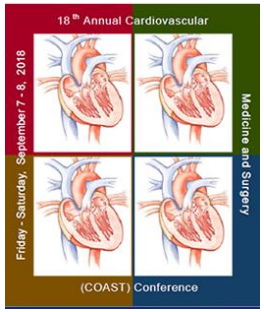
Kaiser Permanente 18th Annual
Cardiovascular Medicine & Surgery COAST Conference

TVT Registry: What Have We Learned?



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
September 8, 2018

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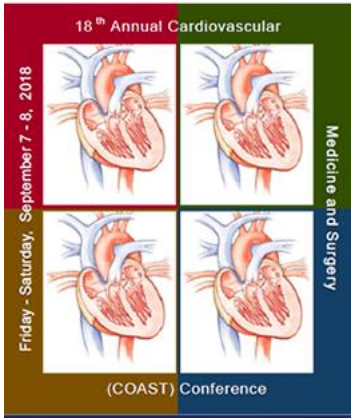
Ralph Brindis, MD, MPH, MACC, FSCAI, FAHA

Relevant Relationships:

1. Senior Medical Officer, External Affairs
   ACC National Cardiovascular Data Registry

2. Advisory Panel Member
   FDA Cardiovascular Devices



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National Cardiovascular Data Registry

- Nearly 20 years of experience
- Largest, most comprehensive, outcomes-based cardiovascular patient data repository in U.S.
- Ten registries

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Trusted Third Party

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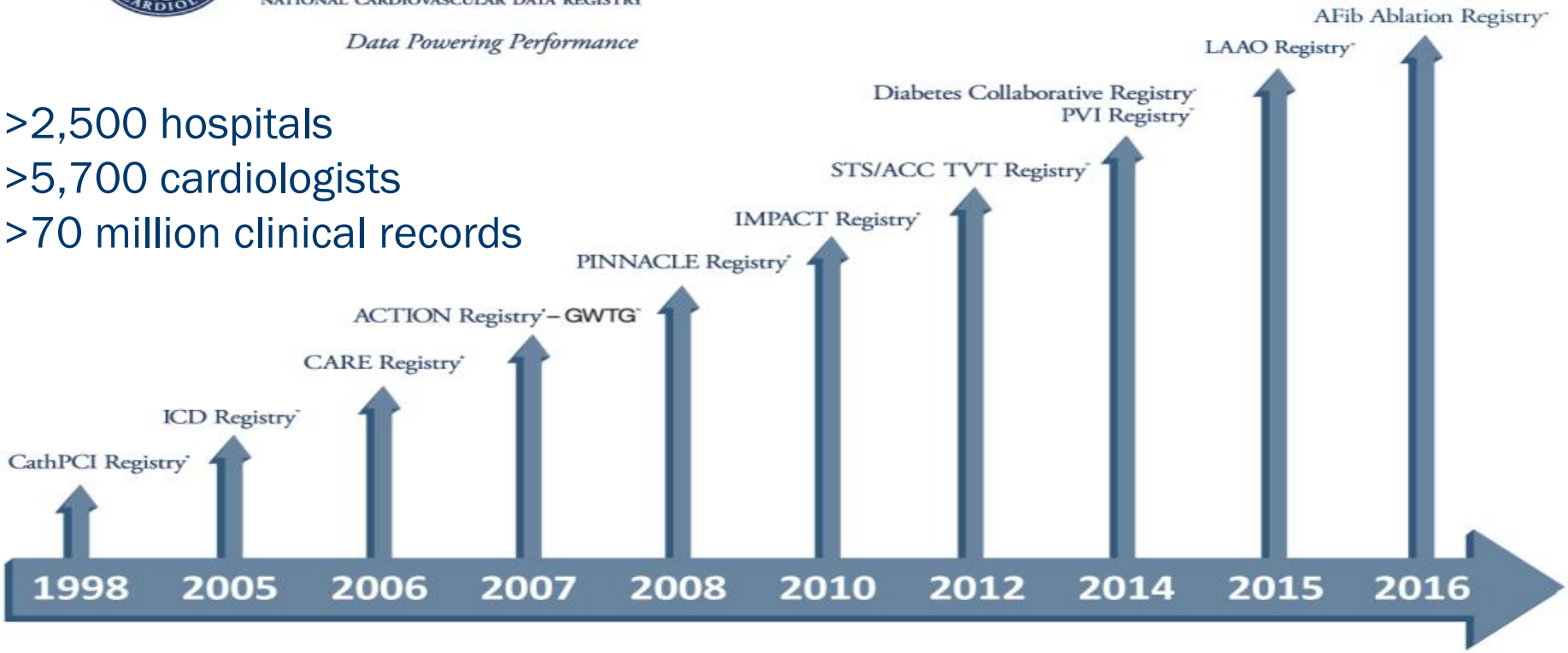
Data Powering Performance

