Vascular Quality Initiative®

# Post-Approval Device Surveillance Project Using the VQI Registry

Jack L. Cronenwett, Medical Director

Society for Vascular Surgery Patient Safety Organization

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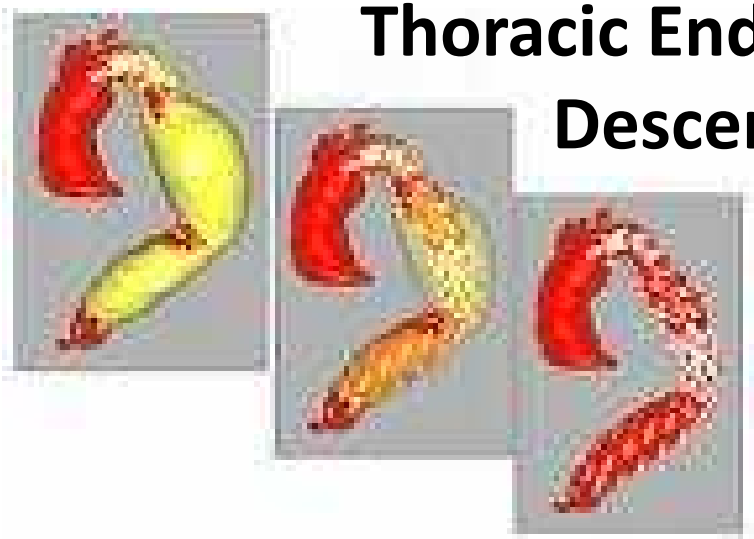
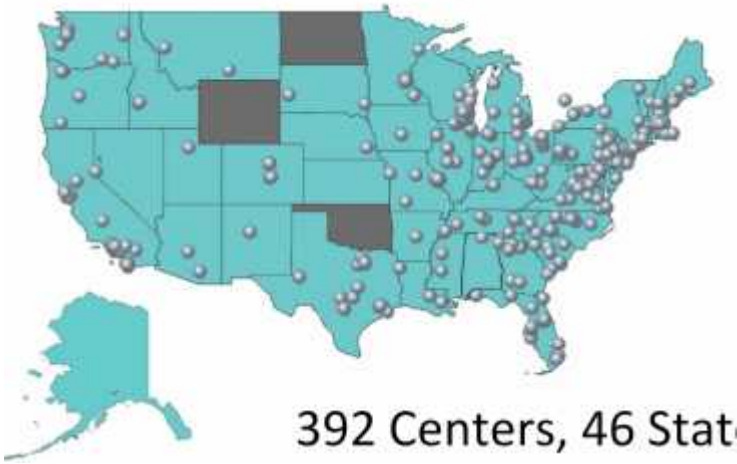


## Thoracic Endovascular Aortic Repair (TEVAR of Descending Aortic Dissection

- TEVAR devices by Gore and Medtronic approved for broad use based on pre-market study of acute complicated dissection
- Post-approval surveillance of 400 patients required to verify safety and effectiveness in acute and chronic dissection procedures

VQI Participating Centers



392 Centers, 46 States

- Used existing network of VQI sites to recruit 40 centers that volunteered to participate
- Much of needed data already being entered in a system familiar to site coordinators
- Additional data collection at treatment plus annual 5-year follow-up

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**Post Approval Surveillance – Patient Safety Organization**

- SVS PSO collects care data without informed consent
- Site contract is simple extension of existing PSO contract
- De-identified, line-by-line data about their device only is transmitted to each sponsor for analysis
- Aggregate summary of all devices is sent to the FDA
- PSO Steering Committee monitors project, queries sites about data questions, prepares scientific publications
- M2S staff monitor site performance, prepare reports for the FDA and company sponsors on behalf of the PSO

