Disclosures

Joseph Bavaria, MD

- Abbott/St. Jude Medical - Co-Primary Investigator/Consultant: M1: Under $10,000
- Edwards Lifesciences - Primary Investigator: N/A: Not Applicable
- Medtronic Cardiovascular - Primary Investigator/Speakers Bureau: N/A: Not Applicable
- Vascutek USA, Inc. - Co-Primary Investigator, Consultant: M1: Under $10,000
- W.L. Gore & Associates, Inc - Primary Investigator, Consultant: M2: Between $10,000 and $100,000
- Boston Scientific – Co-Investigator: M1: Under $10,000

Carl Tommaso, MD

- No disclosures
Collaborative Approach

Society Presidents nominated 3 representatives.

Co-Chairs agreed on by societies.

2 additional members (cardiologist and surgeon) added for expertise in registries and outcomes.

4 members do not perform TAVR.
2012 INSTITUTIONAL REQUIREMENTS

- CARDIAC CENTERS
- TRIAL CENTERS
- VOLUME
  - PCI
  - CABG
  - AVR
- HEART TEAM
- FACILITIES
- REGISTRY
Why Volume?

Learning Curve:

Volume/Outcomes Evidence

Evidence:

Update Rationale

2012
Rational dispersion for a complex technology with a learning curve

2018
Learning curve still evident in less mature programs; evolving understanding of quality
Skills/Volume to Risk Adjusted Outcomes

Skills and Volume

2012

Quality and Risk Adjusted Outcomes

2018
2018 Focal Point: Quality

- Structure
- Process
- Outcome

- Direct comprehensive assessment of quality required; volume is not a substitute for quality
Structural Requirements

- Volume (required to reliably measure quality)
- Multi-disciplinary team (MDT)
- Training
- Facility
Key Quality Issue: Variability

- Not volume, although important to informing
- Not access, market will drive adoption of high quality
- Variability in quality
  - Need to determine the contributing factors to variability is the most pressing issue for the next 5 years
TVT Registry: Volume/30 Day Mortality
TVT Registry
Volume/30 Day Mortality
Over 100 Cases

Volume/outcome relationship flattens when statistical noise is removed
Volume Outcome Relationship for Intraoperative Phase
Variability of 30 Day Outcomes (non-risk adjusted)

Source: TVT Unpublished Data
Variability of 30 Day Outcomes (non-risk adjusted)

Source: TVT Unpublished Data

Signal and/or uncertain statistical validity?
Variability of 30 Day Outcomes (non-risk adjusted)

Source: TVT Unpublished Data

What does a mortality rate higher than 4% mean for any center? Why the variability?
Are Lower Volume Sites Having Worse Outcomes Because They Are Treating Higher Risk Patients?

2016-2017 Complete One-Year Data from STS-ACC TVT Registry

Site Annual TAVR Volume

Site’s Heart Team Assessment of Risk

- High Risk
- Inoperable & Extreme Risk

Frequency of Patients Being Elevated Risk %
How to Interpret Low Volume Outcomes?

- Many centers on the right side have good quality
- Wide error bars for low volume centers
- Statistical validity does not allow us to draw conclusions for low volume centers
- Quality cannot be determined for low volume centers
Volume/Outcomes Quality Assessment

- Optimal quality with reasonable volumes still require review as their results are not predictive of future outcomes
- Concern over red box as poor outcomes in higher volume centers
What to Do When Low Volume

- Engage in robust quality assessment program
- Review of structure and process needed more regularly
- Review outcomes of every case
- Close monitoring of patient selection
Why Does Volume Matter

- Significant questions remain about what causes variation
- Causes of poor outcomes need to be better understood, and the statistical power needed to understand quality is undeniable
  - Volume is the floor upon which quality outcomes can be analyzed without significant statistical noise
- No analysis can be conclusive about low volume sites
- Not a judgement of low volume centers but a statement of fact about statistical power/math
- The ability to understand quality/outcomes is limited below 50 cases
- High variability in outcomes across all volumes
Despite New Technology ... Complex TAVR Procedures and Major Complications Still Occur

2017 TVT Registry Data

- 1/17 need alternative access

Complications:
- 2% In-hospital mortality
- 2.4% Life-threatening bleed
- 1.2% Major vascular complications
- 2% Stroke
- 9% Complete heart block
- 1.8% Cardiac arrest

