotid Endarterectomy

Adjusted for: age, gender, race, hypertension, diabetes, pre-op beta blocker, CAD, CHF, COPD, stress test, discharge ASA, discharge statin, prior radiation therapy, pre-op MRA

Observed significantly different than expected:
* p<0.05
**p<0.01
Factors Associated with LOS > 1 Day after CEA

- Major Adverse Events: 23%
- IV Meds Required for Hyper- or Hypotension: 31%
- Unexplained: 11%
- Patient Factors: 18%
- Process Factors: 7%
- Low Surgeon Volume: 10%

Vascular Quality Initiative®
Suprainguinal Bypass
• N= 710
• 42% CLI
• Mean ABI = 0.65

Suprainguinal PVI
• N= 7,083
• 24% CLI
• Mean ABI = 0.65
• 24% TASC C-D

Location:
- Aorto-fem
- Fem-fem
- Ax-fem
- Aorta
- Com Iliac
- Ext Iliac

(Elective, occlusive disease)
Vascular Quality Initiative® 2011-2012

Suprainguinal Bypass
• N= 710
• 42% CLI
• Mean ABI = 0.65

Suprainguinal PVI
• N= 7,083
• 24% CLI
• Mean ABI = 0.65
• 24% TASC C-D

(Elective, occlusive disease)

Treatment:
- PTA Only: 7%
- Bare Stent: 82%
- Covered Stent: 11%
## Suprainguinal One Year Treatment Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Bypass</th>
<th>PVI</th>
<th>P&lt;</th>
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<tbody>
<tr>
<td><strong>Claudication</strong></td>
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<tr>
<td>Death</td>
<td>6.0%</td>
<td>4.6%</td>
<td>ns</td>
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<tr>
<td>Amputation</td>
<td>0.8%</td>
<td>0.3%</td>
<td>ns</td>
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<tr>
<td>Re-intervention</td>
<td>10.8%</td>
<td>8.9%</td>
<td>ns</td>
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<tr>
<td><strong>CLI</strong></td>
<td></td>
<td></td>
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<tr>
<td>Death</td>
<td>15%</td>
<td>18%</td>
<td>ns</td>
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<tr>
<td>Amputation</td>
<td>3.7%</td>
<td>7.2%</td>
<td>ns</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>3.7%</td>
<td><strong>11%</strong></td>
<td>.03</td>
</tr>
</tbody>
</table>
Vascular Quality Initiative® 2011-2012

**Infrainguinal Bypass**
- N = 7,131
- 64% CLI
- Mean ABI = 0.55
- 62% Autogenous Vein

**Infrainguinal PVI**
- N = 11,956
- 52% CLI
- Mean ABI = 0.74
- 44% TASC C-D

(Elective, occlusive disease)
Infrainguinal Bypass

- N = 7,131
- 64% CLI
- Mean ABI = 0.55
- 62% Autogenous vein

Infrainguinal PVI

- N = 11,956
- 52% CLI
- Mean ABI = 0.74
- 44% TASC C-D

(Elective, occlusive disease)
<table>
<thead>
<tr>
<th></th>
<th>Bypass</th>
<th>PVI</th>
<th>P&lt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claudication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>3.9%</td>
<td>5.5%</td>
<td>ns</td>
</tr>
<tr>
<td>Amputation</td>
<td>2.4%</td>
<td>1.6%</td>
<td>ns</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>16%</td>
<td>22%</td>
<td>.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CLI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>17%</td>
<td>27%</td>
<td>.0001</td>
</tr>
<tr>
<td>Amputation</td>
<td>10%</td>
<td>15%</td>
<td>.01</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>18%</td>
<td>21%</td>
<td>ns</td>
</tr>
</tbody>
</table>
Claudication: % Treated by Bypass (vs. PVI)

All VQI Centers Mean = 26%

Infrainguinal Treatment

76% Bypass

Procedure Selection Variation

Centers with ≥ 10 Procedures

VQI Centers
Critical Limb Ischemia: % Treated by Bypass (vs. PVI)

