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

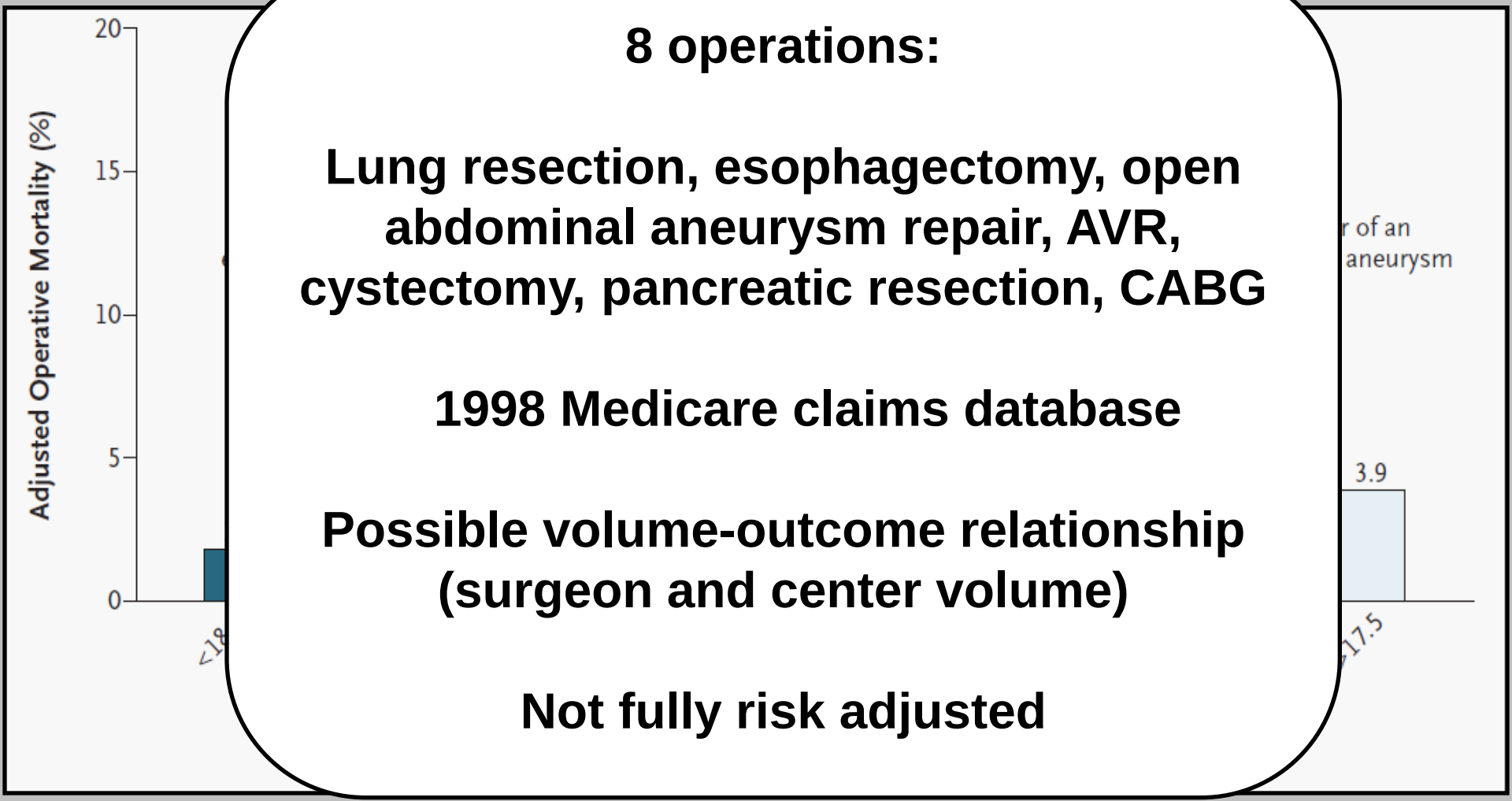
Setting a New Standard for Hospital Accreditation—Together

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

NEJM 2003;349:2117-27

ACCF/AHA/SCAI 2013 Update of the Clinical Competence Stater

A Report
American
to Revise

ttee

Writing Committee Members

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SCAI
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†Society for
‡American Heart Association representative

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**

JACC 2013;62:357-96

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)