Mean Age of Patients Undergoing TAVR in US
- 2012: 82 years
- 2017: 80 years
Variability: Unanswered Questions

<table>
<thead>
<tr>
<th>Why is quality highly variable?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Does variability smooth out without enough cases?</td>
</tr>
<tr>
<td>• Are there common variables among sites with higher mortality?</td>
</tr>
<tr>
<td>• Patient selection</td>
</tr>
<tr>
<td>• Experience – cumulative site and operator</td>
</tr>
<tr>
<td>• Number of operators</td>
</tr>
<tr>
<td>• Team processes</td>
</tr>
<tr>
<td>• Institutional resources</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Where to invest quality improvement resources?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Highest O/E mortality</td>
</tr>
<tr>
<td>• Highest absolute number of deaths</td>
</tr>
<tr>
<td>• Case review of each death among all sites</td>
</tr>
</tbody>
</table>
### Surgeon Results

<table>
<thead>
<tr>
<th>Surgeon</th>
<th>Total Number of Cases</th>
<th>In-Hospital Mortality</th>
<th>30-Day Readmission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bavaria, Joseph E.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG without Valve</td>
<td>6</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Total Valve</td>
<td>241</td>
<td>1.2%</td>
<td>7.2%</td>
</tr>
<tr>
<td>Valve without CABG</td>
<td>199</td>
<td>0.5%</td>
<td>7.8%</td>
</tr>
<tr>
<td>Valve with CABG</td>
<td>42</td>
<td>4.8%</td>
<td>NR</td>
</tr>
</tbody>
</table>

**In-Hospital Mortality**
- Actual Percent
- Expected Range
- Rating

**30-Day Readmission**
- Actual Percent
- Expected Range
- Rating
Process Requirements
Patient Voice and Selection

- MDT review
- Patient selection/appropriate use
- Shared decision making
### Quality Metric Focus

<table>
<thead>
<tr>
<th>Mortality</th>
<th>Complications</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>In hospital</td>
<td>Stroke-TIA</td>
<td>KCCQ</td>
</tr>
<tr>
<td>30 day</td>
<td>Bleeding</td>
<td></td>
</tr>
<tr>
<td>One year (in development)</td>
<td>Vascular complications</td>
<td></td>
</tr>
<tr>
<td>All risk adjusted</td>
<td>Pacemaker</td>
<td></td>
</tr>
</tbody>
</table>

Composite measures – risk adjusted (under development)
Interpreting Performance with Box and Whisker Plot

- Helps to benchmark performance to other sites
- Star ratings and funnel plots under development
Registry Role

- Answer outstanding questions
- Long term outcomes
- Variability in application to real life populations
- Outcomes in evolving populations – low and intermediate risk
- Measure quality of life
- Inform quality assessment and process improvement
SAVR Requirements

- Shared decision making
- Referral relationship for TAVR
- Experience and availability (see program requirements)
New Program Requirements
Experience for a New Program

- Prior TAVR experience with participation in 100 transfemoral TAVRs lifetime, including 50 TAVRs as primary operator
- Being board eligible or certified in either interventional cardiology or cardiothoracic surgery
- Certification of device-specific training on device(s) to be used.
- The site must have documented expertise, state of the art technology and dedicated board certified imager that is a member of the MDT.
  - Echocardiography: TTE, TEE and 3D
  - CT Scan and MR imaging
TAVR Surgeon Requirements for a New TAVR program

- 100 lifetime SAVRs or 25 per prior year or 50 over 2 years and ≥20 SAVRs in the year prior to TAVR program initiation Board eligible or certified by the American Board of Thoracic Surgery or equivalent
## Institutional Requirements

<table>
<thead>
<tr>
<th>PCI</th>
<th>Vascular interventions</th>
<th>Pacemaker capabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum volume: 300 PCI/year</td>
<td>Physicians experienced and competent in vascular arterial interventions*</td>
<td>Experienced and competent physicians for temporary and permanent pacemaker placement and management</td>
</tr>
<tr>
<td>Active participation in the NCDR/Cath PCI Registry or a validated state/multi-institutional consortium that gathers and reports risk-adjusted and benchmarked outcomes</td>
<td>Quality metric: PCI in-hospital risk-adjusted mortality (NQF endorsed) above the bottom 25th percentile for the most recent 4 consecutive quarters.</td>
<td>On-site services should be available 24 hours/day and 7 days/week to handle conduction disturbances as a result of TAVR</td>
</tr>
</tbody>
</table>
SAVR

Requirement for New Program

Minimum hospital SAVR volume:
40 per prior year or 80 over 2 years.

