Perspective on the state of evidence regarding procedural volume requirements for hospitals to maintain and start TAVR programs

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Disclosure

I, Larry L. Wood, am an employee of Edwards Lifesciences. I receive compensation in the form of salary and equity.

Draft Expert Consensus Documents have significant health policy and patient access implications

2017 AATS/ACC/ASE/SCAI/STS Expert Consensus System of Care Draft Documents
(Operator and Institutional TAVR Requirements and Optimizing Care for VHD Patients)

MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2017 AATS/ACC/ASE/SCAI/STS Expert Consensus Systems of Care Document
A Proposal to Optimize Care for Patients with Valvular Heart Disease

A Joint Report of the American Association for Thoracic Surgery, American College of Cardiology, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

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MULTISOCIETY EXPERT CONSENSUS SYSTEMS OF CARE DOCUMENT

2017 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Requirements for Transcatheter Aortic Valve Replacement

A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons

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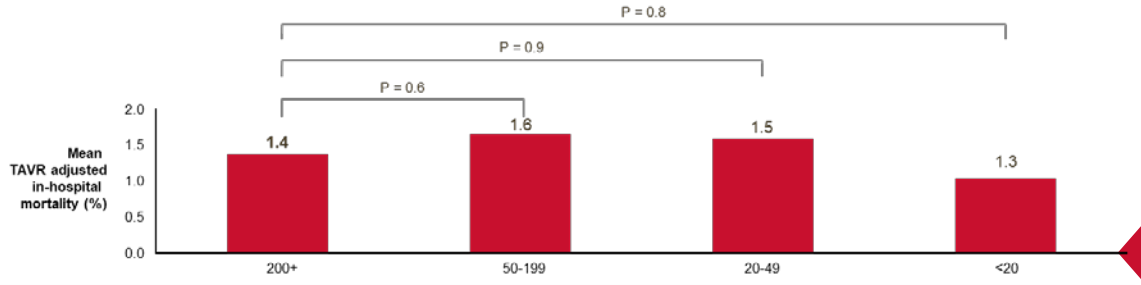
Low confidence in evidence supporting volume thresholds

Current Society Expert Consensus Documents are based on expert opinion with **limited** and **insufficient** supporting evidence.

The **harms** of limiting access to TAVR by requiring certain volume thresholds **outweighs** the proposed **benefits**. Volume requirements **create unintended barriers** to undertreated populations.

Intuitively, volume outcome relationships make sense



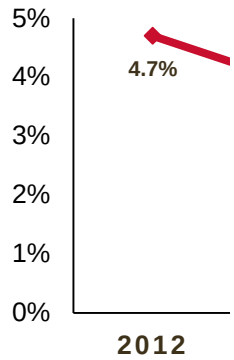
2016 TAVR center volumes				
# of centers	33	261	134	62
95% confidence interval	(1.14, 1.70)	(1.36, 1.78)	(1.05, 1.89)	(0.29, 2.23)
Percent of TAVR volumes (adjusted)	7%	53%	27%	13%

Data Source: 2016 100% SAF Medicare. Center volumes based on Medicare Fee-For-Service claims adjusted for Medicare Advantage and private pay share from MEDPAR/HCUP.

See appendix for risk adjustment methodology.