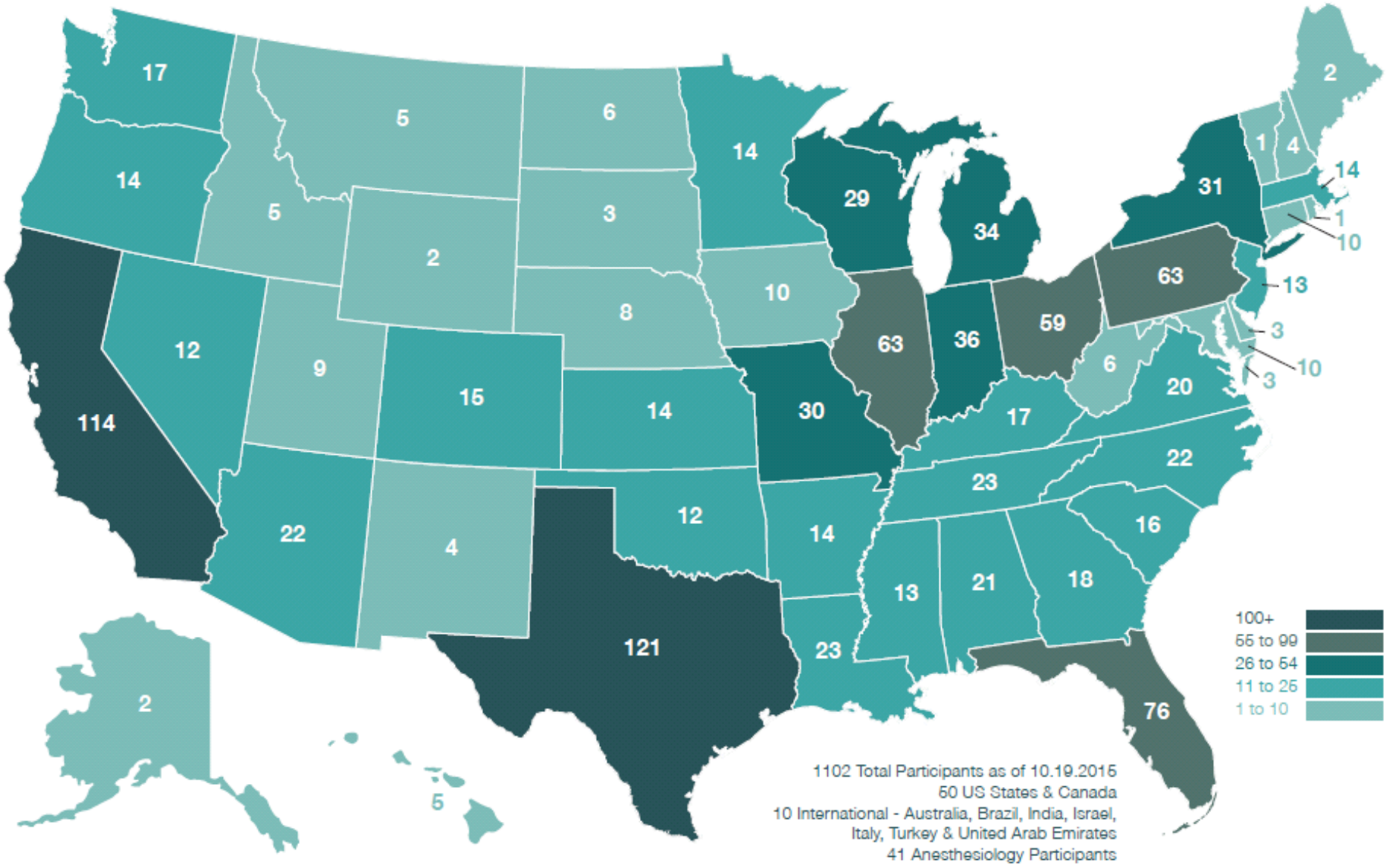
JACC Intv 2016;9:2077-85

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 10.19.2015
50 US States & Canada
10 International - Australia, Brazil, India, Israel, Italy, Turkey & United Arab Emirates
41 Anesthesiology Participants

The Society of Thoracic Surgeons Adult Cardiac Surgery Database

- ***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”:

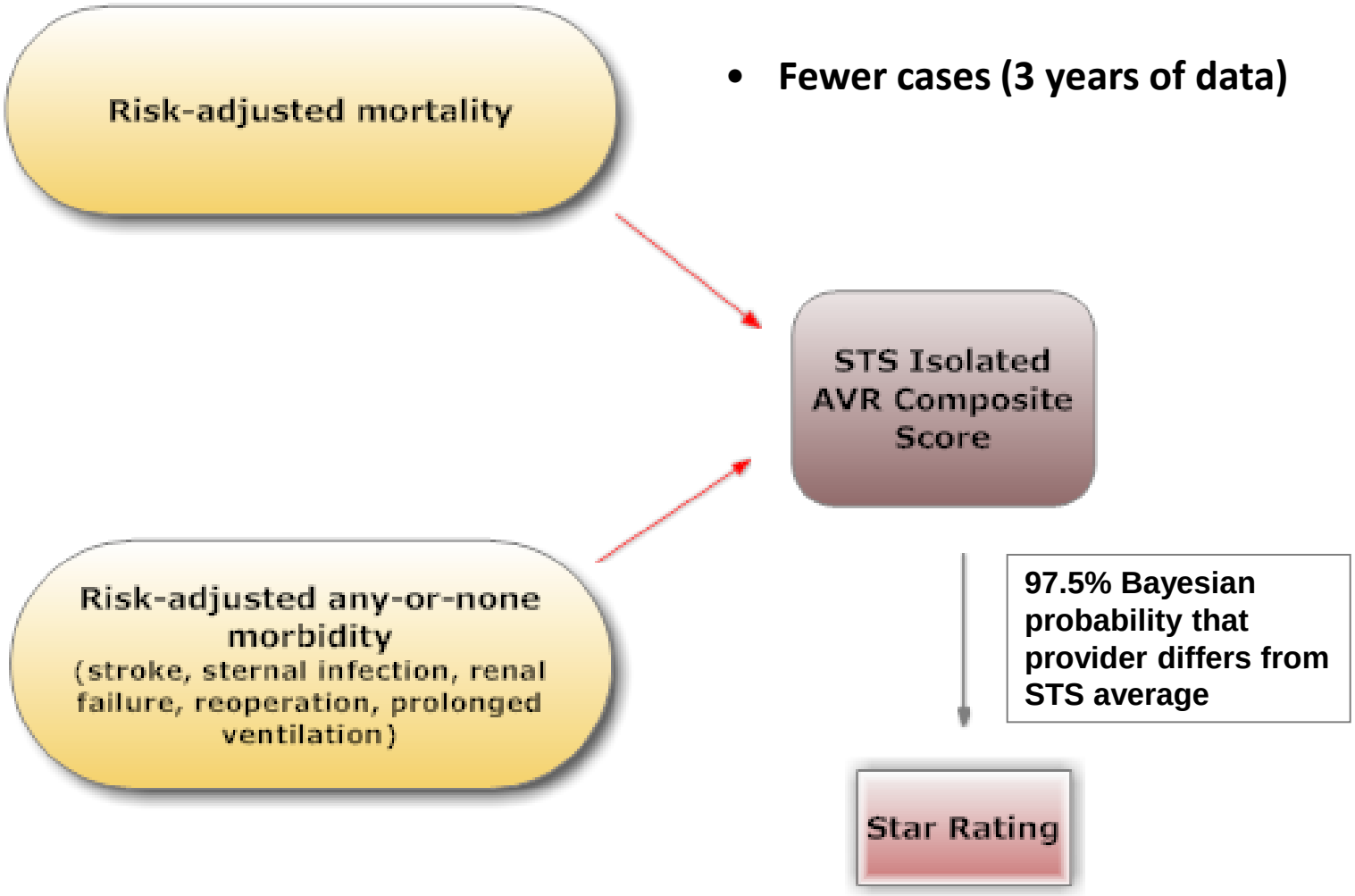
1 Star program – lowest performance
2 Star program – “as-expected” performance
3 Star program – highest performance

STS AVR Composite Score

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

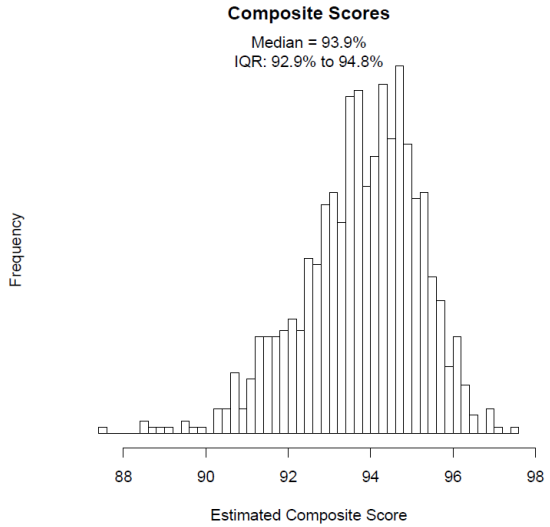
- Note: Transcatheter Aortic Valve procedures are not included in the AVR Composite Score

STS AVR Composite Score



- **Fewer cases (3 years of data)**

STS AVR Composite Score



		2012 H 3	2013 H 1	2013 H 3	2014 H 1	2014 H 3	2015 H 1	2015 H 3
Star Rating	1	3%	3%	2.7%	3.35%	3.85%	4.22%	3.77%
	2	91%	91%	91.4%	88.98%	87.58%	87.89%	88.36%
	3	6%	6%	5.9%	7.67%	8.57%	7.89%	7.87%

ConsumerReportsHealth

Consumer Reports

Safety | **Patient Experience** | **Heart Surgery** | **Maternity**

These Ratings were derived from data submitted by hospitals to The Society of Thoracic Surgeons. The Ratings are based on data from the medical records of patients, considered the "gold standard" for quality measurement. The methods used to derive these Ratings have been endorsed by The National Quality Forum, a nonprofit organization that endorses consensus standards for measuring and publicly reporting

Ratings Key: ● ABOVE AVERAGE ○ AVERAGE ● BELOW AVERAGE

Overall Heart Bypass Surgery Performance	●
Patient Survival Patients have a 98% chance of surviving at least 30 days after the procedure and of being discharged from the hospital.	●
Avoiding Major Complications Patients have a 89% chance of avoiding all five of the major complications.	○
Recommended Medications Patients have a 96% chance of receiving all four of the recommended medications.	●
Optimal Surgical Technique Patients have a 99% chance of receiving at least one optimal surgical graft.	●

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

Overall Aortic Valve Replacement Surgery	●
Patient Survival Patients have a 98% chance of surviving at least 30 days after the procedure and of being discharged from the hospital.	●
Avoiding Major Complications Patients have a 89% chance of avoiding all five of the major complications.	●

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

These data come from The Society of Thoracic Surgeons Adult Cardiac Surgery Database and its participants. They provide important information to be considered, among other factors, in choosing a health care provider.

