THE PRESENT AND FUTURE

STATE-OF-THE-ART REVIEW

STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

John D. Carroll, MD,[a] Michael J. Mack, MD,[b] Sreekanth Vemulapalli, MD,[c] Howard C. Herrmann, MD,[d] Thomas G. Gleason, MD,[e] George Hanzel, MD,[f] G. Michael Deeb, MD,[g] Vinod H. Thourani, MD,[h] David J. Cohen, MD, MSc,[i] Nimesh Desai, MD, PHD,[j] Ajay J. Kirtane, MD, SM,[k] Susan Fitzgerald, MSN, RN,[l] Joan Michaels, MSN, RN,[l] Carole Krohn, BSN, RN,[m] Frederick A. Masoudi, MD, MSPH,[a] Ralph G. Brindis, MD, MPH,[n] Joseph E. Bavaria, MD[j]

ABSTRACT

The STS-ACC TVT Registry (Society of Thoracic Surgeons–American College of Cardiology Transcatheter Valve Therapy Registry) from 2011 to 2019 has collected data on 276,316 patients undergoing transcatheter aortic valve replacement (TAVR) at sites in all U.S. states. Volumes have increased every year, exceeding surgical aortic valve replacement in 2019 (72,991 vs. 57,626), and it is now performed in all U.S. states. TAVR now extends from extreme- to low-risk patients. This is the first presentation on 8,395 low-risk patients treated in 2019. In 2019, for the entire cohort, femoral access increased to 95.3%, hospital stay was 2 days, and 90.3% were discharged home. Since 2011, the 30-day mortality rate has decreased (7.2% to 2.5%), stroke has started to decrease (2.75% to 2.3%), but pacemaker need is unchanged (10.9% to 10.8%). Alive with acceptable patient-reported outcomes is achieved in 8 of 10 patients at 1 year. The Registry is a national resource to improve care and analyze TAVR's evolution. Real-world outcomes, site performance, and the impact of coronavirus disease 2019 will be subsequently studied. (STS/ACC Transcatheter Valve Therapy Registry [TVT Registry]; NCT01737528) (J Am Coll Cardiol 2020;76:2492–516) © 2020 by The Society of Thoracic Surgeons and the American College of Cardiology Foundation.

SPECIAL REPORT

STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

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Division of Cardiology, Department of Medicine, University of Colorado School of Medicine, Aurora Colorado; Baylor Scott and White Health Heart Hospital–Plano, Plano, Texas; Duke Clinical Research Institute and Division of Cardiology, Department of Medicine, Duke University Health Care System, Durham, North Carolina; Cardiovascular Division, Department of Medicine, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania; Division of Cardiac Surgery, Brigham & Women's Hospital & Harvard Medical School, Boston Massachusetts; Department of Cardiovascular Medicine, Beaumont Hospital, Royal Oak, Michigan; Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; Department of Surgery, Piedmont Hospital, Atlanta, Georgia; University of Missouri-Kansas City School of Medicine, Kansas City, Missouri; Division of Cardiovascular Surgery, University of Pennsylvania, Philadelphia, Pennsylvania; Cardiovascular Research Foundation and Department of Medicine, Columbia University, New York, New York; American College of Cardiology, Washington, DC; The Society of Thoracic Surgeons, Chicago, Illinois; and Philip R. Lee Institute for Health Policy Studies, University of California-San Francisco, San Francisco, California

The STS-ACC TVT Registry (Society of Thoracic Surgeons–American College of Cardiology Transcatheter Valve Therapy Registry) from 2011 to 2019 has collected data on 276,316 patients undergoing transcatheter aortic valve replacement (TAVR) at sites in all U.S. states. Volumes have increased every year, exceeding surgical aortic valve replacement in 2019 (72,991 vs. 57,626), and it is now performed in all U.S. states. TAVR now extends from extreme- to low-risk patients. This is the first presentation on 8,395 low-risk patients treated in 2019. In 2019, for the entire cohort, femoral access increased to 95.3%, hospital stay was 2 days, and 90.3% were discharged home. Since 2011, the 30-day mortality rate has decreased (7.2% to 2.5%), stroke has started to decrease (2.75% to 2.3%), but pacemaker need is unchanged (10.9% to 10.8%). Alive with acceptable patient-reported outcomes is achieved in 8 of 10 patients at 1 year. The Registry is a national resource to improve care and analyze TAVR's evolution. Real-world outcomes, site performance, and the impact of coronavirus disease 2019 will be subsequently studied. (STS/ACC Transcatheter Valve Therapy Registry [TVT Registry]; NCT01737528).

Ann Thorac Surg 2020;■:■-■

Knowledge Generated from Patient-Level Data Submitted by over 700 TAVR Sites and now over 300,000 Patients Who have Been Treated from 2011-2020 in the US.

A Major Goal of TVT Registry: Improving the Quality of Patient Care

Time	Topic	Speaker
1:00 PM ET	Introduction	Dr. John Carroll • MD, FACC, Chair, STS/ACC TVT Registry Steering Committee, Professor of Medicine/Director of Interventional Cardiology, University of Colorado Dr. Vinod Thourani • MD, FACC, Co-chair STS/ACC TVT Registry Steering Committee, Bernie Marcus Chairman, Department of Cardiovascular Surgery, Marcus Heart Valve Center, Piedmont Heart Institute, Atlanta GA
1:05	Public Reporting: Overview and Specifics of the STS-ACC TVT Registry Public Reporting Process	Dr. Ralph Brindis • MD, MPH, MACC, Chair of the STS/ACC TVT Registry Public Reporting Workgroup; Clinical Professor of Medicine Department of Medicine and Philip R. Lee Institute for Health Policy Studies, UCSF and Senior Medical Officer, external affairs, NCDR
1:20	Methodology to be used by TVT Registry for Public Reporting	Dr. Nimesh Desai • MD, PhD, Chair, STS/ACC TVT Registry Risk Model Workgroup; Co-Director, Thoracic Aortic Surgery Program and Associate Professor in the Division of Cardiovascular Surgery at the Hospital of the University of Pennsylvania
1:35	Methodology used by US News & World Report for Public Reporting	Ben Harder • Chief of Health Analysis and Managing Editor, U.S. News & World Report Tavia Binger • MSPH, Senior Health Data Analyst, U.S. News & World Report
2:00	Comparisons of Methodology and Experience in Public Reporting from the Society of Thoracis Surgeons	Dr. David Shahian • MD, FACC, Co-Chair, STS/ACC TVT Registry Public Reporting Workgroup, Professor of Surgery, Harvard Medical School; Vice President, Center for Quality and Safety at Massachusetts General Hospital
2:15	Questions and Discussions	Dr. David Cohen • MD, MSc, Co-Chair STS/ACC TVT Registry Risk Model Workgroup, University of Missouri-Kansas City

When the Public Wants to Know: Public Outcomes Reporting

Ralph Brindis, MD, MPH, MACC, FSCAI, FAHA
Clinical Professor of Medicine, UCSF
Dept. of Medicine & the Philip R. Lee Institute for Health Policy Studies
Senior Medical Officer, External Affairs,
ACC National Cardiovascular Data Registry
November 2020

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Public Reporting in Medicine is Not New

The train has left the station, and it ain't coming back

And . . . The public has increasing expectations

Outside Third Party Assessors Alternative Facts??? (Fake News?)

ProPublica Journalism in the Public Interest

RateMDs DOCTORS YOU CAN TRUST

Angie's list

yelp Real people. Real reviews.

healthgrades How America finds a doctor

DoctorScorecard.com

vitals where doctors are examined

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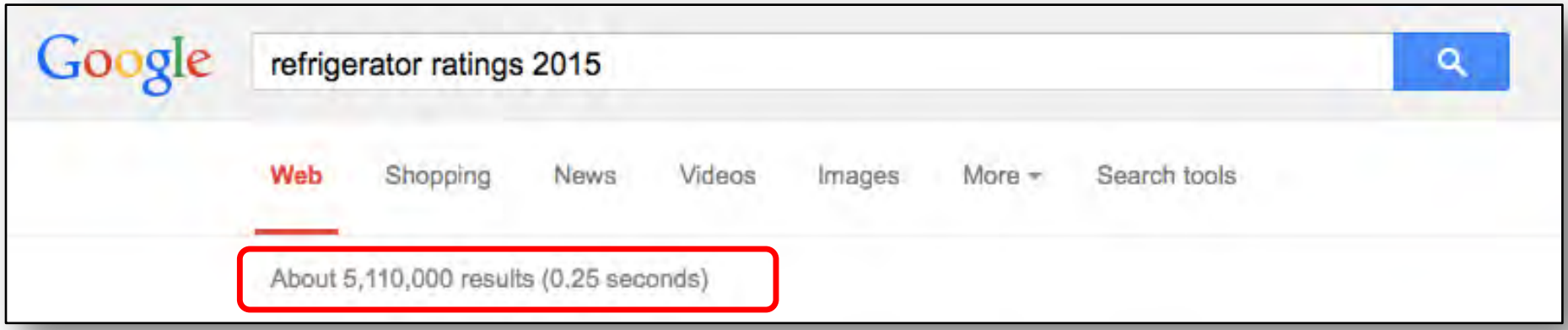
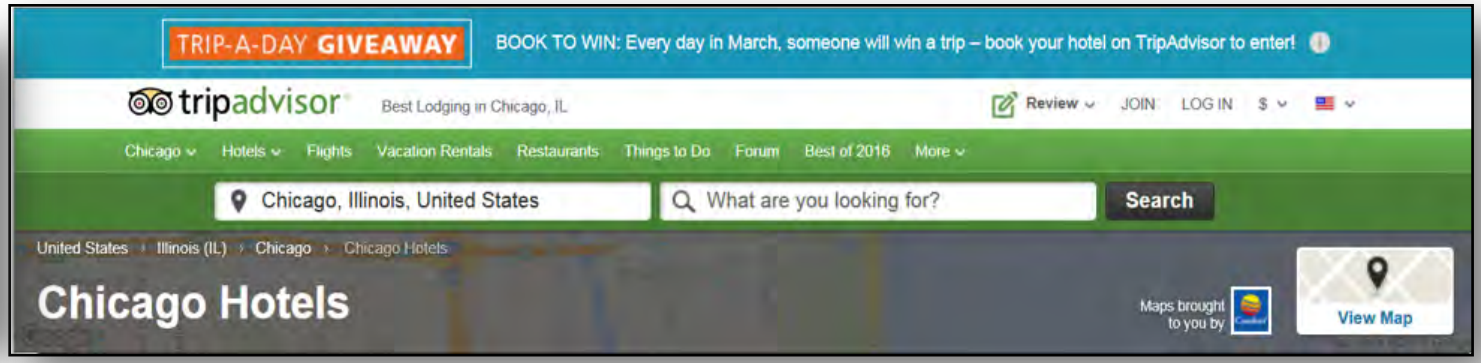
Want to Buy a Refrigerator?



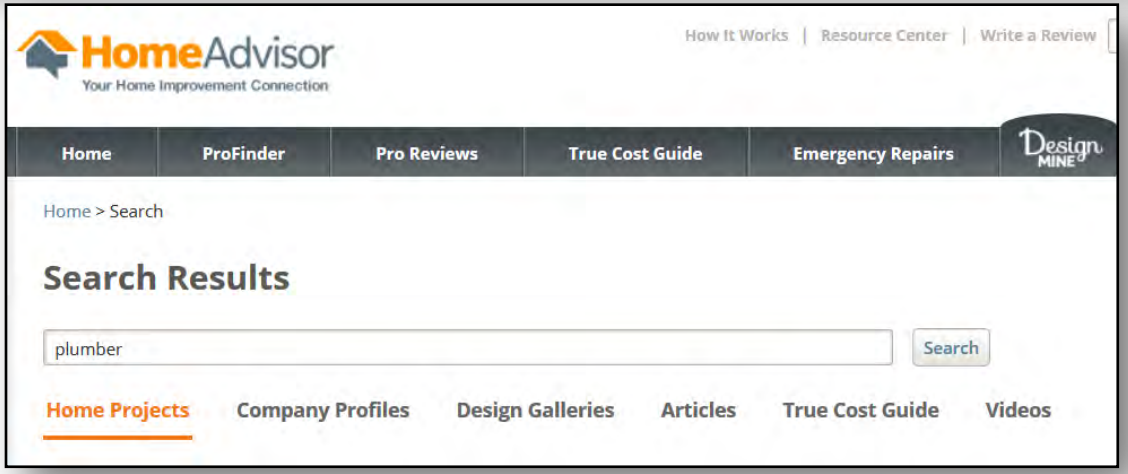
5.1 Million results

Need Advice on Hotels or a Plumber?

tripadvisor



HomeAdvisor



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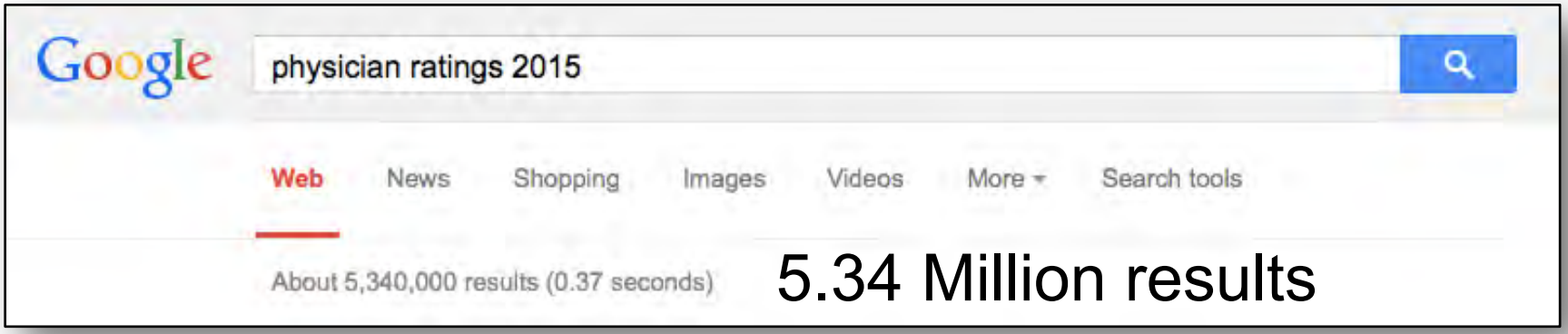
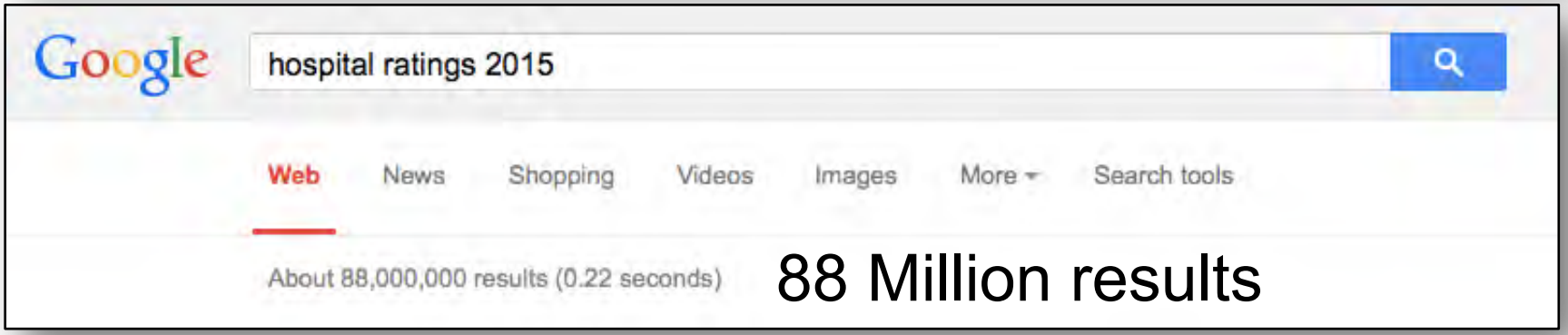
What About a Doctor or Hospital?





