SVS Vascular Quality Initiative

➤ Overview of SVS VQI
  – Jack L. Cronenwett, M.D.

➤ Starting a Regional Quality Group
  – John (Jeb) W. Hallett, M.D.

➤ Uses for Regional Registry Data
  – Phillip P. Goodney, M.D.
Overview of SVS VQI

Jack L. Cronenwett, M.D.
• New Initiative in 2011

• Mission:
  – To improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information.

• Goal:
  – Participation by all SVS members organized into regional study groups.
3 Components:

• SVS Patient Safety Organization
• M2S Pathways data collection - reporting system
• Regional study groups
  – Based on Vascular Study Group of New England
3 Components:

- SVS Patient Safety Organization
The Patient Safety Act of 2009

• Established a framework by which hospitals and providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of interventions and outcomes.

• Supervised by the Agency for Healthcare Research and Quality (AHRQ).
• Protects work product (any comparative data) from discovery in federal or state court
• Eliminates need for informed consent or IRB approval to include patient identified data
• Precludes comparative data to be used for punitive purposes, such as quality assurance
• Allows only de-identified data to be published
  – Statistical de-identification of patient, provider, hospital
• Strong penalties for any violation of privacy
SVS PSO Policies

• Focus on quality improvement
• Each center owns their data
• Use common data elements
• Enter all consecutive procedures
• Submit claims data for audit and enter missing data
• Obtain one year follow-up at office visit
• Benchmarking is anonymous
• Reports cannot be used for competitive marketing
Organization

• Quality improvement efforts at the regional level
  – Ownership, responsibility, traction, durability
  – Semi-annual meetings to implement QI projects

• Data collection, analysis at the PSO level
  – Efficiency, benchmarking, risk-adjustment
  – Regional control of data by representation in PSO

• Distributed network of regional QI groups organized around a national vascular registry
PSO Governing Council: 4 representatives from SVS, 1 from each region, Medical Director (ex officio)

VSGNE Quality Committee

Carolinas Quality Committee

Florida Quality Committee

So. Calif Quality Committee

VSGNE Research Advisory Committee

Carolinas Research Advisory Committee

Florida Research Advisory Committee

So. Calif Research Advisory Committee

PSO Quality Committee: 1 Representative from each regional RAC plus SVS appointees
**PSO Governing Council:** 4 representatives from SVS, 1 from each region, Medical Director (ex officio)

- Conducts business of PSO, report to SVS Board
- Approve recommendations of PSO Quality Committee

Richard Cambria, MD, Chair  
Anton Sidawy, MD, Vice Chair  
Larry Kraiss, MD  
Louis Nguyen, MD  
Michael Stoner, MD  
Jens Jorgenson, MD (NE)  
Jeb Hallett, MD (Carolinas)  
Adam Beck, MD (Florida)  
Mark Davies, MD (Southern)  
Fred Weaver, MD (S. California)  
TBD, representatives from other regional groups  
Jack Cronenwett, MD, Medical Director, ex officio
**Vascular Quality Initiative**

**PSO Governing Council:** 4 representatives from SVS, 1 from each region, Medical Director (ex officio)

Larry Kraiss, MD, Chair  
Philip Goodney, MD  
Jeb Hallett, MD  
Greg Landry, MD  
Andres Schanzer, MD  
Marc Schermerhorn, MD  
Thomas Wakefield, MD  
Jack Cronenwett, MD, ex officio

- Develop national quality improvement projects
- Recommend best practices based on PSO analyses
- Evaluate requests for de-identified datasets for quality research that involve more than one region

**PSO Quality Committee:** 1 Representative from each regional RAC plus SVS appointees
Vascular Quality Initiative

PSO Governing Council: 4 representatives from SVS, 1 from each region, Medical Director (ex officio)

Regional Quality Committee
- Control regional data use within the SVS PSO
- Analyze and evaluate regional data
- Approve regional quality research requests

Regional Research Advisory Committee
- Evaluate requests for de-identified datasets for regional quality research
- Make recommendations to PSO Quality Committee for cross regional analyses, research or best practices

PSO Quality Committee: 1 Representative from each regional RAC plus SVS appointees
Vascular Quality Initiative

SVS PSO Staff

Carrie Bosela, RN, CPC
Administrative Director

Donald Likosky, PhD
Epidemiologist
Additional Benefits to PSO Members

• Supports internal quality improvement at both hospital and provider level
• Data collection meets CMS’ Carotid Artery Stent Facility Recertification requirements
• Vascular Surgery Board has accepted VQI participation for Part 4 of Maintenance of Certification
CMS Physician Quality Reporting System

<table>
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<th>Year</th>
<th>Bonus</th>
<th>Supplement*</th>
<th>Penalty</th>
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<td>2.0%</td>
<td></td>
<td></td>
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<tr>
<td>2011</td>
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<tr>
<td>2012-2014</td>
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<td>2015</td>
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<td>1.5%</td>
</tr>
<tr>
<td>2016 +</td>
<td></td>
<td></td>
<td>2.0%</td>
</tr>
</tbody>
</table>

% of all Medicare Part B claims
* If participate in maintenance of board certification program approved by CMS