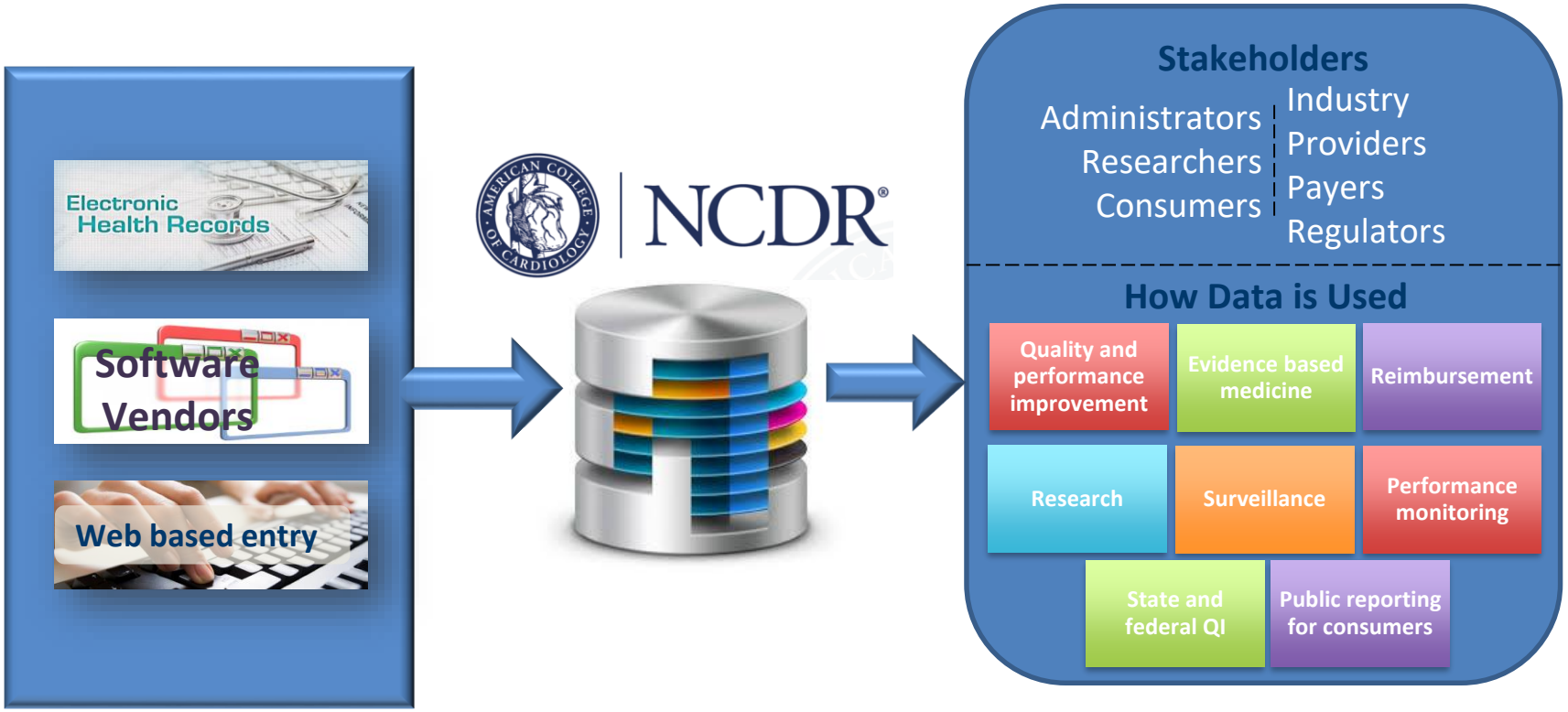
>2,500 hospitals
>5,700 cardiologists
>70 million clinical records



Name	Disease or Device	Facility	Sites	Patient Records
PINNACLE	Coronary artery disease, heart failure, atrial fibrillation, hypertension, diabetes, peripheral arterial disease	Outpatient	550	35,000,000
Diabetes	Diabetes and cardiometabolic care	Outpatient	329	1,000,000
***CathPCI**	Percutaneous coronary interventions Diagnostic catheterizations	Hospital/Free Standing	1,730	20,000,000
***ICD**	Implantable cardioverter defibrillators	Hospital	1,867	2,000,000
ACTION-ACS	Acute coronary syndrome STEMI and NSTEMI	Hospital/EMS	1030	1,200,000
***PVI**	Carotid artery revascularization Lower extremity	Hospital/Free Standing	214	350,000 (CAS & CEA)
***IMPACT**	Congenital heart disease Pediatric and Adult	Hospital	100	70,000
***STS/ACC TVT**	Transcatheter Valve Therapy	Hospital	577	150,000
***LAAO**	Left atrial appendage occlusion procedures	Hospital	369	10,000
***AF Ablation**	AF ablation procedures	Hospital	41	1,500