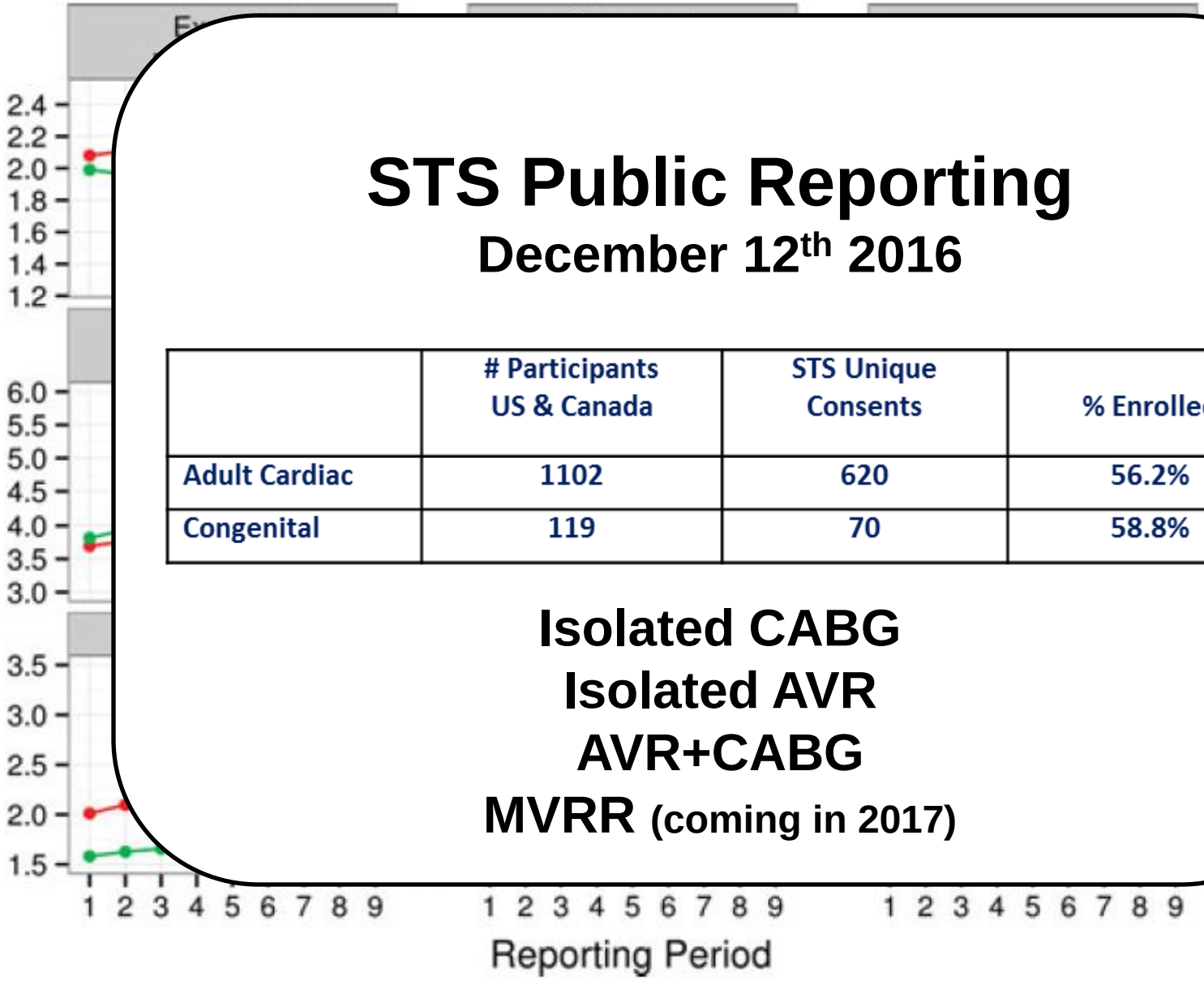
No Evidence of Risk Aversion

STS Public Reporting

December 12th 2016

	# Participants US & Canada	STS Unique Consents	% Enrolled
Adult Cardiac	1102	620	56.2%
Congenital	119	70	58.8%

Isolated CABG
Isolated AVR
AVR+CABG
MVRR (coming in 2017)



OUTCOMES

2005 to 2014

Outcomes	CABG (n = 144,940)	AVR (n = 29,158)	AVR + CABG (n = 18,016)	MVR (n = 6,857)	MVR + CABG (n = 2,582)	MV Repair (n = 8.658)	MV Repair + CABG (n = 4,205)
Mortality, %							
In-hospital	1.7	1.9	3.2	4.2	9.2	1.0	4.3
Operative[a]	2.1	2.4	3.9	4.9	9.9	1.2	5.1
Major morbidity, %							
Reoperation[b]	2.3	3.9	4.7	5.8	7.5	2.7	5.4
DSWI/mediastinitis	0.3	0.2	0.2	0.1	0.4	0.1	0.3
Permanent stroke	1.3	1.1	2.3	2.0	3.8	0.9	2.5
Prolonged ventilation >24 h	8.2	7.9	13.4	18.5	30.8	5.0	21.8
Renal failure	2.0	2.0	3.8	4.3	7.9	1.1	5.4

MVR + CABG	2,496	2,582	3
MV repair + CABG	4,518	4205	–7
AVR + MVR	1,032	1,851	79

Ann Thorac Surg 2016;101:24–32

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

Participant-Specific Adjusted Rate (%)

