The Vascular Quality Initiative:

Vascular Implant Surveillance & Interventional Outcomes Network

(VISION):

Better, Faster, cheaper

Philip P. Goodney, MD, MS
Society for Vascular Surgery Patient Safety Organization
Jack Cronenwett, MD, Art Sedrakyan, MD PhD MDEpiNet
(FDA 1U01FD005478-01)
Launched by Society for Vascular Surgery in 2011
Launched by Society for Vascular Surgery in 2011

- **Mission:** To improve the quality, safety, effectiveness and cost of vascular health care by collecting and exchanging information.
Vascular Quality Initiative®

Participating Center Growth

VQI Participating Centers

376 Centers, 45 States + Ontario
17 Regional Quality Groups

- Pacific NW Vascular Study Group
- Mid-America Vascular Study Group
- Midwest Vascular Collaborative
- Great Lakes Vascular Study Group
- Upper MidWest Vascular Network
- Michigan Vascular Study Group
- Vascular Study Group of New England
- Vascular Study Group of Greater New York
- Mid-Atlantic Vascular Study Group
- Virginias Vascular Study Group
- Carolinas Vascular Quality Group
- MidSouth Vascular Study Group
- Southern Vascular Outcomes Network
- Southern California Vascular Outcomes Improvement Collaborative
- Rocky Mountain Vascular Quality Initiative

AK
HI
## Total Procedures Captured (as of 3/1/2016)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Procedures Captured</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>87,659</td>
</tr>
<tr>
<td>Carotid Endarterectomy</td>
<td>64,285</td>
</tr>
<tr>
<td>Infra-Inguinal Bypass</td>
<td>29,113</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>25,634</td>
</tr>
<tr>
<td>Hemodialysis Access</td>
<td>23,984</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>10,422</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
<td>9,901</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>7,972</td>
</tr>
<tr>
<td>Thoracic and Complex EVAR</td>
<td>5,762</td>
</tr>
<tr>
<td>IVC Filter</td>
<td>4,740</td>
</tr>
<tr>
<td>Lower Extremity Amputations</td>
<td>4,858</td>
</tr>
<tr>
<td>Varicose Vein</td>
<td>3,456</td>
</tr>
</tbody>
</table>

**VQI Total Procedure Volume**
Why national device surveillance networks are a good idea...
Why this is a good idea...

DG
66 year old male
6.2 cm AAA

2013
Why this is a good idea...

DG
66 year old male
6.2 cm AAA

2014
Why this is a good idea...

DG
66 year old male
6.2 cm AAA

2015
Why this is a good idea...

DG
66 year old male
6.2 cm AAA

2016
Why this is a good idea...

DG
66 year
6.2 cm AAA
2016

No Symptoms
Why this is a good idea...

DG
66 year old male
6.2 cm AAA
2016

No Symptoms

3 Different Surgeons, 2 Different Hospitals
Why this is a good idea...

DG
66 year old male
6.2 cm AAA
2016

No Symptoms

3 Different Surgeons, 2 Different Hospitals

Risk of Mortality if His Aneurysm Ruptures = 50%
Why this is a good idea...

DG
66 year old male
6.2 cm AAA
2016

Reliable Surveillance After Vascular Care is a Key Priority for Patients, Providers, Payers, and Regulatory Agencies
Our “VISION” for the Data In VISION

Clinical and Technical
Data Available in
Registries about
procedures, patients,
and devices
Our “VISION“ for the Data In VISION

Clinical and Technical Data Available in Registries about procedures, patients, and devices

+ Long-term, generalizable follow-up using linkages to Medicare Claims, Under-65 data sources, PCORnet, and other sources
Our “VISION“ for the Data In VISION

Clinical and Technical Data Available in Registries about procedures, patients, and devices + Long-term, generalizable follow-up using linkages to Medicare Claims, Under-65 data sources, PCORnet, and other sources = National repository of Linked Analytic Datasets within VISION
Our “VISION” for the Data In VISION

Clinical and Technical Data Available in Registries about procedures, patients, and devices

+ Long-term, generalizable follow-up using linkages to Medicare Claims, Under-65 data sources, PCORnet, and other sources

= National repository of Linked Analytic Datasets within VISION

Low – Cost, but High Value Data for generalizable, real-world effectiveness research in vascular care
Our “VISION“ for the Data In VISION

Registry Data + Data Partners = Successful CRN

Long-term, generalizable follow-up using linkages to Medicare Claims, Under-65 data sources, PCORnet, and other sources

Clinical and Technical Data Available in Registries about procedures, patients, and devices

National repository of Linked Clinical Claims Analytic Datasets for VISION Registry Data

Low – Cost, but High Value Data for generalizable, real-world effectiveness research in vascular care
Current linkages....

Start With VQI Data

Mr. Jones (name, SS#)
Clinical Factors (comorbidities)
Implant Data (Graft XYZ)
Surgical Details (how it was placed)
Surgeon Details
Hospital Information
Short term complications
Current linkages....

Start With VQI Data

- Mr. Jones (name, SS#)
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Data Linkages to Medicare Claims
The Dartmouth Institute
Current linkages....

