How Should an Advanced Valve Center Be Evaluated?

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Disclosures

• No Relevant Financial Disclosures

• Chair, STS Task Force on Public Reporting
What is “Excellence”?

- Term ‘center of excellence’ remains ill-defined, open to self-designation instead of accreditation
- Donabedian triad: Structure, Process, Outcomes
- Volume-Outcome Relationship
  - strength and association varies
  - center vs. operator, outcome measure (mortality, repair rate, stroke), does the slope of the volume-outcome relationship have an inflection point for reasonable interpretation, low-volume procedures
What is “Excellence”?

- Participation in registries, transparency, public reporting – all in meaningful effort to enhance quality, Teams, Resources, Committed Leadership
- Process of appropriate use
- Shared decision making
- Procedural and Post-procedural Protocols
- Safety, Cost, Performance Improvement
- Scholarship, Innovation and Education
- Peer or third party determination (star rating, JC)
The ACC and AHA

Setting a New Standard for Hospital Accreditation—Together

Richard A. Chazal, MD, FACC, President, American College of Cardiology
Steven Houser, MD, FAHA, President, American Heart Association
Objectives

• Impact of Volume or Experience on Quality
• Risk Assessment and Risk Aversion
• Current and Future of Public Reporting
  • PCI, TAVR, Surgery

• Facilitated Discussion: How We Should Evaluate Advanced Valve Centers?
8 operations:

Lung resection, esophagectomy, open abdominal aneurysm repair, AVR, cystectomy, pancreatic resection, CABG

1998 Medicare claims database

Possible volume-outcome relationship (surgeon and center volume)

Not fully risk adjusted
Institutional volumes of < 200 PCI have worse overall outcomes

Highlights the potentially confounding relationship between:

- facility volume
- operator volume (annual, lifetime)
- operator non-PCI experience
Public Reporting of Interventions is happening in several forms today (administrative claims vs. registry data)

Highlighted Issues:
• Adequacy of Risk Models – validity of risk calculators, patients at extreme risk spectrum, excluding high risk patients from public reporting
• Risk Aversion – complex cases, cardiac arrest, rescue PCI (these are often the most to gain)
The Society of Thoracic Surgeons
Adult Cardiac Surgery Database

• **Began as a voluntary Database of All Cardiac Operations in 1989**
• **6,000,000+ operations, 95% of all operations in the United States**
• **Focusing on robust clinical data for Outcome Measurement:**

  - Accurate Clinical Data
  - Homogeneous Target Populations
  - Robust Risk Adjustment
  - Multi-dimensional End Points
  - State-of-the-art Statistical Methodologies
  - Appropriate Methods of Outlier Determination
The Society of Thoracic Surgeons (STS) National Database
Adult Cardiac Surgery Database Participants

1102 Total Participants as of 10.19.2016
60 US States & Canada
10 International - Australia, Brazil, India, Israel, Italy, Turkey & United Arab Emirates
41 Anesthesiology Participants

100+ 55 to 99 26 to 54 11 to 25 1 to 10
Bayesian Hierarchical Statistical Modeling for Risk and Outcome

Multi-variable Logistic Regression for Risk Assessment
Relative Risk Calculation using Multi-dimensional End Points
  - Mortality (30-day or in-hospital)
  - Major Morbidity (stroke, reoperation, prolonged ventilation, renal failure, infection)
  - Process Measures

Participant Center Specific Event Rate Determination
  - Risk-Standardized Absence of Event rates
  - Higher score indicates better performance
  - Rescaled to End Points (process measures, mortality or any or none major morbidity)
  - Calculation of Bayesian Scale which is summarized in a “Star Rating”:
    1 Star program – lowest performance
    2 Star program – “as-expected” performance
    3 Star program – highest performance
STS AVR Composite Score

• Composite measure with 2 domains:
  • Absence of operative mortality
  • Absence of major morbidity

• Note: Transcatheter Aortic Valve procedures are not included in the AVR Composite Score
STS AV R Composite Score

- Fewer cases (3 years of data)

Risk-adjusted mortality

Risk-adjusted any-or-none morbidity (stroke, sternal infection, renal failure, reoperation, prolonged ventilation)

97.5% Bayesian probability that provider differs from STS average

Star Rating
## STS AVR Composite Score

![Histogram of Composite Scores]

**Median:** 93.9%
**IQR:** 92.9% to 94.8%

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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3%</td>
<td>3%</td>
<td>2.7%</td>
<td>3.35%</td>
<td>3.85%</td>
<td>4.22%</td>
<td>3.77%</td>
</tr>
<tr>
<td>2</td>
<td>91%</td>
<td>91%</td>
<td>91.4%</td>
<td>88.98%</td>
<td>87.58%</td>
<td>87.89%</td>
<td>88.36%</td>
</tr>
<tr>
<td>3</td>
<td>6%</td>
<td>6%</td>
<td>5.9%</td>
<td>7.67%</td>
<td>8.57%</td>
<td>7.89%</td>
<td>7.87%</td>
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</table>
### Heart Surgery