Ann Thorac Surg 2016;101:2265–71

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**

Circ Cardiovasc Qual Outcomes 2016;9:560-565

2016 Annual Report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

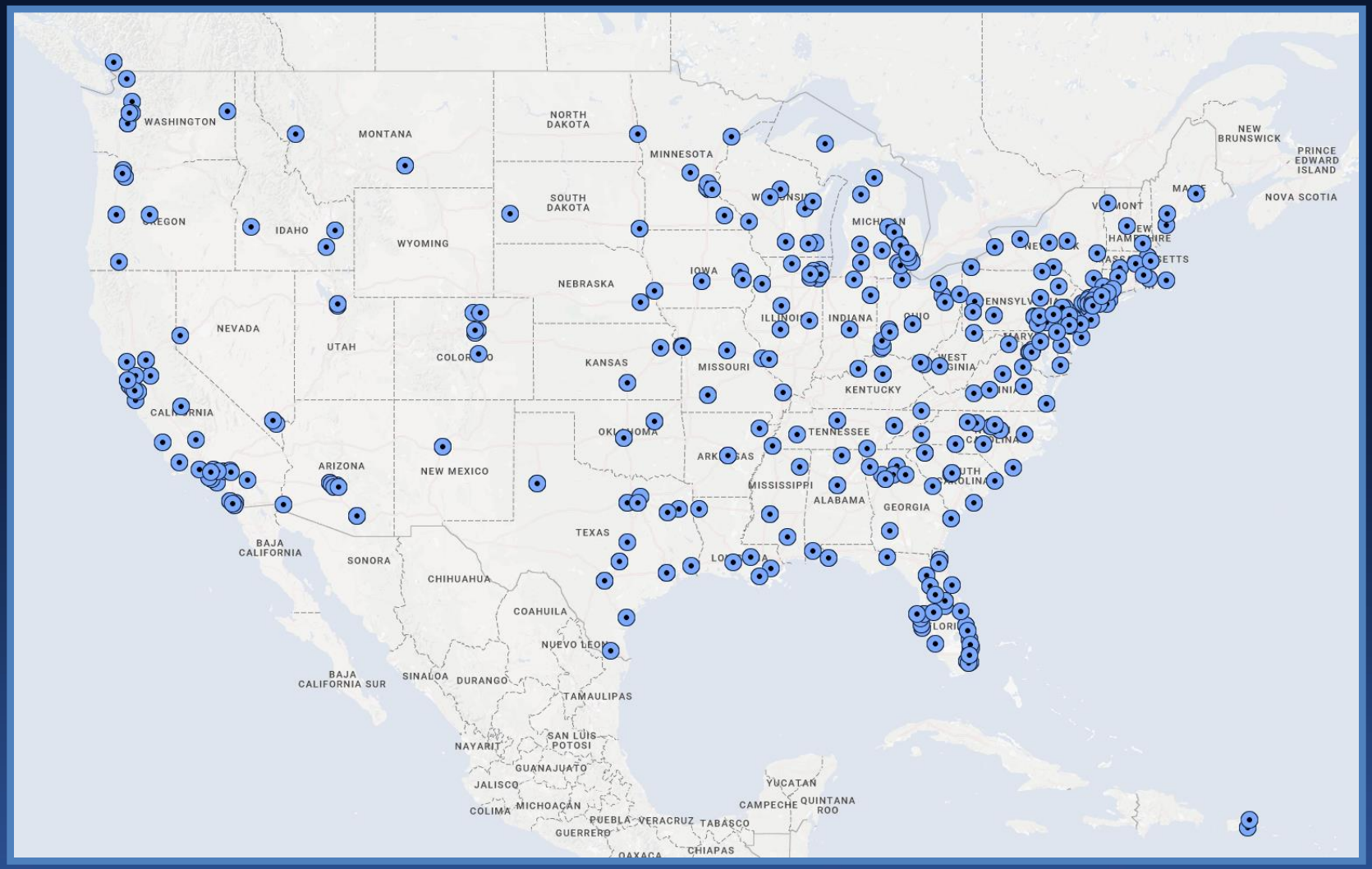
Running Head: Annual Report of the STS/ACC TVT Registry

Frederick L. Grover, MD[1] , Sreekanth Vemulapalli, MD[2], John D. Carroll, MD[3], Fred H. Edwards, MD[4], Michael J. Mack, MD,[5] Vinod H. Thourani, MD[6], Ralph G. Brindis, MD, MPH[7], David M. Shahian, MD[8], Carlos E. Ruiz, MD[9], Jeffrey P. Jacobs, MD[10] George Hanzel, MD[11], Joseph E. Bavaria, MD[12], E. Murat Tuzcu, MD[13],Eric D. Peterson, MD, MPH[2], Susan Fitzgerald, RN, MS[14], Matina Kourtis, MS[15] ,Joan Michaels, RN, MSN[14] , Barbara Christensen, MSHA, RN[14], William F. Seward, MA,[15] Kathleen Hewitt, MSN,RN, [14] and David R. Holmes, Jr, MD[16], for the STS/ACC TVT Registry