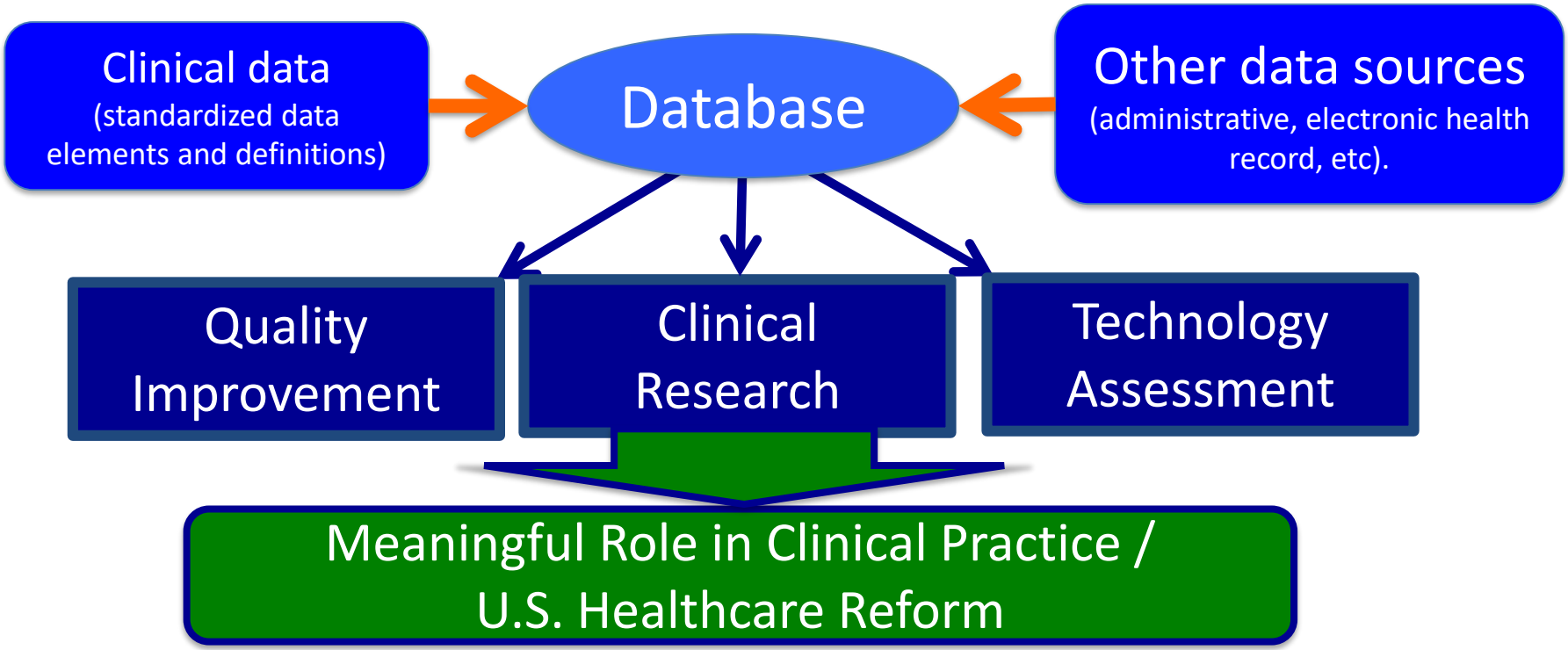
**device registries*

NCDR Data Serves Many Purposes



Clinical Registries

Not Just "Data"



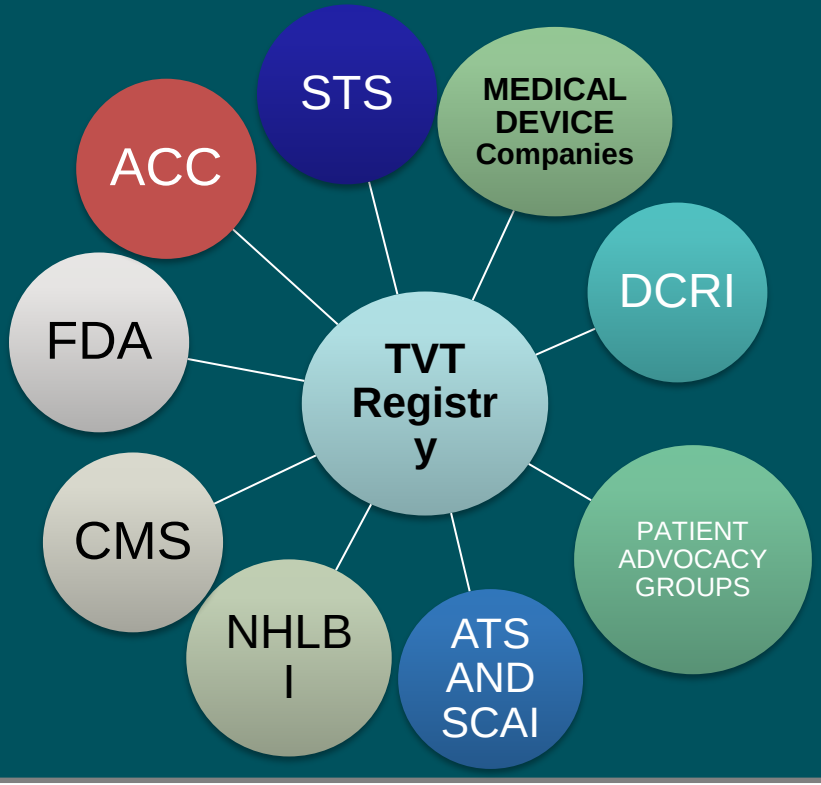
ACC/AHA/STS Statement on the Future of Registries and The Performance Measurement Enterprise.
J Am Coll Cardiol; October 2015

Rational Dispersion for the Introduction of Transcatheter Valve Therapy

Michael J. Mack, MD
David R. Holmes Jr, MD

JAMA, November 16, 2011
Vol 306, No. 19 2149-2150.