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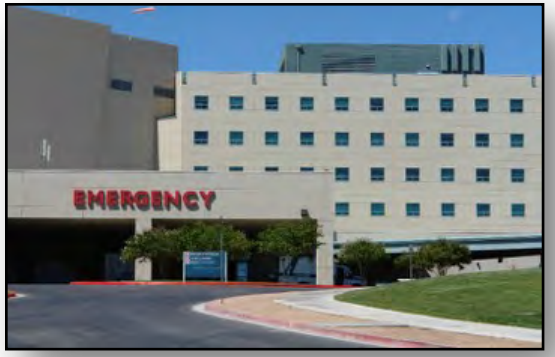
Why Should You Care About Public Reporting?

Are choices about your healthcare equal in importance to your choice of airlines, schools, hotels, refrigerators and plumbers?



Should the consumer, have access to information about the quality of healthcare facilities and providers?

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The Status of Public Reporting

1. There is an explosion of activity in many different directions
2. It draws a large crowd
3. Some think it's beautiful
4. Some think it's very scary
5. You can get hurt if not used properly

Public Reporting: Benefits to Patient Care

- **Public Reporting of data encourages:**
  - Transparency of outcomes
  - Attention to quality metrics by hospitals and physicians
  - Contributions to national data registries
  - Adjustments of techniques to improve results
  - Increased choice by consumers -more shared decision making

- **Public reporting is becoming more widespread**
  - Physicians/patients should be aware of publicly available reports
  - Physicians should be prepared to review reports as patients ask questions
  - Physicians should be prepared to share their own outcomes

ACC Public Reporting Mission Statement

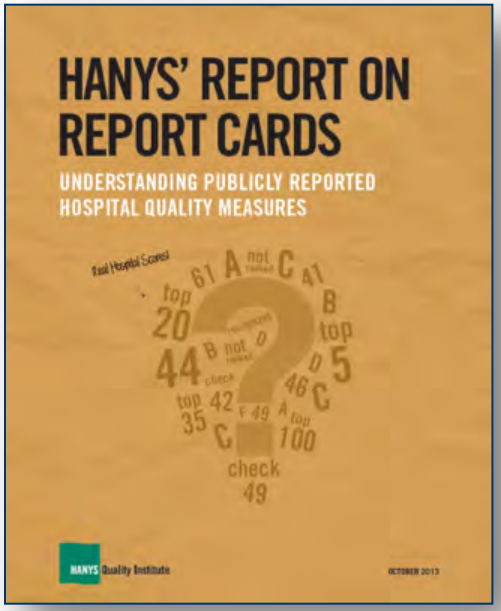
- Monitor the quality of CV patient care being provided in a transparent manner.
- Ensure reporting is based on high quality data, is administered with minimal collection burden employing clinically valid & methodologically sound measures.
- Provide measures that are actionable and consistent with the Triple Aim without causing unintended consequences in access to care.
- Foster relationships of trust through collaboration between patients and their CV care team with information that is credible, understandable, and actionable.
- Enable patients and CV professionals to advocate for policies at the federal and state level that support achieving the Triple Aim.
- This mission in providing open access to information on quality of care is championed as an ethical responsibility of the profession.

On the Internet Now

Federal Government	• Hospital Compare • Physician Compare • Payments to physicians
State Government	• State Public Reporting Programs • MA, NY, PA, CA, TX, others
Independent Groups	• HealthGrades,ProPublica • USNWR, Truven, Leapfrog • Consumer Reports, Others …
Insurance providers	• Aetna, BCBS • Others, but you don't know it
Consumer Websites	• RateMD.com, Angie's List • Yelp, Others . . .

Inconsistencies in Reporting and Ratings of Hospitals

Healthcare Association of New York State



Healthcare Association of New York State

HANYS' REPORT CARD ON HOSPITAL REPORT CARDS

HANYS' EVALUATION	REPORT CARD
★★★	THE JOINT COMMISSION QUALITY CHECK Latest report as of April 2013 version, 2011 user guide
★★★	DOH HOSPITAL-ACQUIRED INFECTION REPORT Latest report as of September 2012
★★★	CMS HOSPITAL COMPARE Latest report as of April 2013
★★★	DOH HOSPITAL PROFILE QUALITY SECTION Latest report as of July 2013
★★	NIAGARA HEALTH QUALITY COALITION NEW YORK STATE HOSPITAL REPORT CARD Latest report as of 2011
★	LEAPFROG HOSPITAL SAFETY SCORE Latest report as of October 2012
★	TRUVEN HEALTH ANALYTICS 100 TOP HOSPITALS Latest report as of February 2013
★	HEALTHGRADES AMERICA'S BEST HOSPITALS Latest report as of 2013
★	*CONSUMER REPORTS* HOSPITAL SAFETY RATINGS Latest report as of November 2012
☆	*U.S. NEWS AND WORLD REPORT* Latest report as of July 2013

★★★ If the report card fully met all, or nearly all, of the criteria, the report card was awarded three stars.

★★ If the report card fully met some of the criteria and partially met others, the report card was awarded two stars.

★ If the report card fully or partially met few or none of the criteria, the report card was awarded one star.

½ If the report card fully met only one criteria, partially met few, or did not meet any of the criteria, the report card was awarded a half star.

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Grading the Graders

http://www.hanys.org/quality/data/report_cards/2013/

- Transparent methodology
- Evidence-based measures
- Measure alignment
- Appropriate data source
- Current data
- Risk-adjusted data
- Data quality
- Consistent data
- Hospital preview

Inconsistencies in Reporting and Ratings of Hospitals


PATIENT ENGAGEMENT

By J. Matthew Austin, Ashish K. Jha, Patrick S. Romano, Sara J. Singer, Timothy J. Vogus, Robert M. Wachter, and Peter J. Pronovost

National Hospital Ratings Systems Share Few Common Scores And May Generate Confusion Instead Of Clarity

Health Affairs 2015; 34:423-30

CONCLUSIONS

- Compared 4 national rating systems
  USNWR, HealthGrades, Leapfrog, Consumer's Reports
- Designated "high" and "low" performers and examined ratings overlap
- No hospital was rated a high performer in all 4 rating systems
- Only 10% of the 844 hospitals rated as a "high performer" in one rating system were rated as a high performer by any other rating system

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Why Are There Inconsistencies?

Administrative Data →

1. "Claims" data are derived from reimbursement information (bills) sent to Medicare
2. Contains: Demographic data, admission/discharge, diagnoses, procedures, date of death, . . .
3. Linkage to other external datasets: US census, cancer registries, national death index, etc . . .
4. Available, inexpensive

Limitations

1. Co-existing diseases (HBP, diabetes) underdiagnosed and missed
2. Limited diagnosis codes - - - improved by ICD-10
3. Limited clinical information
4. Many services excluded
5. Delayed reporting
6. Medicare FFS only

Why Are There Inconsistencies?

Clinical Data
(NCDR, STS)

1. Derived from clinical registries (STS, NCDR, . . .)
2. Comprehensive
3. Contains extensive clinical data
4. Composite data available
5. Risk adjustment more robust

Limitations

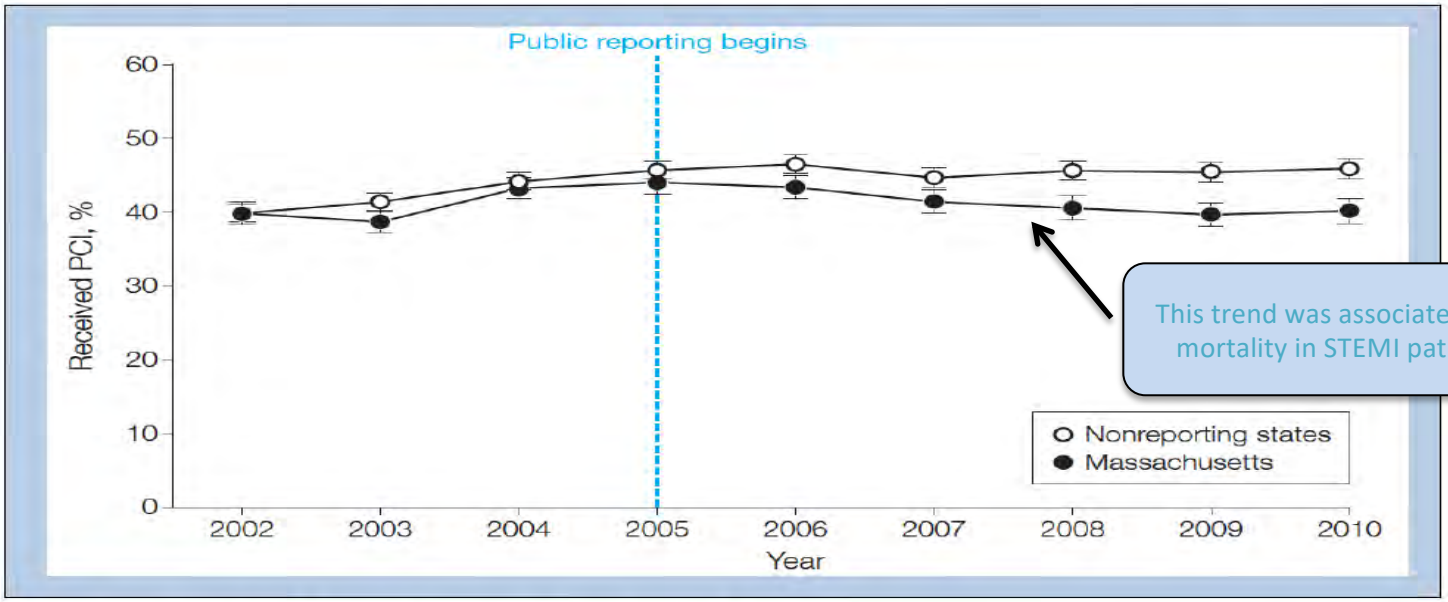
1. Labor intensive to collect
2. Costly
3. Audited, but only a modest percentage of records.
4. Still may lack some data elements that can effect clinical outcomes (inadequate risk-adjustment)

A Need for Caution - - The Bad *(Ugly)*

Even something that seems innocent and well-intentioned can have negative consequences.

Unintended Consequences: Less PCI for Acute MI

There has been a decrease in the proportion of AMI patients treated with PCI in MA versus other states.



This trend was associated with increased mortality in STEMI patients (p=0.004)

Joynt K. et al. JAMA 2012;308(14) 1460-1468.

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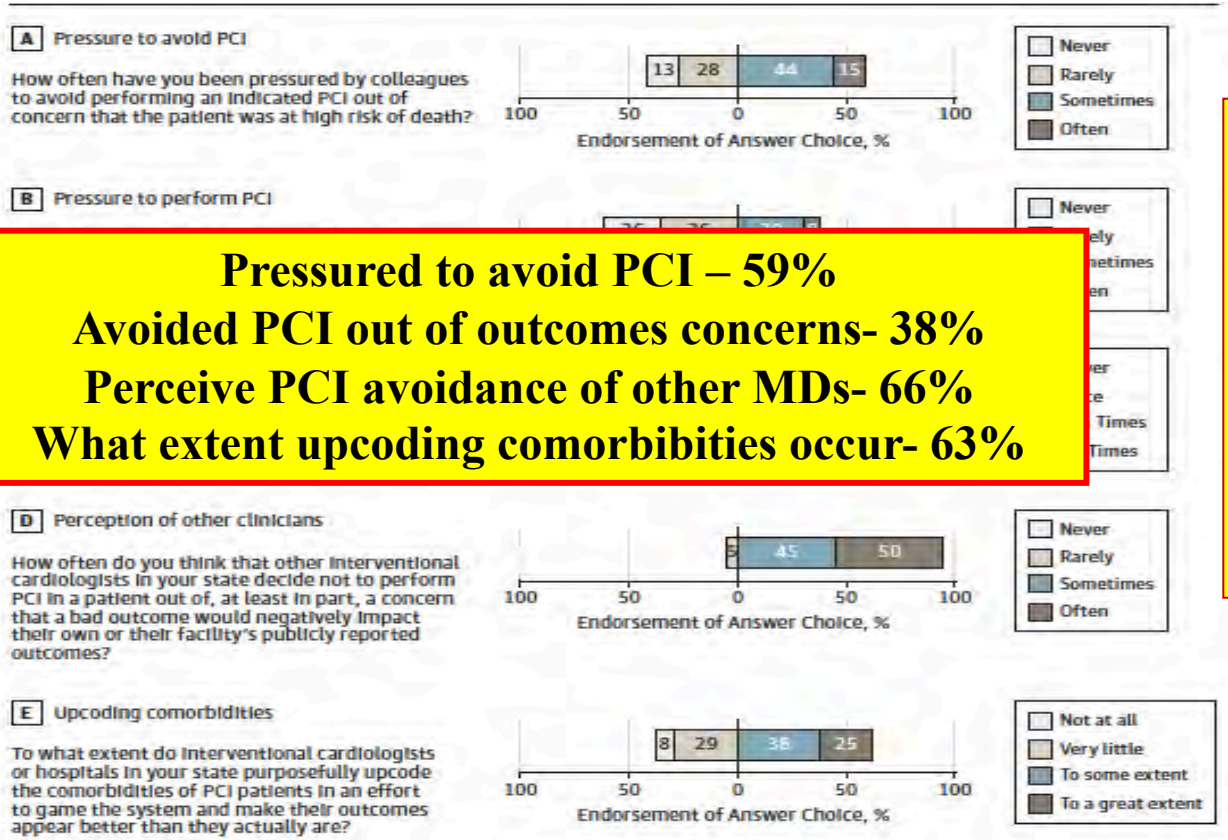
Public Reporting of PCI

Risk Aversion, and Gaming of Public Reporting Systems



Pressured to avoid PCI – 59%
Avoided PCI out of outcomes concerns- 38%
Perceive PCI avoidance of other MDs- 66%
What extent upcoding comorbibities occur- 63%

Responses from 149 interventional cardiologists in Mass. & New York

Blumenthal et.al., JAMA Cardiol 2018

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PCI Risk Adjustment Models Only Fit the Data Collected

What About?

- Down Time
- Initial Rhythm
- Bystander CPR
- Aortic Stenosis
- CABG/SVG Intervention
- Surgery Refusal
- Ongoing Bleeding
- Prior/Recent Stroke
- Stent Thrombosis
- PAD
- Multivessel Disease
- Proximal LAD Infarct

Straight Forward Cases??