All VQI Centers Mean = 31%

Procedure Selection Variation

100% Bypass

0% Bypass
Vascular Quality Initiative® 2011-2012

AAA Repair – Open
- 6.0 cm Mean Diameter
- 31% Retroperitoneal
- 46% Supra-renal clamp
- 45% Tube graft

EVAR
- 5.6 cm Mean Diameter
- 91% General anesthesia
- 8% Uni-iliac, fem-fem

(Elective, non-ruptured)
<table>
<thead>
<tr>
<th>AAA Repair – Open</th>
<th>EVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.0 cm Mean Diameter</td>
<td>5.6 cm Mean Diameter</td>
</tr>
<tr>
<td>31% Retroperitoneal</td>
<td>91% General anesthesia</td>
</tr>
<tr>
<td>46% Supra-renal clamp</td>
<td>8% Uni-iliac, fem-fem</td>
</tr>
<tr>
<td>45% Tube graft</td>
<td></td>
</tr>
<tr>
<td>2 Units PRBC</td>
<td>1 Units PRBC</td>
</tr>
<tr>
<td>4 Days in ICU</td>
<td>0.8 Days in ICU</td>
</tr>
<tr>
<td>9 Days hospitalized</td>
<td>2.8 Days hospitalized</td>
</tr>
</tbody>
</table>

(Elective, non-ruptured)
## Non-ruptured AAA Repair Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Open</th>
<th>EVAR</th>
<th>P&lt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In Hospital:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>4.1%</td>
<td>0.9%</td>
<td>.0001</td>
</tr>
<tr>
<td>MI</td>
<td>4.8%</td>
<td>1.6%</td>
<td>.0001</td>
</tr>
<tr>
<td><strong>One Year:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>8.0%</td>
<td>8.9%</td>
<td>ns</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>4.7%</td>
<td>5.0%</td>
<td>ns</td>
</tr>
<tr>
<td>Sac increase &gt; 5 mm</td>
<td></td>
<td>9.4%</td>
<td></td>
</tr>
<tr>
<td>Endoleak Type I, III</td>
<td></td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Endoleak Type II</td>
<td></td>
<td>14%</td>
<td></td>
</tr>
</tbody>
</table>
In-hospital Mortality after Non-Ruptured Open AAA Repair
Regional Variation

2,720 Procedures, 2003 to 2012

Observed — Expected

Adjusted for: COPD, creatinine, site of proximal clamp
% Elective AAA Repair Done as EVAR

All VQI Centers Mean = 79%

Procedure Selection Variation

41% EVAR
Vascular Quality Initiative®

Conclusion

• VQI national dataset allows us to study:
  – Regional and center variation in outcome and process
  – Comparative effectiveness of procedures and process
• VQI national dataset is useful for:
  – Quality improvement projects
  – Scientific research projects
  – Medical device evaluation
• Valuable for all VQI members and regional groups
  – Variation indicates opportunity for improvement
Smoking Cessation Strategies - QI Project

- Comprehensive Programs:
  Nicotine Replacement Products
  Physician counseling
  Support Groups

Vascular Surgeons do not have the resources to support comprehensive programs. Therefore, failure rates are high.

- AHEC:
  Area Health Education Centers
  Locally controlled, federally funded organizations to improve health education for patients
  Model program at University of Florida for smoking cessation
  Will try to replicate this in other places
VQI Update &
A New Divisional Quality Initiative:
Increasing Smoking Cessation

Yuming Lin, MSM, Vida Rivera, BA and Adam W. Beck, MD
AGENDA

- Introduce Implementation Strategy for Smoking Cessation Quality Initiative
  - Provider education: pharmacotherapy of smoking cessation
  - New divisional workflow

- Outline Provider’s Protocol to Increase Smoking Cessation

- When a Patient Can’t Afford a Prescription

- VQI Update with Yuming
  - Procedure cumulative summary by July 31, 2013
  - Major outcomes by center
  - Pre-op meds usage by center
  - Post-op meds usage by center
  - 12 charts report
  - Risk adjusted report
  - Follow-up rate update
  - Smoking cessation documentation and follow-up rate update report

