A Coordinated Registry Network Based on the Vascular Quality Initiative: VISION

Vascular Implant Surveillance & Interventional Outcomes Network

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On Behalf of VISION
Vascular Quality Initiative®

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.

• **3 Components:**
  – National Registries in a Patient Safety Organization
  – Regional Quality Improvement Groups
    • Based on Vascular Study Group of New England, 2002
  – Web-based data collection - reporting system
National Registries for All Major Vascular Procedures

- **Carotid disease**
  - Endarterectomy and stenting

- **Aortic disease**
  - Open and endovascular abdominal aneurysm repair
  - Endovascular repair thoracic aorta

- **Lower extremity arterial disease**
  - Bypass, interventional procedures, amputation

- **Medical Management of PAD (in development)**
- **Dialysis access**
- **Vena cava filters**
- **Varicose veins**
Many Devices Used in Vascular Treatment

<table>
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<tr>
<th>Procedure</th>
<th>Devices Included</th>
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<tr>
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<td>Patch Type</td>
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<td>Stent, Protection Device Type</td>
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<td>IVC Filter</td>
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<td>Varicose Veins</td>
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Advantages of VQI Registry Data

• Allows data from all patients to be included
  – Not biased by those who only give consent

• Much more detailed information than claims data
  – Pre-, intra-, and post-op variables (> 150 per procedure)

• One year follow-up for key outcomes
  – Completed in physician’s office

• All consecutive procedures – allows rate calculation
  – Audited against hospital and physician claims data

• Identified data allows linkage with other sources
  – Medicare claims, Social Security Death Index
360 Centers, 46 States + Ontario

250,000 Procedures
7,500 per Month
Vascular Quality Initiative

Need for Coordinated Research Network

• Lack of quality data comparing device, treatment types
  – International issue facing all patients and physicians

• Multiple specialties treating same disease
  – Cardiologists, radiologists, surgeons
  – Different treatment types likely biased by training

• Lack of consensus about best treatment methods
  – Carotid endarterectomy vs. stenting
  – Peripheral artery bypass vs. interventional treatment
  – Open vs endovascular aortic treatment
Carotid Artery Treatment by Stent (vs endarterectomy)

- Insufficient Evidence to Reach Consensus
- Surgical vs. Interventional Treatment
- Mean 13% Stenting
- 47%
PAD: Critical Leg Ischemia Treated by Bypass (vs. PVI)

- Insufficient Evidence to Reach Consensus
- Lack of Device Comparative Studies

Mean 31% Bypass
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VQI registry includes multi-specialty physicians

- 2500 Specialists Performing All Procedures
  - 47% Vascular Surgery
  - 11% Cardiology
  - 17% Radiology
  - 5% Other
  - 4% Cardiac Surgery

- 1600 Specialists Performing PVI Procedures
  - 38% Vascular Surgery
  - 26% Cardiology
  - 26% Radiology
  - 10% Other
  - 10% General Surgery

2500 Specialists Performing All Procedures
1600 Specialists Performing PVI Procedures

VQI registry includes multi-specialty physicians
Current VQI Device Evaluation Projects

• Many devices used to treat vascular disease
• Devices approved after limited testing in selected patients in centers of excellence
• In practice, devices may be used outside indications for use and in less experienced centers
• Data about device performance in real world practice can inform physicians, FDA and manufacturers, to optimize treatment benefits for patients
• VQI is sharing non-identifiable data regarding new device outcomes with FDA and manufacturers
Current VQI Device Evaluation Projects

• Post-approval surveillance, FDA-industry collaborative
  – Endovascular grafts for aortic dissection
  – Endovascular graft for angulated neck AAA repair

• Development of objective performance goals
  – Use historical VQI data to compare new devices
  – Lower extremity drug eluting stents

• Evaluation of approved devices for new indications
  – When used in real world treatment beyond disease ranges evaluated in pre-market trials
Our VISION: Creating Coordinated Registry Network

- VQI data: patient identifiers, 250,000 procedures
  - One year follow-up in 70%
- Medicare, and possibly commercial claims linkage for late procedure outcomes
  - Sufficient to judge outcomes: re-intervention, failure
- Other vascular registries
  - New York City All-Payer Claims and Clinical Data Research Network (access to patient EHRs)
  - Kaiser Permanente, Other Payers, Health Systems
  - International Consortium of Vascular Registries (ICVR)
Our VISION: Surveillance and Outcomes

• Develop a national device surveillance network for vascular devices
  – The VQI registry will be linked to CMS and NY State discharge claims, and possible commercial claims, for post-market device evaluation and surveillance
  – VQI and KP vascular registries will initiate a distributed network creation

• Link regional VQI registry data to claims and electronic health data from the NY CDRN
  – Create enhanced regional cohorts of patients through linkage of NY regional VQI data with NYC-CDRN that has EHRs from medical centers in New York
International Consortium of Vascular Registries (ICVR)

- MDEpiNet initiated consortium of 12 registries
  - Australia, Denmark, Finland, Germany, Hungary, Iceland, Netherlands, New Zealand, Sweden, Switzerland, United Kingdom, United States
  - Launched November, 2014
- Projects focused on international device evaluation
  - Prospective: Para-renal AAA repair and EVAR
  - Retrospective: Variation CEA/CAS, AAA/EVAR, LEB/PVI
VISION Conclusions

• Registry-based CRN is a pragmatic and efficient way to create a device surveillance system
• Allows partnership with major stakeholders to build a sustainable infrastructure
• Attractive for clinician-scientists as an innovative data source for outcomes research
• Leverages national investment in data systems (PCORI-CDRN, Medicare, State, Professional Society data)
• VISION recently funded by FDA ‘1U01FD005478-01’
  – Art Sedrakyan, Principal Investigator
VISION is about Integration and Coordination

- FDA and other Stakeholders Including Patients
- Link to PCORI CDRN
- Link to Medicare, Commercial Claims and All-Payer NY Data
- Inter-National Registries
- Device Companies for PAS and Surveillance

Vascular Implant Surveillance and Intervventional Outcomes Network