- MI Post ERCP-Thrombotic Occluded RCA
  - Successful PCI
  - Developed post ERCP-pancreatitis
  - Ranson Criteria Predicted 100% death at 48 hrs

- MI preop Biliary Cancer-"Do Everything", Withdrawal of Care HD #2 for Obstructive Liver failure, No longer surgical

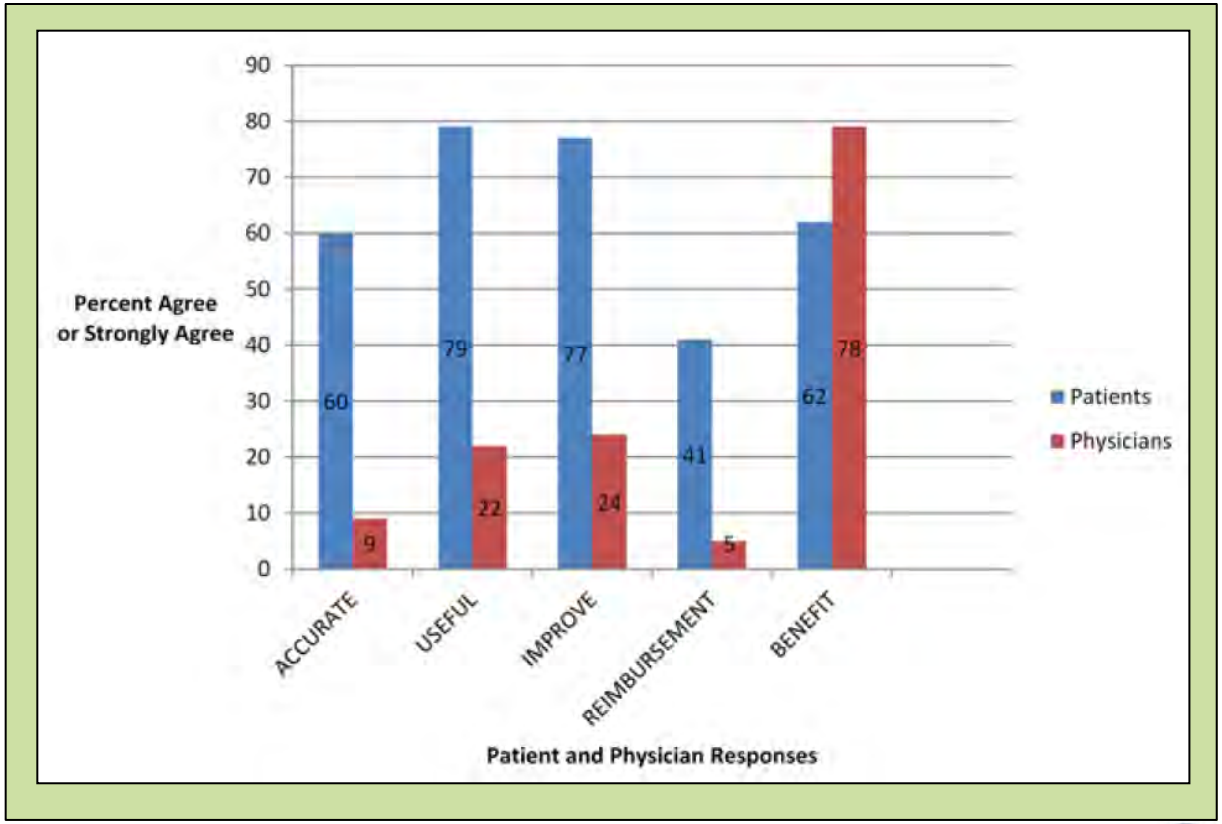
- Post Infarction VSD. Diagnosed in lab. PTCA alone RCA. Refused by Surgery. Died 5 days after VSD occluder placed

- Liver Laceration from CPR Recognized 2 hours after successful PCI for Stent Thrombosis. Surgeons Unable to stop bleeding

Physician vs Patient Perceptions

While MD's remain concerned….
patient perceptions of public report value stand in stark contrast.

Patient vs. Physician Perceptions



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Source: Fernandez G et al.
Circ CV Qual Outcomes 2017

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Does Public Reporting Work?

QUALITY OF CARE

By Geoffrey C. Lamb, Maureen A. Smith, William B. Weeks, and Christopher Queram

Publicly Reported Quality-Of-Care Measures Influenced Wisconsin Physician Groups To Improve Performance

Wisconsin Collaborative for Healthcare Quality

20 physician groups; 582 affiliated clinics – voluntary reporting

14 metrics: diabetes care, CAD, uncomplicated hypertension and screening or preventative measures

Findings:

1) Improved performance in most metrics during public reporting

2) Physician groups motivated by public reporting

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Lamb GC et al. Health Affairs 2013;32:536-43

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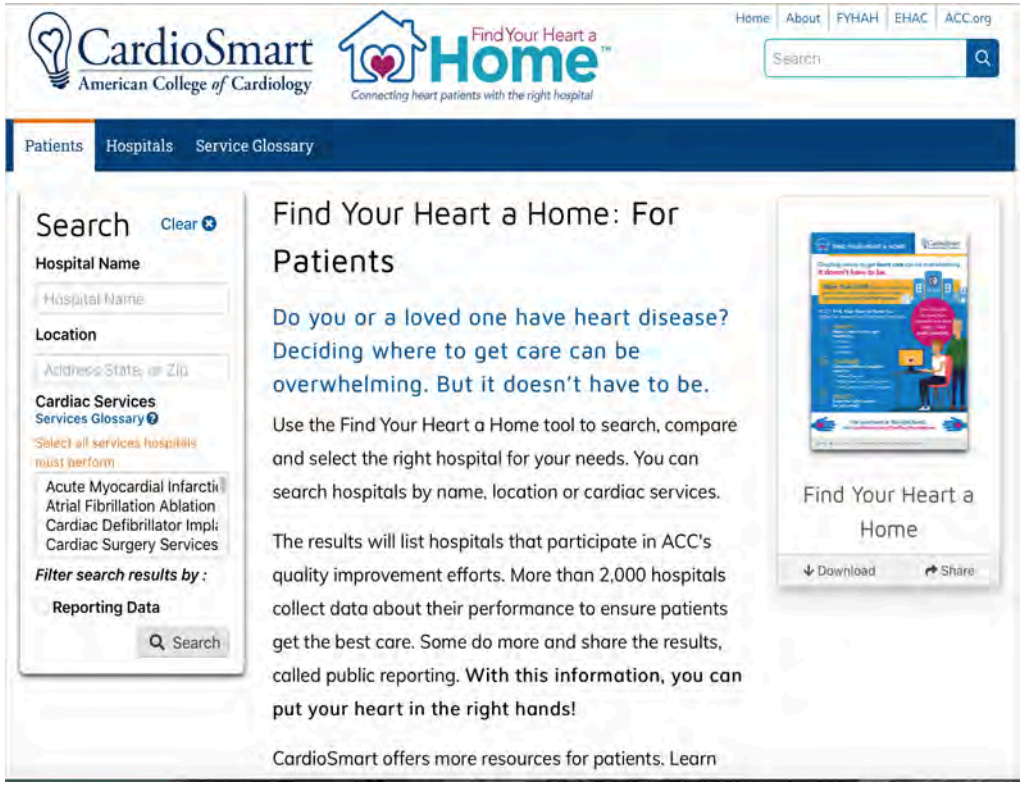
ACC's Heart a Home campaign for patients & their families

- Public can look up hospital information on ACC's consumer website CardioSmart.org
- All NCDR hospitals receive a profile page to promote CV services
- Information is managed by hospitals



http://FindYourHeartAHome.org

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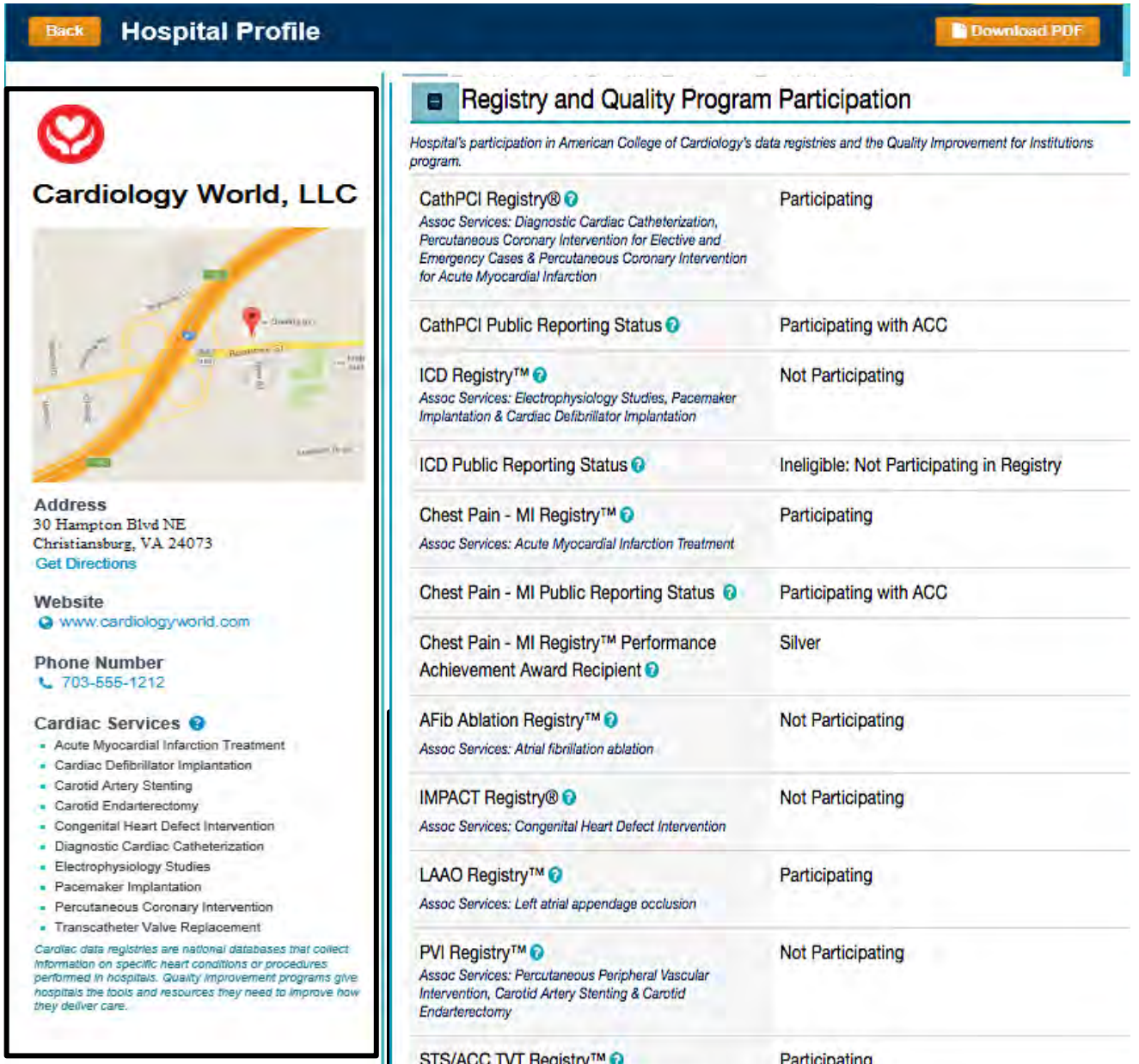
- **Unique profile for every NCDR hospital**
  - Bookmark or download .pdf
  - Sites can use in marketing
- **General Hospital data**
  - Map/address/directions
  - Website/Phone
  - Cardiac Services
- **ACC programs**
  - Registries
  - Public Reporting status
  - Other Programs: QII, CP-MI Performance Award
- **Metrics (if opt-in)**
  - Procedure volume
  - NQF endorsed metrics initially utilized and now expanded beyond that scope



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Star Scores

Implantable Cardiac Defibrillator Metrics

Hospital performance for patients who have had an implantable cardiac defibrillator

Number of initial ICD implant procedures performed	474
Proportion of patients with left ventricular systolic dysfunction who had ACE-I or ARB prescription addressed on discharge	★★★★
Proportion of patients with prior MI who had beta-blocker prescription addressed on discharge	★★★★
Proportion of patients with left ventricular systolic dysfunction (LVSD) who had beta-blocker prescription addressed on discharge	★★★★
Composite: Proportion of patients prescribed all discharge medications (ACE-I/ARB and/or beta-blocker) for which they were eligible	★★★★

Diagnostic Catheterization and Percutaneous Coronary Intervention Metrics

Hospital performance for patients who have had a cardiac catheterization or PCI (angioplasty)

Number of PCI/angioplasty procedures performed during the calendar year.	1468
Use of Aspirin to reduce the chance of blood clots after PCI/angioplasty.	★★★★
Use of a P2Y12 inhibitor medication to reduce the chance of blood clots after PCI/angioplasty.	★★★★
Use of a Statin to decrease cholesterol after PCI/angioplasty.	★★★★
Use of all recommended medications (Aspirin, P2Y12 inhibitor medication, and Statin) to reduce the chance of blood clots and decrease cholesterol after PCI/angioplasty.	★★★★

Acute Myocardial Infarction (AMI) Metrics

Hospital performance for patients who have had an acute myocardial infarction (heart attack)

Number of acute myocardial infarctions (MIs) treated during the calendar year.	416
All Heart Attack Care	★★★★
Urgent Heart Attack Care	★★★★

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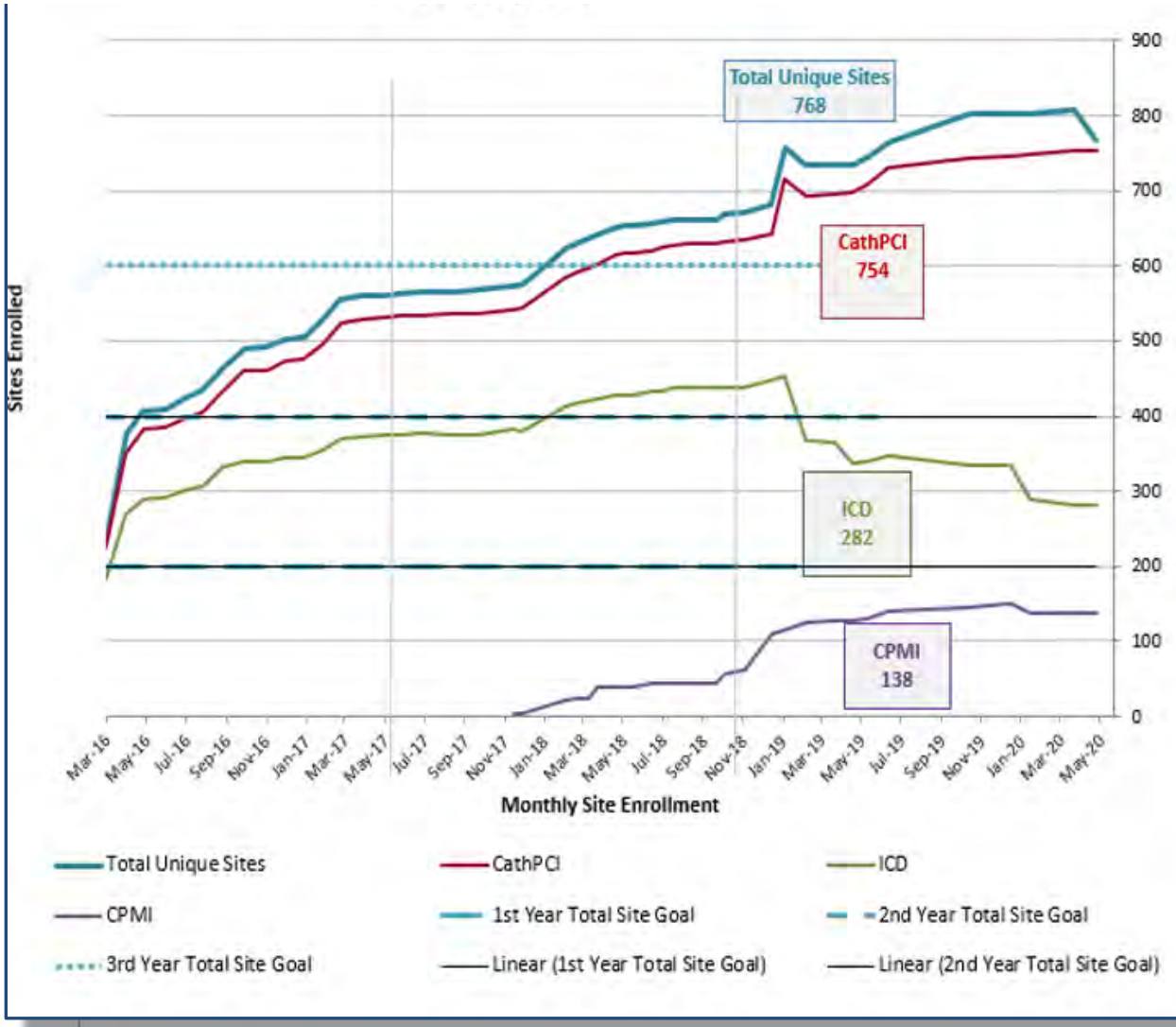
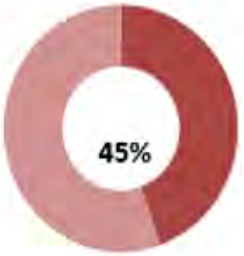
Public Reporting Status May 2020





CathPCI
44.54 % of Registry sites have opted in

ICD
31.72% of Registry sites opted in

CPMI
18.60% of Registry sites opted in

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ACC's Voluntary Public Reporting is Recognized by Key Stakeholders

https://media.beam.usnews.com/8c/7b/6e1535d141bb9329e23413577d99/190709-bh-methodology-report-2019.pdf, page 6

BlueCross BlueShield Association

Blue Distinction® Centers for Cardiac Care 2018 Provider Survey

Percutaneous Coronary Intervention (PCI) Procedures

12. Does your facility report to the National Cardiovascular Data Registry (NCDR®) CathPCI Registry® **AND** has your facility reported on **ALL** Adult Percutaneous Coronary Intervention (PCI) procedures performed at your facility from July 1, 2016 through June 30, 2017?