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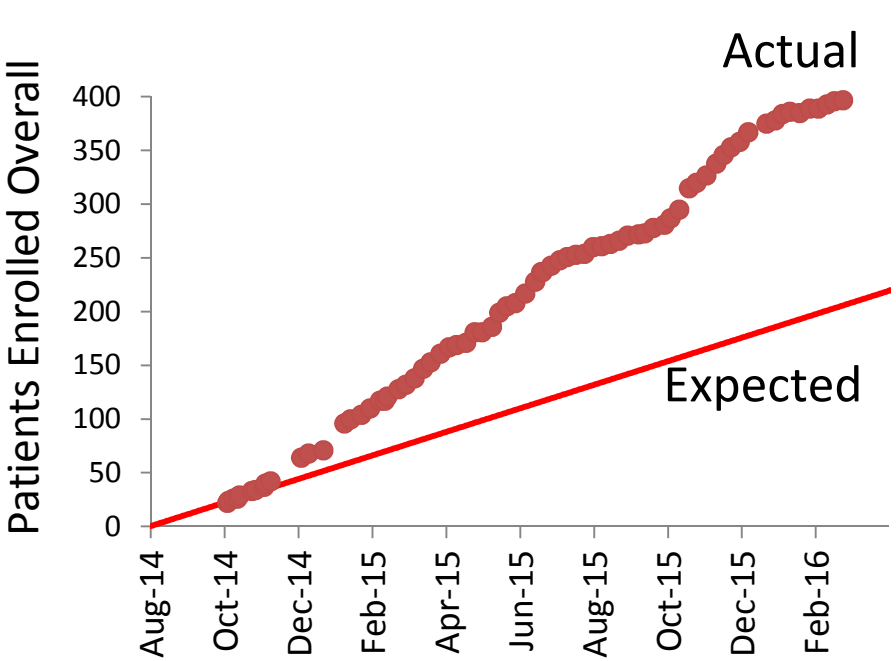
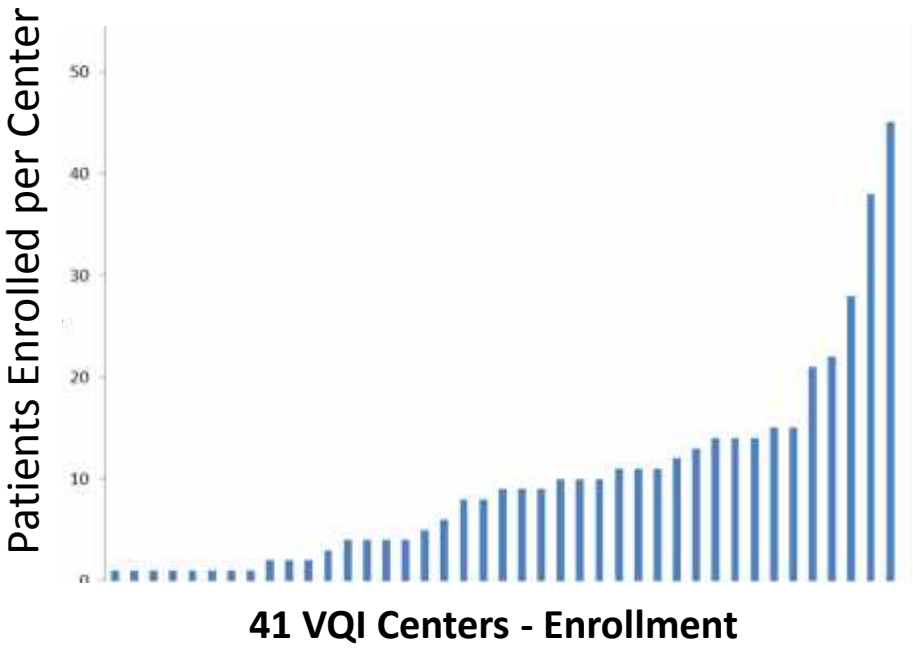
## VQI TEVAR Dissection Project Enrollment Rate

400 Patients Enrolled
Twice as Fast as Expected




Real-World Mix of Large
and Small Centers




**41 VQI Centers - Enrollment**

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## Post Approval Surveillance – Patient Safety Organization

- Collaboration between SVS PSO Steering Committee, FDA and the sponsor helps design a pragmatic surveillance protocol
  - Data collection requirements that fit real world registries
  - Follow-up time points appropriate for standard of care
- Data queries by sponsor, FDA or Steering Committee are addressed within PSO, including obtaining additional documents
- Patients matched with SSDI and Medicare claims to collect survival and some data even if lost-to-follow-up
- Overall cost judged to be below industry standard

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- **Result = Rapid, Efficient, Flexible, Cost-Effective Projects**

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