TVT Registry Collaborative Partnership



- Clinical Registry Program
- Quality/Outcomes Research
- Device Surveillance
- Post-Approval Studies
- IDE Studies
- Network for RCTs

The Goals of the TVT Registry

- Learn from patient-level data
  - Regulatory – device surveillance
  - Quality improvement
    - Insights into patient selection, etc.
    - Feedback, benchmarking, and best practices at a site level
    - Patient education and informed decision-making
  - Research – important hypotheses tested to expand our understanding
- Be a driving force in improving our health care system

Types of Outcomes Reported

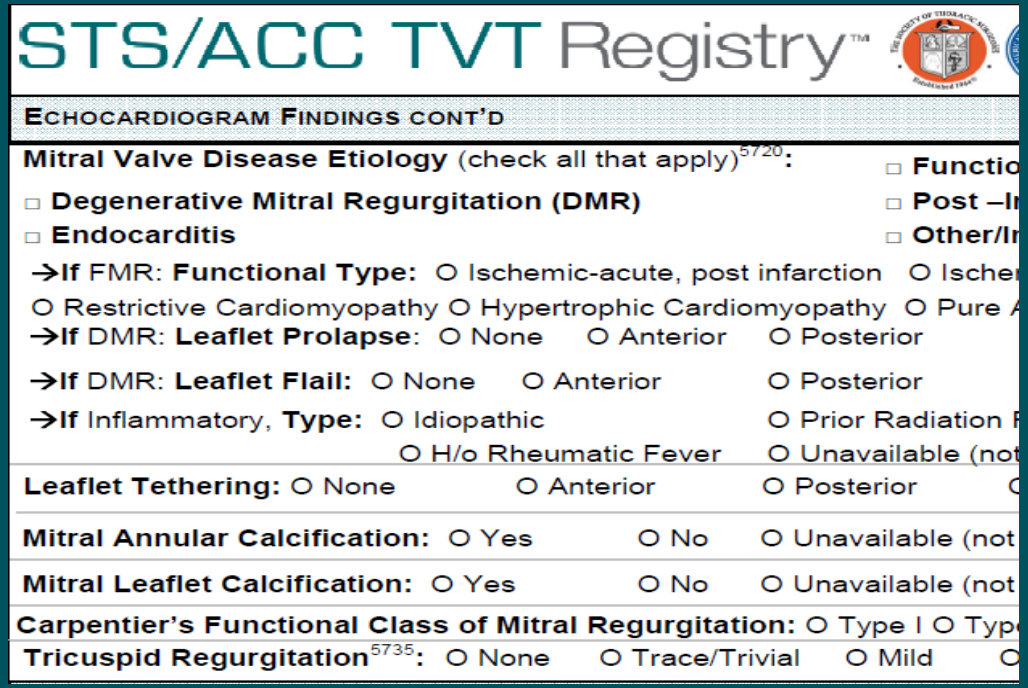
Early/in hospital or 30 day	In hospital and 30-day - Mortality, Stroke, Repeat Valve Procedure
Late-yearly	1-year - Mortality, Stroke, Repeat Valve Procedure
Length of Follow-up	30-Day, 1-Year, and up to 5 years via CMS data linkage
Functional Outcomes	Pre-procedure, 30-day, and 1-year Kansas City Cardiomyopathy Questionnaire (KCCQ)
Quality of Life	Same as above
Frailty	Pre-procedure, 30-day, and 1-year 5 Meter Walk
Economic Outcomes	Planned via CMS data linkage

Kansas City Cardiomyopathy Questionnaire

- Activity – walking level ground and stairs
- Fatigue – how often and how bothersome
- Shortness of breath – how often and how bothersome
- Heart failure limit your enjoyment of life?
- Does your heart failure affect your lifestyle?
  - Hobbies, recreational activities
  - Visiting friends/family outside the home

Data Elements and Definitions

- Health Status (KCCQ)
- Six Minute Walk
- 30 day and 1 year follow-up
- Adjudication of
  - TIA/Stroke
  - Re-interventions
  - Heart failure readmission



STS/ACC TVT Registry™

ECHOCARDIOGRAM FINDINGS CONT'D

Mitral Valve Disease Etiology (check all that apply)[5720]: ☐ **Functio**

☐ **Degenerative Mitral Regurgitation (DMR)** ☐ **Post –I**

☐ **Endocarditis** ☐ **Other/I**

→**If** FMR: **Functional Type:** O Ischemic-acute, post infarction O Ische

O Restrictive Cardiomyopathy O Hypertrophic Cardiomyopathy O Pure

→**If** DMR: **Leaflet Prolapse**: O None O Anterior O Posterior

→**If** DMR: **Leaflet Flail:** O None O Anterior O Posterior

→**If** Inflammatory, **Type:** O Idiopathic O Prior Radiation

O H/o Rheumatic Fever O Unavailable (not

Leaflet Tethering: O None O Anterior O Posterior

Mitral Annular Calcification: O Yes O No O Unavailable (not

Mitral Leaflet Calcification: O Yes O No O Unavailable (not

Carpentier's Functional Class of Mitral Regurgitation: O Type I O Typ

Tricuspid Regurgitation[5735]: O None O Trace/Trivial O Mild

How are Data in the TVT Registry Used and By Whom?