☐ YES (Complete Question 12a) ☐ NO

12a. Does your facility participate in the CathPCI Registry® Public Reporting on American College of Cardiology (ACC) Cardiosmart®? Cardiosmart Find-Your-Heart-a-Home

☐ YES ☐ NO

13. Does your facility have the CathPCI Registry® Institutional Outcomes Report 2017Q2, including four (4) consecutive quarters of data, where "Yes" is marked under "Included in Executive Summary" for having passed **ALL** CathPCI Registry® data quality report checks in the "Inclusion Summary" on page 3?

☐ YES (Complete Questions 13a – 13n) ☐ NO

https://www.bcbs.com/blue-distinction-specialty-care; Cardiac Care Provider Survey

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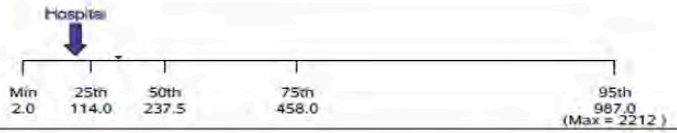
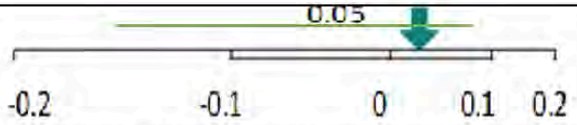
The Society of Thoracic Surgeons

STS/ACC TVT Registry
Public Reporting Metrics
Patients with TAVR as of 2019 q4
Hospital ABC (123456)

AMERICAN COLLEGE of CARDIOLOGY

Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume (commercial procedures only)		Distribution of Annual Hospital Volume
	Cumulative	Average annual volume (Jan 1 2017 to Dec 31, 2019)	
December, 2011	750	60	

My Hospital TAVR 30 Day Composite[1,2] (95% Interval)	Eligible Patients (Jan 1, 2017 –Dec 31, 2019)	Participant Rating	Distribution of Participant Estimates
0.05 (-0.15 to 0.12)	160	★★	

[1] 30 Day Composite consists of six ordered categories based on the worst possible outcome (30-day death) to the best possible outcome (e.g. alive and free of major complications) during hospitalization and the 30-day follow-up period as defined below:

1. 30-day death
2. 30-day stroke
3. 30-day life-threatening/major bleed
4. Acute kidney injury (stage III)
5. 30-day >=2+ (mod-sev) paravalvular leak
6. None of the above

[2]The TAVR 30-day Mortality/morbidity composite is reported as a "win difference"
>0 implies "My Hospital" has better than expected performance
<0 implies "My Hospital" has worse than expected performance

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STS/ACC TVT Registry Public Reporting Metrics
Hospital ABC (123456)
Jan 1, 2017-Dec 31, 2019

TAVR 30-Day Composite

Number of Eligible	TAVR 30-DAY Composite Win Difference (Site Benefit)	
Patients	**Estimate**	**95% Interval**
160	0.05	(-0.15 to 0.12)

TAVR 30-Day Composite Details

Number of patients with observed outcome in each composite outcome category

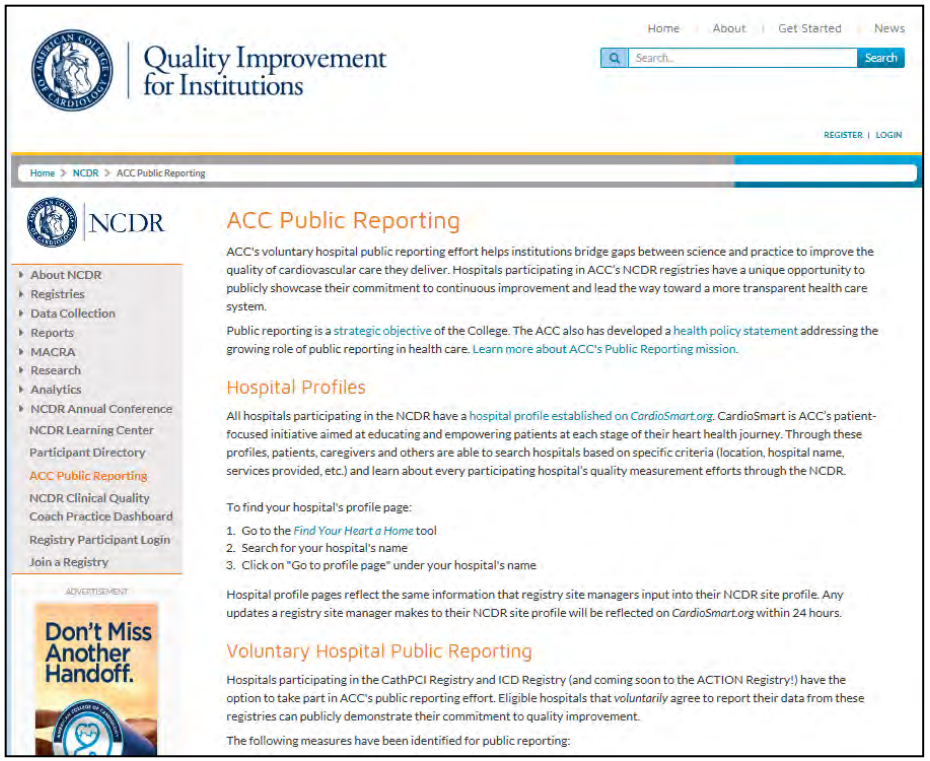
Composite Outcome Category	My Hospital		Registry	
(Worst Observed Outcome)	**Number**	**Percent**	**Number**	**Percent**
Death (30 day)	4	2.5%	1671	3.2%
Stroke (30 day)	1	0.6%	1077	2.0%
Life threatening/major bleeding (30 day)	8	5.0%	3024	5.8%
Acute kidney injury (in-hospital AKI stage III or 30 day new dialysis)	2	1.3%	336	0.6%
>=2+ (mod-sev) paravalvular leak (30 days)	4	2.5%	1304	2.5%
None of the above	141	100.0%	45149	85.9%

Comparison of observed and expected outcome for cumulative outcome categories

Composite Cumulative Outcomes	Obs (%)	Exp (%)	O / E Ratio
Death	x.x%	x.x%	xx.x (xx.x – xx.x)
Death or Stroke	x.x%	x.x%	xx.x (xx.x – xx.x)
Death or Stroke or Bleeding	x.x%	x.x%	xx.x (xx.x – xx.x)
Death or Stroke or Bleeding or AKI	x.x%	x.x%	xx.x (xx.x – xx.x)
Death or Stroke or Bleeding or AKI or PVL	x.x%	x.x%	xx.x (xx.x – xx.x)

Hospitals have a preview period before star-ratings are made public

- Hospital-specific support for public reporting also available on Quality Improvement for Institutions
- Specific publicly reported measures and methodology
- **Opt-in form available for download for each public reporting registry program**



http://cvquality.acc.org

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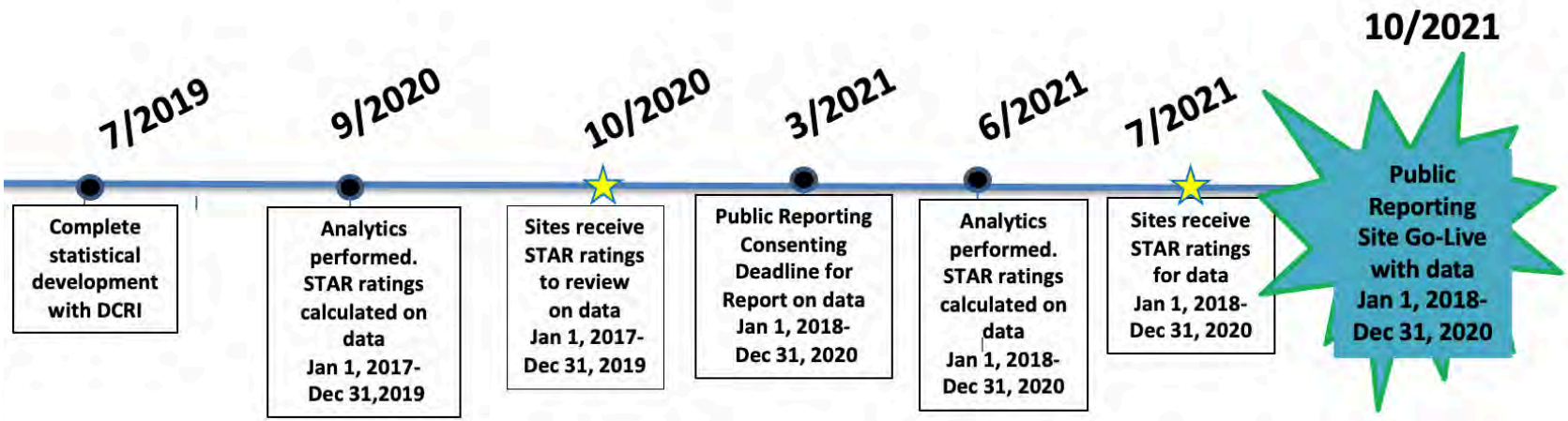
Tentative Plan: TVT Registry Public Reporting

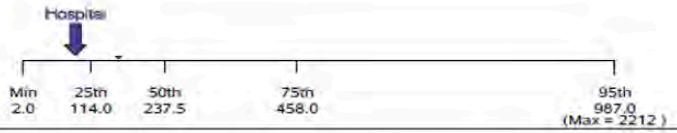
- 2020Q4: Sites preview their PR metrics with Jan 1, 2017- Dec 31, 2019 data
- 2021Q1: Sites consent (opt in) to voluntary PR
  - Opening and closing dates for consenting TBD (January- March)
  - Sites consent through the NCDR consenting process
  - **Sites can opt out of Public Reporting at any time**
- 2021q2 (date TBD) – Composite model available on Registry dashboard with data covering January 1, 2018-December 31, 2020 (and updated quarterly)
- 2021q3 – TVT Registry Public Reporting metrics launched to public (for consenting sites only)

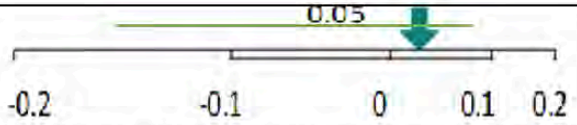


The Society of Thoracic Surgeons

STS/ACC TVT Registry
Public Reporting Metrics
Patients with TAVR as of 2019 q4
Hospital ABC (123456)

AMERICAN COLLEGE of CARDIOLOGY

Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume (commercial procedures only)		Distribution of Annual Hospital Volume
	Cumulative	Average annual volume (Jan 1 2017 to Dec 31, 2019)	
December, 2011	750	60	

My Hospital TAVR 30 Day Composite[1,2] (95% Interval)	Eligible Patients (Jan 1, 2017 –Dec 31, 2019)	Participant Rating	Distribution of Participant Estimates
0.05 (-0.15 to 0.12)	160	★★	

[1] 30 Day Composite consists of six ordered categories based on the worst possible outcome (30-day death) to the best possible outcome (e.g. alive and free of major complications) during hospitalization and the 30-day follow-up period as defined below:

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6. None of the above

[2]The TAVR 30-day Mortality/morbidity composite is reported as a "win difference"
>0 implies "My Hospital" has better than expected performance
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A Composite Metric For Benchmarking Site Performance In Transcatheter Aortic Valve Replacement: Results From The STS/ACC TVT Registry

Nimesh D. Desai MD PhD
On behalf of the STS/ACC TVT Registry Risk Modeling Subcommittee

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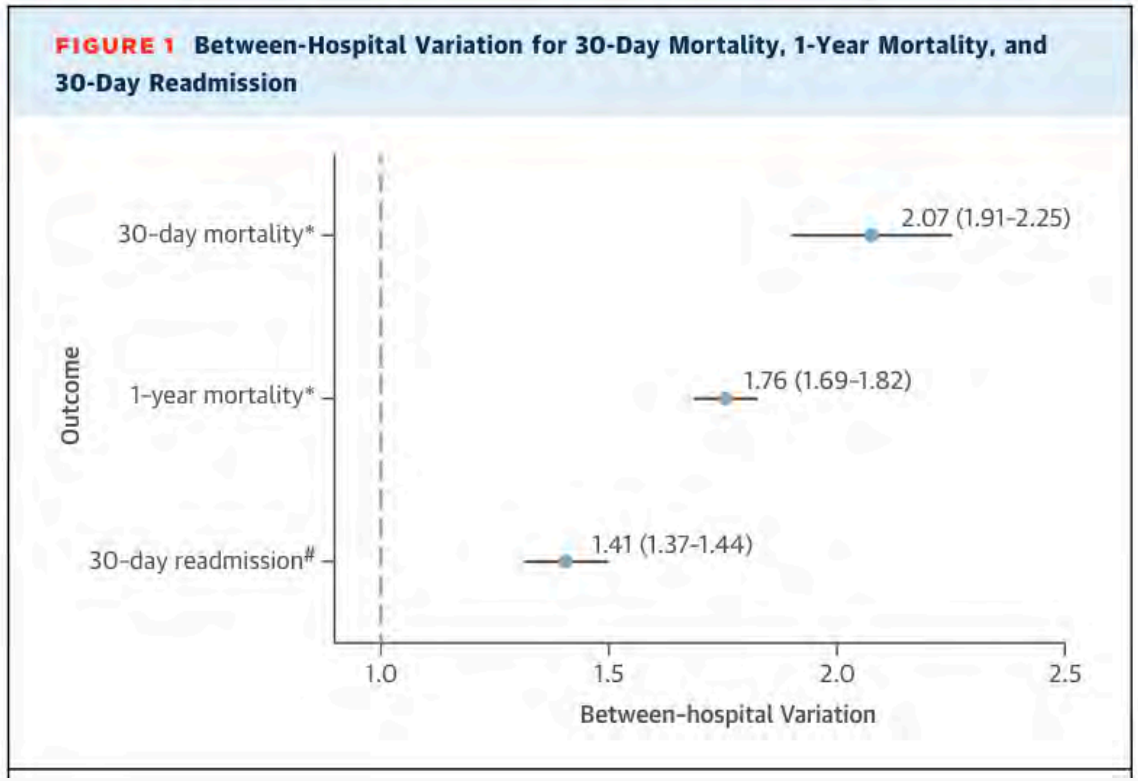
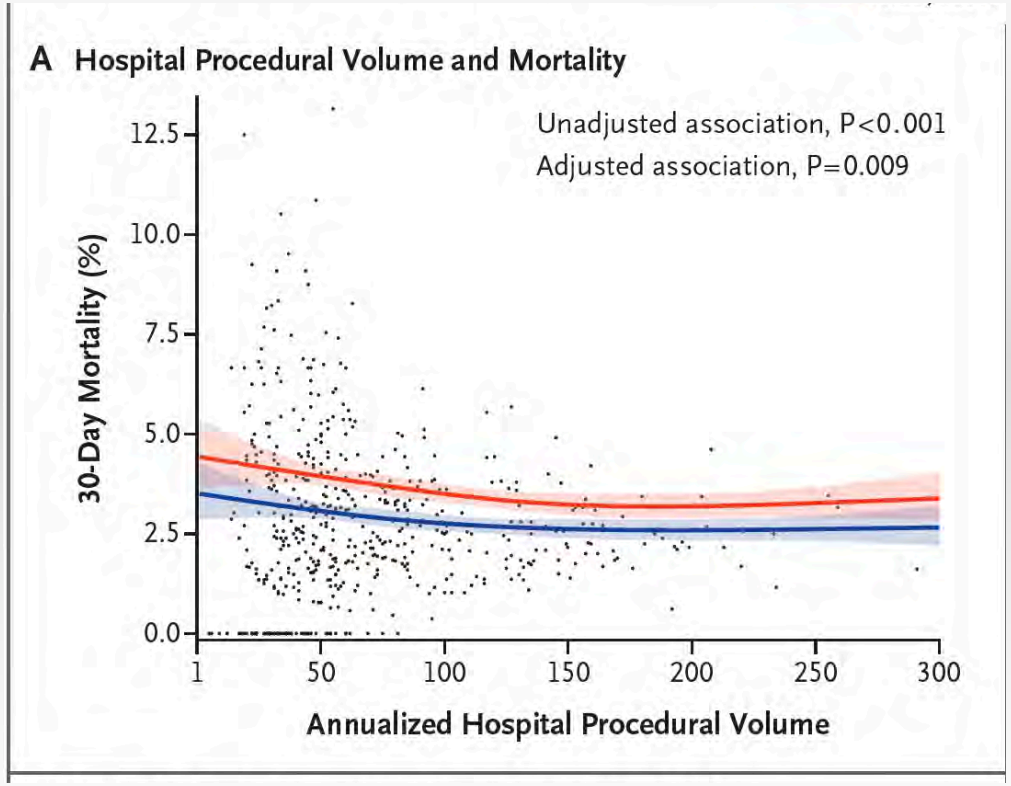
TAVR Outcomes in the United States