JACC 2016; 9 December – In press

Courtesy of V. Thourani

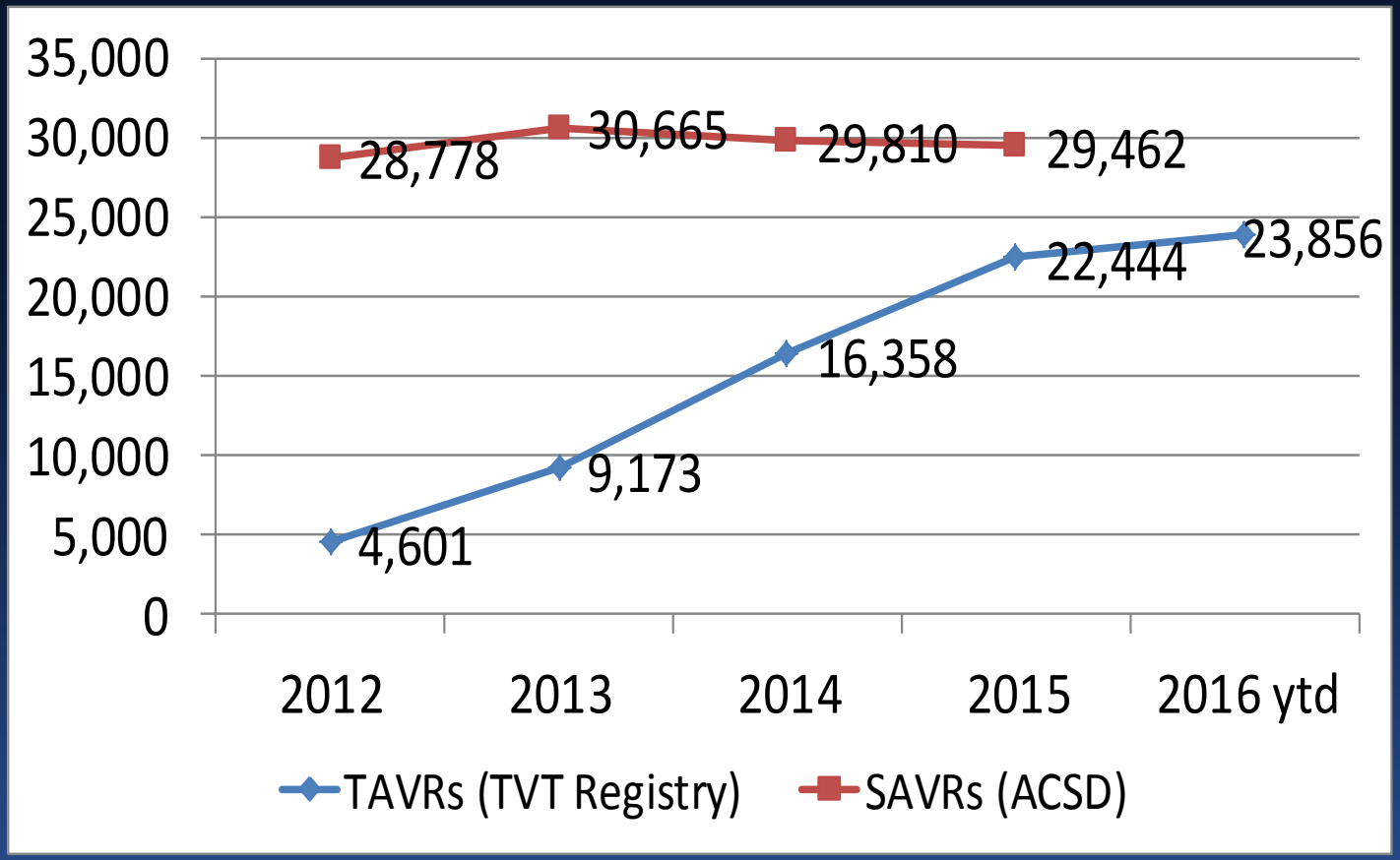
TAVR Sites in US = 477



Alaska: 1

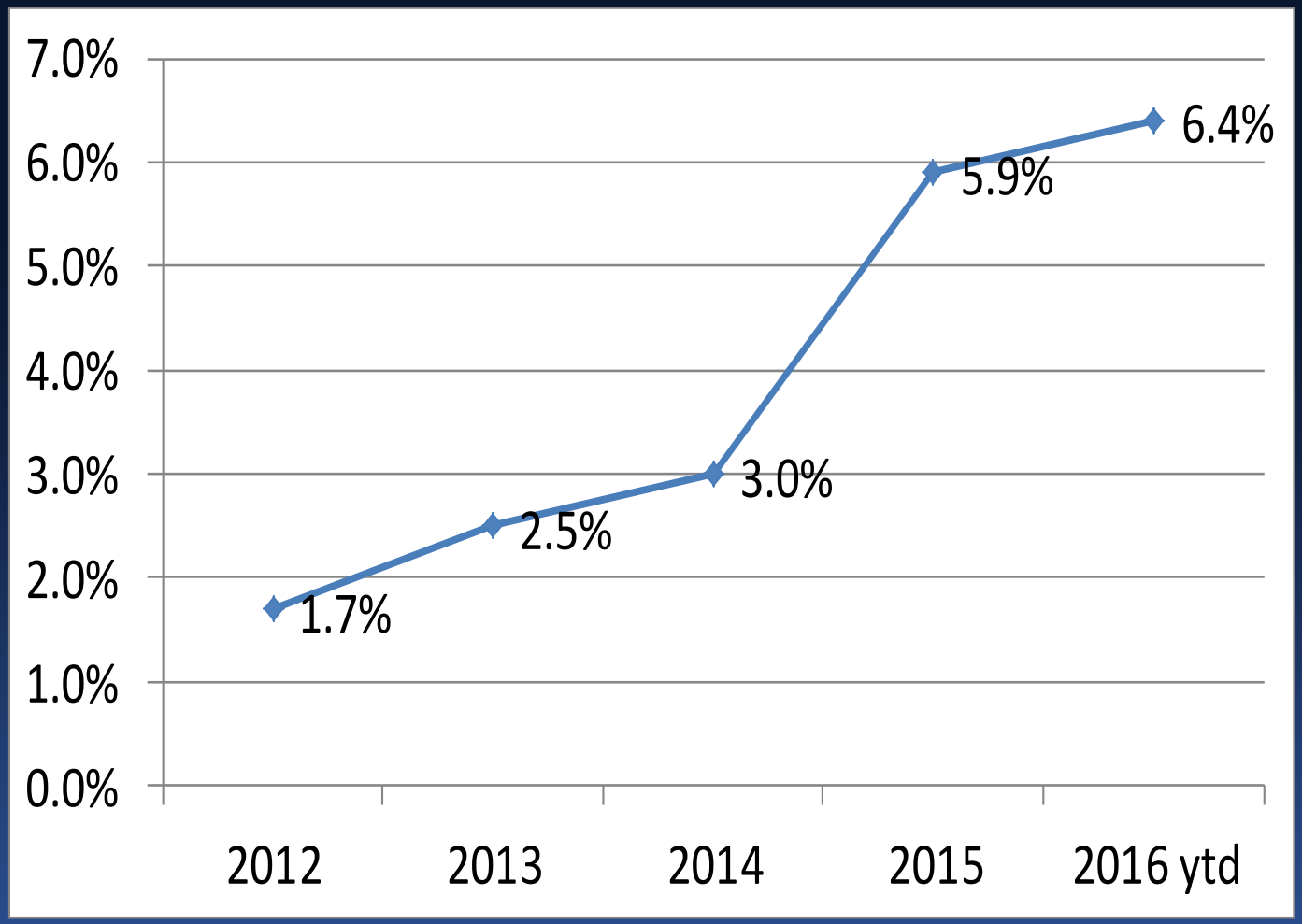
Hawaii: 1

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

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

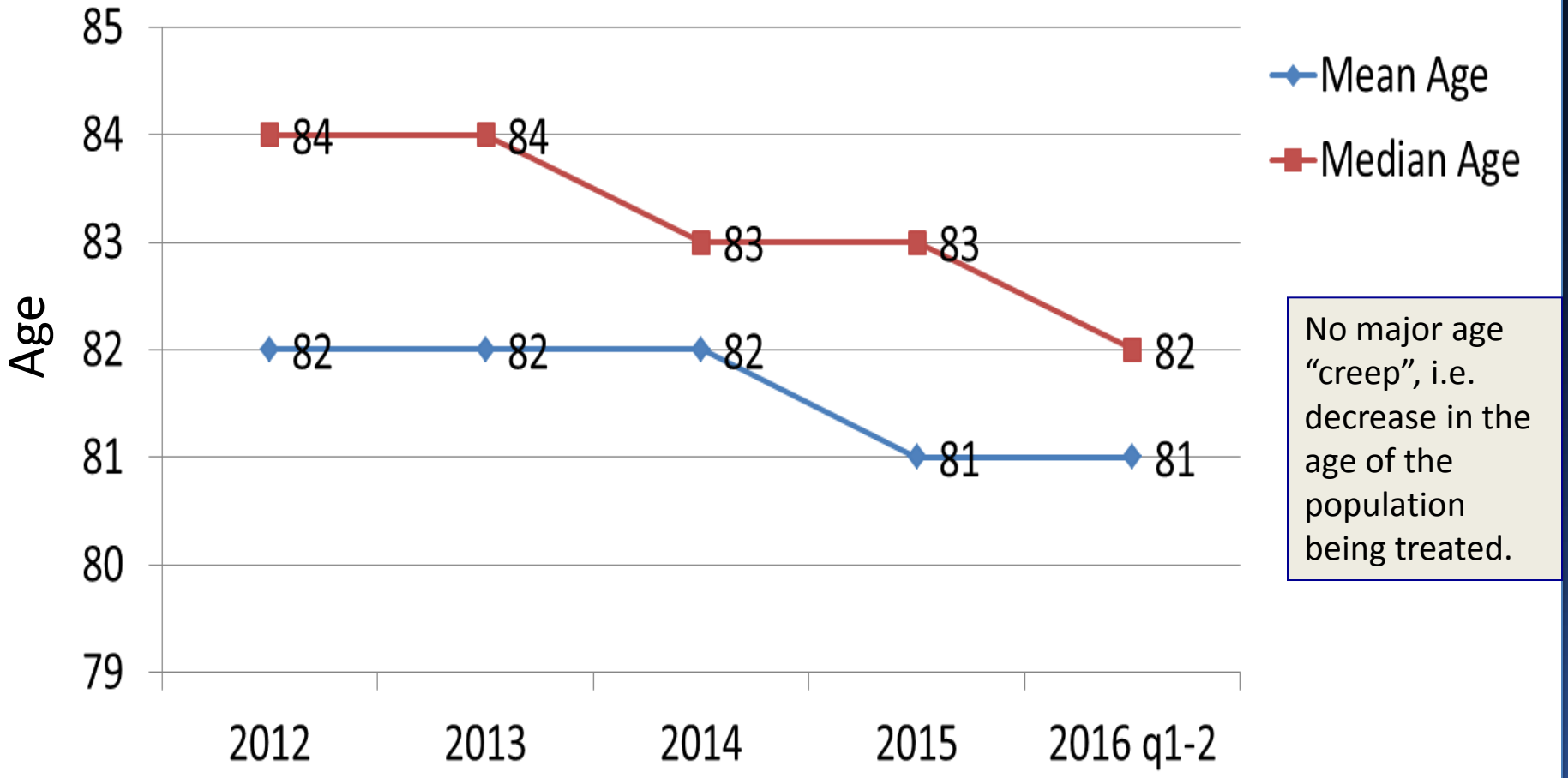


