

Lessons from the STS/ACC Transcatheter Valve Therapy Registry

“The TVT Registry”

Representing the American College of Cardiology

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Disclosures

John Carroll

- STS-ACC Transcatheter Valve Therapy Registry Steering Committee
- Investigator in Transcatheter Valve Trials
 - Edwards Lifesciences: PARTNER 2, ACTIVE, CLASP (<\$10,000)
 - Abbott: COAPT, SUMMIT, EXTEND (<\$10,000)
 - Medtronic: Low risk TAVR versus SAVR (<\$10,000)
 - Chair: DSMB and CEC Committees for Tendyne (>\$10,000)
- ACC Conflicts
 - Nothing to Disclose



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This is the US National Registry Developed to Fulfill the Needs as Articulated in the 2012 National Coverage Decision on Transcatheter Aortic Valve Replacement (TAVR)

The STS-ACC Transcatheter Valve Therapy National Registry

A New Partnership and Infrastructure for the Introduction and Surveillance of Medical Devices and Therapies

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Ralph G. Brindis, MD, MPH,§ Frederick L. Grover, MD,* Eric D. Peterson, MD, MPH,||
Murat Tuzcu, MD,¶ David M. Shahian, MD,# John S. Rumsfeld, MD, PhD,**
Cynthia M. Shewan, PhD,†† Kathleen Hewitt, MSN, RN,‡‡ David R. Holmes Jr, MD,§§
Michael J. Mack, MD|||

J Am Coll Cardiol 2013;62:78–86

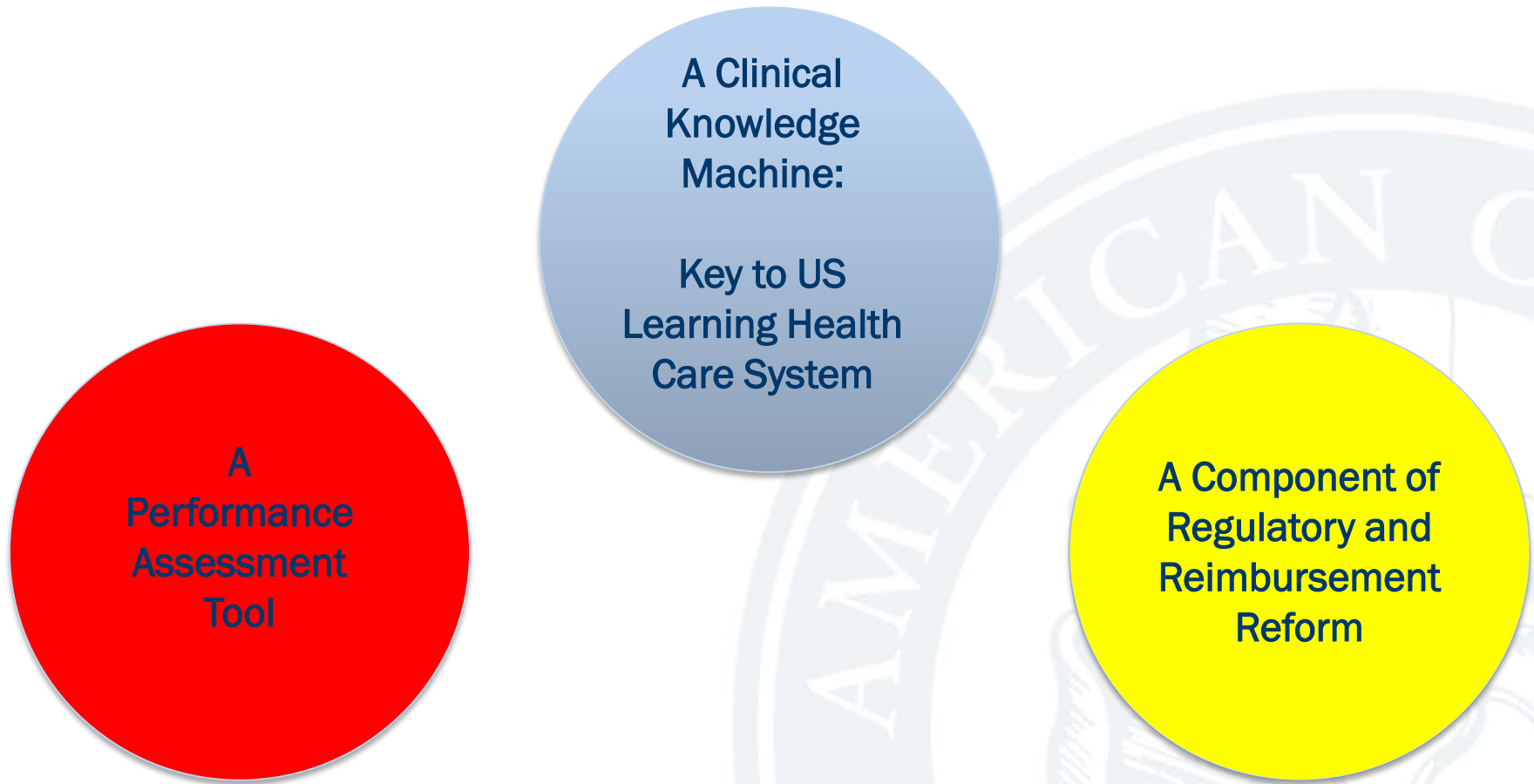
- “The intent of the TVT registry is to provide a data repository and reporting infrastructure to monitor the safety and effectiveness of TVT devices.”
- “The TVT registry represents a new model combining the needs of the medical device industry, regulatory and reimbursement agencies, clinicians, hospitals, patients, researchers, and professional societies.”
- “The TVT registry will have multiple innovations.”