Data submitted to M2S for SVS VQI can be submitted to CMS for PQRS reporting
Methods:

• Assess quality by comparing common, uniform procedures across centers and providers
  – CEA, CAS, oAAA, EVAR, TEVAR, LEB, PVI, Dialysis

• Use variation in process and outcome across centers to determine best practice
  – Identify processes associated with best outcomes
  – Make recommendations for best practice

• Provide benchmark reports to change practice
Vascular Quality Initiative

Unique Aspects of Database

• One year follow-up for key outcomes
  – Completed in physician’s office
• Prospective, consecutive cases
  – Audited against claims data
• Both center and physician level reports
  – Benchmark comparison with others
• Detailed clinical data
  – Pre-, intra-, and post-op variables
• Academic and community hospitals
  – Real world practice
3 Components:

• SVS Patient Safety Organization

• M2S Pathways data collection - reporting system
Partnership with M2S

• **M2S Clinical Data Pathways**
  – Developed based on VSGNE data forms and reports
  – Secure web-based data collection and analysis system
  – Real-time benchmarked reports for major outcomes and complication per physician and center

• **Efficient data entry**
  – Drop down menus for data entry with help text
  – Error trapping at time of entry
  – Segments for entry by different personnel
<table>
<thead>
<tr>
<th><strong>General Information</strong></th>
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</thead>
</table>

**Patient Data:**
- Zip: 11111
- Medicare FFS: Yes
- Gender: Male
- Race: White
- Height: 70 inches
- Weight: 180 lbs
- Weight (cm): 178
- Weight (kg): 82

**Admission Data:**
- Visit Code: 2222
- Admit Date: 01/01/2006
- Discharge Date: 01/05/2006
- Surgeon: Surgeon, John
- Surgery Date: 01/03/2006
- Discharge Status: Home
- Transfer from?: No
### Procedure Information

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<th>Field</th>
<th>Value</th>
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</tr>
<tr>
<td>Side</td>
<td>Right</td>
</tr>
<tr>
<td>Patch</td>
<td>Bovine pericardium</td>
</tr>
<tr>
<td>Heparin</td>
<td>Yes</td>
</tr>
<tr>
<td>Re-explore artery after closure?</td>
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<td>Monitoring</td>
<td></td>
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<td>Awake</td>
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<td>Stump Pressure</td>
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<td>Doppler</td>
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<td>Angiogram</td>
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<td>Protamine</td>
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<td>Dextran</td>
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<tr>
<td>EEG</td>
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<td>Other</td>
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</tr>
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<td>Highest intra-op</td>
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<tr>
<td>Duplex</td>
<td>Yes</td>
</tr>
<tr>
<td>Flowprobe</td>
<td>No</td>
</tr>
<tr>
<td>Proximal Endovasc</td>
<td>No</td>
</tr>
</tbody>
</table>
Vascular Quality Initiative

Post-op Data Entry – Nurse Practitioner

### Post-Op Information

**Cranial Nerve Injury:**
- VII: No
- IX: No
- X: No
- XII: No
- Other: No

**Ipsilat Neurologic Event:** TIA

**Contralat Neurologic Event:** No

**IV Med Required for:**
- Hypertension: No
- Hypotension: Yes

**Complications:**
- Myocardial Infarction: No
- CHF: No
- Dysrhythmia (new): No
- Wound Infection: No
- Reperfusion Symptoms: None
- Return to OR: No

**Discharge Medications:**
- ASA: Yes
- Plavix: No
- Other Antiplatelet: No
- Statin: Yes
- Beta Blocker: Yes

**Peri-Op Antibiotic Ordered?:**
- Start <1hr Pre-op: Yes
- Stop <24hr Post-op: No, for medical reason
- 1st-2nd Gen Cephalosporin: Yes
Death or Major Amputation after Lower Extremity Bypass by Surgeon

Surgeon ordered by Rate of Procedures per Year, Low to High
Risk Adjusted Outcome Reports

Observed/Expected Ratio for Stroke or Death after CEA by Medical Center

5126 VSGNNE Carotid Endarterectomies 2003 to 2008

Data Source: VSGNNE database

More strokes/deaths than expected
Operating as expected
Fewer strokes/deaths than expected

Regional mean O/E ratio - 1.009

* p <.05 versus region and expected
# No observed strokes/deaths

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Selected Quality Measures for Each Procedure

Elective Endo AAA Repair - VSGNNE
January 2003 - December 2007: Region, N=701 (blue) and DHMC, N=285 (red)

- Use of Beta-Blockers
- Use of Aspirin or Plavix
- Use of Statins
- Volume
- Unfit for Open Repair
- Any Endoleak at Completion
- Type I or III Endoleak
- Estimated Median Blood Loss
- Not Extubated in Operating Room
- Post-operative Complications
- Not Discharged Home
- Mortality

January 2003 - December 2007: Region, N=701 (blue) and DHMC, N=285 (red)
Real Time Reports on Web

Select Complications to Include:

- Lower Extremity Bypass Complications – Organized by Surgeon
  Arranged by Increasing Annual Rate of Procedure
  n = 3379
Mortality or Major Amputation after Lower Extremity Bypass:
Include: Diabetes, dialysis, pre-adm living, statin use, indication, pathology, ambulation pre-op, prosthetic vs. autogenous graft status
3 Components:

• SVS Patient Safety Organization
• M2S Pathways data collection - reporting system
• Regional study groups
  – Based on Vascular Study Group of New England
Why Regional Study Groups?

