

2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement

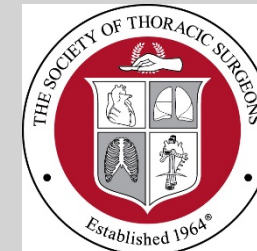
MEDCAC Meeting
July 25, 2018



AMERICAN ASSOCIATION
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**The Society
of Thoracic
Surgeons**

Disclosures

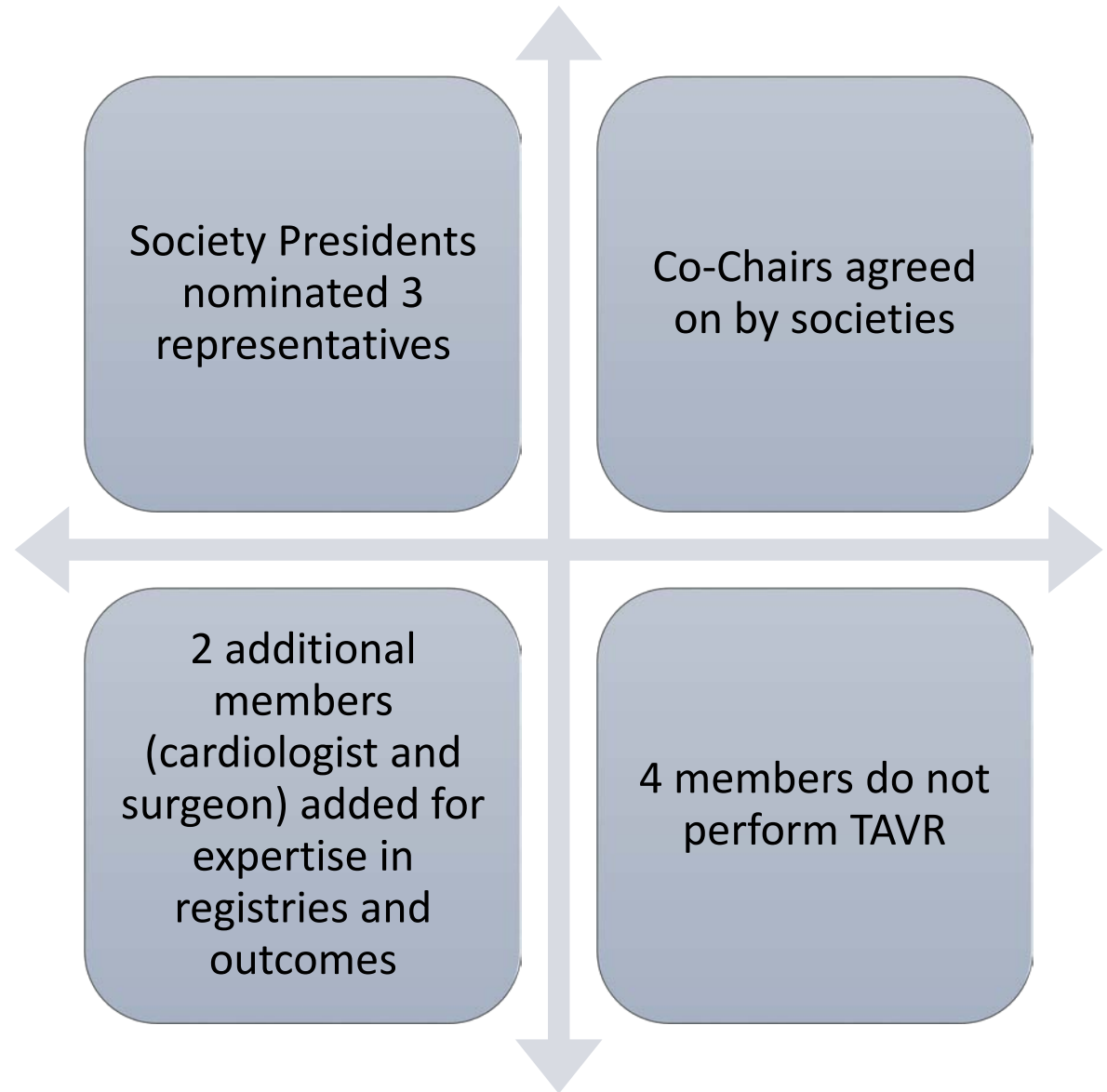
Joseph Bavaria, MD

- 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



2012 INSTITUTIONAL REQUIREMENTS

CARDIAC
CENTERS

TRIAL CENTERS

VOLUME

- PCI
- CABG
- AVR

HEART TEAM

FACILITIES

REGISTRY

Why Volume?

Learning Curve:

Volume/ Outcomes Evidence

Alli O, Rihal CS, Suri RM et al.
Learning curves for transfemoral
transcatheter aortic valve
replacement in the PARTNER-I trial:
Technical performance. Catheter
Cardiovasc Interv. 2016; 87:154-62.

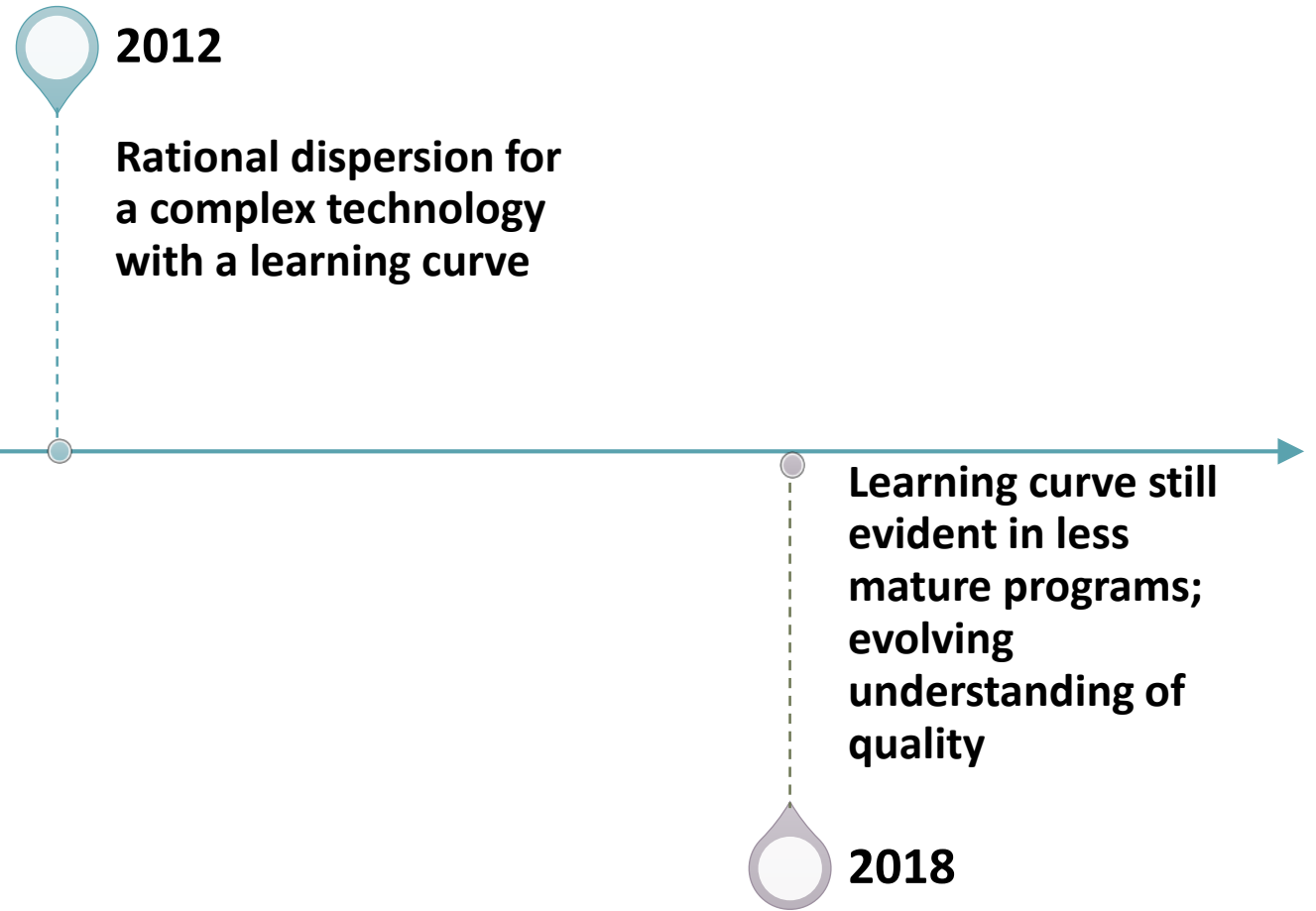
Tommaso CL. Learning curves for
TAVR: Not quite see one, do one
teach one. Catheter Cardiovasc
Interv. 2016; 87:163-4.