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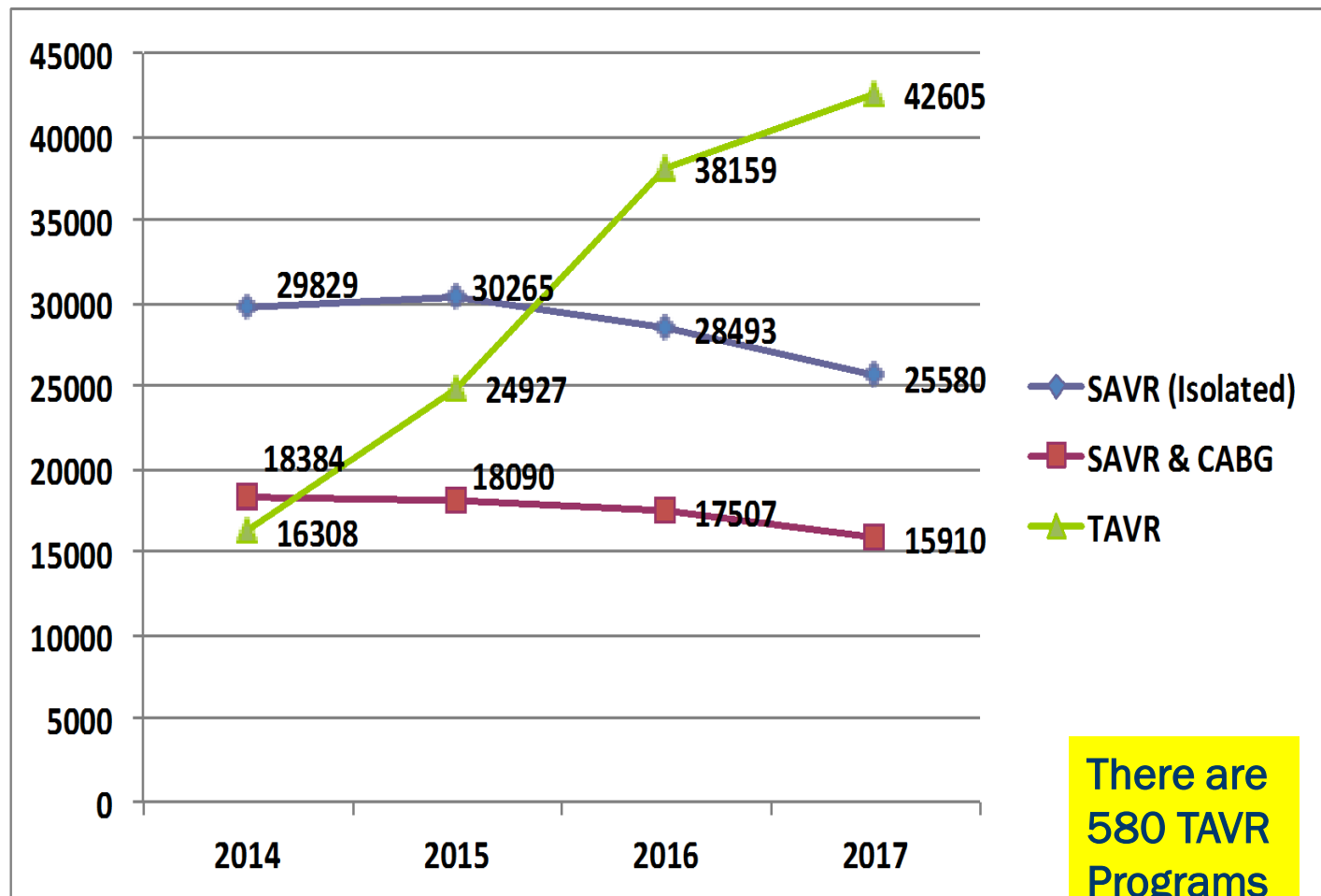
The Need for a Clinical Registry