Wide variation in TAVR mortality is occurring at the SITE level



Murugiah et al JACC 2015



Vemulapalli et al NEJM 2019

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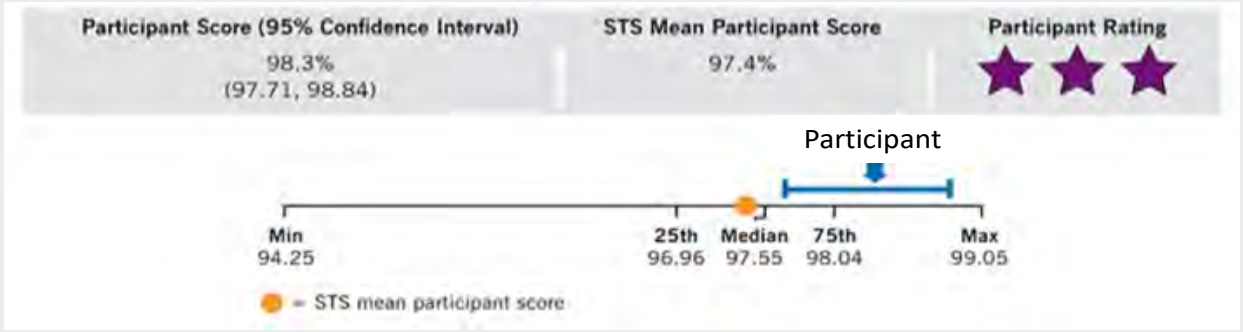
Going Beyond Mortality Outcomes:

Why Develop a Composite Morbidity and Mortality Measure for TAVR?

- ***Patients care about outcomes beyond peri-procedural mortality***
  - ***Alive and Well with improved functional status and quality of life***
- Composite measures can summarize all available information about the quality of care delivered using high quality, validated clinical data
- Move away from surrogate measures of quality such as volume towards real clinical outcomes
- Concept is well established in CABG, Valve Surgery



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Study Purpose

- *The purpose of this study was to determine if there is site-level variation in quality of care in TAVR in the United States using a novel patient-centric 30-day composite outcome measure.*

Key Features:

- Fatal and Non-Fatal Outcomes
- Robust, non-parsimonious
- Incorporating novel data elements such as gait speed and KCCQ
  - functional status, patient reported health status
- Highly patient-centric, meaningful endpoints
- Responsive to changes in patient populations and technologies

Methods: Patient Cohort

- All patients undergoing TAVR in the United States for symptomatic aortic stenosis between Jan 1, 2015 – Dec 31, 2017 were included from the STS/ACC TVT Registry
- Based on conventions established for the TVT 30-day mortality model, data from hospitals with >10% missing data for the outcome variable and other key study variables were excluded.

Derivation cohort of Composite Mortality and Morbidity Risk Model

Inclusion-Exclusion	Sites	Records
Inclusion: Index TAVRs procedures in patients discharged from 01JAN2015-31DEC2017	556	114121
Inclusion: Sites with >=90% completeness data for Ranked Endpoint, KCCQ-baseline and 5 m walk	301	54217
Inclusion: Ranked Endpoint status available	301	52561

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Methods: Development of Ranked Composite Outcome
Understanding what Matters to Patients

- The selection and rank order of the periprocedural complications for the composite was determined by their adjusted association with 1-year mortality and patient quality of life(KCCQ)
  - Not Expert Opinion, Delphi Process
- Any outcome with significant HR was maintained
- (New Pacemaker and Major Vascular complications were not significant)

	1-yr Mortality		***1-yr KCCQ-OS***	
30-day Non-fatal complications after TAVR	Adjusted Hazard Ratio	P-value	Adjusted Estimate	P-value
Any stroke	2.2(1.7,2.9)	<.001	-5.8 (-9.2,-2.4)	<.001
Major or Life-threatening/Disabling Bleed	1.9(1.4,2.6)	<.001	-.41 (-2.0,1.19)	0.619
Acute kidney injury (Stage III)	1.8(1.4,2.4)	<.001	-3.3 (-6.8,0.28)	0.071
Paravalvular Leak (Moderate/Severe)	1.5(1.2],1.8)	<.001	-2.0 (-3.8,-.30)	0.021

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TVT Risk Model Composite: Global Ranking of Endpoints

Death	• In-Hospital or 30-day mortality
Stroke	• In-Hospital or 30-day stroke
Bleed	• In-hospital or 30-day VARC major/life threatening/disabling bleed
AKI	• In-hospital of 30-day creatinine increase or 30 day new dialysis (AKI III)
PVL	• In-hospital or 30-day moderate/severe peri-valvular leak (PVL)
None	• None of the above

If a patient experienced multiple outcomes captured in the global rank composite measure, the outcome with the highest rank was assigned.

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Results:
Morbidity and Mortality Composite Components

Frequency of Global Ranking Categories in Study Cohort

Endpoint Category	Number (N = 52,561)	Percent
1 = In-hospital/30-day death	1671	3.2%
2 = In-hospital/30-day stroke	1077	2.0%
3 = In-hospital/30-day VARC major/life threatening/disabling bleed	3024	5.8%
4 = AKI: In-hospital/30-day sig creatinine increase or new dialysis	336	0.6%
5 = In-hospital/30-day moderate/severe peri-valvular leak (PVL)	1304	2.5%
6 = None of the above	45149	85.9%

Primary End-point Assessment:

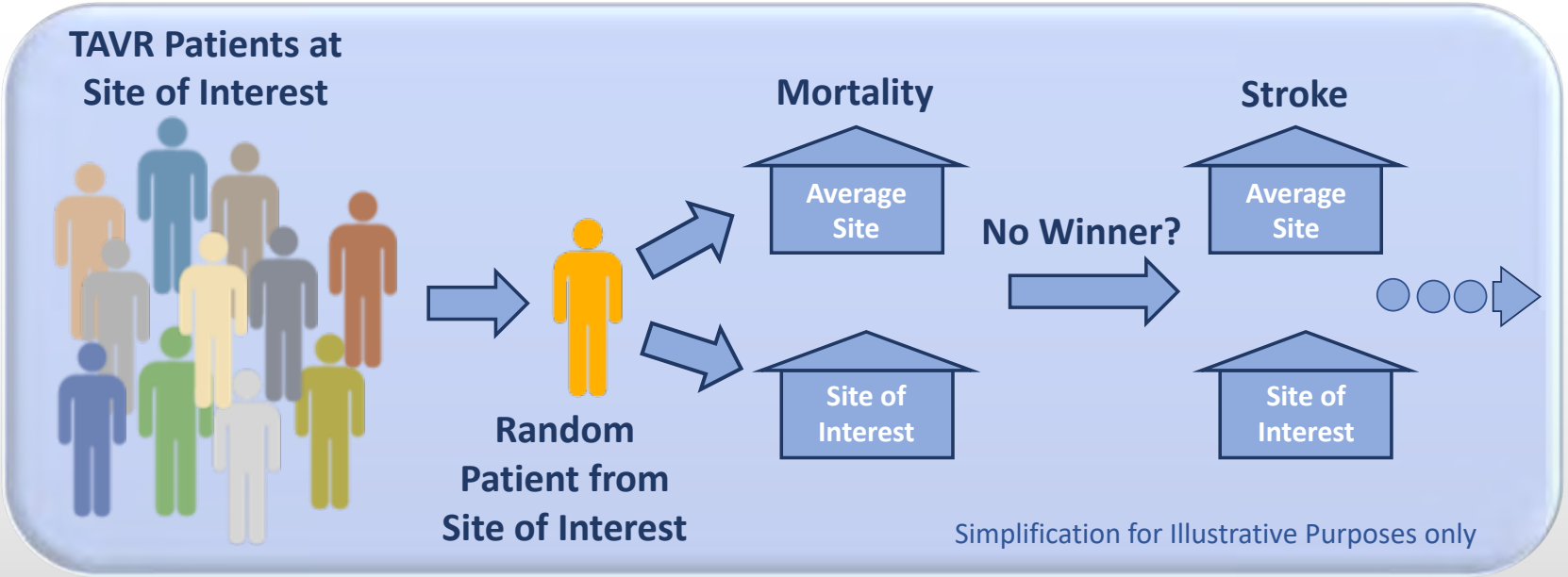
Overall Model:

Hierarchical multi-category logistic regression model which estimates a set of hospital-specific odds ratios

Site Difference

Novel metric incorporating elements similar to 'Win Ratio'

Risk Adjusted with 46 Covariates incl. Baseline KCCQ and Gait Speed



SITE DIFFERENCE =
pRandom Patient does Worse at Avg Hospital –
pRandom Patient does Better at Avg Hospital

Positive Site Difference is good, Negative Site Difference is bad.

Sites whose outcomes were outside 95% confidence intervals of the average sites were considered to be performing worse or better than expected. No prespecified outlier proportions.

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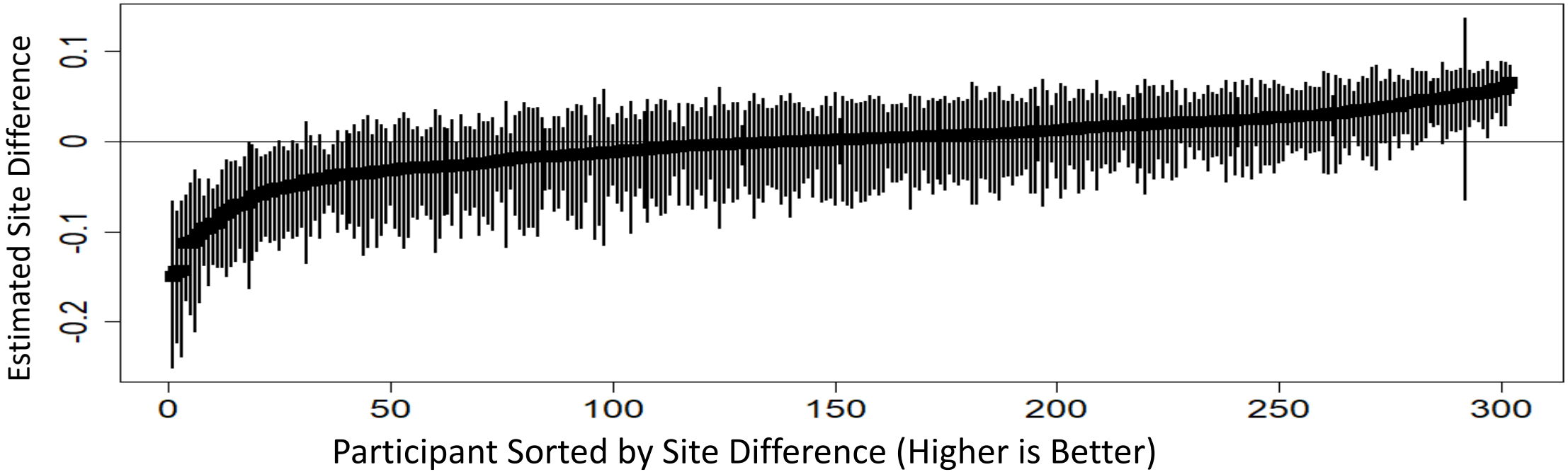
Results: TVT Risk Model – Site Difference Morbidity and Mortality Composite (3 yr)

Number of Hospitals by Statistical Categorization Based on 95% Interval

Worse Than Expected	As Expected	Better Than Expected
34 / 301 (11%)	242 / 301 (80%)	25 / 301 (8%)



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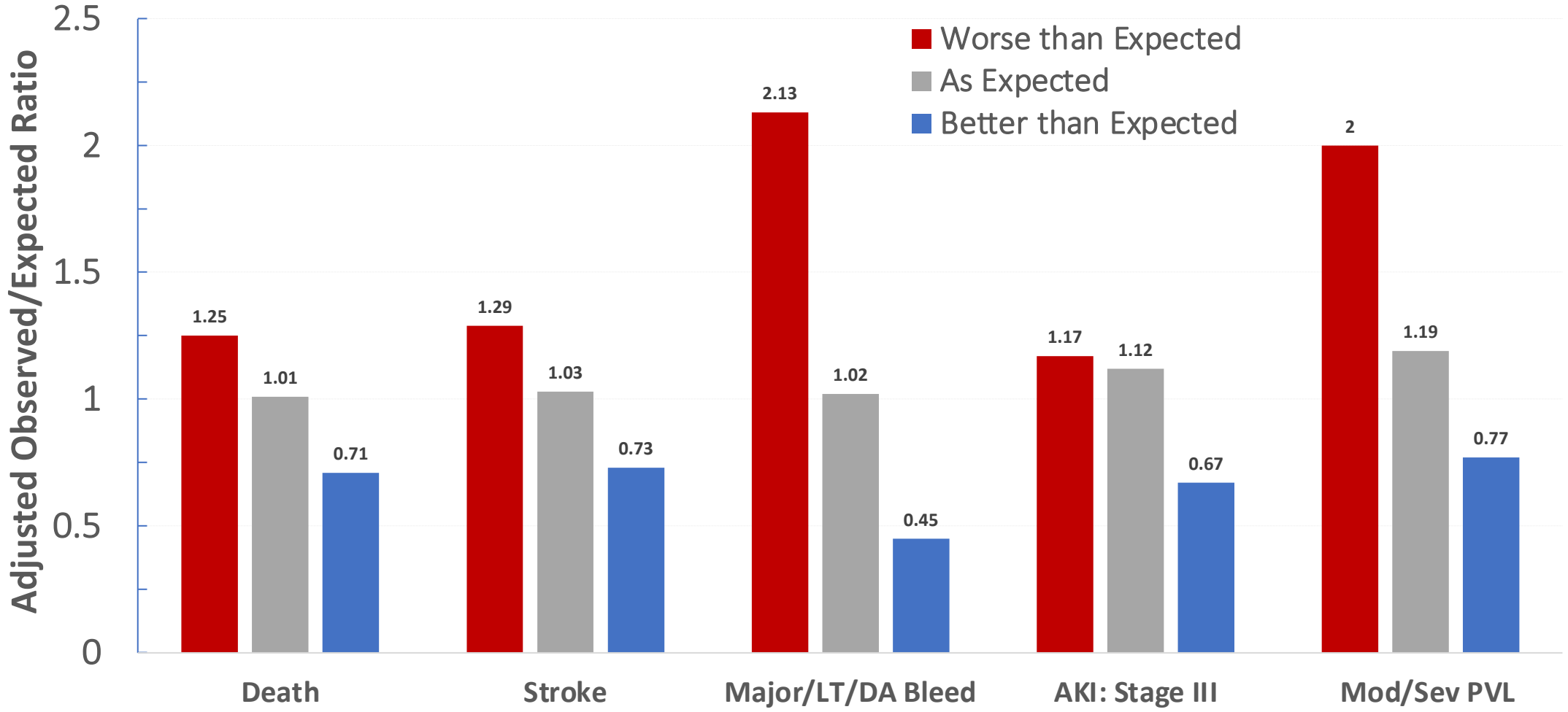
Validity: Risk Adjusted Outcomes by Site Status