Minha S, Waksman R, Satler LP et al.
Learning curves for transfemoral
transcatheter aortic valve
replacement in the PARTNER-I trial:
Success and safety. Catheter
Cardiovasc Interv. 2016; 87:165-75.

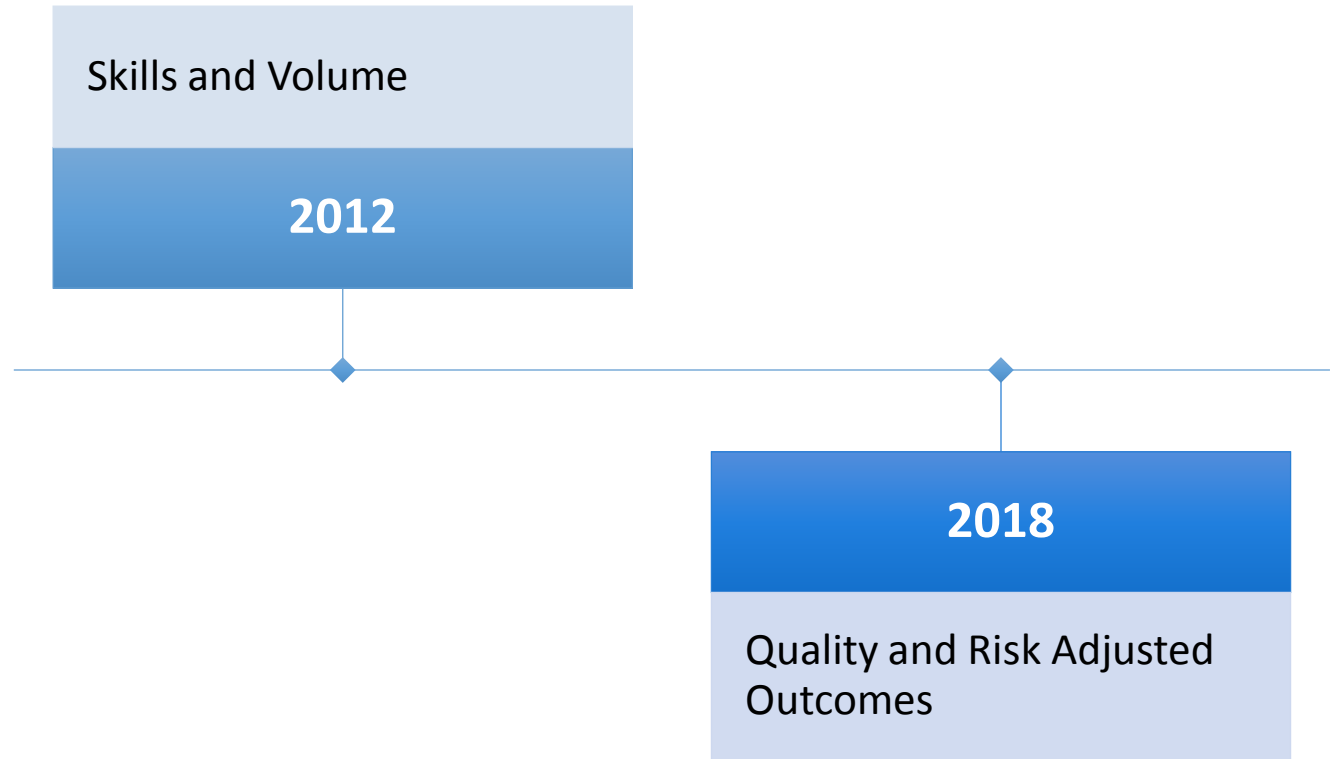
Suri RM, Minha S, Alli O et al.
Learning curves for transapical
transcatheter aortic valve
replacement in the PARTNER-I trial:
technical performance, success, and
safety. J Thorac Cardiovasc Surg.
2016; 152:773-80 e14.

Carroll J, Vemulapalli S, Dai D et al.
The association between procedural
experience for transcatheter aortic
valve replacement and outcomes:
insights from the STS/ACC TVT
Registry. J Am Coll Cardiol. 2017

Update Rationale



Skills/Volume to Risk Adjusted Outcomes





2018 Focal Point:

Quality

- Structure
 - Process
 - Outcome
-
- Direct comprehensive assessment of quality required; volume is not a substitute for quality



Structural Requirements

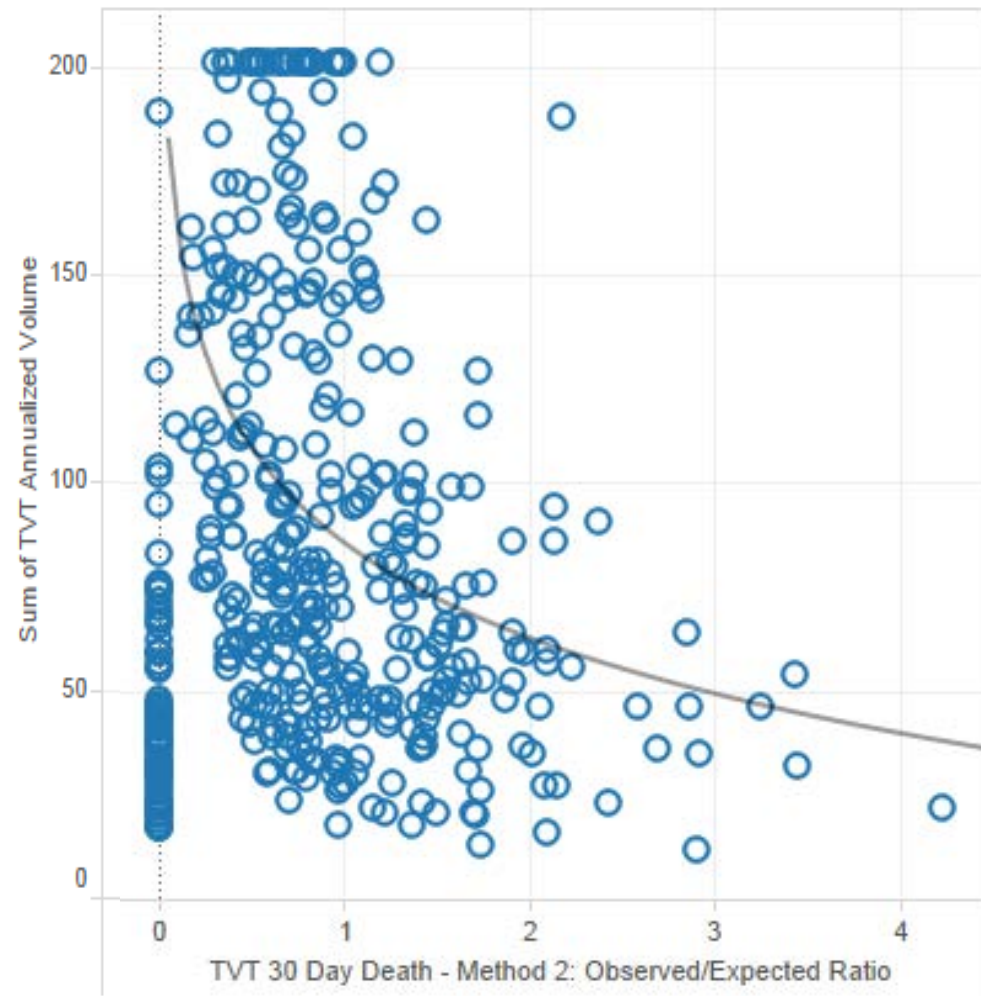
- Volume (required to reliably measure quality)
- Multi-disciplinary team (MDT)
- Training
- Facility