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The Dramatic Increase in the Number of US Patients Needing Aortic Valve Replacement

SAVR
(Surgical)
&
TAVR
(Transcatheter)
Volumes



There are
580 TAVR
Programs
in the US

Sources:
STS/ACC TVT Registry Database as of
STS Database



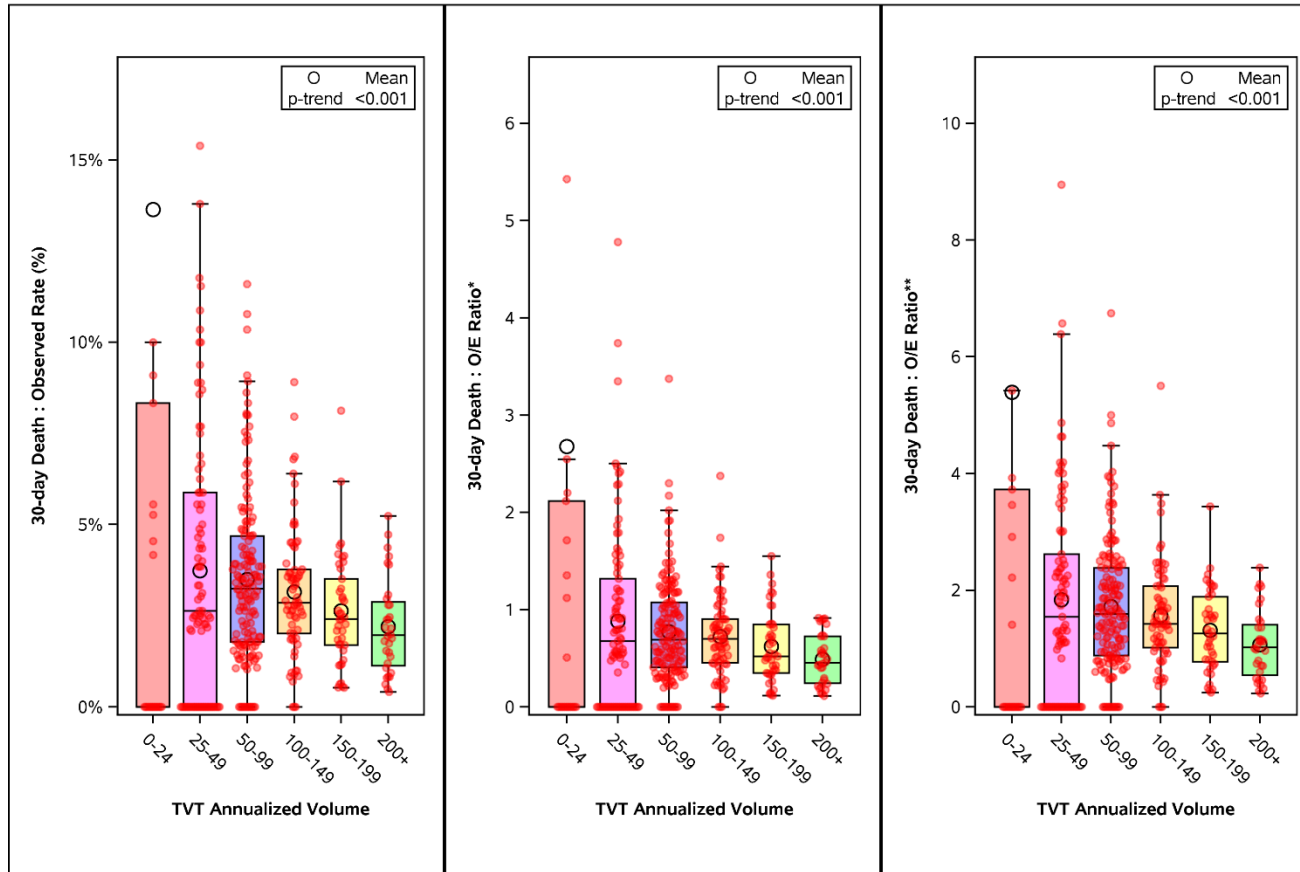
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Site Variability in Quality Outcomes