**Overall Heart Bypass Surgery Performance**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Survival</td>
<td>●</td>
</tr>
<tr>
<td>Avoiding Major Complications</td>
<td>○</td>
</tr>
<tr>
<td>Recommended Medications</td>
<td>●</td>
</tr>
<tr>
<td>Optimal Surgical Technique</td>
<td>○</td>
</tr>
</tbody>
</table>

*These ratings are based on 135 heart bypass operations performed between January 2011 and December 2011. Surgeons in the group may have performed additional heart bypass operations that are not included here, either at other hospitals or combined with other surgical procedures. [Read more](#).*

### Aortic Valve Replacement Surgery

**Overall Aortic Valve Replacement Surgery**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Survival</td>
<td>●</td>
</tr>
<tr>
<td>Avoiding Major Complications</td>
<td>●</td>
</tr>
</tbody>
</table>

*These ratings are based on 220 aortic valve replacement operations performed between January 2011 and December 2011. Surgeons in the group may have performed additional aortic valve replacement operations that are not included here, either at other hospitals or combined with other surgical procedures. [Read more](#).*
No Evidence of Risk Aversion

STS Public Reporting
December 12th 2016

<table>
<thead>
<tr>
<th></th>
<th># Participants US &amp; Canada</th>
<th>STS Unique Consents</th>
<th>% Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Cardiac</td>
<td>1102</td>
<td>620</td>
<td>56.2%</td>
</tr>
<tr>
<td>Congenital</td>
<td>119</td>
<td>70</td>
<td>58.8%</td>
</tr>
</tbody>
</table>

- Isolated CABG
- Isolated AVR
- AVR+CABG
- MVRR (coming in 2017)
### OUTCOMES

#### 2005 to 2014

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>CABG (n = 144,940)</th>
<th>AVR (n = 29,158)</th>
<th>AVR + CABG (n = 18,016)</th>
<th>MVR (n = 6,857)</th>
<th>MVR + CABG (n = 2,582)</th>
<th>MV Repair + CABG (n = 8,658)</th>
<th>MV Repair + CABG (n = 4,205)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mortality, %</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital</td>
<td>1.7</td>
<td>1.9</td>
<td>3.2</td>
<td>4.2</td>
<td>9.2</td>
<td>1.0</td>
<td>4.3</td>
</tr>
<tr>
<td>Operative&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.1</td>
<td>2.4</td>
<td>3.9</td>
<td>4.9</td>
<td>9.9</td>
<td>1.2</td>
<td>5.1</td>
</tr>
<tr>
<td><strong>Major morbidity, %</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation&lt;sup&gt;b&lt;/sup&gt;</td>
<td>2.3</td>
<td>3.9</td>
<td>4.7</td>
<td>5.8</td>
<td>7.5</td>
<td>2.7</td>
<td>5.4</td>
</tr>
<tr>
<td>DSWI/mediastinitis</td>
<td>0.3</td>
<td>0.2</td>
<td>0.2</td>
<td>0.1</td>
<td>0.4</td>
<td>0.1</td>
<td>0.3</td>
</tr>
<tr>
<td>Permanent stroke</td>
<td>1.3</td>
<td>1.1</td>
<td>2.3</td>
<td>2.0</td>
<td>3.8</td>
<td>0.9</td>
<td>2.5</td>
</tr>
<tr>
<td>Prolonged ventilation &gt;24 h</td>
<td>8.2</td>
<td>7.9</td>
<td>13.4</td>
<td>18.5</td>
<td>30.8</td>
<td>5.0</td>
<td>21.8</td>
</tr>
<tr>
<td>Renal failure</td>
<td>2.0</td>
<td>2.0</td>
<td>3.8</td>
<td>4.3</td>
<td>7.9</td>
<td>1.1</td>
<td>5.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CABG</th>
<th>MVR + CABG</th>
<th>MV repair + CABG</th>
<th>AVR + MVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,496</td>
<td>2,582</td>
<td>4,518</td>
<td>4,205</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>–7</td>
<td>79</td>
</tr>
</tbody>
</table>
Overall Mortality 2.9% for MVRR  
1% MV Repair  
Sternotomy 72.5%, Mini 14.2%, Robotic 7% overall, 11% for MV repair  
Repair Rate for Primary MR has increased to 75% overall
22,248 TAVR at 318 sites 2011-2014
40-factor Bayesian mortality risk model
5.1% mortality, IQR 4.3-6.1
Risk model: Age>75, low BSA, GFR, Dialysis, CAS, Severe COPD, Severe TR, Alternative Access, Acuity Category 2-4