- National registries offer power of large database for research, risk-adjusting, benchmarking
  - Don’t operationalize quality improvement
- Regional quality groups create local ownership, responsibility, vehicle for QI projects
  - Experience in New England
- Opportunity to combine both factors in VQI
Regional Quality Improvement

• Aggregate data across providers and hospitals to reveal variation in process and outcome that can be analyzed to select best practice

• Implement specific quality improvement projects after defining best practice

• Provide benchmark comparison data to incent practice change
VSGNNE 2003
9 Participating Hospitals
VSGNE 2011
27 Participating Hospitals
25 - 950 Hospital Beds

Fletcher Allen Health Care
Dartmouth-Hitchcock Medical Center
Rutland Regional Medical Center
Catholic Medical Center
Berkshire Medical Center
Baystate Medical Center
St. Francis Hospital
Hartford Hospital
Yale-New Haven Hospital

Eastern Maine Medical Center
Cottage Hospital
Lakes Region Hospital
Central Maine Medical Center
Concord Hospital
Elliot Hospital
Tufts Medical Center
Boston Medical Center
Beth Israel Deaconess Medical Center
Massachusetts General Hospital
Brigham & Women’s Hospital
Charlton Memorial Hospital
Caritas St. Anne’s Hospital
St. Luke’s Hospital

Hartford Hospital
St. Luke’s Hospital
18,000 Procedures Reported
CEA, CAS, oAAA, EVAR, LEB, PVI (2003-2010)

Power Lies in Data
Accumulated Over Time
Focus on Quality Improvement

- **Semi-annual Meetings**
  - Critical to success, durability of group
  - Stimulate cooperative quality projects
  - Overcome insular nature of practice with granular conversations about quality
Recent Meeting Agenda

• AV access and TEVAR working groups report
• CLI treatment preference survey results
• Panel: Lower extremity bypass: Techniques that work
• VSG CRI cardiac risk online prediction tool
• Predicting respiratory failure after elective OAAA repair
• Carotid patch and re-stenosis update
• Intensive glucose management in LEB patients
• Outcomes of LEB after previous interventional treatment
• MI rates in diabetics after LEB
• Clinical improvement vs. graft patency in LEB
• Impact of increased beta blocker usage
• Statin use working group report
• New QI projects and clinical uses for registry
• Variation in complication rates by center and procedure
Results to Date

• Since February, 2011
6 Regional Groups Exist:
- New England
- Mid-Atlantic
- Carolinas
- Florida
- Texas
- Southern California

5 Regional Groups Forming:
- Virginia
- Georgia
- Michigan
- Ontario, Canada
- Rocky Mountain area
Vascular Quality Initiative

Number of Participating Centers

87 Centers, 30 States
> 2000 Procedures per Month
## Total Procedures Captured (as of May 31, 2011)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>25,809</td>
</tr>
<tr>
<td>Carotid Endarterectomy</td>
<td>9,798</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>756</td>
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<tr>
<td>Endovascular AAA Repair</td>
<td>2,883</td>
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<tr>
<td>Open AAA Repair</td>
<td>2,154</td>
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<tr>
<td>Peripheral Vascular Intervention</td>
<td>4,191</td>
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<tr>
<td>Infra-Inguinal Bypass</td>
<td>5,043</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
<td>843</td>
</tr>
<tr>
<td>TEVAR</td>
<td>8</td>
</tr>
</tbody>
</table>
Based on VSGNE fees prior to M2S web-based system
  - 10% Decrease from previous VSGNE hospital fees

Data Management Fee (M2S)
  - Maintenance of web-based system for data entry, real-time reporting, benchmarking, and ability to download institutional data for research/additional analyses

PSO Fee
  - Overall governance of SVS VQI
  - Quality analysis, oversight of web-based system
  - Design of data entry forms, development of risk-adjusted algorithms

Regional Group Fee (so far only applicable in VSGNE)
  - Regional group meeting and staffing cost (max $2000 in VSGNE)
### Vascular Quality Initiative

#### M2S Annual Fee

Based on procedure volume and number of procedure types entered

<table>
<thead>
<tr>
<th>Annual Volume of Procedures</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7*</th>
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</thead>
<tbody>
<tr>
<td>1-5</td>
<td>$400</td>
<td>$800</td>
<td>$1,200</td>
<td>$1,600</td>
<td>$2,000</td>
<td>$2,400</td>
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<tr>
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<td>$3,200</td>
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<td>$4,800</td>
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<tr>
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<td>$2,600</td>
<td>$3,900</td>
<td>$5,200</td>
<td>$6,500</td>
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<td>$5,400</td>
<td>$7,200</td>
<td>$9,000</td>
<td>$10,800</td>
<td>$11,340</td>
</tr>
<tr>
<td>60+</td>
<td>$2,300</td>
<td>$4,600</td>
<td>$6,900</td>
<td>$9,200</td>
<td>$11,500</td>
<td>$13,800</td>
<td>$14,490</td>
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</tbody>
</table>