- October 2013 FGVSG Meeting in Orlando, FL
  - Agenda Topics – any requests?
NEW DIVISIONAL WORKFLOW
NEW DIVISIONAL WORKFLOW

- Identify patients
  - CSRs will ask each new patient and returning patient if they currently smoke and will document by checking box “Smoke QI” in vascular DB.
  - There will be another box that says “Currently Smoke” for follow up appts

- Patients will be identified on clinic lists from the DB providers receive

- Providers will follow their protocol in clinic

- Yuming and Vida will document initial visit and follow-up information in DB (dependent upon good documentation from providers)

- Tentative quarterly review of information to assess results
NEW DIVISIONAL WORKFLOW

- **Goals:**
  - Assess number of patients treated with each intervention
  - Assess number of patients that participated in AHEC programs
  - Assess number of patients that successfully quit at their follow-up visits
  - Assess follow-up rate
    - To start, we will just follow-up with patients that return to clinic. If follow-up rate is very low after the first review, we may start calling patients that don’t return
Provider’s protocol
Provider’s Protocol

- Engage in a kind discussion regarding the importance of smoking cessation.

- Acknowledge empathetically that quitting is hard, and do not trivialize the difficulties with smoking cessation ("I understand that is very difficult to quit, but...”).

- If patient is pregnant, do not prescribe any medication or NRT, and recommend patient quit immediately.
PHARMACOTHERAPY

FIRST-LINE:
WELLBUTRIN + NICOTINE REPLACEMENT THERAPY
Wellbutrin
Bupropion (Zyban, Wellbutrin SR, Bupropion SR)

- Increases dopamine in the brain
- Contraindications: eating disorder, seizure disorder, current use of bupropion, recent abrupt discontinuation of alcohol or benzodiazepines, MAOI therapy within 14 days, dialysis, pregnancy, documented allergy to Wellbutrin

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>150mg daily for 3 days, then twice daily</td>
<td>Medications that lower seizure threshold</td>
<td>Insomnia</td>
</tr>
<tr>
<td>Initiation is 1-2 weeks before quit date</td>
<td>Severe liver disease</td>
<td>Dry mouth</td>
</tr>
<tr>
<td>Duration is 7-12 weeks</td>
<td>Pregnancy</td>
<td>Nervousness</td>
</tr>
<tr>
<td>Avoid bedtime dosing to minimize insomnia</td>
<td>Contraindication within 14 days of use of MAOI inhibitor</td>
<td>Rash</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Constipation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Seizures</td>
</tr>
</tbody>
</table>
NICOTINE REPLACEMENT THERAPY (NRT)
**PREferred: Transdermal Patch**

- Prescribe to all patients receiving Wellbutrin

- Use one patch/day on a hairless skin area between your neck and waist, rotating placement daily
  - Cost: Box of 14 patches, both 14mg and 21mg is $38, or free at AHEC

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 4 weeks: 21mg patch</td>
<td>Pregnancy</td>
<td>Skin reactions</td>
</tr>
<tr>
<td>Next 2 weeks: 12mg patch</td>
<td>Unstable Angina</td>
<td>Insomnia</td>
</tr>
<tr>
<td>Next 2 weeks: 7mg patch</td>
<td>Serious Arrhythmias</td>
<td>Vivid dreams (not nightmares)</td>
</tr>
<tr>
<td>2 weeks post MI</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
If nicotine patch requires supplementation or is contraindicated/refused:
**Nicotine Gum**

- Chew and park 1 piece 30 minutes every 1-2 hours
  - Avoid eating or drinking for 15 minutes before or during chewing
  - Cost: Box of 100 2mg pieces is $48; box of 100 4mg pieces is $68