Highlighted Issue:
• Several institutional factors affecting hospital-level outcome variation – but overall outlook is good with community sites achieving similar outcome to pivotal trial sites
2016 Annual Report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

Running Head: Annual Report of the STS/ACC TVT Registry

Frederick L. Grover, MD¹, Sreekanth Vemulapalli, MD², John D. Carroll, MD³, Fred H. Edwards, MD⁴, Michael J. Mack, MD⁵, Vinod H. Thourani, MD⁶, Ralph G. Brindis, MD, MPH⁷, David M. Shahian, MD⁸, Carlos E. Ruiz, MD⁹, Jeffrey P. Jacobs, MD¹⁰ George Hanzel, MD¹¹, Joseph E. Bavaria, MD¹², E. Murat Tuzcu, MD¹³, Eric D. Peterson, MD, MPH², Susan Fitzgerald, RN, MS¹⁴, Matina Kourtis, MS¹⁵, Joan Michaels, RN, MSN¹⁴, Barbara Christensen, MSHA, RN¹⁴, William F. Seward, MA,¹⁵ Kathleen Hewitt, MSN,RN,¹⁴ and David R. Holmes, Jr, MD¹⁶, for the STS/ACC TVT Registry
TAVR Sites in US = 477

Alaska: 1
Hawaii: 1
TAVR and SAVR* Procedures
In the TVT Registry and STS ACSD*
54,782 commercial TAVR

* SAVR= isolated surgical aortic valve replacement; ACSD=Adult Cardiac Surgery Database
Source: STS/ACC TVT Registry Database as of Oct 18, 2016; STS ACSD 2015 Annual Report
Represents predominantly TAVR performed for degenerated surgically implanted tissue valves.

This is an FDA approved (2015) indication for both commercially available types of TAVR valves.

% of TAVRs that are Elective Valve-in-Valve Procedures

Source: STS/ACC TVT Registry Database as of Oct 18, 2016
TAVR: Mean and Median Age

Source: STS/ACC TVT Registry Database. 70,651 records as of Oct 18, 2016

No major age "creep", i.e. decrease in the age of the population being treated.
A technology-enabled shift in access for TAVR continues to unfold.

Source: STS/ACC TVT Registry Database as of Oct 18, 2016
Median LOS (Days)

Source: STS/ACC TVT Registry Database. 70,651 records as of Oct 18, 2016
One Year Mortality after TAVR (CMS linked records)

Source: DCRI query
17,562 records as of 9-12-16

<table>
<thead>
<tr>
<th>Year</th>
<th>Mortality Rate</th>
</tr>
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<tbody>
<tr>
<td>2012</td>
<td>25.8%</td>
</tr>
<tr>
<td>2013</td>
<td>22.2%</td>
</tr>
<tr>
<td>2014</td>
<td>21.6%</td>
</tr>
</tbody>
</table>

Source: DCRI query
17,562 records as of 9-12-16
TAVR: Site Performance on Novel Assessment of Functional State and Patient Reported Health Status

5 Meter Walk Test at Baseline

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Completed</td>
<td>26%</td>
<td>64%</td>
<td>77%</td>
<td>84%</td>
</tr>
</tbody>
</table>

KCCQ at Baseline

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Completed</td>
<td>36%</td>
<td>77%</td>
<td>88%</td>
<td>92%</td>
</tr>
</tbody>
</table>

BETTER AND MORE COMPLETE DATA NEEDED
Aortic Regurgitation-most recent at Discharge or at 30 days (%) Post-TAVR

Among non missing values for Aortic Regurgitation at Discharge or at 30 days Post-TAVR.
Value through Data

Public Reporting

• Isolated CABG
• Isolated AVR
• AVR+CABG
• Isolated MVRR & MVRR+CABG coming in 2017-2018
• TVT Registry and TAVR coming soon!
• Level 1 AVC
  • Virtual Research Data File
  • TVT-CMS linkage to assess the Value – Outcomes/Cost Relationship (Pain and Shame)
How Should an Advanced Valve Center be Evaluated?

- What performance measures should define an advanced valve center? *Patient-focused*

- *Outcome measures*...Should we go beyond 30-day mortality and major morbidity...durable repair rates of primary MR, PVL in TAVR, late stroke? Value and Cost?

- *Process measures*...robustness of heart team, resources of facilities (hybrid room), etc.?

- Should we develop a hybrid TAVR-SAVR composite scores (TMVR-SMVRR) to assess?

- Should advanced valves centers voluntarily publicly report? How should they be accredited???