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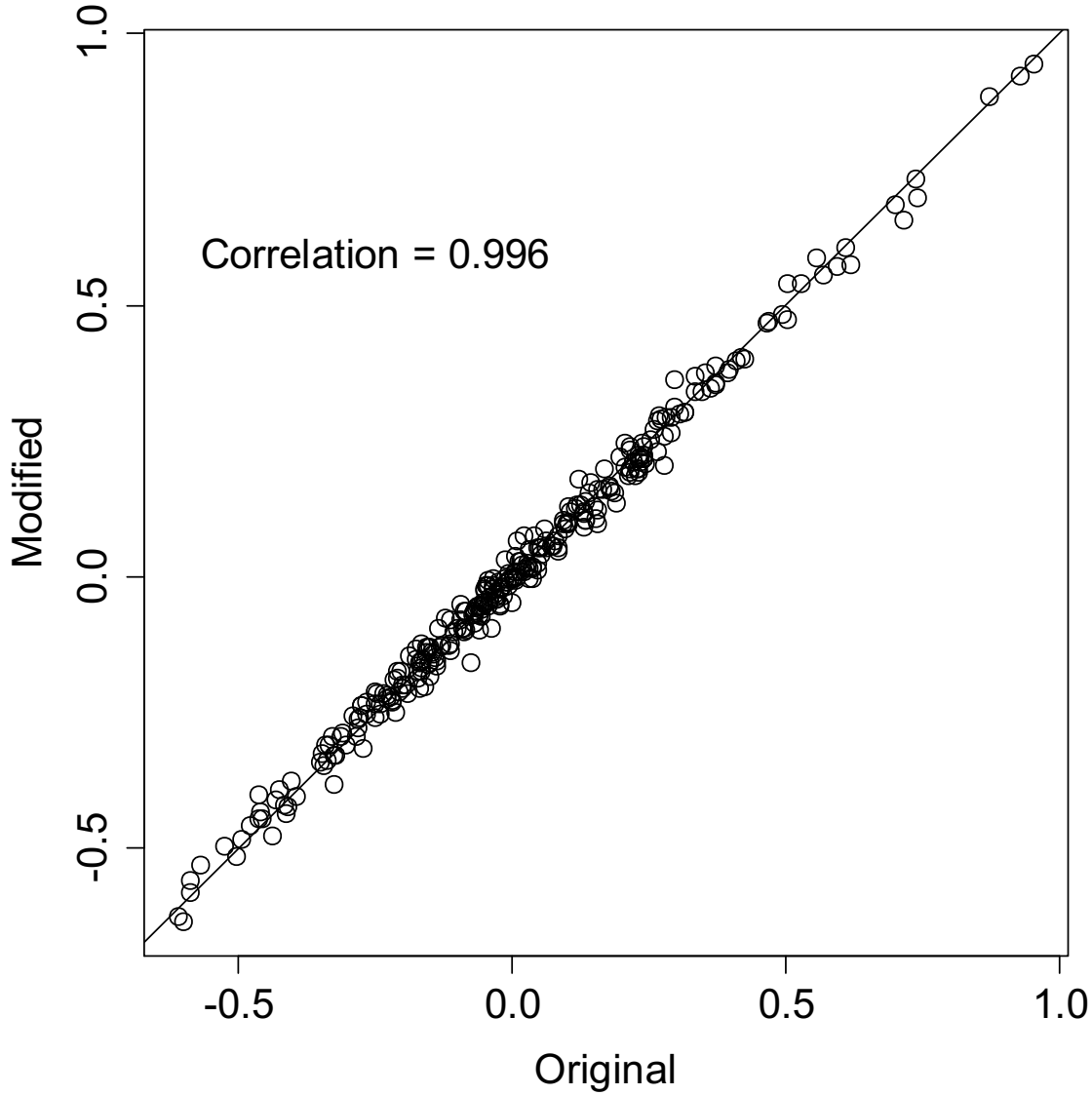
Sensitivity Analyses: Remove KCCQ and Gait Speed

Eligible Centers in cohort: 301 to 447

8% Better than Expected
80% As Expected
12% Worse than Expected

1 of 301 Original Sites Change Star Category



Sensitivity Analyses: 3 State instead of 6 State model

Death

- **In-Hospital or 30-day mortality**

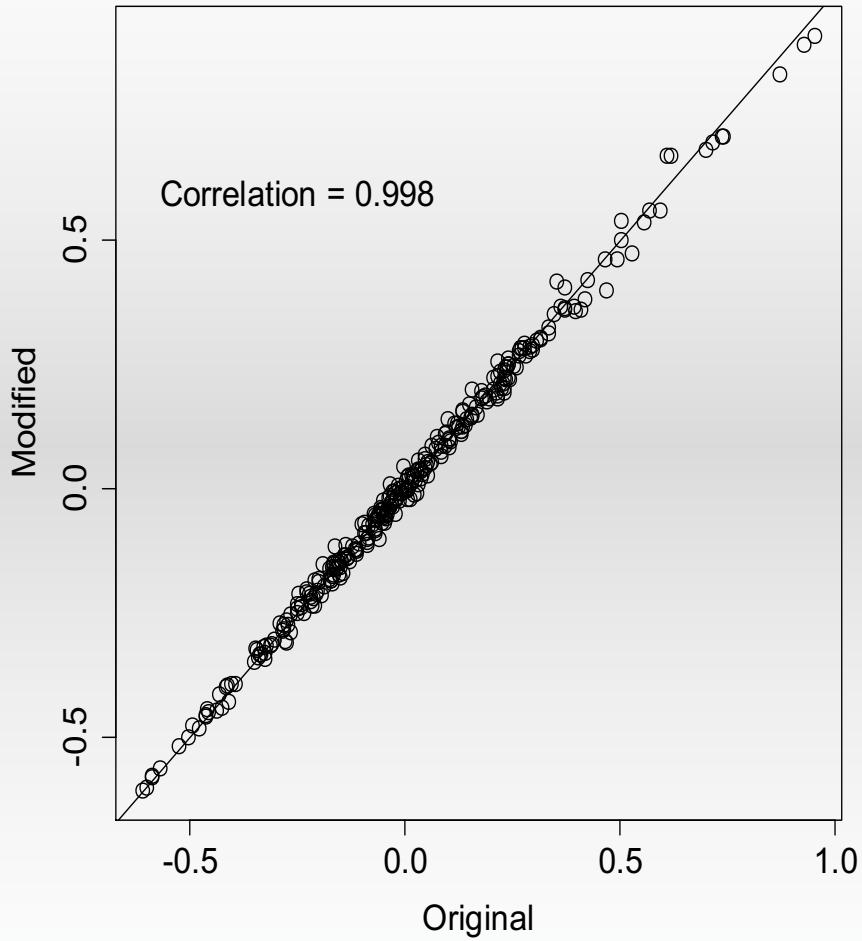
Major Comp

- **In-Hospital or 30-day major complication**

None

- **None of the above**

2 of 301 Sites Change Star Category



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Reliability Testing

- Reliability: A measure of how well one can confidently distinguish the performance of one site from another (Signal to Noise)
- There are three main drivers of reliability: sample size, differences between sites, and measurement error.

Value below 0.5 indicates poor reliability

Value above 0.5 indicates acceptable reliability

Values above 0.7-0.8 are desirable

Potential Causes of Poor Reliability:

- **Low Event Rates**
- **Short Periods of Observation(1-3 years of data)**
- **Programs with Small Sample Size**
- **Limited Variation in Outcomes b/w Programs**

Estimated reliability as a function of volume threshold for reporting

Hospital TAVR Volume	Outcome Measure	
	30-Day Mortality	30-Day Mortality and Morbidity Ranked Composite
Hospitals with at least 10 cases	0.14	0.58
Hospitals with at least 25 cases	0.17	0.62
Hospitals with at least 50 cases	0.19	0.67
Hospitals with at least 75 cases	0.22	0.71
Hospitals with at least 100 cases	0.26	0.74
Hospitals with at least 200 cases	0.34	0.82
Hospitals with at least 500 cases	0.50	0.89

Derived from Monte Carlo Simulation

How does the model perform with contemporary data?

Jan 1, 2015 to Dec 31, 2017

Endpoint Category	Number	Percent
Death	1671	3.2%
Stroke	1077	2.0%
VARC Major or LT/Disabling Bleed	3024	5.8%
AKI (Stage III)	336	0.6%
Moderate/Severe peri-valvular leak	1304	2.5%
None of the above	45149	85.9%

Worse Than Expected	As Expected	Better Than Expected
34 / 301 (11%)	**242 / 301 (80%)**	**25 / 301 (8%)**

Jan 1, 2018 to Jun 30, 2019

Endpoint Category	Number	Percent
Death	1307	2.6%
Stroke	1009	2.0%
VARC Major or LT/Disabling Bleed	2513	5.0%
AKI (Stage III)	250	0.5%
Moderate/Severe peri-valvular leak	625	1.2%
None of the above	45037	88.8%

Worse Than Expected	As Expected	Better Than Expected
34/373 (9%)	**328/373 (88%)**	**11/373 (3%)**

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Limitations

- Missing baseline KCCQ-12 and gait speed data limited the number of sites included in this analysis.
  - Sensitivity analyses showed that exclusion of these variables did not meaningfully change the categorization of sites
  - significant educational efforts are being made to improve compliance and the inclusion of these variables within the TVT registry remains ***mandated*** by CMS.
  - **2019: 92% completeness for KCCQ**

Conclusions

- We developed a novel patient-centric composite outcome for TAVR based on 30-day outcomes and their ranked association with both 1-year mortality and quality of life.
- We have identified significant site-level variation in mortality and major complications after TAVR procedures in the United States.
- The model demonstrated excellent performance including internal validity and moderate to high reliability even when including lower-volume programs
- This 30-day composite metric is appropriate for high-stakes applications such as public reporting.

STS/ACC Registry Risk Modeling Subcommittee:
Chairs: Nimesh D. Desai MD PhD, David J Cohen MD MSc
Members: John Carroll MD, Sreekanth Vemulapalli MD, Sean O'Brien PhD, John Forrest MD, Vinod Thourani MD, Ajay Kirtane MD, Brian O'Neil MD, Pratik Manandhar MD, David Shahian MD, Vinay Badhwar MD, Suzanne V Arnold MD MHA, Joseph E Bavaria MD
ACC/STS Staff: Carole Crohn, Joan Michaels, Susan Fitzgerald, Donna Macdonald

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Methodology for Rating TAVR Centers

November 19, 2020

Presented by Tavia Binger, MSPH

Overall Goal of U.S. News TAVR Ratings:

Provide patients & families with patient decision support that is data-driven and easy to understand so that they can make the best decision for their health.

Key Differences Between USN & TVT Ratings

	USNWR	STS/ACC TVT Registry
Eligible Sites	Any hospital that billed Medicare for TAVR	Must participate in TVT
Primary Data Source	CMS Medicare inpatient claims	Chart abstraction
Patient Population	Medicare fee-for-service, age 65+	All TAVR recipients
Analytic Time Period	2-year lag, 5-year window	Rolling 3-year window
Outcomes/ Endpoints	Death, stroke, discharge not home, readmission	Death, stroke, major/life threatening bleeding, acute kidney injury, paravalvular leak
Structural Indicators	Nurse staffing, Volume, etc.	Not included
Statistical Testing for Outlier Determination	$p<0.25$	$p<0.05$
Public Reporting	Involuntary, began July 2020	Voluntary, starts in 2021

How U.S. News & World Report evaluated hospitals in...

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

BEST HOSPITALS U.S.News & WORLD REPORT 2020-21

Patient Outcomes

These measures are central to the ratings. To avoid penalizing hospitals that care for sicker or poorer patients, each is adjusted to account for clinical and socioeconomic differences.

- Readmission Prevention
- Prevention of Stroke
- Discharge to Home
- Survival

+

Processes of Care & Resources

To gauge how capable a hospital is at providing care, U.S. News combines key structural and process of care measures.

- Volume
- Cardiac ICU
- Nurse Staffing
- ICU Specialists
- Patient Experience

=

Overall Rating

Out of **621** hospitals that offered patients this procedure, **568** performed enough cases to be rated. The others had very limited experience in this procedure.

High Performing

Only **93** hospitals earned a High Performing rating in aortic valve surgery.

Average

367 Hospitals earned an Average rating.

Below Average

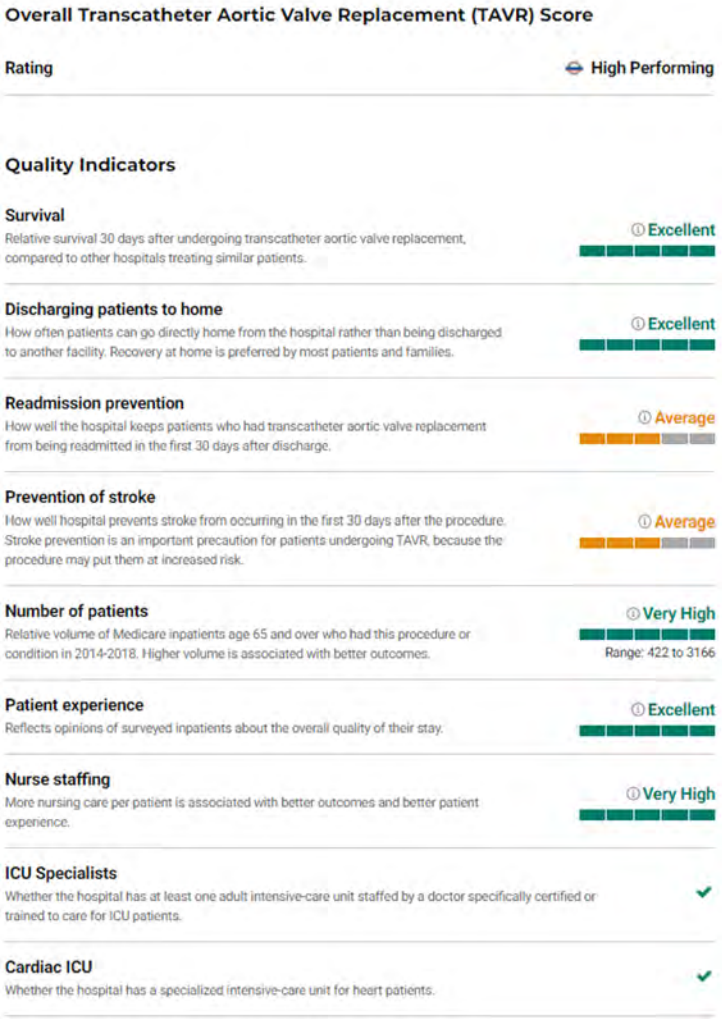
108 hospitals received a Below Average rating.

About U.S. News Best Hospitals Procedures & Conditions Methodology

- U.S. News reviewed over **50** million records of patient care provided at more than **4,500** hospitals. Aortic valve surgery was one of 10 procedures and conditions in which those hospitals were rated.
- More than **1,425** hospitals were rated High Performing in at least one procedure or condition. But only **37** got that top rating in all ten areas of care.