Key Quality Issue: Variability



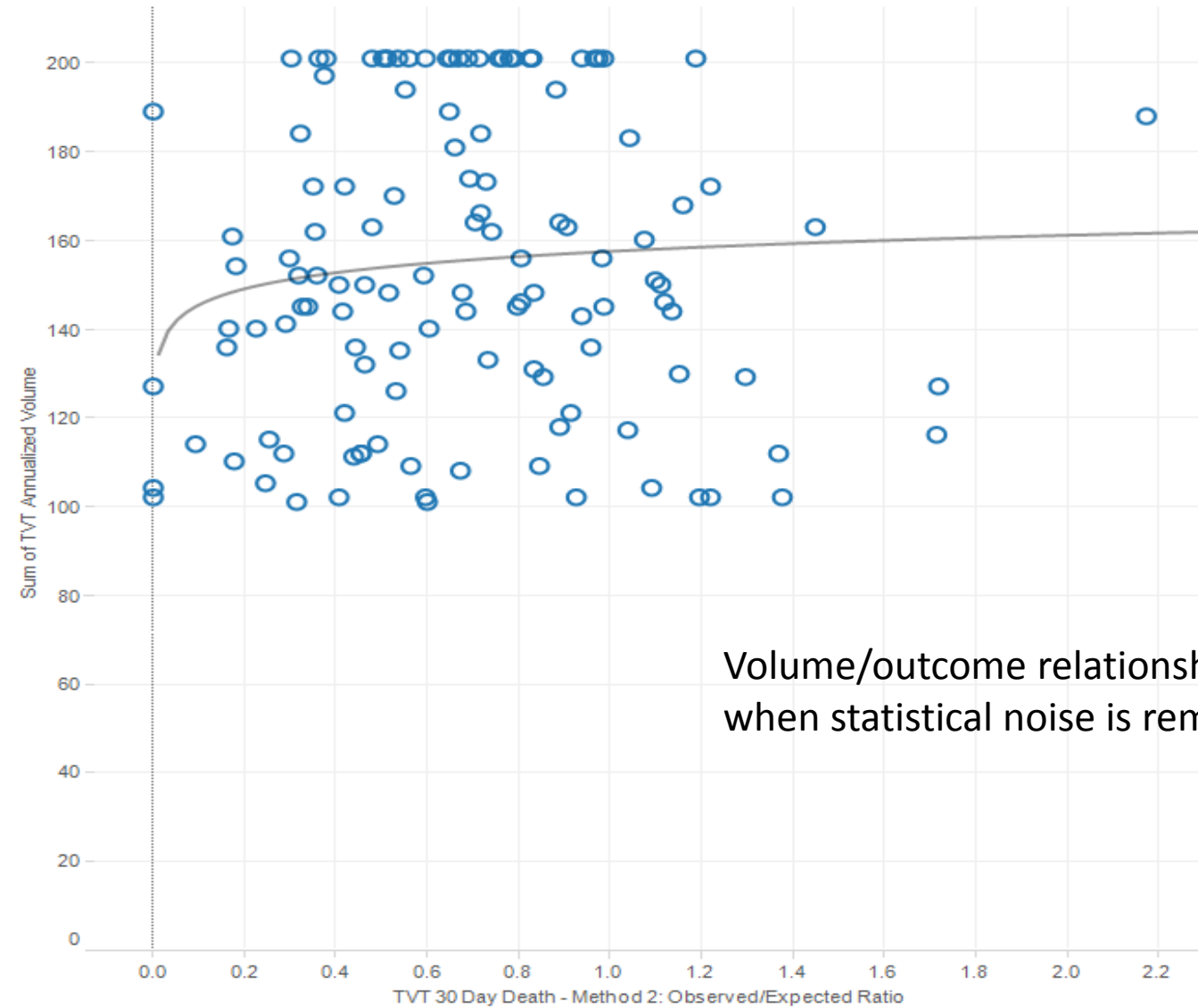
- Not volume, although important to informing
- Not access, market will drive adoption of high quality
- **Variability in quality**
 - Need to determine the contributing factors to variability is the most pressing issue for the next 5 years

TVT Registry:
Volume/30
Day
Mortality



TVT Registry Volume/30 Day Mortality Over 100 Cases

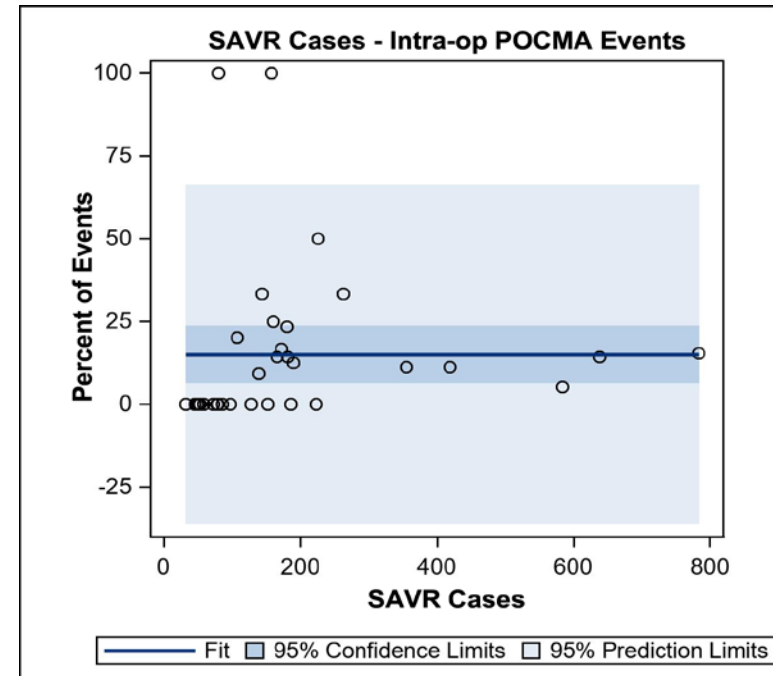
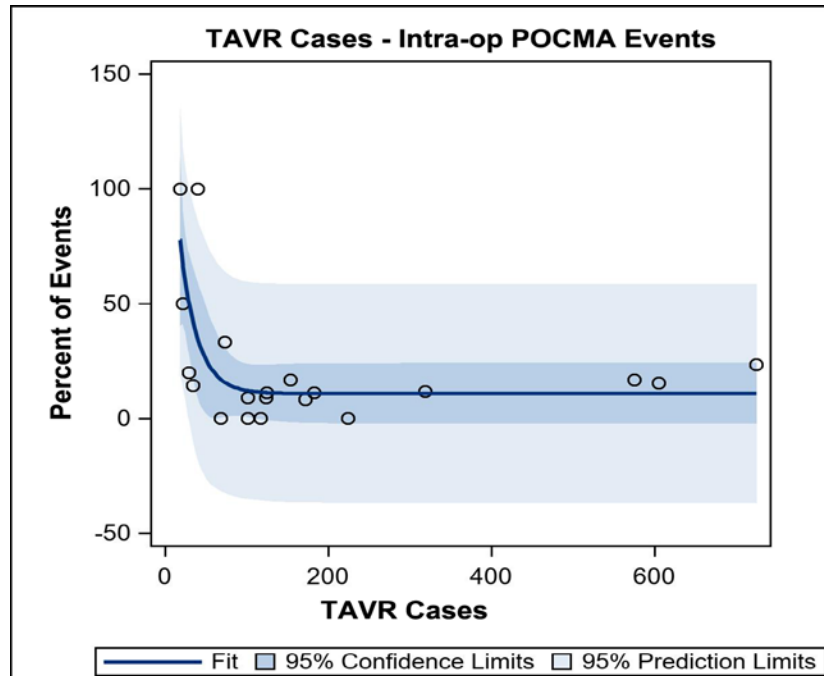
Sheet 43



Volume/outcome relationship flattens
when statistical noise is removed

Sum of TVT 30 Day Death - Method 2: Observed/Expected Ratio vs. sum of TVT Annualized Volume. Details are shown for Site ID. The data is filtered on TVT Annualized Volume as an attribute, AVRRepl Any: 2017H1 volume (1/01/2016-12/31/2016) as an attribute, TVT: # Quarters and AVR Any and TAVR as an attribute. The TVT Annualized Volume as an attribute filter ranges from 100 to 201. The AVRRepl Any: 2017H1 volume (1/01/2016-12/31/2016) as an attribute filter ranges from 0 to 1,042. The TVT: # Quarters filter keeps 4. The AVR Any and TAVR as an attribute filter ranges from 12 to 544. The view is filtered on Site ID, which excludes 1997364, 2139276 and 335146.