Especially of Concern in Low Volume Programs

30-day Mortality/Volume

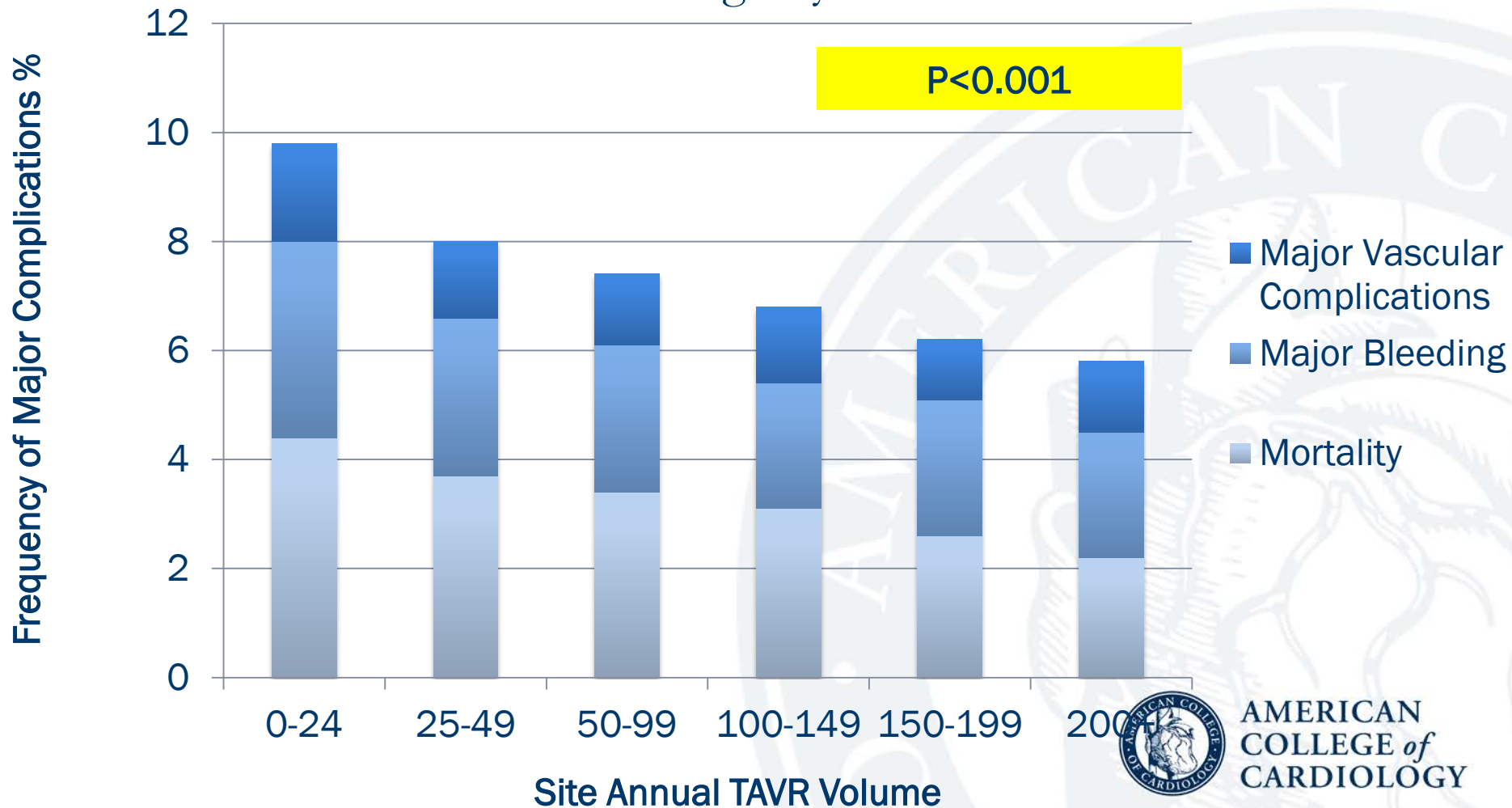
Sites with index TAVR from 2016 onwards are removed