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>4mg if smoke &gt;25 cigs/day</td>
<td>Recent MI</td>
<td>Dyspepsia</td>
</tr>
<tr>
<td>2mg if smoke &lt;25 cigs/day</td>
<td>Serious arrhythmias</td>
<td>Hiccups</td>
</tr>
<tr>
<td>At least 1 piece every 1-2 hours</td>
<td>Unstable angina</td>
<td>Mouth and jaw soreness</td>
</tr>
<tr>
<td>Max: 24 pieces/day</td>
<td>Pregnancy</td>
<td>Increased Salivation</td>
</tr>
<tr>
<td>Duration: 12 weeks</td>
<td>Recent dental work or dentures</td>
<td></td>
</tr>
</tbody>
</table>
**NICOTINE LOZENGE**

- Use 9-15 lozenges/day for 6 weeks, then taper for 6 weeks
  - Dissolves in mouth over 30 minutes
  - Don’t chew or swallow, and rotate areas of mouth
  - Avoid eating or drinking 15 minutes before or during chewing

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>4mg if time to first cigarette &lt;30 min</td>
<td>Recent MI</td>
<td>Nausea</td>
</tr>
<tr>
<td>2mg if time to first cigarette is &gt;30 min</td>
<td>Serious arrhythmias</td>
<td>Cough</td>
</tr>
<tr>
<td>At least 1 lozenge every 1-2 hours for the first 6 weeks</td>
<td>Unstable angina</td>
<td>Hiccups</td>
</tr>
<tr>
<td>Max: 20 lozenges/day</td>
<td>Pregnancy</td>
<td>Dyspepsia</td>
</tr>
<tr>
<td>Duration: 12 weeks</td>
<td></td>
<td>Flatulence</td>
</tr>
</tbody>
</table>
**NICOTINE NASAL SPRAY**

- **Directions for Use:** Press in circles on sides of bottle and pull to remove cap. Prime pump before first use. Blow nose. Tilt head back slightly and insert tip of bottle into nostril as far as comfortable. Breathe through mouth and spray once in each nostril. Wait 2-3 minutes before blowing nose.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2 doses/hr (1 dose=1 spray)</td>
<td>Recent MI</td>
<td>Nasal/throat irritation</td>
</tr>
<tr>
<td>Min: 8 doses/day</td>
<td>Serious arrhythmias</td>
<td>Rhinitis</td>
</tr>
<tr>
<td>Max: 40 doses/day</td>
<td>Angina</td>
<td>Tearing</td>
</tr>
<tr>
<td>Use for 3-6 months</td>
<td>Pregnancy</td>
<td>Sneezing</td>
</tr>
<tr>
<td></td>
<td>Chronic nasal disorders</td>
<td>Cough</td>
</tr>
<tr>
<td></td>
<td>Severe reactive airway disease</td>
<td>Headache</td>
</tr>
</tbody>
</table>
**NICOTINE INHALER**

- **Directions for Use:** Inhale into back of throat or puff in short breaths. Avoid eating or drinking 15 minutes before or during use. Nicotine in cartridge is depleted after 20 minutes of active puffing, and open cartridges remain potent for 24 hours.

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initially 1 cartridge every 1-2 hrs (each cartridge delivers 4mg nicotine over 80 inhalations)</td>
<td>Recent MI</td>
<td>Mouth/throat irritation</td>
</tr>
<tr>
<td>6-16 cartridges/day</td>
<td>Serious arrhythmias</td>
<td>Cough</td>
</tr>
<tr>
<td>Duration of therapy is 3-6 months, start tapering after 3 months</td>
<td>Angina</td>
<td>Headache</td>
</tr>
<tr>
<td></td>
<td>Pregnancy</td>
<td>Rhinitis</td>
</tr>
<tr>
<td></td>
<td>Bronchospastic disease</td>
<td>Dyspepsia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hiccups</td>
</tr>
</tbody>
</table>
PHARMACOTHERAPY
SECOND-LINE: CHANTIX
**Varenicline (Chantix)**

- MAO partial agonist/antagonist for nicotine receptors (makes smoking less pleasurable)
- Contraindications: CrCl <30ml/min, dialysis, suicidal ideations, clinical depression, pregnancy, documented allergy to Chantix