- **Hospitals and Clinicians**
  - Hospital quality assessment and improvement reports with national benchmarks.
  - Documentation for hospitals of Appropriate Use Criteria (AUC) for their patients.
- **Industry and FDA**
  - Real-world outcomes of approved devices and site operations
  - Post-approval studies and some IDE studies
  - Device surveillance
  - Potential expansion of indications considerations.
- **CMS**
  - National Coverage Decision requirements mandated by CMS.
  - Evidence development on new treatments covered under CED
- **Patients and Families**
  - Refinements in patient selection and outcomes in different groups
  - Patient decision aids and educational material using real-world outcomes of treatments.
- **Everyone**
  - Risk model development and reporting of risk-adjusted outcome measures.
  - Research presentations and publications

TAVR Outcome Metrics at 1 Year

Distribution of Hospital Performance

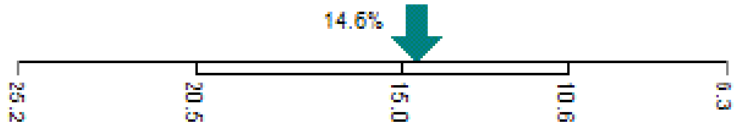
10th percentile — 90th percentile

Better →

18 **Observed Mortality – 1 year**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
14.6%	15.0%	6.3%

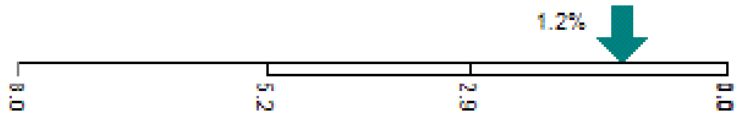
Your hospital's proportion of patients with TAVR who have expired within one year of the TAVR procedure. [Detail Line:1044]



19 **Stroke (any)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.2%	2.9%	0.0%

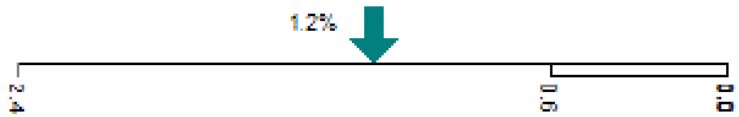
Your hospital's proportion of patients with TAVR with a stroke documented at 1 year. This includes hemorrhagic, ischemic or undetermined strokes. [Detail Line:1061]



20 **Aortic Valve Reintervention (surgery or intervention)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
1.2%	0.0%	0.0%

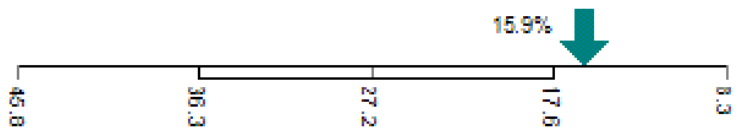
Your hospital's proportion of patients with TAVR with a surgical or interventional aortic valve reintervention within 1 year post procedure. [Detail Line:1019]