O/E Ratio* = Observed/Expected Ratio where E = STS Risk Score
 O/E Ratio** = Observed/Expected Ratio where E = Predicted 30-day mortality adjusted for list of variables
 Sites with Observed Rate >65% are not displayed (n=3; 0-24)
 Sites with O/E Ratio* >15 are not displayed (n=2; 0-24)
 Sites with O/E Ratio** >10 are not displayed (n=3; 0-24)

30 Day Composite Major Outcomes Related to Site Annual Volume

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





The Need to Rapidly Learn About New Treatments

CMS: Coverage with Evidence Development

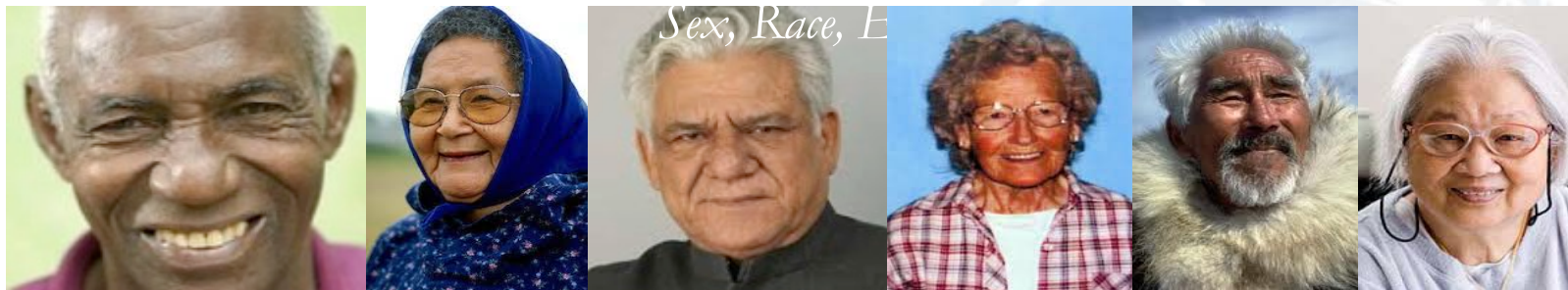
Who is Undergoing Transcatheter Valve Therapy in the USA?

Do they all benefit?

Are there unexpected problems?

How can patients, families, and clinicians make optimal decisions on whether it is the best treatment for them?

TAVR versus SAVR?



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Quality-of-Life Outcomes

After Transcatheter Aortic Valve Replacement

A Report From the STS/ACC Transcatheter Valve Therapy Registry

The KCCQ Questionnaire assesses patient-reported health status.
Patients fill this out pre, 30 days and one year post TAVR.

***“Overall, 62.3% of patients had a favorable outcome at 1 year
(alive with reasonable quality of life).”***

JAMA Cardiology
2017;2(4):409-416.
Arnold S et al.

Ongoing Questions:

How can we improve patient selection, procedure performance, and post procedure care to increase the % of patients benefitting from TAVR at one year?

How does Surgical AVR compare to TAVR?



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CED Questions

- Variability in TAVR outcomes
 - What accounts for differences in site performance?
 - Also true for Surgical AVR?
- Patient selection refinement
- Performance in real life populations over time
 - Long term mortality
 - Long term quality of life
- Choices between SAVR and TAVR implications as indications broaden



TVT Registry:

Provides Data to Answer the Questions Being
asked at MEDCAC

Provides Data to Answer Outstanding CED
Questions

Supports the 2018 Update of TAVR Operator and
Institutional Requirements



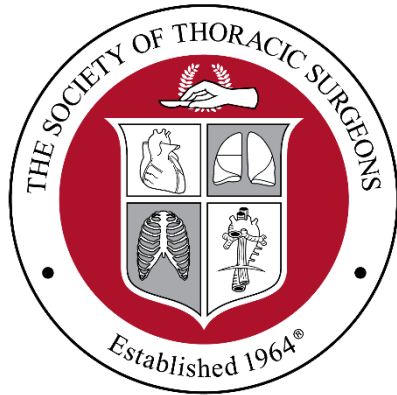
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Conclusions

- The TVT Registry provides all stakeholders with comprehensive data to address issues of site performance, scientific evidence on key issues related to variability in patient care, and facilitates improvement in the US regulatory and reimbursement health care systems.
- Going forward with the on-going rapid transformation in the treatment of valvular heart disease a Coverage with Evidence Development (CED) National Coverage Determination (NCD) is necessary to address these issues involving surgical, transcatheter, medical and palliative care of patients with aortic valve disease.
 - The TVT Registry is essential to understand and guide
 - Registry and external assessment (accreditation) would provide flexibility to understand rather than freeze static requirements in an evolving field



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