**Procedure Types:** CEA, CAS, oAAA, EVAR, LEB, PVI, TEVAR

*10% Discount for >6 modules
Based on procedure volume and number of procedure types entered

**Number of Procedure Types**

<table>
<thead>
<tr>
<th>Annual Volume of Procedures</th>
<th>1</th>
<th>2</th>
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*10% Discount for >6 modules

Procedure Types: CEA, CAS, oAAA, EVAR, LEB, PVI, TEVAR
Total Annual Fee

SVS PSO Fee is 40% of M2S Fee Capped at $4,000

### Number of Procedure Types

<table>
<thead>
<tr>
<th>Annual Volume of Procedures</th>
<th>1</th>
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<tr>
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<td>$1,120</td>
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<td>6-15</td>
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<tr>
<td>16-30</td>
<td>$1,820</td>
<td>$3,640</td>
<td>$5,460</td>
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<td>$9,100</td>
<td>$10,920</td>
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<tr>
<td>31-60</td>
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<tr>
<td>60+</td>
<td>$3,220</td>
<td>$6,440</td>
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Procedure Types: CEA, CAS, oAAA, EVAR, LEB, PVI, TEVAR

*10% Discount for >6 modules
# Vascular Quality Initiative

## Total Annual Fee

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</tbody>
</table>

*10% Discount for >6 modules

Procedure Types: CEA, CAS, oAAA, EVAR, LEB, PVI, TEVAR
Cost of Data Entry

- Pathways system allows multiple users to enter data on a single form
  - But there is a cost for quality data entry

- Multiple approaches for data entry using different personnel
  - RNs, NPs, PAs, physicians, coders, data managers

- Data entry time estimates by institutional procedure volume:
  - High (750 procedures/year): 10-15 hours per week
  - Medium (250 procedures/year): 5 hours per week
  - Small (100 procedures/year): 1-2 hours per week
## Vascular Quality Initiative

### Comparisons with NSQIP

<table>
<thead>
<tr>
<th>Registry:</th>
<th>SVS PSO</th>
<th>NSQIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Center Benchmark Reports</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Surgeon Benchmark Reports</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Number of Procedures</td>
<td>9 Major Classes</td>
<td>Few, CPT based</td>
</tr>
<tr>
<td>Selection of Cases</td>
<td>All, Consecutive</td>
<td>Sampling</td>
</tr>
<tr>
<td>Follow-up</td>
<td>One year</td>
<td>30 days</td>
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<tr>
<td>Participant Meetings</td>
<td>Semi-annual</td>
<td>No</td>
</tr>
<tr>
<td>PSO Protected</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>PQRS Reporting</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Annual Cost (*Varies by volume)</td>
<td>$560 - 18,500</td>
<td>$35,000</td>
</tr>
</tbody>
</table>
Vascular Quality Initiative

VQI Benefits SVS, the specialty and surgeons

• Promotes quality improvement initiatives while maintaining local control and ownership through regional study groups
• Provides a national registry which positions SVS as the leader in vascular quality research
• Provides an ideal method to benchmark provider performance both regionally and nationally
• Demonstrates hospital and provider commitment to improving vascular health care
Creating Regional Vascular Study Groups

The Carolinas Vascular Study Group

John (Jeb) Hallett, M.D.
Medical Director and Vascular Surgeon
Clinical Professor or Surgery

Roper St. Francis
Heart & Vascular Tower
Charleston, South Carolina
A regional registry for quality assurance and improvement: The Vascular Study Group of Northern New England (VSGNNE)

Jack L. Cronenwett, MD, Donald S. Likosky, PhD, Margaret T. Russell, MBA, MS, Jens Eldrup-Jorgensen, MD, Andrew C. Stanley, MD, and Brian W. Nolan, MD, for the VSGNNE, Lebanon and Hanover, NH; Portland, Me; and Burlington, Vt
Could we transplant VSG of New England to the South?
By nature, physicians and surgeons are competitive.

Time is money.
Measuring and Reporting Outcomes Would Increase Our Practices
Moving from competition toward collaboration
Three Main Challenges

• *Who pays for the program?*

• *Who enters and analyzes the data?*

• *Does the program really change anything?*
Who Pays?

- **Vascular Service Line Budget**
- **Hospital Quality Department**
- **The Vascular Surgery Division**
- **The Private Vascular Surgeons**
Who Enters and Analyzes the Data?