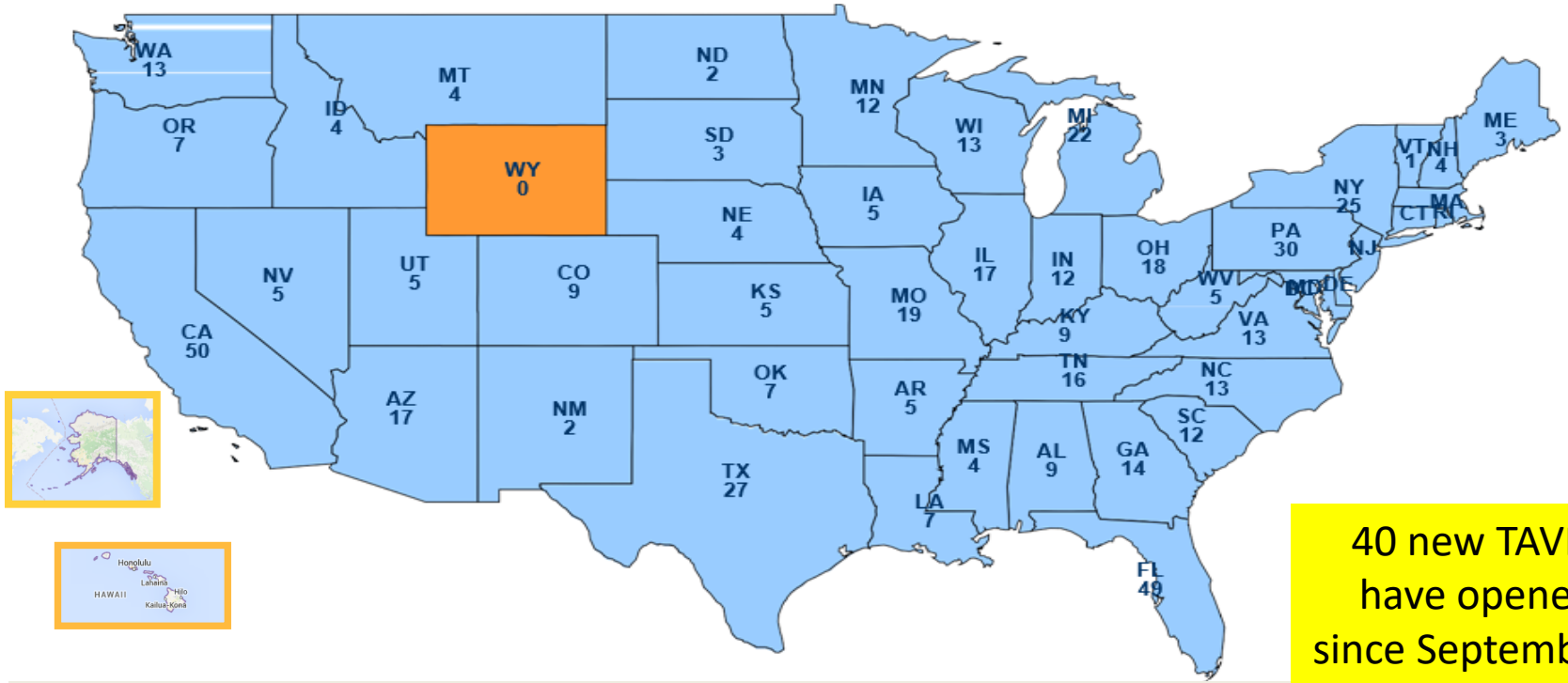
21 **Readmission (any)**

My Hospital	US Hospitals 50th Pctl	US Hospitals 90th Pctl
15.9%	27.2%	8.3%

Your hospital's proportion of patients with TAVR who were readmitted for any reason (valve or not valve related) within 1 year post procedure. [Detail Line:1096]