New This Year

Website Display



Overall Transcatheter Aortic Valve Replacement (TAVR) Score

Rating — High Performing

Quality Indicators

Survival
Relative survival 30 days after undergoing transcatheter aortic valve replacement, compared to other hospitals treating similar patients.
Excellent

Discharging patients to home
How often patients can go directly home from the hospital rather than being discharged to another facility. Recovery at home is preferred by most patients and families.
Excellent

Readmission prevention
How well the hospital keeps patients who had transcatheter aortic valve replacement from being readmitted in the first 30 days after discharge.
Average

Prevention of stroke
How well hospital prevents stroke from occurring in the first 30 days after the procedure. Stroke prevention is an important precaution for patients undergoing TAVR, because the procedure may put them at increased risk.
Average

Number of patients
Relative volume of Medicare inpatients age 65 and over who had this procedure or condition in 2014-2018. Higher volume is associated with better outcomes.
Very High
Range: 422 to 3166

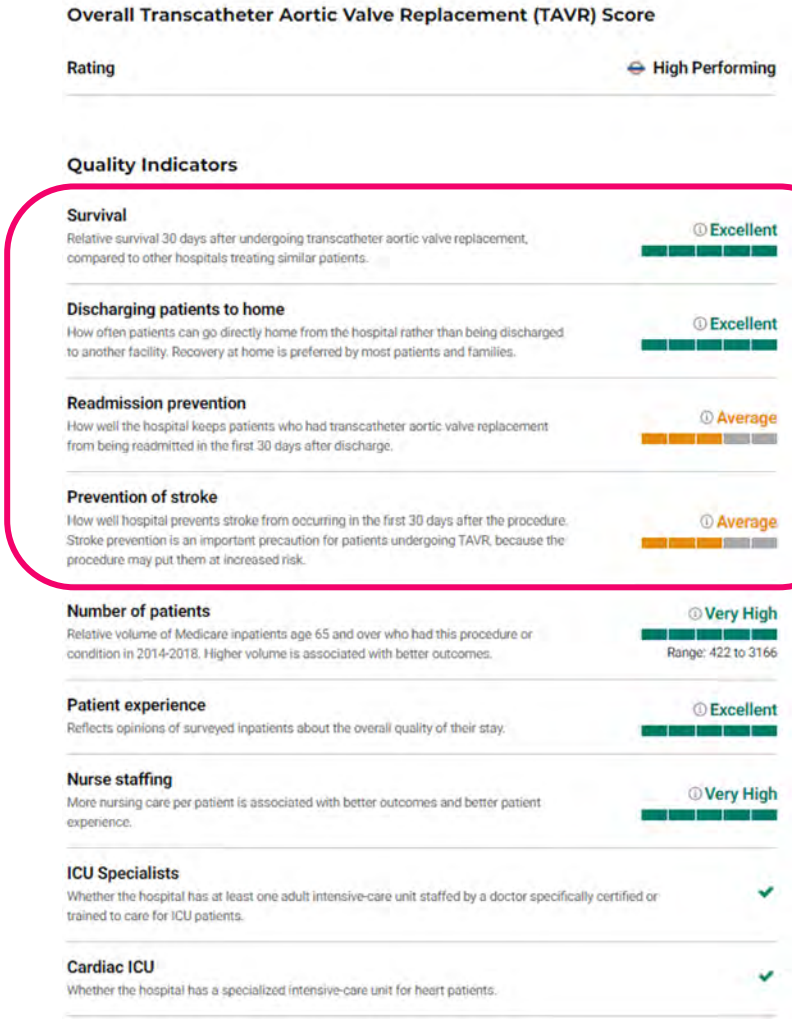
Patient experience
Reflects opinions of surveyed inpatients about the overall quality of their stay.
Excellent

Nurse staffing
More nursing care per patient is associated with better outcomes and better patient experience.
Very High

ICU Specialists
Whether the hospital has at least one adult intensive-care unit staffed by a doctor specifically certified or trained to care for ICU patients.
✔

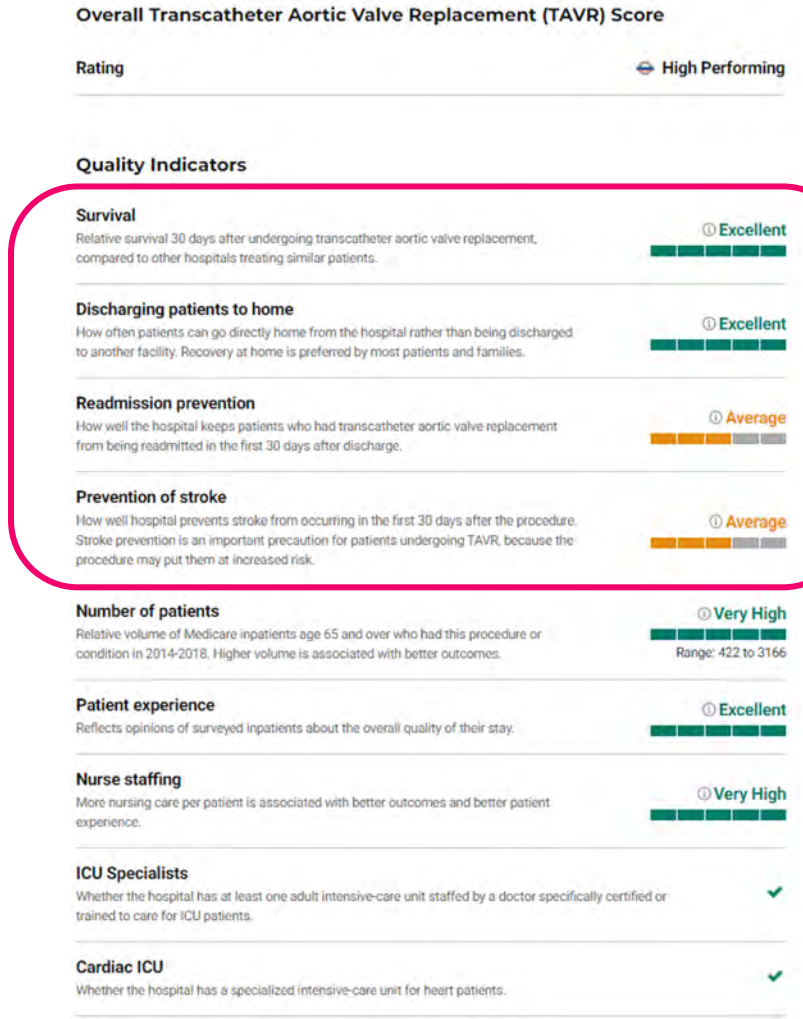
Cardiac ICU
Whether the hospital has a specialized intensive-care unit for heart patients.
✔

Website Display



5-tiered Outcomes

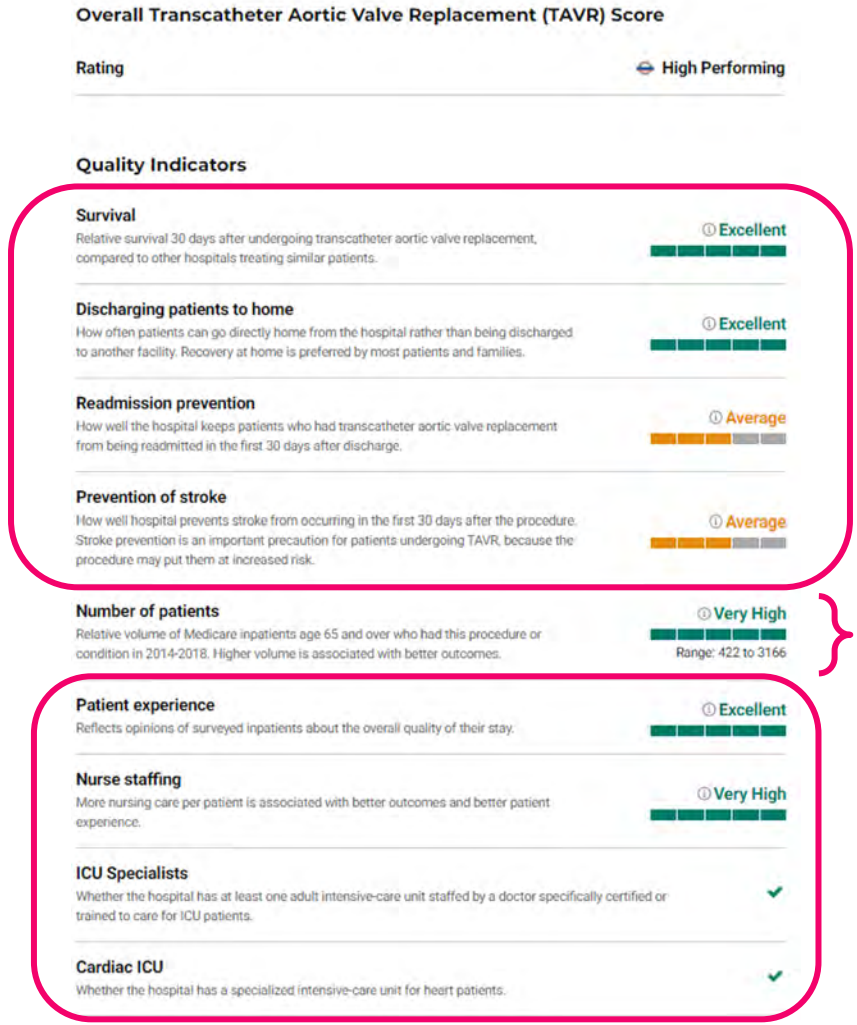
Website Display



5-tiered Outcomes

Volume range

Website Display

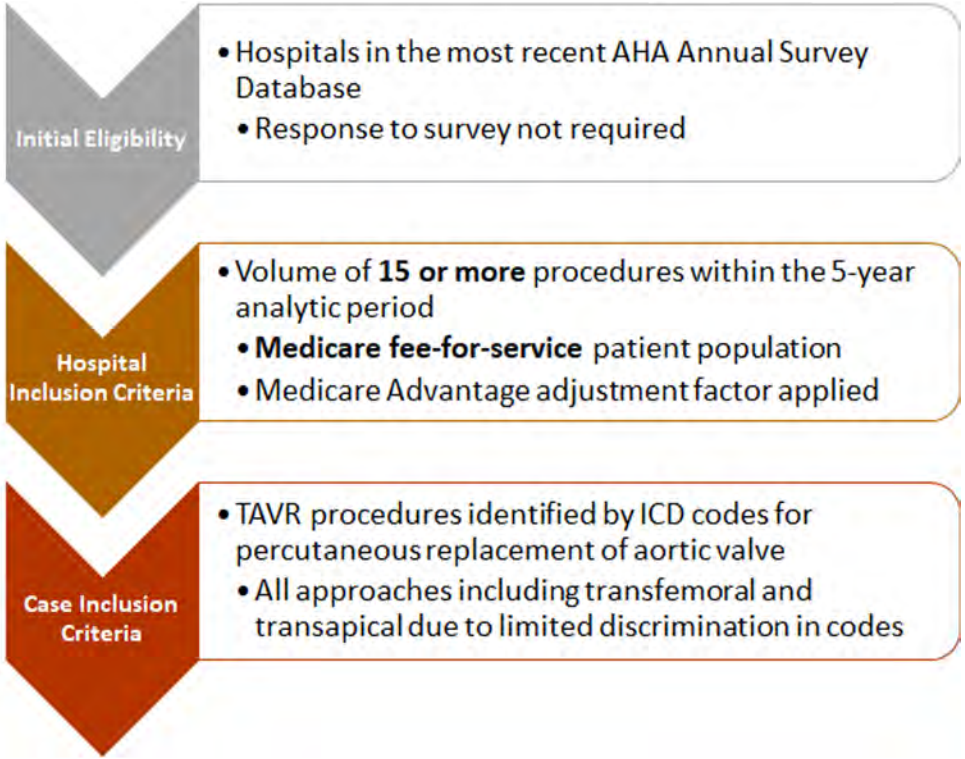


5-tiered Outcomes

Volume range

Structure & process measures

Eligibility & Inclusion Criteria



In addition to existing inclusion criteria for Procedures & Conditions Rating methodology

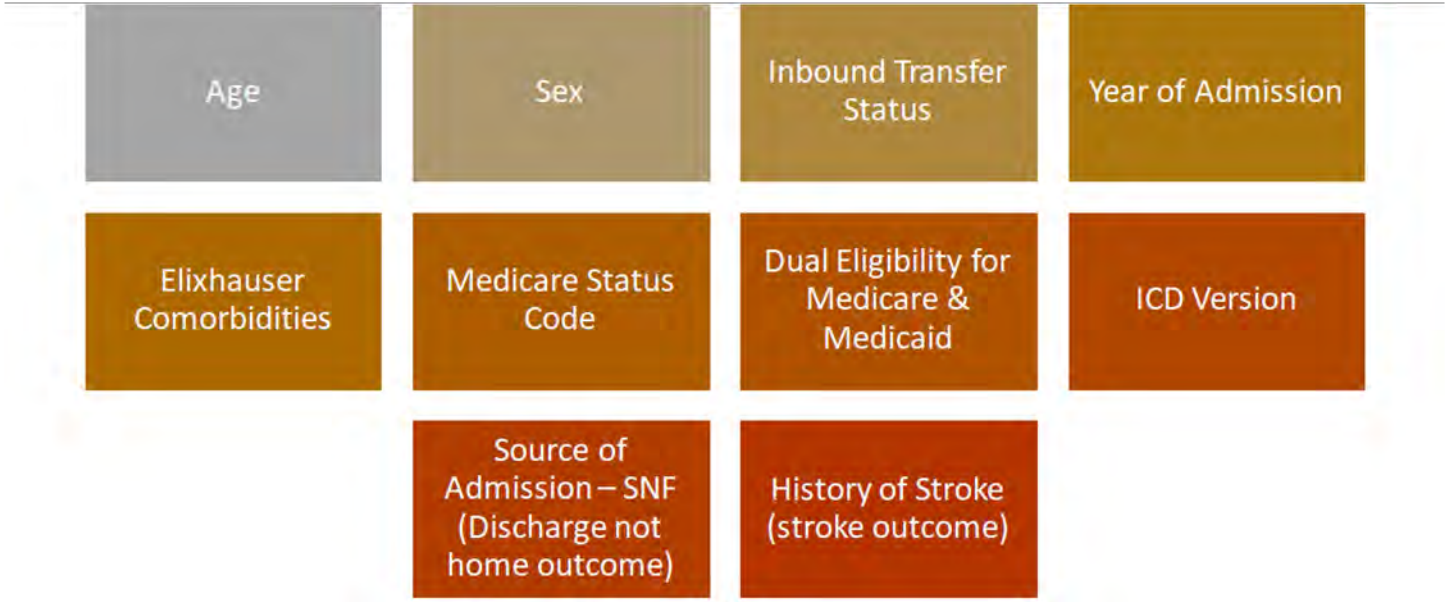
Definition of the TAVR cohort

ICD-10-PCS Code	ICD-10 PCS Description
02R.F37Z	Replacement of Aortic Valve with Autologous Tissue Substitute, Percutaneous Approach
02R.F38Z	Replacement of Aortic Valve with Zooplastic Tissue, Percutaneous Approach
02R.F3JZ	Replacement of Aortic Valve with Synthetic Substitute, Percutaneous Approach
02R.F3KZ	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Percutaneous Approach
02R.F37H	Replacement of Aortic Valve with Autologous Tissue Substitute, Transapical, Percutaneous Approach
02R.F38H	Replacement of Aortic Valve with Zooplastic Tissue, Transapical, Percutaneous Approach
02R.F3JH	Replacement of Aortic Valve with Synthetic Substitute, Transapical, Percutaneous Approach
02R.F3KH	Replacement of Aortic Valve with Nonautologous Tissue Substitute, Transapical, Percutaneous Approach
X2R.F332	Replacement of Aortic Valve using Zooplastic Tissue, Rapid Deployment Technique, Percutaneous Approach, New Technology Group 2

Risk-adjusted Claims-based Outcome Measures

Outcome	Description	C-stat	Analogous TVT Endpoint
Death	Mortality within 30 days of procedure date	.78	**Yes**
Stroke	Stroke within 30 days of procedure date	.77	**Yes**
Discharge Not Home	Measures discharges to a location other than the patient's home, such as a SNF or LTAC	.80	**No**
Readmission	Unplanned readmissions within 30 days of discharge date	.65	**No**

Risk Adjustment Covariates



All covariates are derived from claims data and applied in multilevel logistic regression models.