- Entered by various members of the provider team
- Verified by a study coordinator or quality staff member
- Analyzed by master’s level study coordinator ± statistician
The Data Coordinator rules!
Is the data making a difference?
Our Method of Quality Improvement

- *Weekly Vascular Case Conference*

- *Monthly review of each surgeon’s “Report Card”*

- *Communication of our outcomes to referring physicians*
Combined Death and Stroke Rate
(number of patients per year)

Annualized rate
1% (6/646)
Length of Hospital Stay (days)
Carotid Endarterectomy

50% reduction in five years
Improving the use of perioperative cardiovascular medications

By 2009, 100% preop

ASA

Plavix

Other Anti-Platelet

Statin

Beta Blockers

Cy05 (N=102)  CY06  CY07  CY08  1Q09 (Jan-Mar)
Unexpected Returns to OR

- 2005: 4%
- 2006: 2%
- 2007: 2%
- 2008: 6%
- 2009:
Unexpected returns to the operating room

Problem:
Increased number of neck hematomas

Solution:
• Check heparin effect with ACT
• Reverse heparin
• Drain the wound
The outcome

The problem improved immediately!
Unexpected Returns to OR

- 2005: 4%
- 2006: 2%
- 2007: 2%
- 2008: 6%
- 2009: 1%
Moving from one hospital to a Carolinas Vascular Study Group
The “game changer”

Software Program
1295 cases in less than a year
CVSG Up and Running!

- **Endovascular Interventions** 585
- **Carotid procedures (CEA/CAS)** 371/65
- **Lower-limb bypasses** 165
- **EVAR** 60
- **Open AAAs** 44
The Urgency for Change

• Outcomes for MOC (Maintenance of Competence, American Board of Vascular Surgery)

• Quality Measures for CMS bonus

• Readmission penalties in the near future
“Just-in-time” Strategic Change

Vascular Quality Initiative
So, just remember this....

- The “quality train” has left the station at full speed
- The SVS Quality Initiative is “ON BOARD”
- Regional vascular study groups will be the key to meaningful change
Regional Registry Data: Good For What?

Philip P. Goodney, MD MS
Vascular Study Group of New England
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training

- Discuss Opportunity For National Expansion Of These Efforts
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training

- Discuss Opportunity For National Expansion Of These Efforts
Everyday Tasks

- Registry Data
  - Keeps track of common vascular operations
- Collects necessary elements for PQRI
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training
- Discuss Opportunity For National Expansion Of These Efforts
Quality Improvement

- Donabedian Model
  - Structure
  - Process
  - Outcome
Structure

- Describe **regional practice** and establish benchmarks for performance

Factors associated with stroke or death after carotid endarterectomy in Northern New England

Philip P. Goodney, MD, Donald S. Likosky, PhD, and Jack L. Cronenwett, MD, for the Vascular Study Group of Northern New England, *Lebanon, NH*
## Univariate Predictors of 30-Day Stroke/Death

<table>
<thead>
<tr>
<th>Variable</th>
<th>Not Present</th>
<th>Present</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urgent Operation</td>
<td>1.7%</td>
<td>3.5%</td>
<td>0.022</td>
</tr>
<tr>
<td>Emergent Operation</td>
<td>1.7%</td>
<td>13.0%</td>
<td>0.0001</td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>1.6%</td>
<td>3.5%</td>
<td>0.045</td>
</tr>
<tr>
<td>Both aspirin and plavix use</td>
<td>3.3%</td>
<td>1.5%</td>
<td>0.04</td>
</tr>
<tr>
<td>Aspirin or plavix use</td>
<td>3.1%</td>
<td>1.5%</td>
<td>0.013</td>
</tr>
<tr>
<td>Ipsilateral cortical stroke (pre-op)</td>
<td>1.6%</td>
<td>3.5%</td>
<td>0.007</td>
</tr>
<tr>
<td>Ipsilateral cortical symptoms (TIA or stroke)</td>
<td>1.4%</td>
<td>2.8%</td>
<td>0.014</td>
</tr>
<tr>
<td>Contralateral Occlusion</td>
<td>1.6%</td>
<td>4.0%</td>
<td>0.014</td>
</tr>
<tr>
<td>Stenosis&lt;60%</td>
<td>1.7%</td>
<td>5.7%</td>
<td>0.029</td>
</tr>
</tbody>
</table>
## Multivariate Model

<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
<th>( p ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin or plavix use</td>
<td>0.4</td>
<td>0.2-0.9</td>
<td>0.02</td>
</tr>
<tr>
<td>Age &gt;70</td>
<td>1.3</td>
<td>0.8-2.3</td>
<td>0.315</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>1.6</td>
<td>1.102.4</td>
<td>0.03</td>
</tr>
<tr>
<td>Symptomatic status</td>
<td>2.4</td>
<td>1.1-5.1</td>
<td>0.02</td>
</tr>
<tr>
<td>Contralateral Occlusion</td>
<td>2.8</td>
<td>1.3-6.2</td>
<td>0.009</td>
</tr>
<tr>
<td>Emergent Procedure (within 6 hours of admission)</td>
<td>7.0</td>
<td>1.8-26.9</td>
<td>0.004</td>
</tr>
</tbody>
</table>
Comparison of Observed and Expected 30-Day Stroke/Death Rate (All Patients)

![Bar chart showing comparison between observed and expected 30-day stroke/death rate across different numbers of risk factors present.]