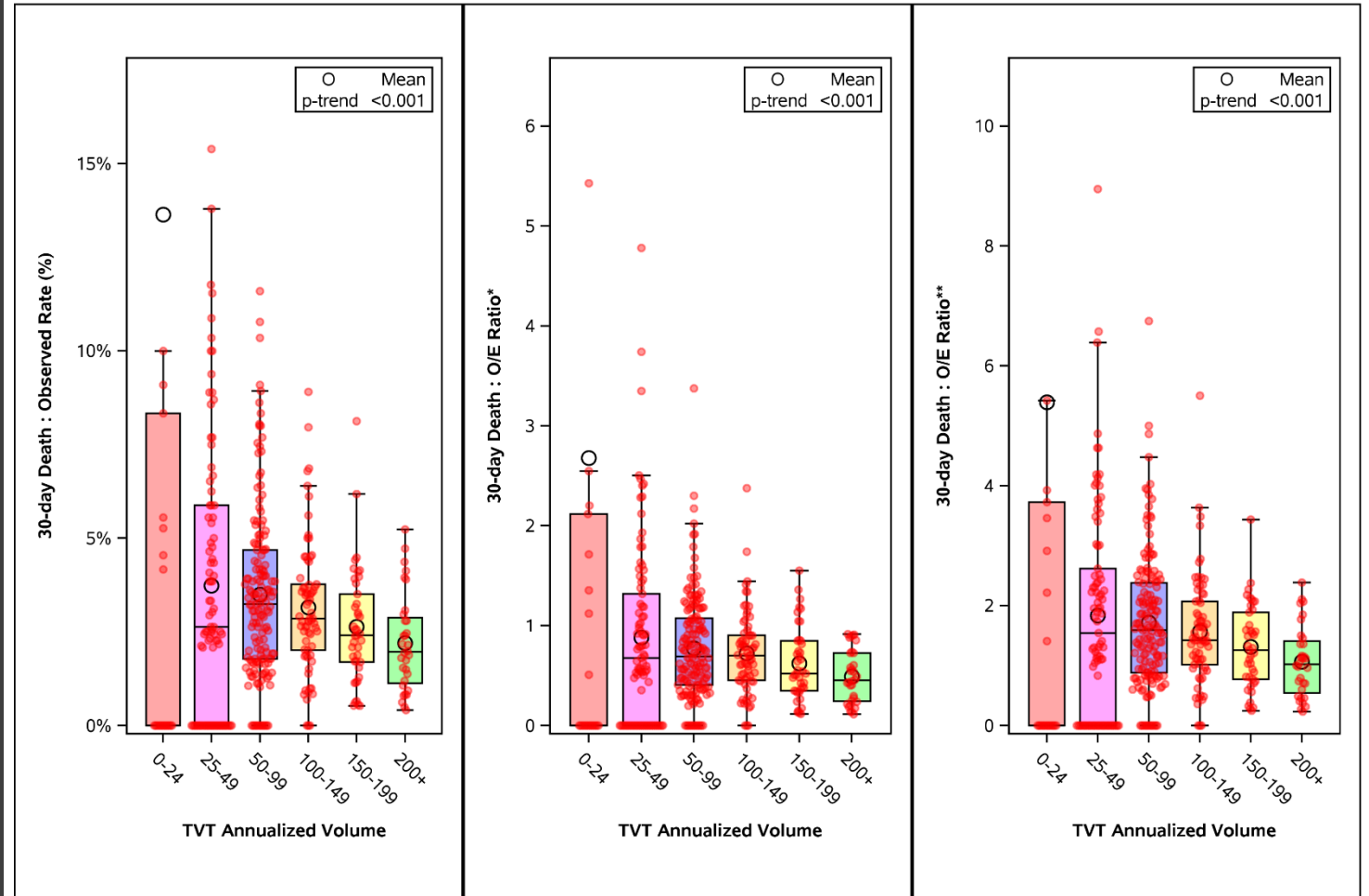
Volume Outcome Relationship for Intraoperative Phase



Variability of 30 Day Outcomes (non-risk adjusted)