Quality assessment/quality improvement program:

≥2 hospital-based cardiac surgeons who both spend ≥50% time at the hospital with the proposed TAVR program

Active participation in the STS National Database or a validated state/multi-institutional consortium that gathers and reports risk-adjusted and benchmarked outcomes

Quality metric: STS 2- or 3-star rating for isolated AVR and AVR plus CABG in both reporting periods during the most recent reporting year
Maintain Program Requirements
### Overview for Maintaining Program

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥50 cases per year or 100 cases over 2 years</td>
<td>Documentation of multidisciplinary approach and patient access to all forms of therapy for aortic valve disease (TAVR, SAVR, and medical therapy) using an SDM process.</td>
</tr>
<tr>
<td>MDT quarterly meetings</td>
<td>Documentation of incorporation of TAVR/SAVR AUC in the patient selection process</td>
</tr>
<tr>
<td>Active institutional participation in the STS/ACC TVT Registry and STS National Database or a validated state/multi-institutional consortium registry</td>
<td>All MDT members will participate in appropriate CME annually</td>
</tr>
</tbody>
</table>
Institutional Experience to Maintain Program

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<th>Vascular interventions</th>
<th>Pacemaker capabilities</th>
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<td></td>
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<tr>
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<td></td>
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</tr>
</tbody>
</table>
SAVR Recommendations for Maintaining Program

≥30 SAVRs (broadly defined) per prior year or 60 over 2 years†

Quality assessment/quality improvement program:

• Active participation in STS National Database to monitor outcomes
• Quality Metric: STS 2 or 3 star rating for isolated AVR and AVR + CABG in both reporting periods during the most recent reporting year
Access to Care

• Requirements focus on access to quality care

• Volume requirements to assess quality are not restrictive but based on the need for statistical reliability

• All centers should have a program to achieve a steady history of quality outcomes using rolling year volumes
ACCESS:
New TAVR Sites Opening in the Last Two Years: Some Appear to Be in Geographically “Underserved” Areas and Some are in Regions with Many Other TAVR Programs

TVT Registry Site Distribution
579 institutions in 51 states/U.S. territories
PROJECTED TAVR GROWTH
<table>
<thead>
<tr>
<th>PROC US</th>
<th>CENTERS</th>
<th>YEARLY</th>
<th>WEEKLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>NUMBER</td>
<td>US</td>
<td>proc/center/yr</td>
<td>proc/week</td>
</tr>
<tr>
<td>15,000</td>
<td>350</td>
<td>43</td>
<td>&lt;1/week</td>
</tr>
<tr>
<td>50,000</td>
<td>500</td>
<td>100</td>
<td>2</td>
</tr>
<tr>
<td>50,000</td>
<td>350</td>
<td>150</td>
<td>3</td>
</tr>
<tr>
<td>100,000</td>
<td>500</td>
<td>200</td>
<td>4</td>
</tr>
</tbody>
</table>
# TVT Demographics

### Age*

<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>25th</th>
<th>75th</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>82</td>
<td>75</td>
<td>86</td>
</tr>
</tbody>
</table>

### Sex

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>54.3%</td>
<td>45.7%</td>
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### Race

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<thead>
<tr>
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<tbody>
<tr>
<td>Missing</td>
<td>1.5%</td>
</tr>
<tr>
<td>White</td>
<td>93.1%</td>
</tr>
<tr>
<td>Black/African</td>
<td>3.8%</td>
</tr>
<tr>
<td>American</td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>1.2%</td>
</tr>
<tr>
<td>Other</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

### Hispanic or Latino Ethnicity

<p>| | |</p>
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<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing</td>
<td>1.9%</td>
</tr>
<tr>
<td>No</td>
<td>93.8%</td>
</tr>
<tr>
<td>Yes</td>
<td>4.3%</td>
</tr>
</tbody>
</table>
Demographic Variations

- Understanding the variables behind variations
  - Broader societal issues for access to care
  - Referral
  - Age of AVR population
Conclusions

- Quality variability, not access nor volume alone is key challenge
- Volume required to assess quality
- Low volume centers should have ongoing case review as metrics unstable
- All centers should engage in ongoing measurement and QI
- Registry essential to assess long term outcomes and variability in evolving patient cohort
- Evolving quality would suggest external review program to understand variability