- **Number of Risk Factors Present**: 0, 1, 2, 3+
- **Expected Rates**: 0.9%, 1.4%, 2.6%, 4.7%
- **Observed Rates**: 0.6%, 1.6%, 2.6%, 4.6%
Our Model Allows Benchmarking

This Risk Prediction Model Allows Comparison of Risk-Adjusted Outcomes Across the Centers in Our Region

1. Calculate Expected Stroke Rate, By Center
2. Divide Observed Rates by Expected Rates
3. Compare Observed/Expected Ratios, Across Centers
Explaining Differences Across Centers

Observed and Expected Risk of 30-Day Stroke/Death

- Center 1: 1.5%
- Center 2: 1.5%
- Center 3: 1.6%
- Center 4: 1.6%
- Center 5: 1.8%
- Center 6: 1.9%
- Center 7: 2.0%
- Center 8: 2.0%
Explaining Differences Across Centers

Observed and Expected Risk of 30-Day Stroke/Death

<table>
<thead>
<tr>
<th>Center</th>
<th>Risk of Stroke/Death at 30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.5% 1.1%</td>
</tr>
<tr>
<td>2</td>
<td>1.5% 0.9%</td>
</tr>
<tr>
<td>3</td>
<td>1.6% 0.0%</td>
</tr>
<tr>
<td>4</td>
<td>1.6% 0.5%</td>
</tr>
<tr>
<td>5</td>
<td>1.8% 1.3%</td>
</tr>
<tr>
<td>6</td>
<td>1.9% 1.2%</td>
</tr>
<tr>
<td>7</td>
<td>4.3%</td>
</tr>
<tr>
<td>8</td>
<td>3.0%</td>
</tr>
</tbody>
</table>

Note: Center 7 has an unusually high risk compared to other centers.
Explaining Differences Across Centers

Observed and Expected Risk of 30-Day Stroke/Death

<table>
<thead>
<tr>
<th>Center</th>
<th>Risk of Stroke/Death at 30 Days</th>
<th>O/E Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.5%</td>
<td>0.6</td>
</tr>
<tr>
<td>2</td>
<td>1.5%</td>
<td>0.7</td>
</tr>
<tr>
<td>3</td>
<td>1.6%</td>
<td>0.0</td>
</tr>
<tr>
<td>4</td>
<td>1.6%</td>
<td>0.3</td>
</tr>
<tr>
<td>5</td>
<td>1.8%</td>
<td>0.7</td>
</tr>
<tr>
<td>6</td>
<td>1.9%</td>
<td>1.4</td>
</tr>
<tr>
<td>7</td>
<td>2.0%</td>
<td>2.1</td>
</tr>
<tr>
<td>8</td>
<td>2.0%</td>
<td>1.5</td>
</tr>
</tbody>
</table>

p < 0.002
Next steps

- Look at the centers that do things well

- Study the surgeon and center-specific processes of care that differ to explain this variation
Process

- Registry Data
  - Allows surgeons to study process of care and its effect on outcomes.

Restenosis after carotid endarterectomy in a multicenter regional registry

Philip P. Goodney, MD, Brian W. Nolan, MD, Jens Eldrup-Jorgensen, MD, Donald S. Likosky, PhD, and Jack L. Cronenwett, MD, for the Vascular Study Group of Northern New England, Lebanon, NH
Studying The Process of Patching

- Biannual meetings: surgeons meet, discuss, and review quality measures and outcomes

- Patch angioplasty was a quality measure selected initially at inception, and
Patch Angioplasty Encouraged

- Biannual meetings: surgeons meet, discuss, and review quality measures and outcomes

- Patch angioplasty was a quality measure selected initially at inception, and
As Rates of Patch Angioplasty Increased…

Restenosis Rates of Patch Angioplasty

80-99% Restenosis

Convention al CEA without Patch

p<0.003
Complications Decreased

80-99% Restenosis

Convention al CEA without Patch

p<0.003
Complications Decreased

Example of Process Improvement That Directly Contributed to Better Outcomes

Convention al CEA without Patch p<0.003
Outcome

- **Forum to develop and validate** new outcome measures

Validation of the PIII CLI risk score for the prediction of amputation-free survival in patients undergoing infrainguinal autogenous vein bypass for critical limb ischemia

Andres Schanzer, MD, a Philip P. Goodney, MD, MS, b Youfu Li, MD, MPH, a Mohammad Eslami, MD, a Jack Cronenwett, MD, b Louis Messina, MD, a and Michael S. Conte, MD, c for the Vascular Study Group of Northern New England, Worcester, Mass; Lebanon, NH; San Francisco, Calif

Validation of the Society for Vascular Surgery’s Objective Performance Goals for critical limb ischemia in everyday vascular surgery practice

Philip P. Goodney, MD, MS, a Andres Schanzer, MD, b Randall R. DeMartino, MD, a Brian W. Nolan, MD, MS, a Nathanael D. Hevelone, MPH, b Michael S. Conte, MD, c Richard J. Powell, MD, a and Jack L. Cronenwett, MD, a for the Vascular Study Group of New England, Lebanon, NH; Worcester, Mass; and San Francisco, Calif
PIII RISK SCORE for CRITICAL LIMB ISCHEMIA

<table>
<thead>
<tr>
<th>POINTS</th>
<th>DIALYSIS</th>
<th>TISSUE LOSS</th>
<th>AGE ≥ 75</th>
<th>HCT ≤ 30%</th>
<th>CAD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

AMP-FREE SURVIVAL RATES (%)