Sites Participating in the STS/ACC TVT Registry

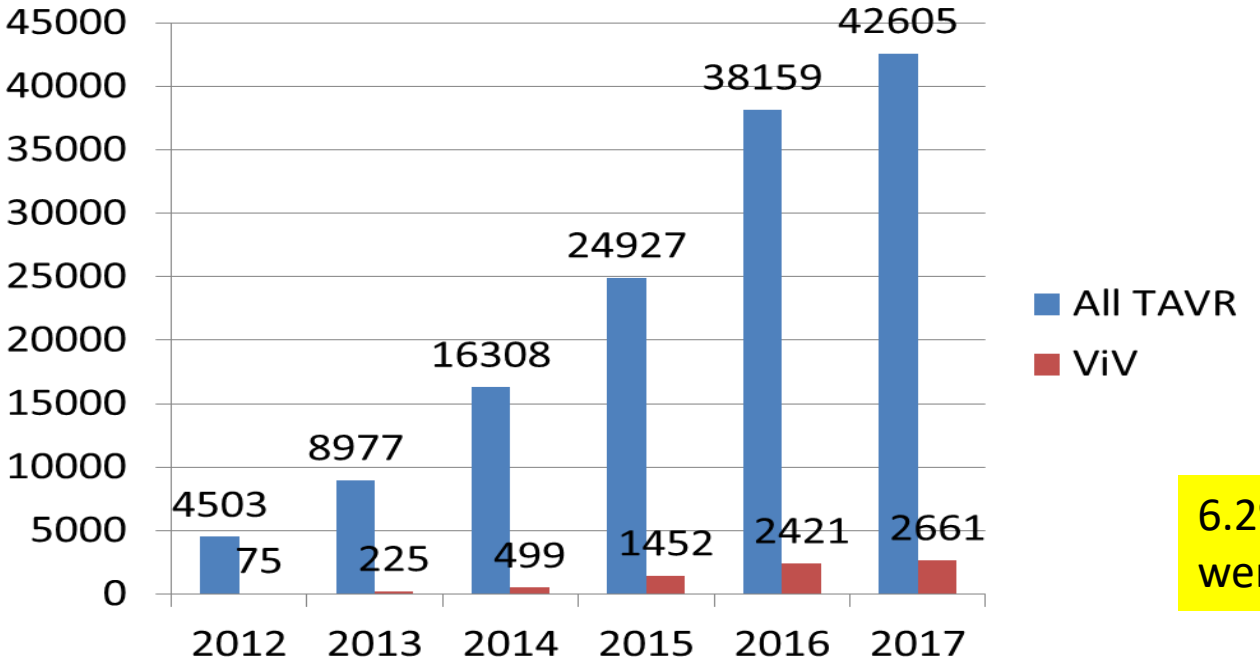


CT:	7
DC:	2
DE:	2
MA:	13
MD:	7
NJ:	13
RI:	1

40 new TAVR sites have opened just since September 2017

577 TAVR Sites enrolled.
298 Sites performing Leaflet Procedures
178 TMVR Sites

Commercial TAVR Submitted to the TVT Registry TAVR and TAVR ViV Procedures

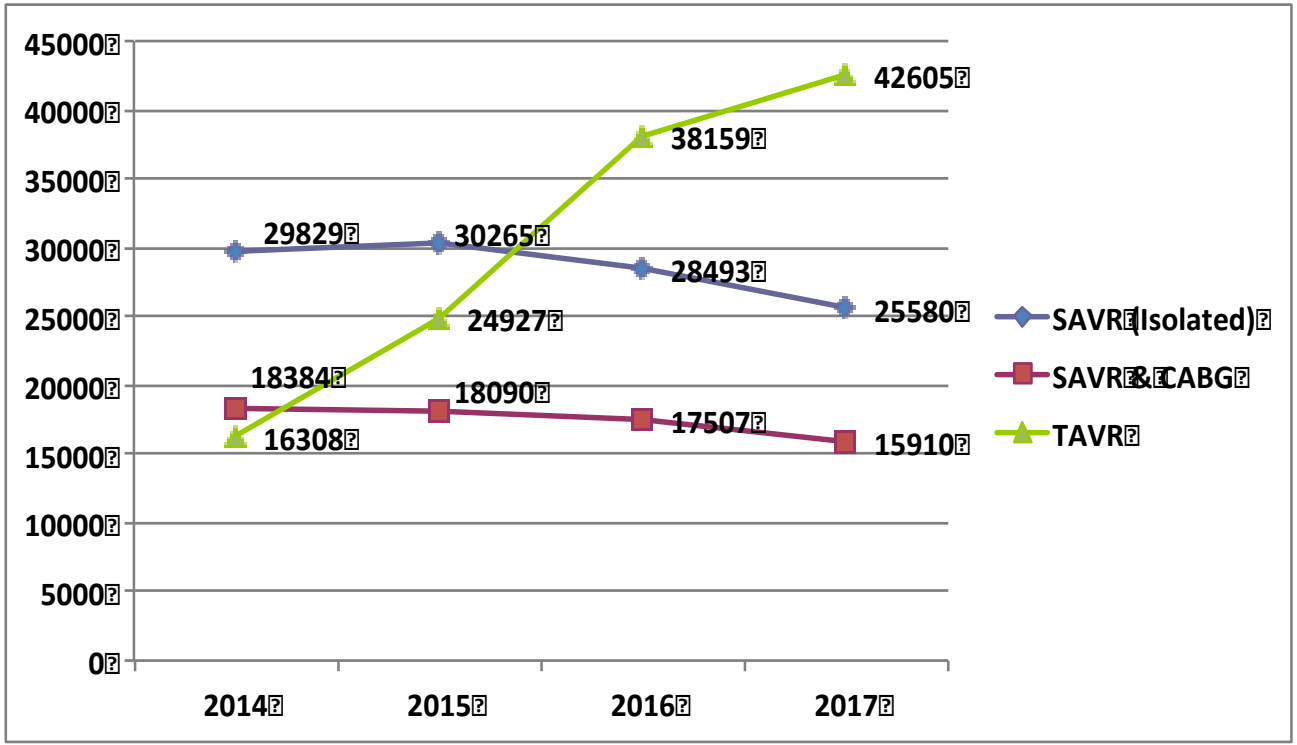


6.2% of TAVRs in 2017 were Valve-in-Valve

STS/ACC TVT Registry Database as of 3-1-18

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

There are 580 TAVR Programs in the US



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STS/ACC TVT Registry Database as of 3-1-18

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Aortic Valve Replacement in 2018:

The Big Picture of AVR from TVT and STS Registries

- There has been a 31% increase in AVR (SAVR & TAVR) in just 4 years.
  - Total AVR in 2014 was 64,085 cases
  - Total AVR in 2017 was 84,095 cases
- TAVR has increased +161% (26,297 cases)
- SAVR has decreased -14% (6,723 cases)

Will this major change in clinical practice continue in the next 5-10 years?

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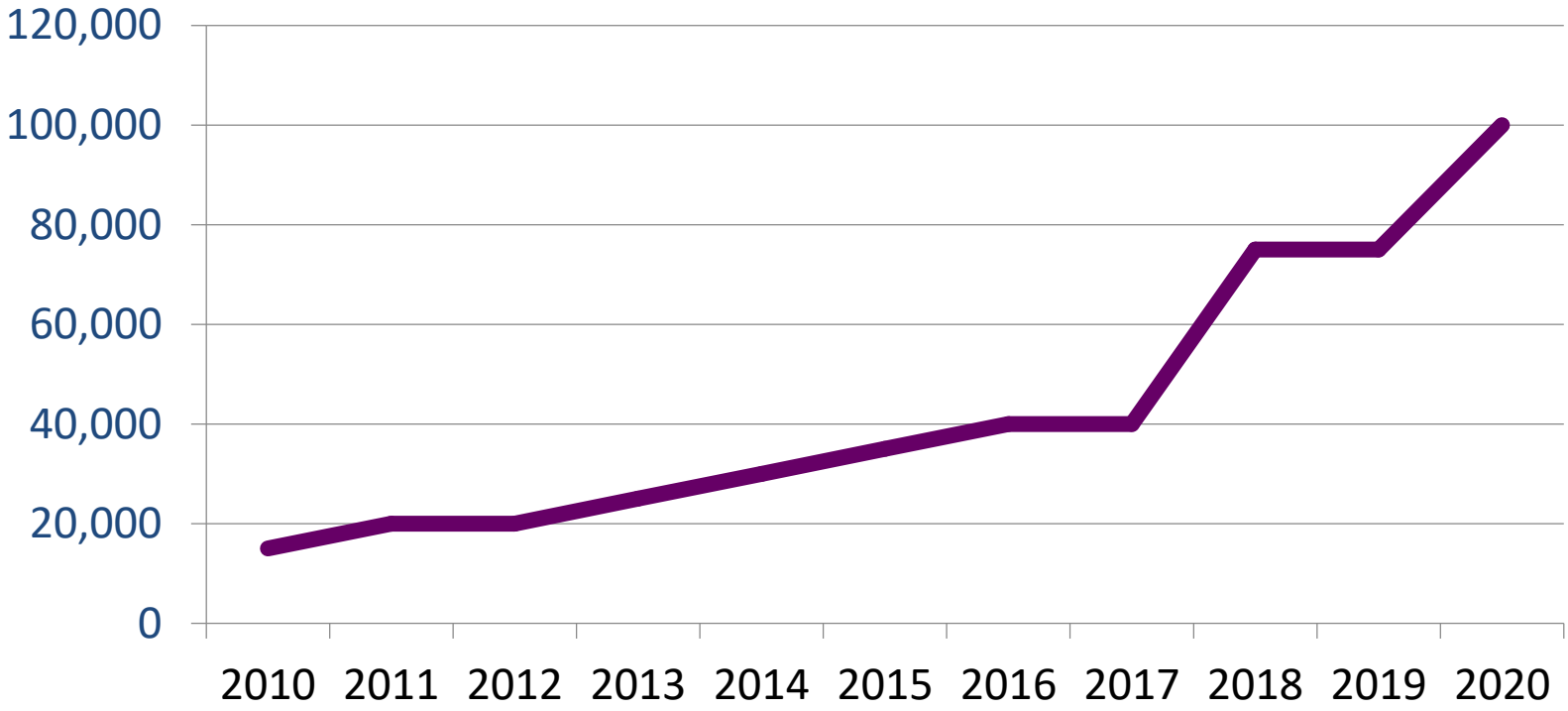
Projected TAVR Growth