Represents predominantly TAVR performed for degenerated surgically implanted tissue valves.

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

Source: STS/ACC TVT Registry Database as of Oct 18, 2016

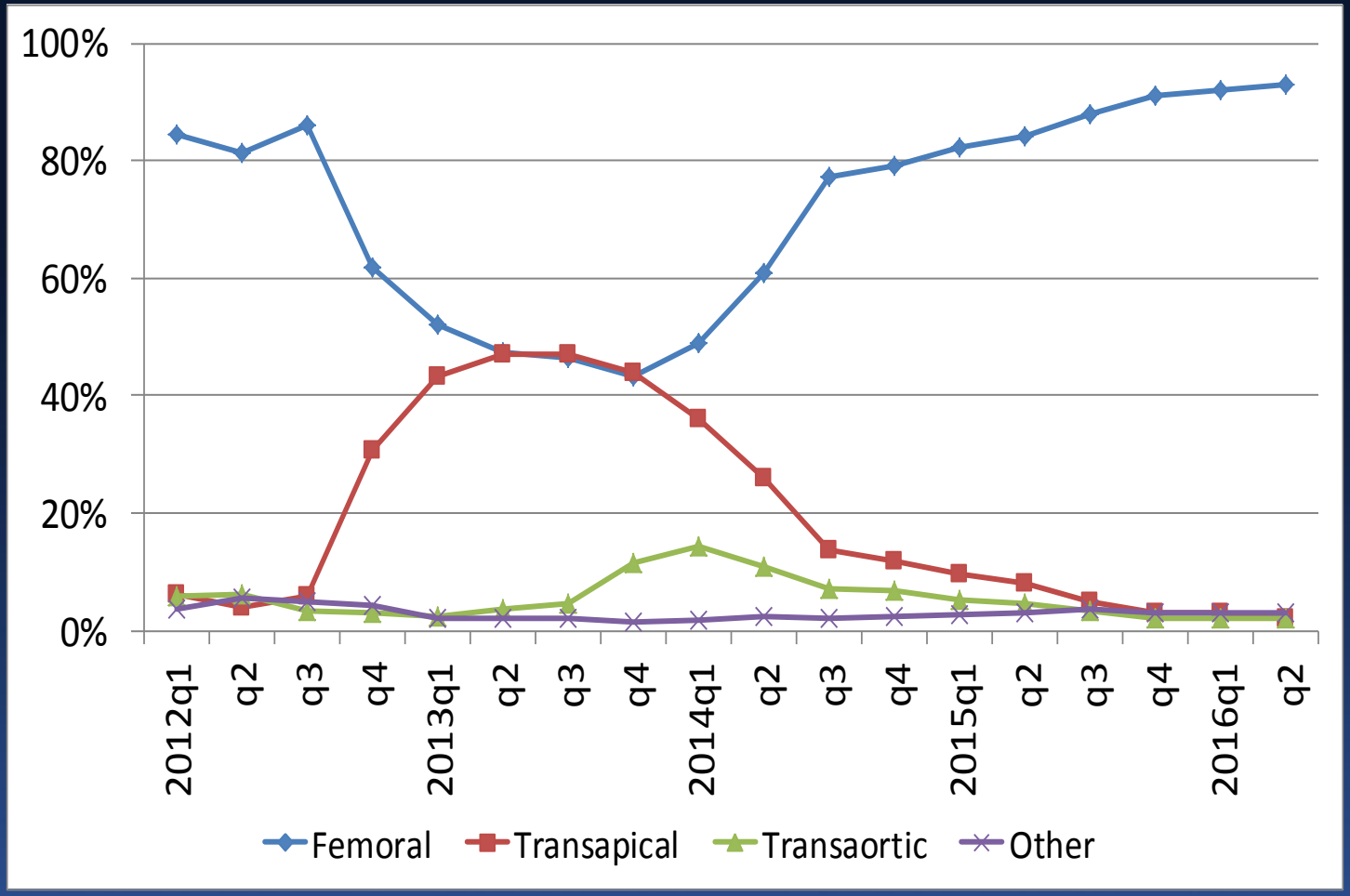
TAVR: Mean and Median Age



No major age "creep", i.e. decrease in the age of the population being treated.