- LOW RISK (≤3 Points): 86%
- MEDIUM RISK (4-7 Points): 73%
- HIGH RISK (≥8 Points): 45%
## Results-Discrimination
### VSGNNE Stratified by Risk Score

<table>
<thead>
<tr>
<th>Risk Categories</th>
<th>Integer Score</th>
<th>Amputation-Free Survival</th>
<th>HR</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>≤3</td>
<td>86.4%</td>
<td>1.0 (ref)</td>
<td>___</td>
</tr>
<tr>
<td>Medium</td>
<td>4-7</td>
<td>74.1%</td>
<td>1.87 (1.40-2.50)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>High</td>
<td>≥8</td>
<td>56.1%</td>
<td>3.48 (2.34-5.18)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>

**AF Survival: VSGNNE**

**VSGNNE DATASET N=1166**

- **Low Risk**: 86%<4 Points
- **Medium Risk**: 74%4-8 Points
- **High Risk**: 56%>8 Points
# Objective Performance Goals (OPGs)

## Safety OPGs at 30 Days
- Major Adverse Limb Events (Amputation or Major Reintervention) (MALE)
- Major Adverse Cardiovascular Events (MI, Stroke or Death) (MACE)
- Above-Ankle Amputation

## Efficacy OPGs at 1 Year
- Freedom from Major Adverse Limb Events or Post-Operative Death (MALE+POD)
- Limb Salvage
- Survival
- Amputation-Free Survival (AFS)
- Freedom From Reintervention or Amputation (RAO)
- Freedom From Reintervention, Amputation, or Restenosis (RAS)
**How Does the VSG Measure Up?**

**VSG Meet all Safety and Efficacy OPGs**

<table>
<thead>
<tr>
<th>Safety Outcomes at 30 Days</th>
<th>SVS OPG Cohort (mean, 95% CI)</th>
<th>OPG</th>
<th>VSGNE (mean, 95% CI)</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Adverse Limb Events (Amputation or Major Reintervention)</td>
<td>6.1% (4.6-7.9%)</td>
<td>&lt;8%</td>
<td>2.5% (1.2-3.4%)</td>
<td>p=0.04</td>
</tr>
<tr>
<td>Major Adverse Cardiovascular Events (MI, Stroke or Death)</td>
<td>6.2% (4.7-8.1%)</td>
<td>&lt;8%</td>
<td>4.2% (3.3-5.4%)</td>
<td>p=0.35</td>
</tr>
<tr>
<td>Above-Ankle Amputation</td>
<td>1.9% (1.1-3.1%)</td>
<td>&lt;3%</td>
<td>1% (0.8-2%)</td>
<td>P=0.53</td>
</tr>
</tbody>
</table>
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training

- Discuss Opportunity For National Expansion Of These Efforts
Research

- Types of Research
  - Risk Modeling
  - Implementation of EBM in the “real world”
  - “Natural Experiments”
Risk Modeling

- Use **large sample sizes** and **precise detail** to refine our ability to predict risk

The Vascular Study Group of New England Cardiac Risk Index (VSG-CRI) predicts cardiac complications more accurately than the Revised Cardiac Risk Index in vascular surgery patients

Daniel J. Bertges, MD, RVT, Philip P. Goodney, MD, Yuanyuan Zhao, MD, Andres Schanzer, MD, Brian W. Nolan, MD, Donald S. Likosky, PhD, Jens Eldrup-Jorgensen, MD, and Jack L. Cronenwett, MD, for the Vascular Study Group of New England, Burlington, Vt; Lebanon, NH; Worcester, Mass; and Portland, Me
VSG-CRI Risk Score

Step 1:
Calculate VSG-RCI Score

Step 2:
Use VSG-CRI Score To Predict Risk of Adverse Cardiac Outcome

<table>
<thead>
<tr>
<th>VSG-CRI Risk Factors</th>
<th># Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥ 80</td>
<td>4</td>
</tr>
<tr>
<td>Age 70-79</td>
<td>3</td>
</tr>
<tr>
<td>Age 60-69</td>
<td>2</td>
</tr>
<tr>
<td>CAD</td>
<td>2</td>
</tr>
<tr>
<td>CHF</td>
<td>2</td>
</tr>
<tr>
<td>COPD</td>
<td>2</td>
</tr>
<tr>
<td>Creatinine &gt; 1.8</td>
<td>2</td>
</tr>
<tr>
<td>Smoking</td>
<td>1</td>
</tr>
<tr>
<td>Insulin Dependant Diabetes</td>
<td>1</td>
</tr>
<tr>
<td>Long term β-Blockade</td>
<td>1</td>
</tr>
<tr>
<td>History of CABG or PCI</td>
<td>-1</td>
</tr>
</tbody>
</table>

Example patient: 80 yr-old smoker with history of CAD and prior CABG.

VSG-CRI score = 4 + 1 + 2 -1 = 6

Fig 2. Vascular Surgery Group Cardiac Risk Index (VSG-CRI) scoring system and predicted risk of adverse cardiac events. CAD, Coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease, CABG, coronary artery bypass grafting, PCI, percutaneous coronary intervention.
VSG-CRI Risk Score

CONCLUSIONS

The VSG-CRI is more accurate than the RCRI for predicting composite cardiac complications in patients undergoing vascular surgery. The VSG-CRI score using the nine clinical variables of age, smoking, insulin-dependent diabetes, CAD, CHF, prior CABG or PCI, long-term β-blocker treatment, COPD, and creatinine ≥1.8 mg/dL stratifies patients into increasing levels of cardiac risk.