A Closer Look: Readmission Outcome Measure

- Based on the CMS Hospital-Wide All-Cause Unplanned Readmission Measure
  - Endorsed by NQF in 2012 (NQF# 1789)
- All unplanned readmissions are counted, regardless of the cause
- Excludes types of care that are always considered planned
  - Examples: chemotherapy, transplant surgery
- Excludes readmissions for most scheduled procedures
  - Examples: hip replacement, spinal fusion
  - *Unless* principal diagnosis indicates an acute admission (Example: acute renal failure)

Composite Model Comparison: TAVR, SAVR, CABG

Measure	Data Source	TAVR	SAVR	CABG
Death	Medicare claims	Yes	Yes	Yes
Stroke	Medicare claims	Yes		
Discharge Not Home	Medicare claims	Yes	Yes	Yes
Readmission	Medicare claims	Yes	Yes	Yes
Prolonged Stay	Medicare claims		Yes	Yes
Procedural Volume (2014-2018)	Medicare claims	Yes	Yes	Yes
Voluntary Public Reporting Status	STS.org	n/a	Yes	Yes
Publicly Reported Composite Score	STS.org	n/a	Yes	Yes
Nurse-Patient Ratio, Intensivist, and Cardiac ICU	Amer. Hosp. Assoc.	Yes	Yes	Yes
Patient Experience	HCAHPS	Yes	Yes	Yes

Composite Model Comparison: TAVR, SAVR, CABG

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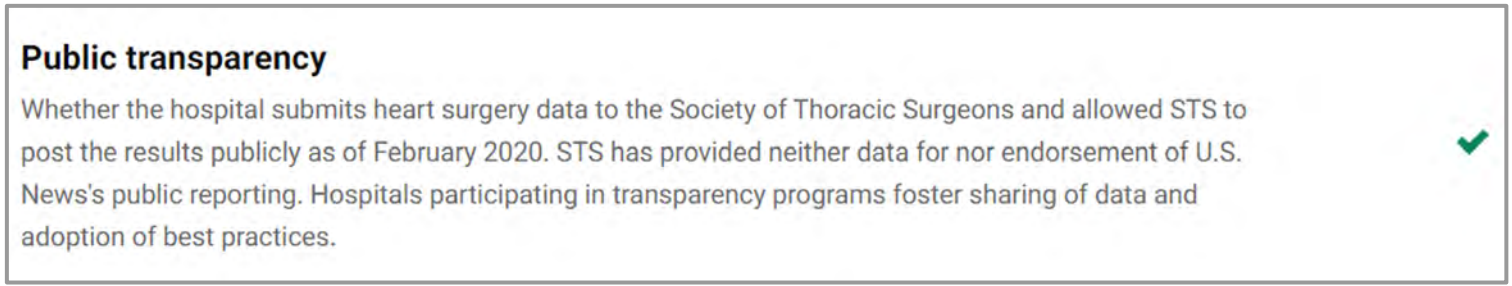
Publicly Reported Composite Score	STS.org	n/a	Yes	Yes
Nurse-Patient Ratio, Intensivist, and Cardiac ICU	Amer. Hosp. Assoc.	Yes	Yes	Yes
Patient Experience	HCAHPS	Yes	Yes	Yes

Future of Public Reporting in TAVR Rating

- Two additional candidate measures:
  - **Public Transparency** (0/1 Indicator)
    - Opt in to public reporting with TVT Registry
    - Cut-off date to be announced in Q1 of 2021
  - **Published STS/ACC Score** (Continuous measure)
    - No display on our website



No. (%) of Centers, by U.S. News Performance Tier

Composite Rating	TAVR	SAVR	CABG
High Performing	91 (15%)	204 (18%)	258 (23%)
Average	369 (59%)	529 (47%)	573 (50%)
Low Performing	110 (18%)	209 (19%)	286 (25%)
Unrated	52 (8%)	186 (16%)	25 (2%)
Total No. of Centers	622 (100%)	1,128 (100%)	1,142 (100%)

Concordance of U.S. News and STS for SAVR

	STS 1-star AVR	STS 2-star AVR	STS 3-star AVR
USN Low Performing	<1%	10%	
USN Average	1%	55%	1%
USN High Performing		23%	7%

Table includes only centers that publicly reported via STS and were rated in AVR by U.S. News in July 2020.

Concordance of U.S. News and STS for SAVR

	STS 1-star AVR	STS 2-star AVR	STS 3-star AVR
USN Low Performing	<1%	10%	
USN Average	1%	55%	1%
USN High Performing		23%	7%

Table includes only centers that publicly reported via STS and were rated in AVR by U.S. News in July 2020.

Statistical testing at **p<0.25** significance level → More hospitals in the High Performing and Low Performing categories

Article Series: Exposing Healthcare Inequalities In America

Race and Risk Post-Surgery: Uncovering Disparities in Aortic Valve Replacement

Do different subgroups experience differential treatment once they arrive at the hospital?

By **Greta Martin**, **Tavia Binger**, and **Ronan Corgel** Aug. 18, 2020, at 9:00 a.m.

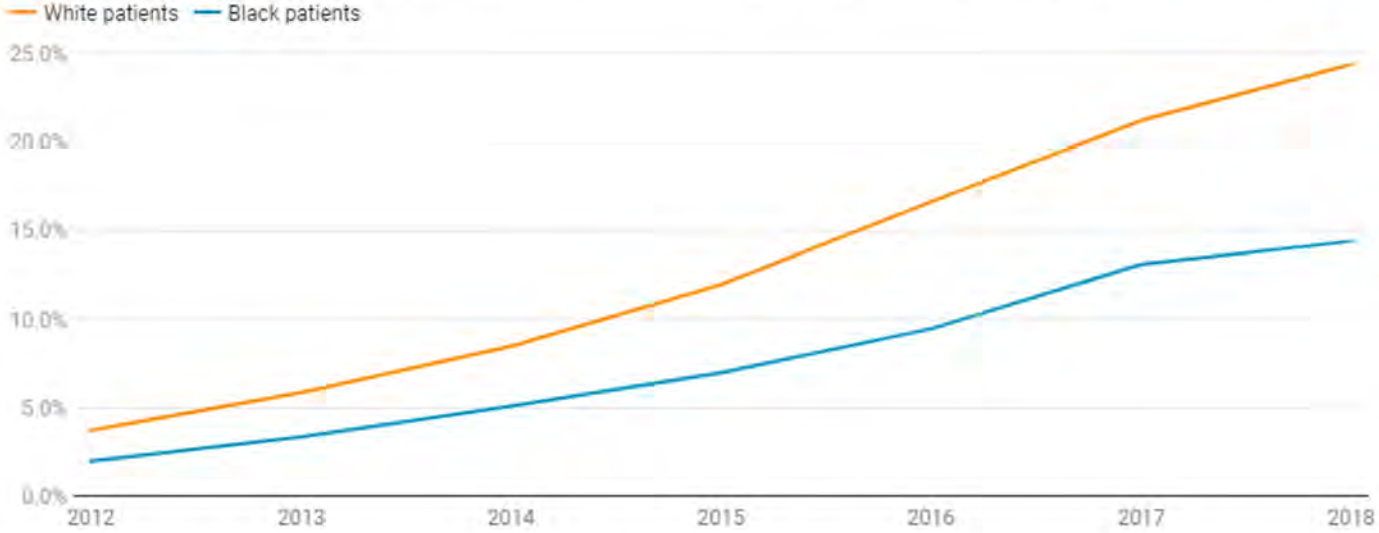
ACCORDING TO A STUDY BY The Commonwealth Fund, America ranks last among industrialized countries in measures of health equity and access to care, and has done so each year the study has been published, starting in 2004. Despite clear advancements in technology and delivery of care, accessing these health care innovations remains more of a privilege than a right in the United States.

In the first piece of this ongoing series, we revealed pronounced racial gaps in who has access to surgical care across several widely performed procedures. Another crucial component of assessing disparities in health care is understanding what happens after patients are able to access care. Do different subgroups experience differential treatment once they arrive at the hospital? In order to examine this question, we took a closer look at racial differences in health outcomes for the same eight procedures examined in the first article, focusing on death and

(GETTY IMAGES)

Figure 4. Percent of Aortic Stenosis Patients Receiving Transcatheter Aortic Valve Replacement (TAVR)

White patients with aortic stenosis are more likely to receive a TAVR surgery than Black patients with the same diagnosis.



The TAVR surgical gap between white and Black aortic stenosis patients has been increasing over the past seven years. In 2018, 24.4% of white patients with aortic stenosis received a TAVR surgery, while only 14.4% of Black patients with aortic stenosis had a TAVR surgery performed on them.

Source: Centers for Medicare and Medicaid Services, 2012 - 2018 • Get the data • Created with Datawrapper

Figure 4. Percent of Aortic Stenosis Patients Receiving Transcatheter Aortic Valve Replacement (TAVR)

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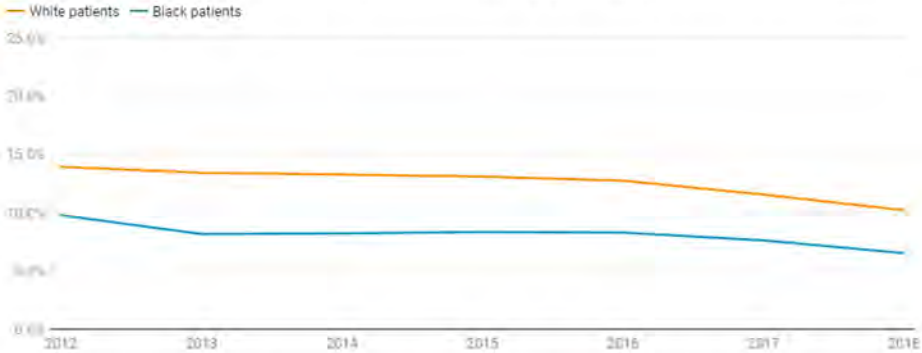
Source: Centers for Medicare and Medicaid Services, 2012 - 2018 • Get the data • Created with Datawrapper

Figure 3. Percent of Aortic Stenosis Patients Receiving Aortic Valve Surgery (AVR)

White patients with aortic stenosis are more likely to receive an AVR surgery than Black patients with the same diagnosis.

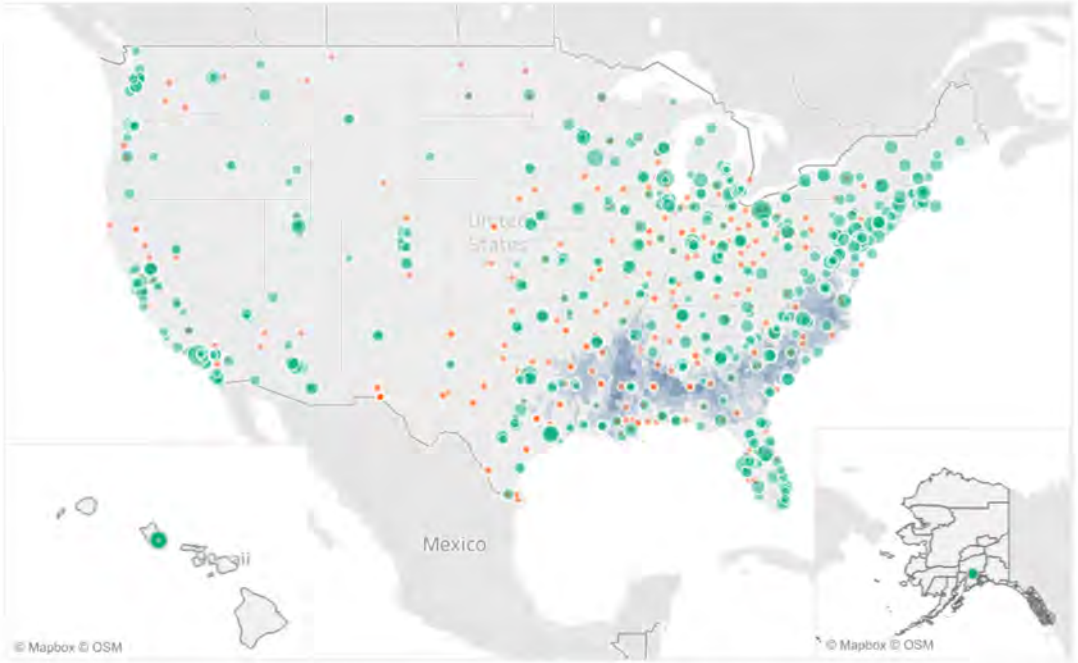


The AVR surgical gap between white and Black aortic stenosis patients has been fairly consistent over the years. In 2018, 10.2% of white patients with aortic stenosis received an AVR surgery, while only 6.5% of Black patients with aortic stenosis had an AVR surgery performed on them.

Source: Centers for Medicare and Medicaid Services, 2012 - 2018 • Get the data • Created with Datawrapper

Map 2. Procedural Volume of AVR and TAVR Hospitals with Counties Shaded by Percent of the Medicare-eligible Population that is Black

Hospitals that offer AVR alone are generally lower in volume than hospitals that offer both AVR and TAVR. Furthermore, high-volume TAVR hospitals are often not located areas that are geographically accessible to Black pati..



Percent of the Medicare-eligible population that is Black

0.0% 78.2%

Combined AVR and TAVR Volume

≤ 50 2,000 4,000
1,000 3,000 5,000

Service Provided

AVR & TAVR
AVR only

Filter by Service

Multiple values

Sources

Procedural volumes are derived using inpatient Medicare claims from the Centers for Medicare and Medicaid Services for 2014-2018. Demographic information is U.S. Census Bureau data from 2014 to 2018.

Health Equity Index

- Goal: Benchmark hospital or system performance on measures of equity
- Domains
  - Access
  - Outcomes
  - Mitigation of Social Determinants of Health
  - Others TBD
- Stay tuned for webinar in early 2021

Link to Register for Webinar:
https://www.usnews.com/news/live-events/healthcare-of-tomorrow

Key Takeaways

- There are fundamental differences between USN and STS/ACC methodology
  - Different patient population
  - Different data source
  - Voluntary vs. involuntary public reporting
  - Statistical testing for outlier determination
  - USN includes structural indicators
- Ratings do not currently use TVT Registry data, but a strong possibility for this in the future

Goal: *Provide patients & families with patient decision support that is data-driven and easy to understand so that they can make the best decision for their health.*

Thank you

STS voluntary public reporting

2010-2020

David M. Shahian, MD

Massachusetts General Hospital, Harvard Medical School

November 19, 2020

Questions (and Answers)

David J. Cohen, MD MSc
University of Missouri-Kansas City

TVT Registry Questions

- ***Why is life-threatening and major bleeding being used as an endpoint?***

- ***What echo is used to measure PVL?***
  - ***post-implant, pre-discharge, 30-day?***

USNWR Questions

- ***If a patient had TAVR in preparation for hip surgery, does the admission for hip surgery count as a readmission?***

TVT Registry Questions

- ***Can we just post our hospital procedural volumes if we do not like our star rating?***

TVT Registry Questions

- ***Why are you using rolling 3-years of data?***

USNWR Questions

- ***Aren't you concerned that sites will send patients home when they really need extended care in order to avoid getting "dinged"?***

TVT Registry Questions

- ***Why do you require 90% complete baseline KCCQ and 5MWT data in order to report?***

USNWR Questions

- ***Does my site get points for being in the TVT registry?***
- ***Does my site get points for publicly reporting in TVT?***

TVT Registry Questions

- ***What timeframe will be included in the 2021 report?***
- ***Do we need to have entered data prior to 2018 in order to be rated?***

TVT Registry Questions

- ***Comprehensive stroke centers will have higher numbers of strokes than non-CSC sites. Is it fair to include this outcome in the quality measure?***

USNWR Questions

- ***How is readmission scored? Does it matter if it is valve-related or non-valve related?***