Except when you look at contemporary data

Expanding TAVR centers has not compromised TAVR outcomes



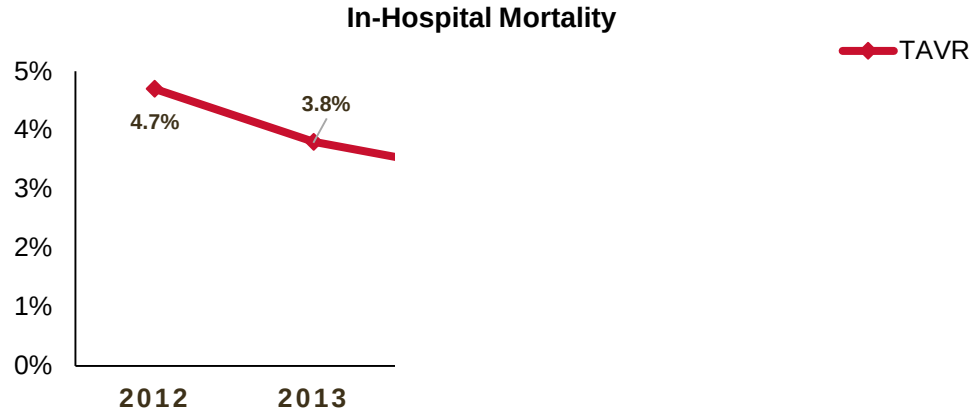
N	TAVR Centers	106

In-Hospital Mortality

TAVR

Source: MedPAR FY2012-FY2017

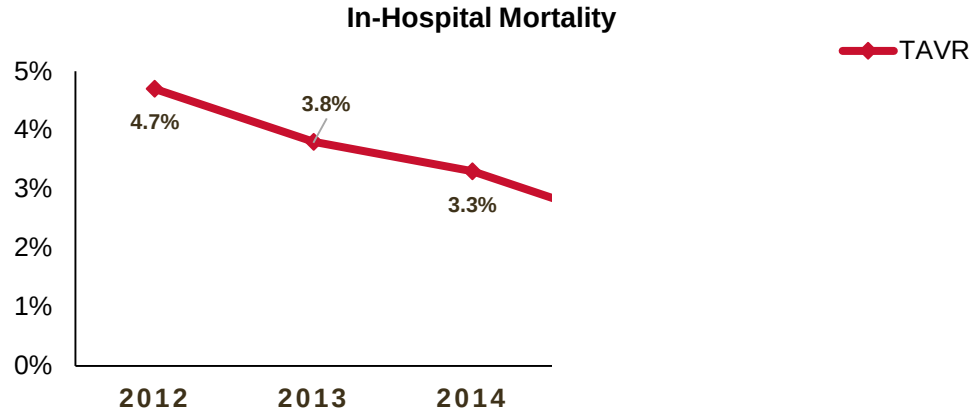
Expanding TAVR centers has not compromised TAVR outcomes



N	TAVR Centers	106	178

Source: MedPAR FY2012-FY2017

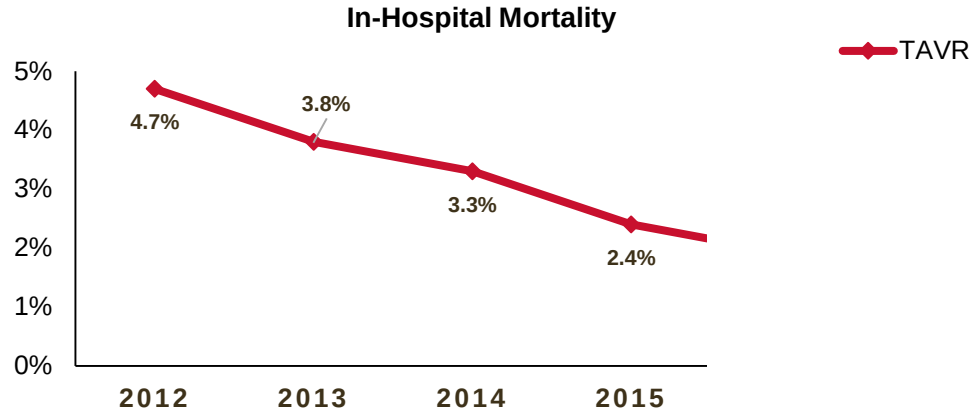
Expanding TAVR centers has not compromised TAVR outcomes



N	TAVR Centers	106	178	239

Source: MedPAR FY2012-FY2017

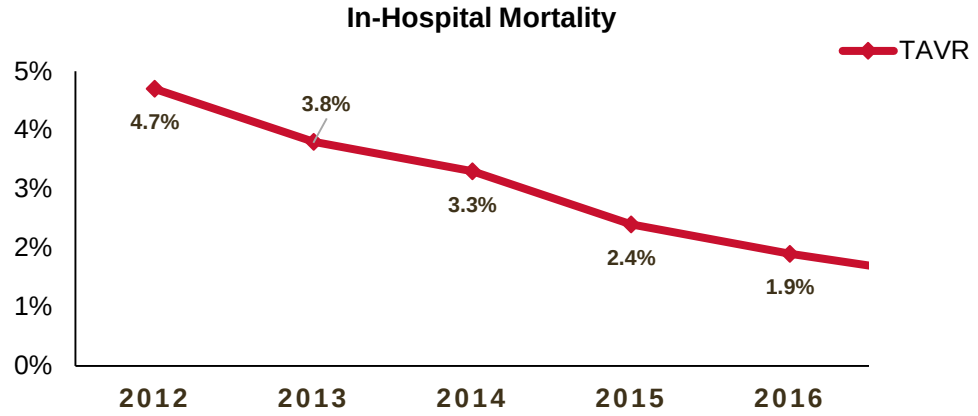
Expanding TAVR centers has not compromised TAVR outcomes