- Risk Calculator available at www.vsgne.org
“Real World” Implementation of EBM

- Study the results when EBM is adopted in QI initiatives

A regional quality improvement effort to increase beta blocker administration before vascular surgery

Philip P. Goodney, MD, MS,¹,² Jens Eldrup-Jorgensen, MD,³ Brian W. Nolan, MD, MS,¹,² Daniel J. Bertges, MD,⁴ Donald S. Likosky, PhD,¹,² and Jack L. Cronenwett, MD,¹,² for the Vascular Study Group of New England, Lebanon and Hanover, NH; Portland, Me; and Burlington, Vt
Beta-Blocker Use in VSGNE

- 2003: Only 68% of patients undergoing major vascular surgery on beta-blockers

- Selected for quality improvement

- Developed techniques to increase use
  - Protocols, pre-printed Rx, letters to MDs

- Feedback to centers and surgeons
Beta Blocker Use in VSGNE

Rate of Beta Blocker Use

Jan-Mar 2003 68%
Increased Beta Blocker Use

Rate of Beta Blocker Use

Jan-Mar 2003 68%

Oct-Dec 2008 88%

P<0.001
BB Use Increased in All Centers

90% Beta Blocker Use Target

- 63%
- 72%
- 76%
- 81%
- 85%
- 88%
- 90%
- 91%
- 91%
- 94%

Proportion

Center

= 2003-2005
= 2006-2008
BB Use Increased by All Surgeons

90% Beta Blocker Use Target

= 2003-2005
= 2006-2008
No Change in Post-op MI Rate

Rate of Beta Blocker Use

Jan-Mar 2003 68%

Rate of Post-op MI

Jan-Mar 2003 5.2%

Oct-Dec 2008 88%

Oct-Dec 2008 5.5%

p = 0.876

p < 0.001
No Change in One Year Mortality

Rate of Beta Blocker Use

Oct-Dec 2008 88%

One Year Mortality

Jan-Mar 2003 68%

Jan-Mar 2003 12.8%

Jan-Mar 2003 12.8%  
Oct-Dec 2008 12.1%  

p=0.782

p<0.001
Conclusion

- Surgeon practice patterns in prescribing beta-blockers can be changed in a regional quality improvement group.

- However, simply prescribing beta-blockers does not reduce MI rate in real-world practice.

- New VSGNE Quality Initiative
  - Target high risk patients earlier
  - Titrate dosage to recommended heart rate
“Natural” Experiments

- Take advantage of **practice variation** and **large sample size** to address difficult questions

Protamine reduces bleeding complications associated with carotid endarterectomy without increasing the risk of stroke

David H. Stone, MD, a Brian W. Nolan, MD, a,b Andres Schanzer, MD, c Philip P. Goodney, MD, a Robert A. Cambria, MD, d Donald S. Likosky, PhD, b Daniel B. Walsh, MD, a and Jack L. Cronenwett, MD, a for the Vascular Study Group of Northern New England, Lebanon, NH; Worcester, Mass; and Bangor, Me
A “Natural Experiment” In Protamine Use

4587 Total CEAs

Protamine: 2087 (46%)

No Protamine: 2500 (54%)
Reoperation for Bleeding

*P=0.001

0.64% (N=14) vs. 1.66% (N=42)

% Patients

Protamine

No Protamine
Thrombotic Complications

*P=NS
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training

- Discuss Opportunity For National Expansion Of These Efforts
Collaboration And Training

- Research Advisory Committee
- NESVS Clinical Research
- Forum for Research Fellows
  - General Surgery and Vascular Trainees
    - Dartmouth
    - UMass
    - University of Vermont
    - University of Utah
    - Many others…
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training
- Discuss Opportunity For National Expansion Of These Efforts
Regional Efforts In New England

Vascular Study Group of New England

- Fletcher Allen Health Care
- Rutland Regional Medical Center
- Dartmouth-Hitchcock Medical Center
- Catholic Medical Center Elliot Hospital
- Berkshire Medical Center
- Baystate Medical Center
- U Mass Medical Center
- St. Francis Hospital
- St. Anne’s Hospital
- Yale New Haven Hospital
- Lakes Region Hospital
- Cottage Hospital
- Eastern Maine Medical Center
- Maine General Medical Center
- Central Maine Medical Center
- Maine Medical Center
- Mercy Hospital
- Concord Hospital
- Massachusetts General Hospital
- Boston Medical Center
- Tufts Medical Center
Future Goals

New Regional Efforts

Link Regional Groups to Study National Practice

“Distributed” Research Network To Improve Vascular Care

Carolinas California SAVS And Others..
Goals

- Review how we have used regional registry data in New England
  - Simple everyday tasks
  - Quality Improvement
  - Research
  - Platform For Collaboration and Training

- Discuss Opportunity For National Expansion Of These Efforts