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

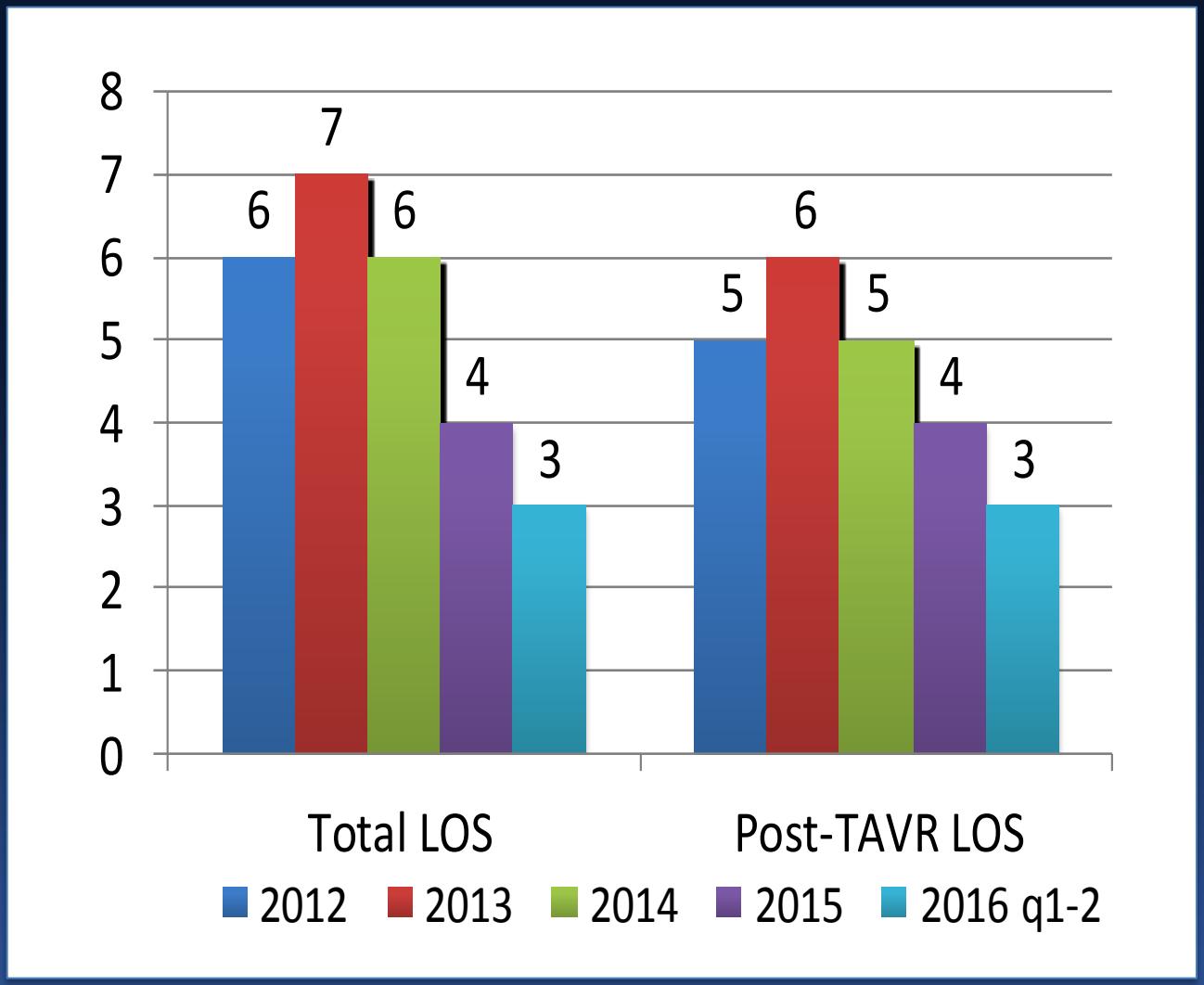
TAVR Access Site



A technology-enabled shift in access for TAVR continues to unfold.

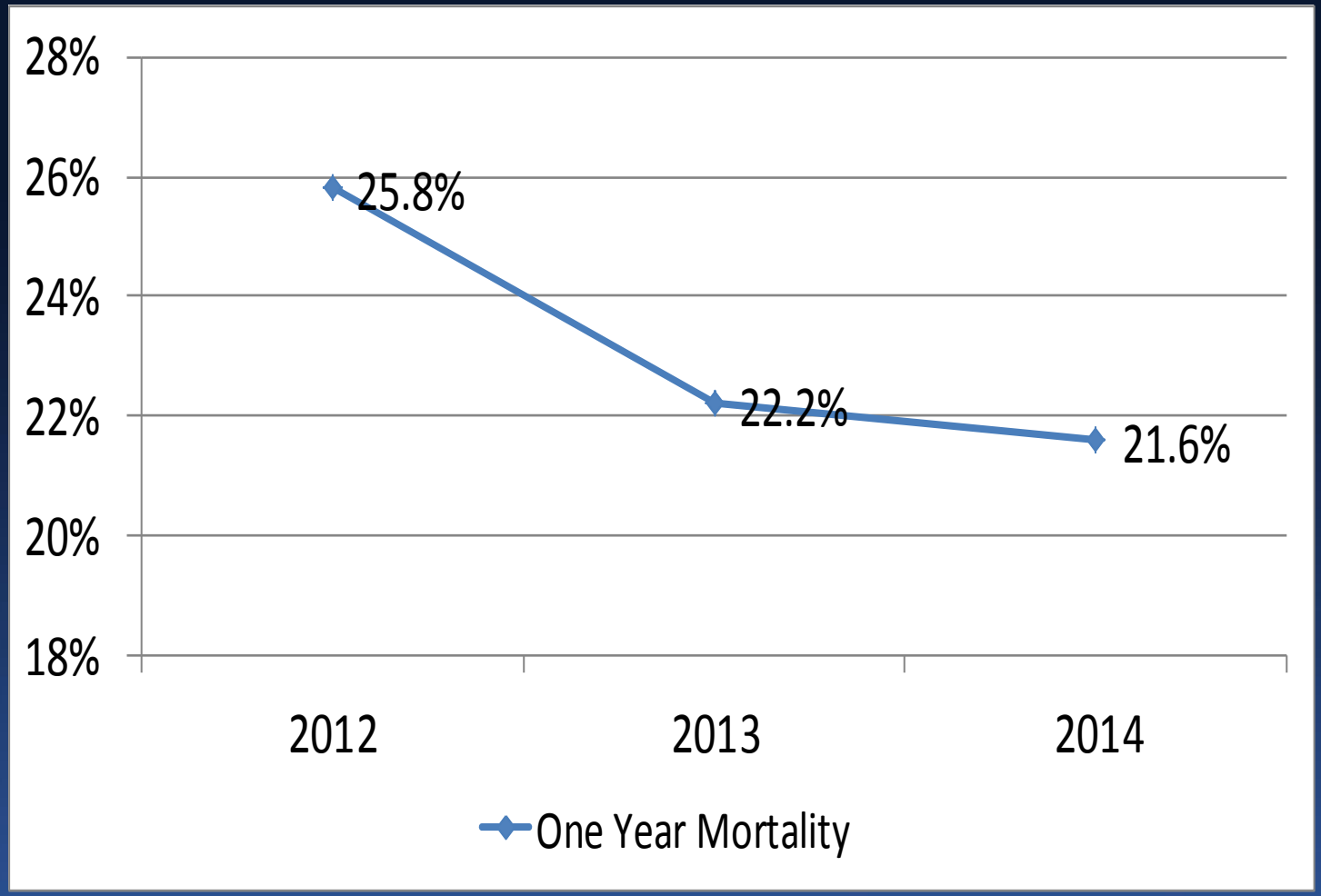
Source: STS/ACC TVT Registry Database as of Oct 18, 2016

Median LOS (Days)