N	TAVR Centers	106	178	239	344

Source: MedPAR FY2012-FY2017

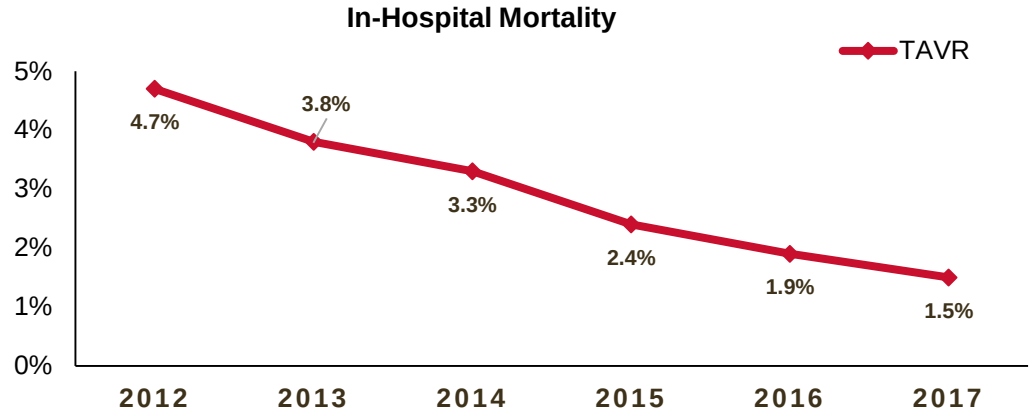
Expanding TAVR centers has not compromised TAVR outcomes



N	TAVR Centers	106	178	239	344	463

Source: MedPAR FY2012-FY2017

Expanding TAVR centers has not compromised TAVR outcomes

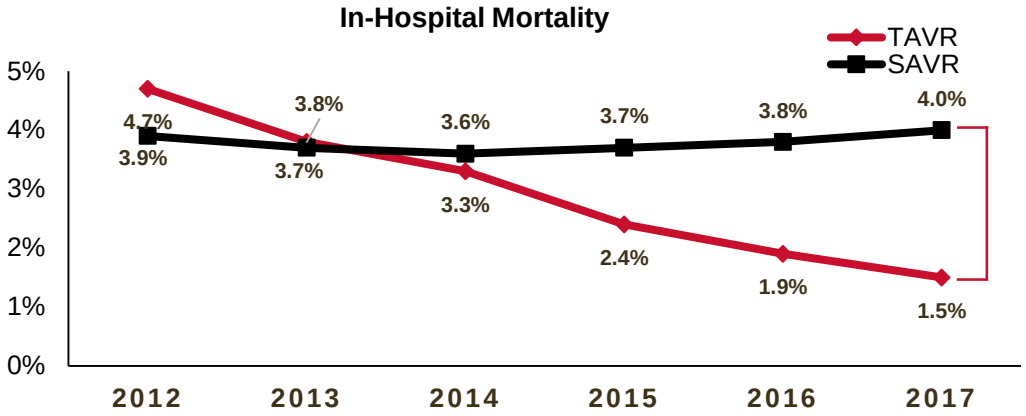


N	TAVR Centers	106	178	239	344	463	540

We started with the 100 most experienced centers, and since then, we have added more than 400 new centers, and outcomes have **improved 3X**

Source: MedPAR FY2012-FY2017

Despite higher risk profiles, TAVR shows continuous improvement in mortality over time



Age	SAVR	76	76	75	75	74	73
	TAVR	83	83	83	83	82	81
Charlson Index	SAVR	2.23	2.22	2.22	2.24	2.17	2.33
	TAVR	3.30	3.24	3.32	3.25	3.10	3.13