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cautions</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1-3: .5mg daily</td>
<td>Severe renal impairment</td>
<td>Nausea (taking meds with a snack helps)</td>
</tr>
<tr>
<td>Days 4-7: .5mg twice daily</td>
<td>Psychiatric disorders (May increase suicidal ideations in patients who are already depressed)</td>
<td>Insomnia/vivid dreams</td>
</tr>
<tr>
<td>Initiate 1 week before quit date</td>
<td></td>
<td>Constipation</td>
</tr>
<tr>
<td>Use 12-24 weeks, or longer</td>
<td></td>
<td>Neuropsychiatric symptoms</td>
</tr>
</tbody>
</table>
Sources:

- Dr. Karen Sando, Pharm. D., CDE. Clinical Assistant Professor and AHEC Pharmacy Coordinator
- Anna Maynard, Tampa AHEC
- Kathy Nichols, Assistant Director at UF AHEC
- FDA Prescription Guidelines. Chantix and Wellbutrin guidelines are on pages 46-56
  [http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/treating_tobacco_use08.pdf](http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/tobacco/clinicians/treating_tobacco_use08.pdf)
- Free online module provided by AHEC. Create a short Elearning user profile and use activation code tob001
  [http://www.aheceducation.com/ELearning/CourseCatalog.aspx](http://www.aheceducation.com/ELearning/CourseCatalog.aspx)
Provider’s Protocol

- Explain to patients why tobacco is addicting, and how Wellbutrin can help by acting on the brain’s nicotine receptors and reduce nicotine withdrawal symptoms.
  - Contraindication list will be provided in clinic for easy access.

- Explain to patients that before Wellbutrin is prescribed, they must choose a quit date and start Wellbutrin 7 days before that date. Their quit date should be on a low stress day to maximize success.

- In preparation for the quit date, ask patients to use the 14mg transdermal patch available free at AHEC.
  - If patients do not want to use the patch, recommend other NRTs. If patients use an NRT and continue with their current smoking habits, they will get sick from nicotine overdose.
Provider’s Protocol

- Discuss side effects: dry mouth and insomnia
  - For insomnia, recommend patient take second dose before 6PM with a snack

- If not discussed, patient is likely to stop medication. They may subside with a lower dose or continued use of medication.

- Encourage patients to contact you, not PCP, if they have severe side effects or questions.

- Encourage patients to pick up a brochure about Wellbutrin and AHEC in the waiting area.
If patient can’t take Wellbutrin, prescribe Chantix. Explain to the patient that Chantix works on the brain’s nicotine receptors to make smoking less pleasurable.

Explain to patients that before Wellbutrin is prescribed, they must choose a quit date and start Wellbutrin 7 days before that date. Their quit date should be on a low stress day to maximize success.

Make sure patient knows they can’t take NRT while on Chantix, and should decrease cigarette consumption by half leading up to quit date.
**Provider’s Protocol**

- Discuss side effects: nausea, insomnia, vivid dreams.
  - For insomnia and vivid dreams, recommend patient take second dose before 6PM with a snack.

- If not discussed, patient is likely to stop medication. They may subside with a lower dose or continued use of medication.

- Encourage patients to contact you, not PCP, if they have severe side effects or questions.

- Encourage patients to pick up a brochure about Chantix and AHEC in the waiting area.
PROVIDER’S PROTOCOL

- Give patient their prescription using a stamp

- Recommend patients start eliminating cigarettes from their home and remove any potential triggers in their home or work to help them deal with cravings and triggers.
  - If other family members smoke, it is recommended they initiate cessation efforts as well, as it will increase the likelihood that the patients as well as the patients’ family members successfully quit.

- Recommend patients go to AHEC for free NRT and/or counseling. 877-U-CAN-NOW (877-822-6669)
If conversation was 3-10 minutes, bill using CPT 99406

- Use template Jen shared using description Smoking Cessation Intervention. Smart phrase is VASSMOKINGCESSATION1TO30

*** is an ongoing smoker, and approximately 5 minutes of discussion was held with the patient regarding smoking cessation. The patient was given a pamphlet regarding AHEC resources for smoking cessation and a Wellbutrin prescription with 14mg transdermal nicotine patches vs. Chantix prescription.

