Vascular Quality Initiative®

Methods for Data Aggregation, Analysis and Sharing with Industry and FDA

Registry Data from VQI

Daniel Bertges, MD

Chair, SVS PSO PVI Registry Committee

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- VQI uses a single vendor (M2S Pathways) for web-based data entry (so it is quickly modifiable)
  - Can add dynamic content or follow-up time points for centers that participate in specific projects
- As a PSO, VQI does not require consent or IRB approval to collect data about standard practice
- Data are aggregated for quality reports that provide anonymous benchmarking to centers and MDs
- Non-identifiable, line-by-line data can be provided for research and device evaluation

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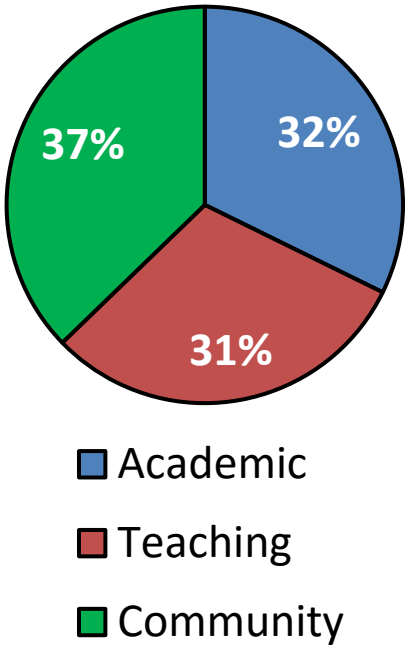
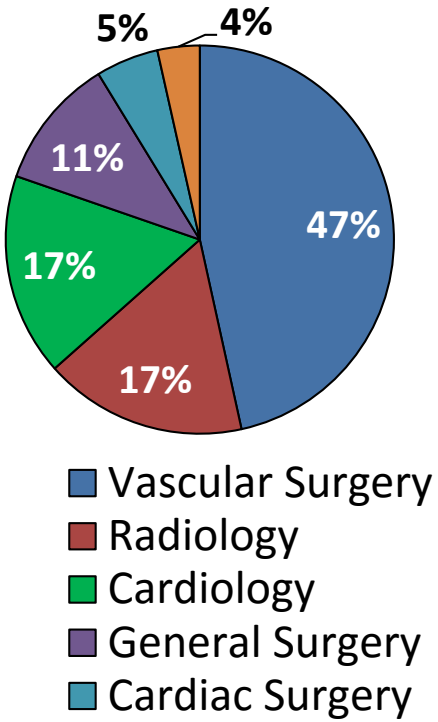
- Registries like VQI provide real-world evidence

Hospital Types

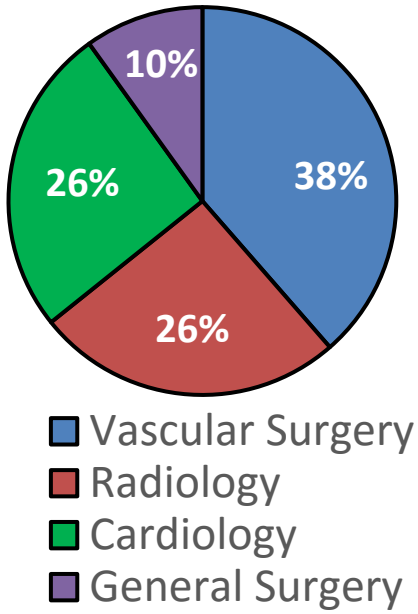


Physician Specialties

All Procedures



PVI Procedures



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VQI Data Sharing with FDA and Industry

- Industry, FDA, VQI develop a protocol (post-approval)
  - Standard of care practice; appropriate for PSO to evaluate device performance and to meet regulatory requirements
- All VQI sites using the registry are invited to participate
- Steering committee selected for project oversight
- A copy of data (de-identified for patient, provider, & hospital) is given to the industry sponsor for analysis and preparation of reports needed by the FDA
- Data queries from industry are resolved by PSO (via access with centers)

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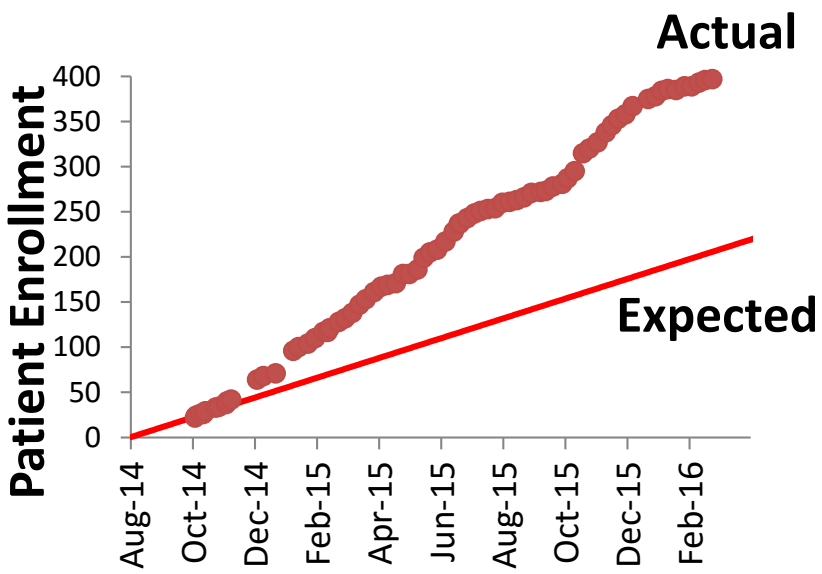
TEVAR for Aortic Dissection Post-Approval Surveillance

- Required by FDA to confirm broader indication for this class of device than evaluated in initial IDE studies
- Total 400 patients with 5 year annual follow-up
  - Supplemental data collected by centers that volunteered



- Completed in half the time estimated by sponsors
- Each sponsor only sees their device data (FDA sees all data)
- Additional 200 patients, with 1 year F/U and standard data entered by all sites to ensure generalizability

VQI Projects with PVI Devices

- FDA-required post-approval surveillance projects with Bard PVI and Medtronic
  - Line-by-line reports (de-identified data) provided to sponsors for analysis and reporting to the FDA
- Objective performance criteria development
  - Using existing data with existing one-year follow-up to quickly generate contemporary device-class control group
  - Can efficiently supplement existing data with new variables by contacting centers that submitted cases
  - Large n makes propensity-matched cohort feasible

Conclusions

- Successful models exist for real-world registry and industry collaboration to efficiently evaluate devices
- Using existing infrastructure and participating centers, such projects can be done quickly, with appropriate data monitoring and at low cost
- Registry data can effectively serve multiple stakeholders in pursuit of quality improvement