Source:
TVT Unpublished Data

30-day Mortality/Volume
Sites with index TAVR from 2016 onwards are removed

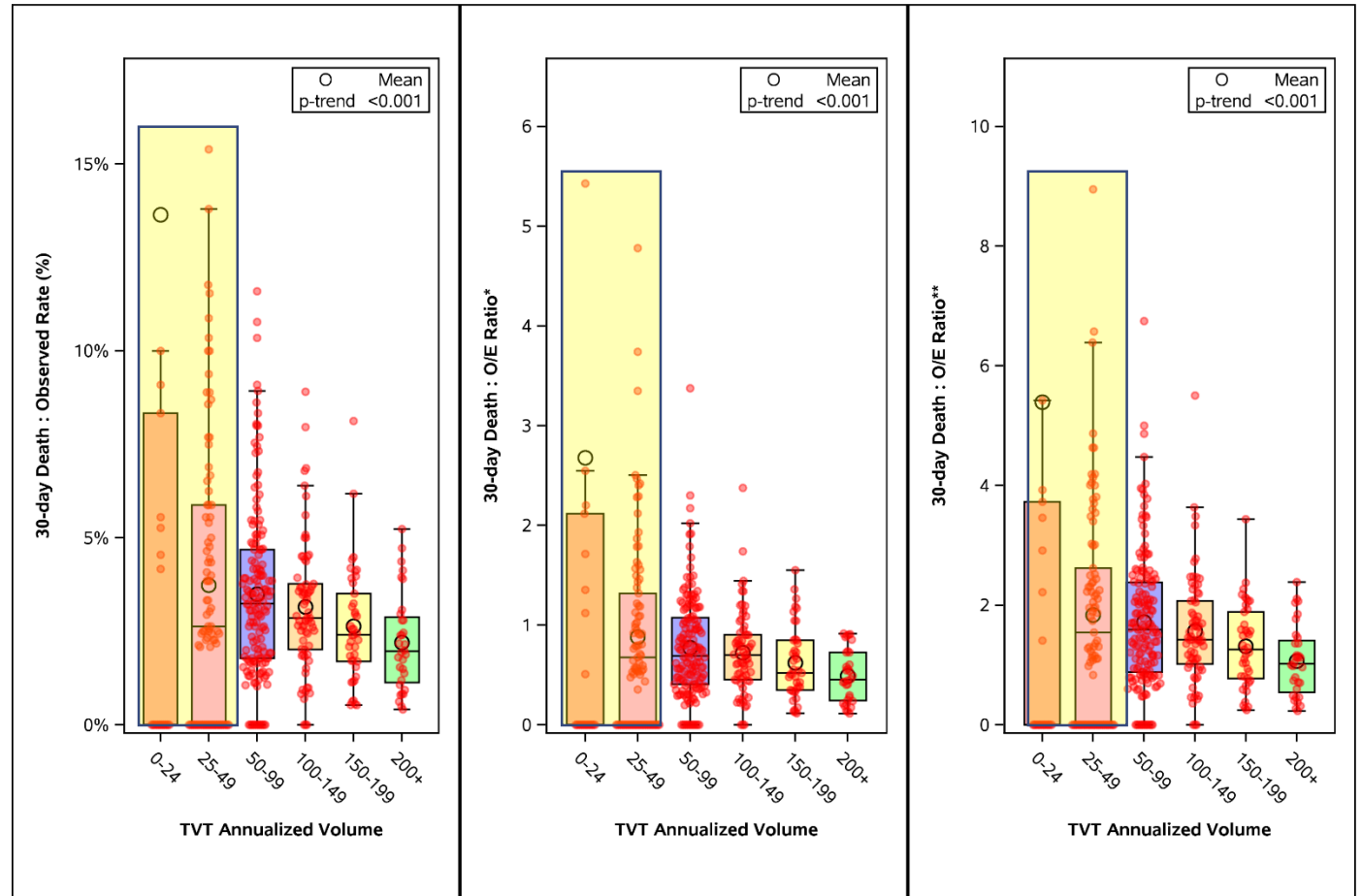


O/E Ratio* = Observed/Expected Ratio where E = STS Risk Score
O/E Ratio** = Observed/Expected Ratio where E = Predicted 30-day mortality adjusted for list of variables
Sites with Observed Rate >65% are not displayed (n=3; 0-24)
Sites with O/E Ratio* >15 are not displayed (n=2; 0-24)
Sites with O/E Ratio**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

Variability of 30 Day Outcomes (non-risk adjusted)

Source:
TVT Unpublished Data

30-day Mortality/Volume
Sites with index TAVR from 2016 onwards are removed

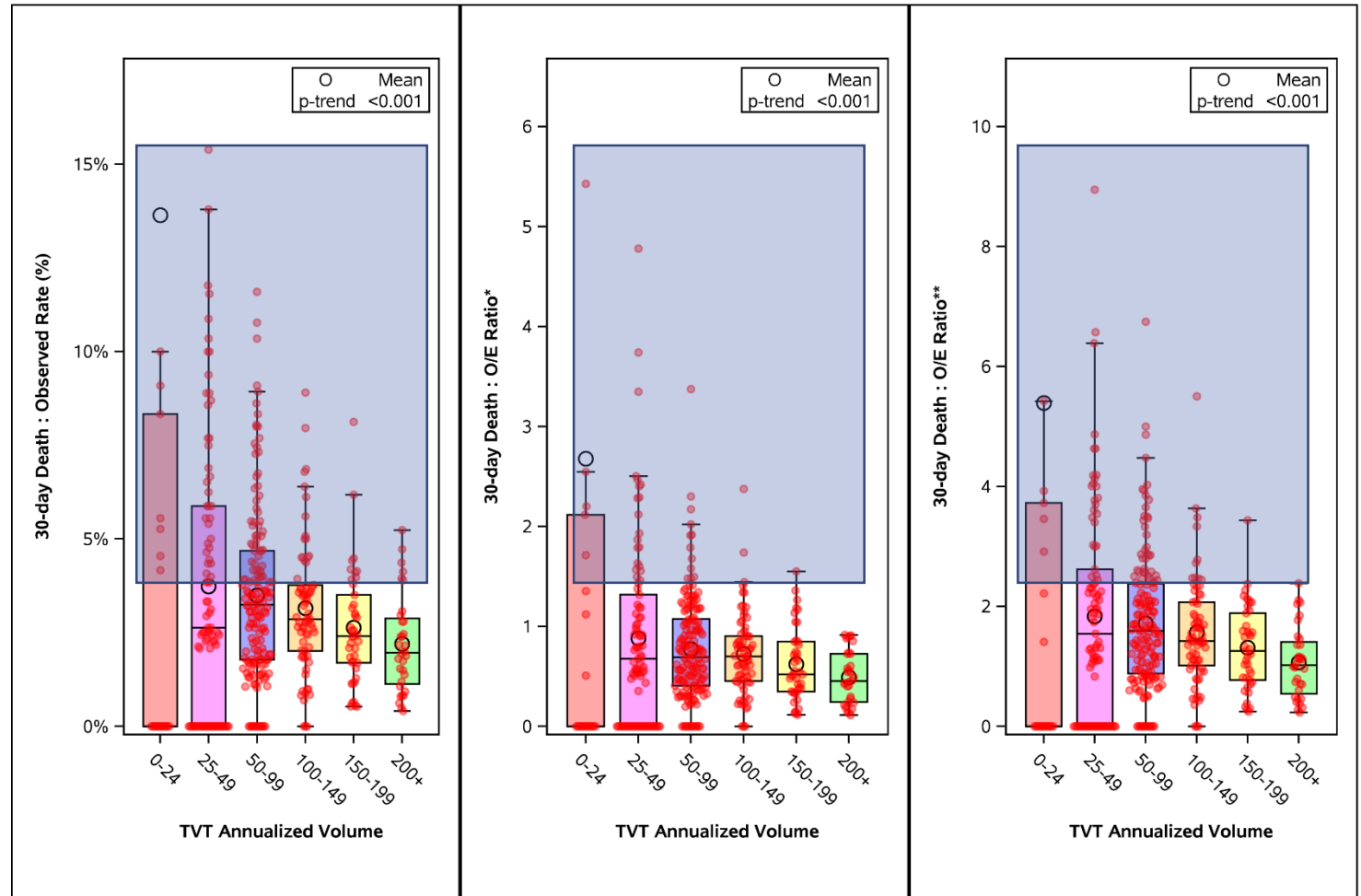


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Sites with O/E Ratio* >15 are not displayed (n=2; 0-24)
Sites with O/E Ratio** >10 are not displayed (n=3; 0-24)

Signal and/or uncertain statistical validity?

Variability of 30 Day Outcomes (non-risk adjusted)

Source:
TVT Unpublished Data



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)

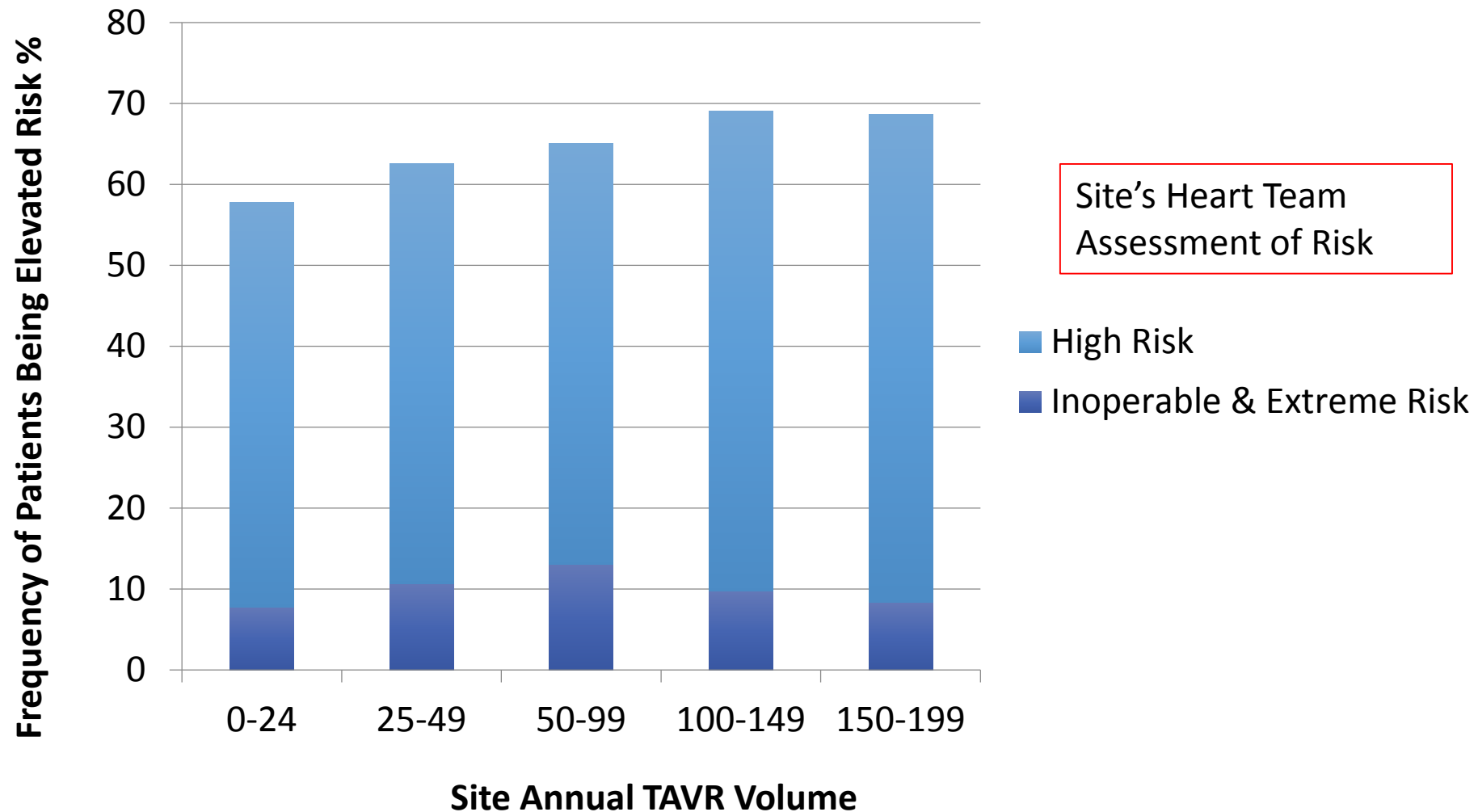
Sites with O/E Ratio* >15 are not displayed (n=2; 0-24)