Even if adding new centers **doubles TAVR mortality**, it would still be **25% better** than surgery

Source: MedPAR FY2012-FY2017

Most experts agree TAVR is going to be the preferred treatment option

"Operable, high-risk patients get TAVR. I'm a surgeon saying that. I've already done the [PARTNER cohort A] trial, and I don't want to do it again," said Dr. Michael Mack, a cardiothoracic surgeon at the Heart Hospital in Plano, Texas. "The results are the same [from TAVR and SAVR] at 30 days, 1 year, and 2 years, but boy do we beat up patients with open surgery. **If it was my mom, she'd get TAVR**," he said in an interview. "**The tie goes to the less invasive treatment**."

Michael Mack
Cardiology News
May 14, 2013

In the over 3000 intermediate-risk patients we have presented in the last 2 days, we've shown that there is strong evidence" that in this population, Sapien 3 TAVR vs surgery "improves clinical outcomes and is the preferred therapy," he said. "**We have to ask: do we think this is a move forward for the betterment of patients? And I would say the answer is a definitive yes**," said Thourani.

Vinod Thourani, speaking to Medscape around his ACC presentation on S3
April 5, 2016

"**I think transcatheter valve technology is going to rule.** It's a great technology, a radical, revolutionary technology. You don't have to open up the chest and put somebody on a heart-lung machine. **In the future — I can't tell you when, but at some time — most aortic valve procedures will be done through a transcatheter approach.**"

Joseph E. Bavaria
The Washington Post
June 10, 2018

"We generally go with TAVR. Most patients want it, and with the equivalence [in outcomes] you usually go with the less invasive procedure."

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Volume quotas are the antithesis of shared decision making

- On Nov 15, 82 year old patient, is referred for AVR evaluation at a **center that is at risk of losing its TAVR program for not meeting volume quota**
- Between Jan 1 – Nov 14, center has performed:
  - 52 TAVRs (2 over volume threshold)
  - 25 SAVRs (5 below volume threshold)
- Hospital dilemma:
  - Perform TAVR and jeopardize TAVR program due to not meeting volume quota?
  - Perform unnecessary SAVR to work towards meeting volume quota?
- By not meeting SAVR volume quota, the center will lose its TAVR program and keep its SAVR program

Picture of actual TAVR patient – Chief Earnest Tate, First African American Police Chief in Selma, AL - Retired

Volume quotas are the antithesis of shared decision making

Patients should be treated as individuals. Treatment decisions should be based on what is best for the patient. **Arbitrary volume quotas should not be a consideration.**

Appendix

Methodology for adjusting in-hospital mortality

- Identified inpatient primary and secondary claims and relevant cardiac procedures on the index admission used to develop a risk adjusted model (RAM) for inpatient mortality
- Categorized ICD9/10 codes in HCC categories
- Model covariates were selected via lasso with forced demographic variables in order to incorporate as many predictors as possible to improve model fit, prediction and power
- Fit the hierarchical models to the data for each condition separately using in-hospital mortality associated with the index procedure (i.e. SAVR or TAVR) as the outcome
- Utilized standardization (ratio of observed/expected *standard; the standard rate was from all hospitals in this population, expected rate is calculated from the model) to adjust mortality[1]
  - Output is akin to showing if this ‘hospital taken on the risk profile of an “average” hospital, what would mortality look like ’
  - Leverages semi-Bayesein methods to adjust for small volumes with clustered model
- Separate models were run for SAVR, TAVR, and PCI
- Pressure tested results with marginal GEE model to further control for small centers[2]

1 Drye 2013, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319769/
2 Truong 2017, https://link.springer.com/article/10.1186/s13063-017-2248-1

Backup: Covariates and AUC for risk-adjustment model

Variables in the final model

- Gender
- Race
- Region
- Age (categorical)
- CCI (categorical)
- CABG
- MVR/r
- TVR/r
- MAZE
- PCI
- Sepsis
- Metatstatic cancer
- Protein calorie malnutrition
- Liver disease
- Immunity disorders
- Drug/alcohol dependence
- MS
- CHF
- Heart arrhythmias
- Vascular disease
- COPD
- Chronic lung
- Renal disease
- Head injury
- Facility (cluster)