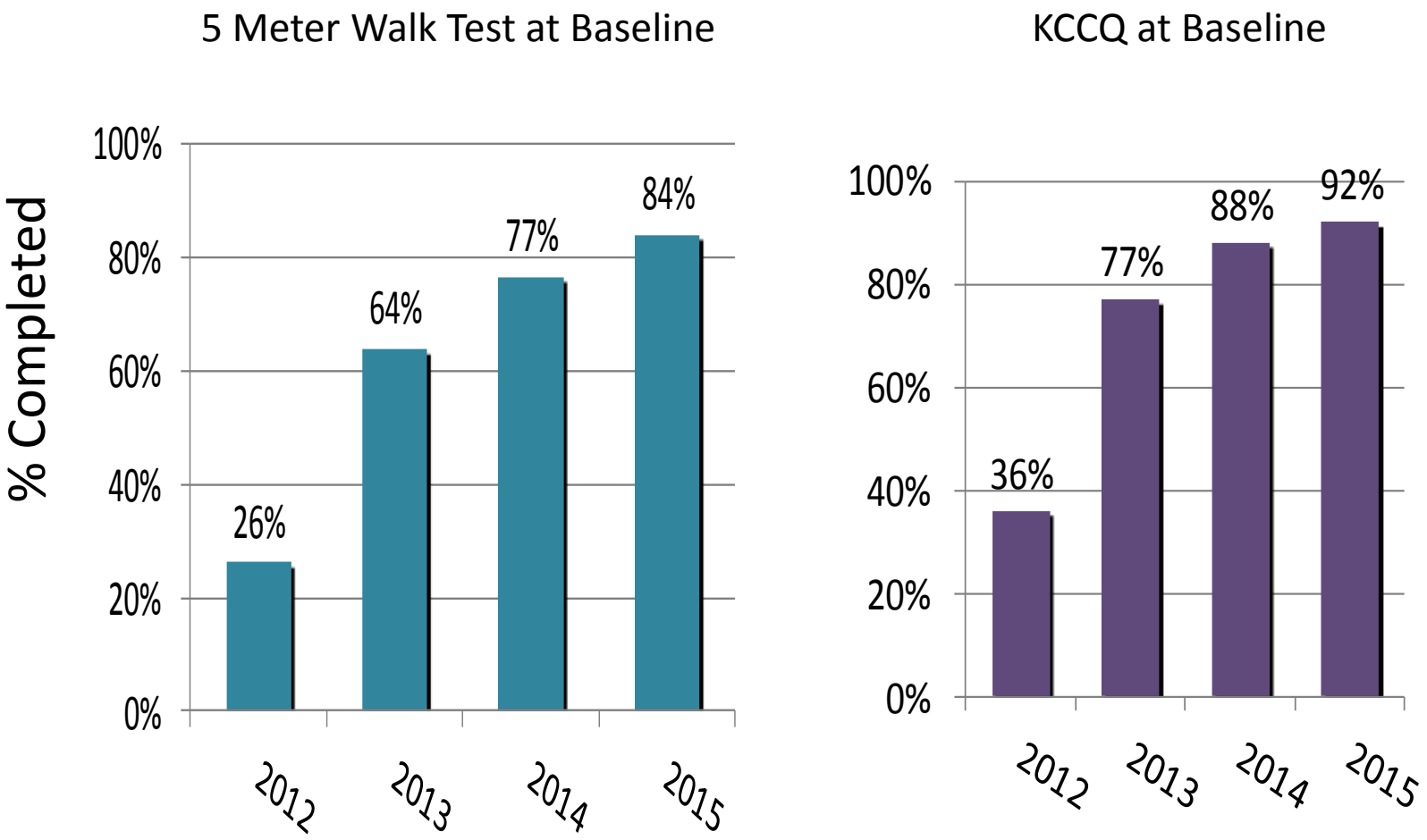
Source: STS/ACC TVT Registry Database. 70,651 records as of Oct 18, 2016

One Year Mortality after TAVR (CMS linked records)



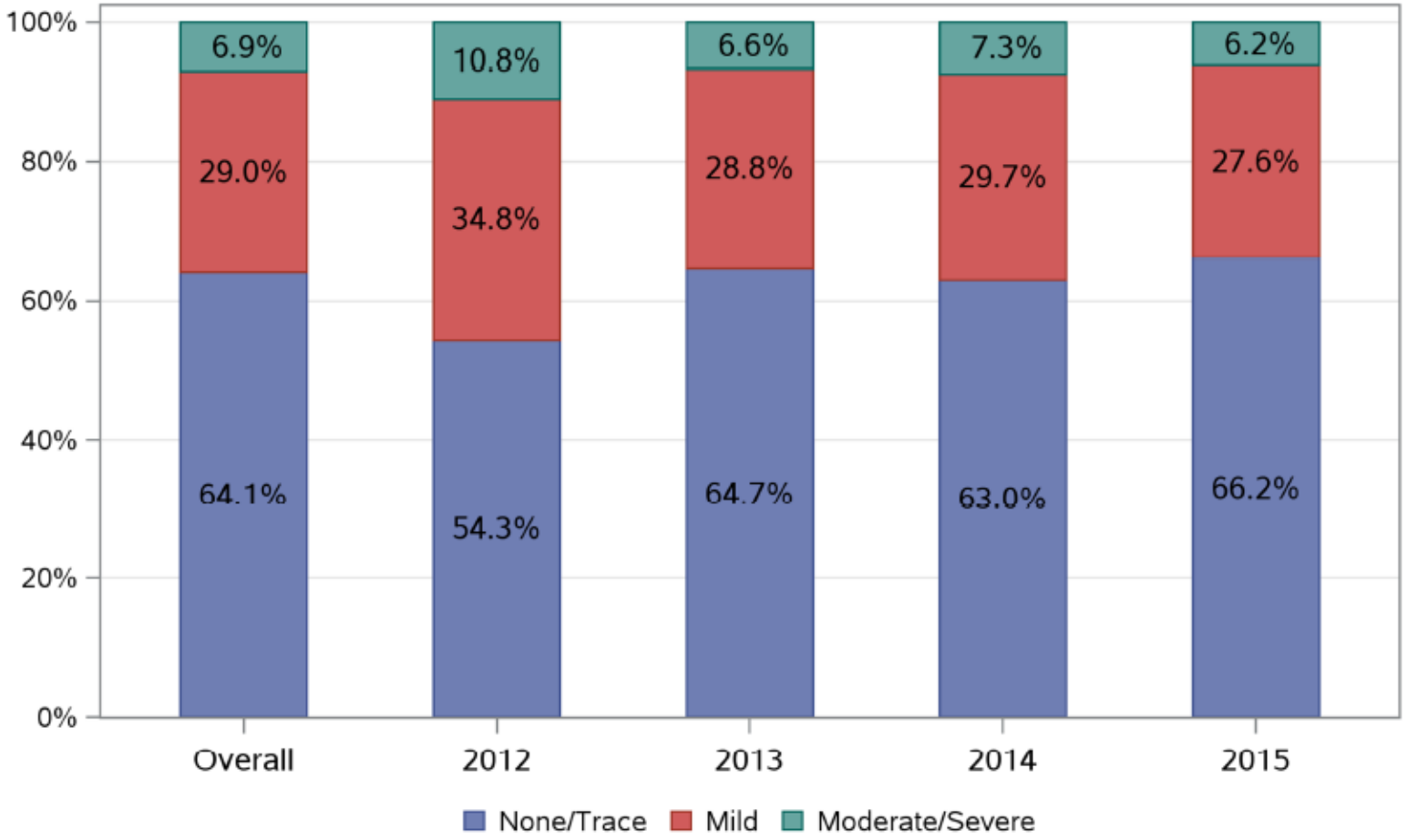
Source: DCRI query
17,562 records as of 9-12-16

TAVR: Site Performance on Novel Assessment of Functional State and Patient Reported Health Status



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 ???