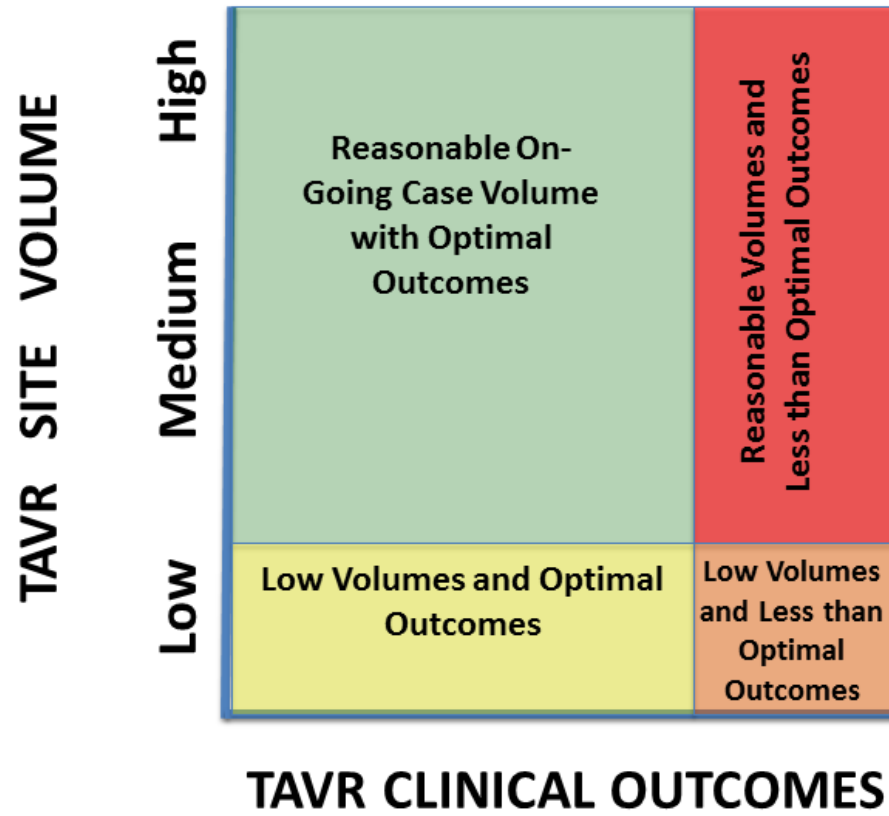
Sites with O/E Ratio** >10 are not displayed (n=3; 0-24)

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





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

TAVR SITE VOLUME	High	Reasonable On-Going Case Volume with Optimal Outcomes	Reasonable Volumes and Less than Optimal Outcomes
	Medium		
	Low	Low Volumes and Optimal Outcomes	Low Volumes and Less than Optimal Outcomes
		TAVR CLINICAL OUTCOMES	

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

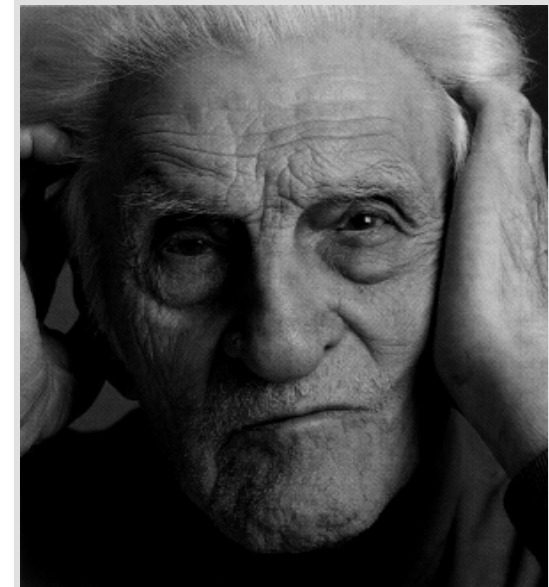
Why Does Volume Matter

- Significant questions remain about what causes variation
- Causes of poor outcomes needs 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

Why is quality highly variable?

- Does variability smooth out without enough cases?
- Are there common variables among sites with higher mortality?
 - Patient selection
 - Experience – cumulative site and operator
 - Number of operators
 - Team processes
 - Institutional resources

Where to invest quality improvement resources?

- Highest O/E mortality
- Highest absolute number of deaths
- Case review of each death among all sites

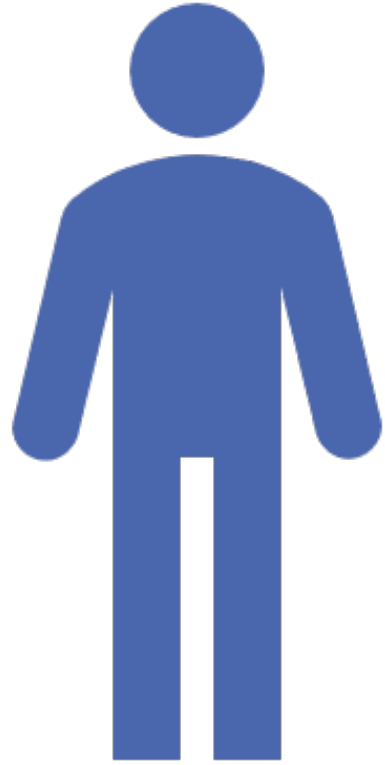
Example of Low Volume Reporting Exclusions

Surgeon Results

Surgeon	In-Hospital Mortality				30-Day Readmission		
	Total Number of Cases	Actual Percent	Expected Range	Rating	Actual Percent	Expected Range	Rating
Bavaria, Joseph E.							
CABG without Valve	6	NR	NR	NR	NR	NR	NR
Total Valve	241	1.2%	0.4% - 3.3%	⊙	7.2%	6.3% - 16.2%	⊙
Valve without CABG	199	0.5%	0.0% - 2.5%	⊙	7.8%	5.6% - 16.7%	⊙
Valve with CABG	42	4.8%	0.0% - 9.5%	⊙	NR	NR	NR