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Data Linkages to Medicare Claims
The Dartmouth Institute

Measure Long-Term Events:

- Survival
- Effectiveness of the Procedure
- Long-Term Device Failures/Revisions
## Devices are a Key Aspect of Vascular Treatment

<table>
<thead>
<tr>
<th>Vascular Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carotid Endarterectomy</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
</tr>
<tr>
<td>Open AAA Repair</td>
</tr>
<tr>
<td>Peripheral Vascular Intervention</td>
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<tr>
<td>Infra-Inguinal Bypass</td>
</tr>
<tr>
<td>Supra-Inguinal Bypass</td>
</tr>
<tr>
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<tr>
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<td>Varicose Veins</td>
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## Devices are a Key Aspect of Vascular Treatment

<table>
<thead>
<tr>
<th>Vascular Treatment</th>
<th>Devices Used for Treatments</th>
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</thead>
<tbody>
<tr>
<td>Carotid Endarterectomy</td>
<td>Patch Type</td>
</tr>
<tr>
<td>Carotid Artery Stent</td>
<td>Stent, Protection Device Type</td>
</tr>
<tr>
<td>Endovascular AAA Repair</td>
<td>Stent Graft Type</td>
</tr>
<tr>
<td>Open AAA Repair</td>
<td>Prosthetic Graft Type</td>
</tr>
<tr>
<td>Peripheral Vascular Intervention</td>
<td>Balloon/Stent/Atherectomy Devices</td>
</tr>
<tr>
<td>Infra-Inguinal Bypass</td>
<td>Prosthetic Graft Type</td>
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<td>Stent Graft Type</td>
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<tr>
<td>Hemodialysis Access</td>
<td>Graft Type</td>
</tr>
<tr>
<td>Lower Extremity Amputation</td>
<td>Bandage, prosthesis type</td>
</tr>
<tr>
<td>IVC Filter</td>
<td>Device Type</td>
</tr>
<tr>
<td>Varicose Veins</td>
<td>Ablation Device, Sclerosants</td>
</tr>
</tbody>
</table>
How this has worked thus far

• Initial funding effort – AHRQ R21 HS021581

• Leveraging Health Information Technology to Avoid Unnecessary Asymptomatic Carotid Revascularization

• This project developed a health information technology (IT) tool that can be used to support clinicians in their decision-making process regarding carotid revascularization surgery in asymptomatic patients with carotid stenosis.

• Project Dates: September 30, 2013 to September 29, 2015
How this has worked thus far

- **Subsequent funding** – FDA U01 FD005478

- **Sedrakyan (PI)** The Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

- To create and analyze novel linked clinical-claims datasets for long-term comparative effectiveness research.

- **Project Dates**: September 30, 2014 to Current
Cost Centers

• Datasets (annual expense)
  • VQI Datasets
  • Medicare claims
    • Part A, B, Denominator, D
    • 2002-current
Cost Centers

• **Datasets (annual expense)**
  - VQI Datasets
  - Medicare claims
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• **Matching Algorithm development (initial and ongoing)**
  - Patient identification
  - Algorithm assessment and improvement
  - Patient-level goals
Cost Centers

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- **Outcome designation**
  - Auditing – internal and external gold standards
  - Bilaterality algorithm designation
Cost Centers

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• **Dataset production and security**
  - PSO regulations
  - Generation and cataloging of blinded and non-blinded datasets
  - Project execution
Cost Centers

• Datasets (annual expense)
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  • Project execution

The Start

First Two Years

$120,000K per year in AHRQ R21 Grant

Allowed algorithm development and initial matching of ~20,000 patients

We matched 0.16 patients per dollar spent...

In other words, $6 per patient for long-term outcome assessment
Vascular Quality Initiative®

Cost Centers:

- Datasets (annual expense)
  - VQI Datasets
  - Medicare claims
    - Part A, B
    - 2002-current
  - Matching Algorithm development (initial and ongoing)
    - Patient identification
    - Algorithm assessment and improvement
    - Patient-level goals
  - Outcome designation
    - Auditing – internal and external gold standards
    - Bilaterality algorithm designation
- Dataset production and security
  - PSO regulations
  - Generation and cataloging of blinded and non-blinded datasets
  - Project execution

Scalable

Most Recent Year:

$150,000K per year in FDA U01 Grant

Second algorithm was better, larger dataset - matching of ~80,000 patients

We matched 0.53 patients per dollar spent...

In other words, $2 per patient for long-term outcome assessment
<table>
<thead>
<tr>
<th>Evaluation Type</th>
<th>R21 (Early Effort)</th>
<th>Cost per patient getting long-term follow-up</th>
</tr>
</thead>
</table>

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<thead>
<tr>
<th>Evaluation Type</th>
<th>R21 (Early Effort)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost per patient getting long-term follow-up</td>
<td>$6</td>
<td></td>
</tr>
</tbody>
</table>

## Cost Per Patient Follow-up Summary

<table>
<thead>
<tr>
<th>Evaluation Type</th>
<th>R21 (Early Effort)</th>
<th>U01 (Current Effort)</th>
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</thead>
<tbody>
<tr>
<td>Cost per patient getting long-term follow-up</td>
<td>$6</td>
<td>$2</td>
</tr>
</tbody>
</table>

*The Costs of Conducting Clinical Research
Ezekiel J. Emanuel et al JCO 2003.*
## Cost Per Patient Follow-up Summary

<table>
<thead>
<tr>
<th>Evaluation Type</th>
<th>R21 (Early Effort)</th>
<th>U01 (Current Effort)</th>
<th>Standard Industry Trial</th>
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</thead>
<tbody>
<tr>
<td>Cost per patient</td>
<td>$6</td>
<td>$2</td>
<td>$6,094*</td>
</tr>
<tr>
<td>getting long-term</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>follow-up</td>
<td></td>
<td></td>
<td></td>
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VISION Conclusions

- Registry-based CRN is an established, pragmatic and efficient way to create a device surveillance system.

- Allows partnership with major stakeholders to build and maintain a sustainable infrastructure.

- Leverages national investment in data systems to develop cost-effective national surveillance system.

- FDA ‘1U01FD005478-01’
  - Art Sedrakyan, Principal Investigator