If conversation was >10 minutes, bill using 99407
PROVIDER’S PROTOCOL: FOLLOW-UP

- At the follow-up appointment, ask patients about smoking status. Use CPT 99406 if conversation >3 minutes (Ok to bill again, when appropriate).
  - Document using smartphrase VASSMOKINGCESSATIONFU with description “Follow up to smoking cessation intervention”

We had the pleasure of following up regarding the patient's smoking cessation efforts:
1)- The patient (is/is not) currently smoking, 2)- (did/did not) join one of the Area Health Education Center (AHEC) cessation programs, and 3)- has used [Wellbutrin/Wellbutrin+NRT/Chantix/just NRT/no medications] to aid in his smoking cessation efforts

- If they have not quit smoking, offer the above prescriptions again.
SUMMARY

- Be supportive and empathetic
- Tell patients about AHEC and provide pamphlet
- Prescribe Wellbutrin + 14mg patch or Chantix
- Discuss side effects
- Encourage patients to follow up with you, not PCP
- Document in Epic
**First Line Therapy:**
Wellbutrin SR (150mg qd for 3 days then 150mg bid for 12 weeks) + 14mg Transdermal Nicotine Patch for first 7 days of use. Day 7 should be quit date.

Do not prescribe Wellbutrin if patient:
- Has a history of seizures
- Has a history of eating disorders
- Is taking another form of bupropion
- Has used another MAOI in the past 14 days
- Is on dialysis
- Is pregnant
- Documented allergy to Wellbutrin

**Second Line Therapy (if there is a contraindication to Wellbutrin/NRT):**
Chantix (0.5mg qd for 3 days then 0.5mg bid for 12 weeks). Day 7 of use should be quit date. No nicotine replacement should be prescribed with Chantix.

Do not prescribe Chantix if patient:
- Has CrCl <30ml/min
- Is on dialysis
- Has had suicidal ideations or is clinically depressed
- Is pregnant
- Documented allergy to Chantix

If patient has a contraindication (other than pregnancy) to both Wellbutrin and Chantix, NRT alone can be recommended/prescribed. Of note, patients with CrCl <30ml/min or on dialysis may use NRT Alone.
When a Patient Can’t Afford a Prescription

- Wellbutrin SR is available generically, and is a covered drug on many third-party plans. As it is not a $4 generic, patients may still need assistance.
  - These forms can be found at: http://www.rxassist.org/

- Chantix has poor coverage on most third-party plans. If you need to prescribe Chantix to a patient with poor coverage, you can seek patient assistance by applying directly to Pfizer and supplying an application and patient income information.
  - Patient assistance forms can be found at: http://www.rxassist.org/. Click on “Provider Center” and type in the name of the drug, and the eligibility and all the forms needed are listed.
Dr. Beck reviewed the ongoing analysis of the arrival/intraoperative heart rate for AAA, LEB and Suprainguinal bypass. This project is ongoing and future data will be released to the VQI as a whole once available.
Dear Dr. ________________

We had the pleasure of seeing __________________ in our office recently in consultation. He/she has a history of Peripheral Vascular Disease (PVD). As you know, PVD is linked to other adverse cardiovascular events, and there are a number of risk factor modification measures that have been demonstrated by a growing body of literature to improve the long-term outcomes of these patients.

Our group is an active participant in The Society for Vascular Surgery’s Vascular Quality Initiative (SVS VQI), which actively promotes risk factor modification measures including such things as: exercise regimens, smoking cessation, statin therapy, anti-platelet therapy, control of hypertension, and perioperative beta-blockade in patients undergoing vascular procedures.

In preparation for a vascular intervention, we may have started new medications on our mutual patient, and we wanted to make sure that you are aware. This plan has been started on a new medication, and you have no objections, please make arrangements for the appropriate clinical follow-up, which we would like to defer to you as the primary physician.

New medications started (citalopram)

Beta-blocker

Statin

ACE inhibitor/ARB

Anti-platelet therapy

Thank you very much for your consideration and continued care of our shared patient. Please do not hesitate to contact our office at __________ if you have any questions.

Sincerely,

*References*