Process
Requirements



Patient Voice and Selection

- MDT review
- Patient selection/appropriate use
- Shared decision making

Outcome Requirements

Quality Metric Focus

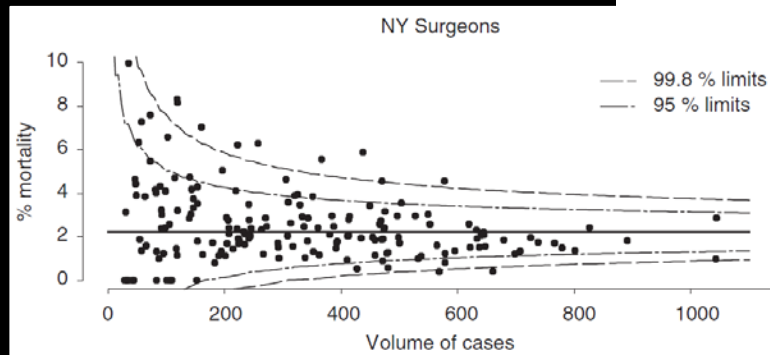
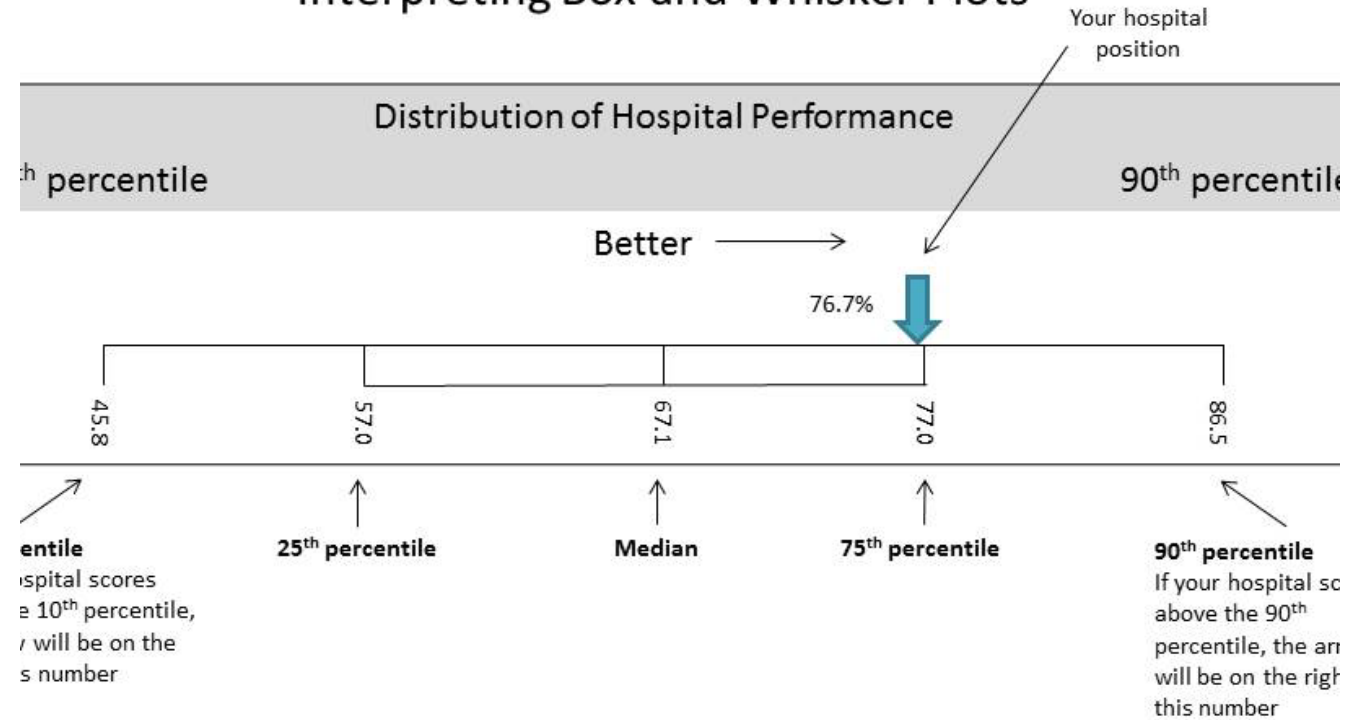
Mortality	Complications	Quality of Life
In hospital 30 day One year (in development) All risk adjusted	Stroke-TIA Bleeding Vascular complications Pacemaker	KCCQ

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

Interpreting Box and Whisker Plots



CABG Results					
Year	Overall Composite Score*	Absence of Operative Mortality	Absence of Major Morbidity	Use of Internal Mammary Artery	Receipt of Required Perioperative Medications
July 2015 - June 2016	★ ★ 92.7	★ ★ 92.2	★ ★ 91.1	★ ★ 99.5	★ ★ ★ 99.5
July 2016 - June 2017	★ ★ 91.7	★ ★ 91.6	★ ★ 92.2	★ ★ 99.5	★ ★ ★ 99.2

AVR Results			
Year	Overall Composite Score**	Absence of Operative Mortality	Absence of Major Morbidity
July 2014 - June 2017	★ ★ ★ 91.9	★ ★ 98.1	★ ★ 92.1

AVR + CABG Results			
Year	Overall Composite Score***	Absence of Operative Mortality	Absence of Major Morbidity
July 2014 - June 2017	★ ★ 93.2	★ ★ 95.7	★ ★ 95.6



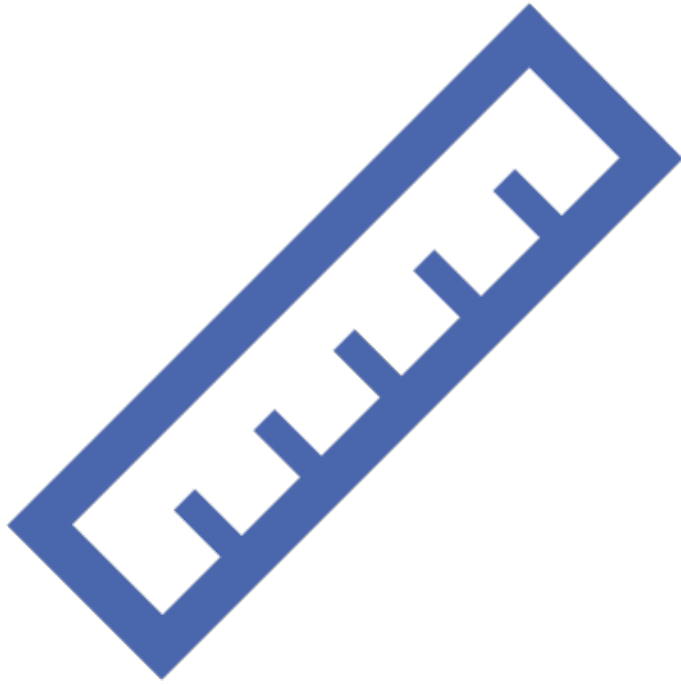
Registry Role

- 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

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

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

≥50 cases per year or 100 cases
over 2 years

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.

Active institutional participation
in the STS/ACC TVT Registry and
STS National Database or a
validated state/multi-
institutional consortium registry

MDT quarterly meetings

Documentation of incorporation
of TAVR/SAVR AUC in the
patient selection process

All MDT members will
participate in appropriate CME
annually

Overview for Maintaining Program

Institutional Experience to Maintain Program

PCI

- ≥ 300 PCIs/year
- Active participation in the NCDR/Cath PCI Registry or a validated state/multi-institutional consortium that gathers and reports risk-adjusted and benchmarked outcomes
- PCI in-hospital risk-adjusted mortality (NQF endorsed) above the bottom 25th percentile for 4 consecutive quarters.

Vascular interventions

- Experienced and competent physicians in vascular arterial interventions

Pacemaker capabilities

- Experienced and competent physicians for temporary and permanent pacemaker placement and management.
- On-site services available 24 hours/day and 7 days/week to handle conduction disturbances as a result of TAVR

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

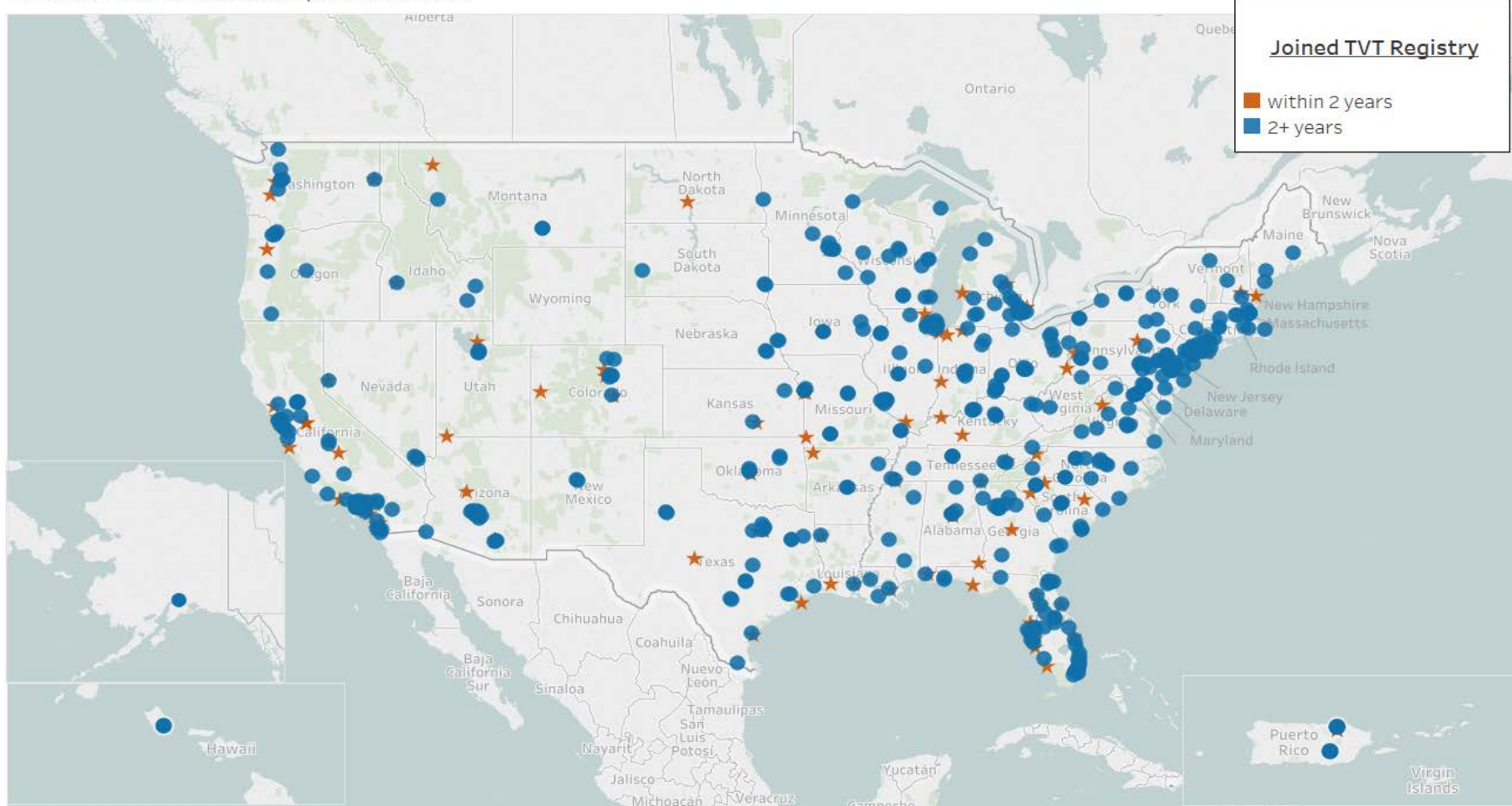
- Requirements focus on access to quality care
- Volume requirements to assess quality **are not restrictive** but based on the need for statistical reliability
- All centers should have a program to achieve a steady history of quality outcomes using rolling year volumes

ACCESS:

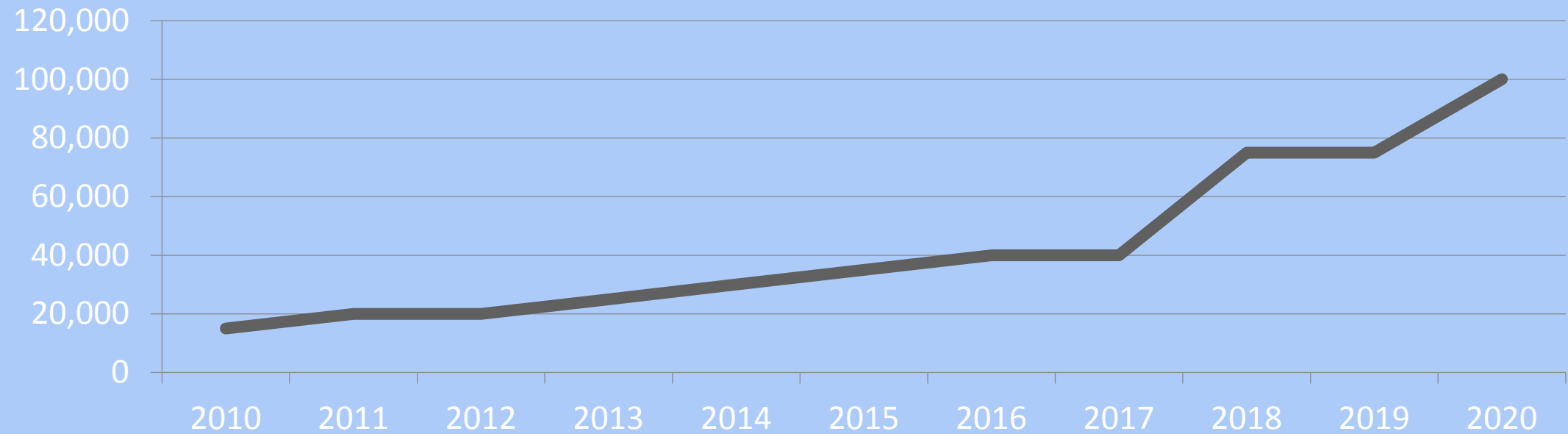
New TAVR Sites Opening in the Last Two Years: Some Appear to Be in Geographically “Underserved” Areas and Some are in Regions with Many Other TAVR Programs

TVT Registry Site Distribution

579 institutions in 51 states/U.S. territories



PROJECTED TAVR GROWTH



VOLUME/CENTER

PROC US	CENTERS	YEARLY	WEEKLY
NUMBER	US	proc/center/yr	proc/week
15,000	350	43	<1/week
50,000	500	100	2
50,000	350	150	3
100,000	500	200	4

TVT Demographics

Age*	Median	82
	25th	75
	75th	86

Race	Missing	1.5%
	White	93.1%
	Black/African American	3.8%
	Asian	1.2%
	Other	0.4%

Sex	Male	54.3%
	Female	45.7%

Hispanic or Latino Ethnicity	Missing	1.9%
	No	93.8%
	Yes	4.3%

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

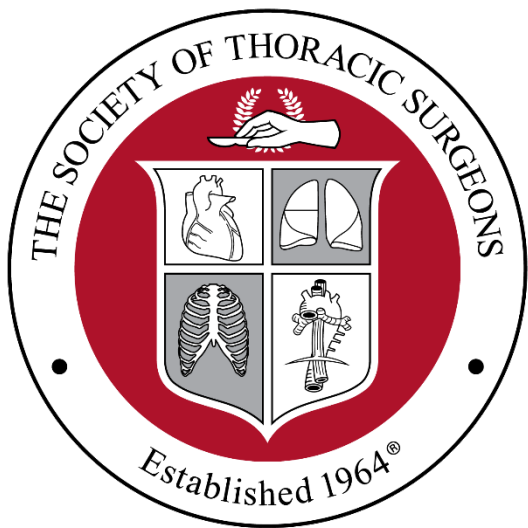
Volume required to assess quality

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



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