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Data Quality

- **Training and Clinical Support Team**
  - Orientation webinars
  - Online FAQs
  - Live customer support
  - Email
  - Monthly webinars
  - Annual meeting with case reviews, etc.
- **Data Entry Integrity**
  - Software value checks
  - Field level range parameters
  - Parent:Child fields
- **Data Completeness**
  - Completeness assessed with everyone data submission
  - Completeness monitoring reports

- **Annual Data Accuracy Audits**
  - Up to 650 records audited annually
- **Adjudication (algorithmic + CEC)**

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NCDR® Data Quality Program (DQP)

Patient data entered

Data saved / quality check performed

Data submitted and DQR submission results reviewed

A series of checks and balances to validate and ensure the quality of the collected data

Data Quality Report (DQR):

- Data checked for errors and completeness

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Data Quality Program
Post Submission

Adjudication

- Verifies and provides additional information for key events (stroke, TIA and repeat intervention, plus CHF admission for MitraClip)

National audit program

- Evaluates accuracy and reliability
- Assesses proper and complete reporting of cases
- Voluntary and self audits

Data Outlier Program

- Provides outlier alerts to Registry participants

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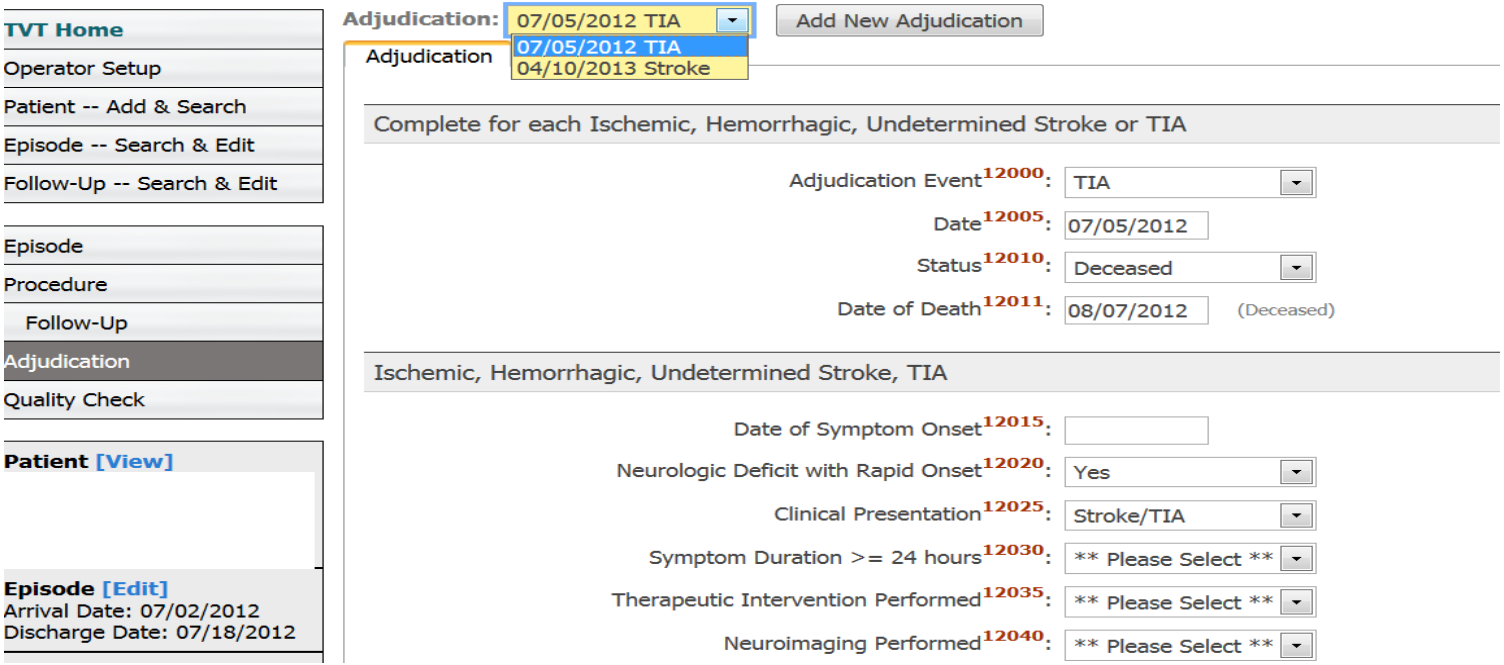
TVT Adjudication Process: Additional Data and Physician Review at DCRI



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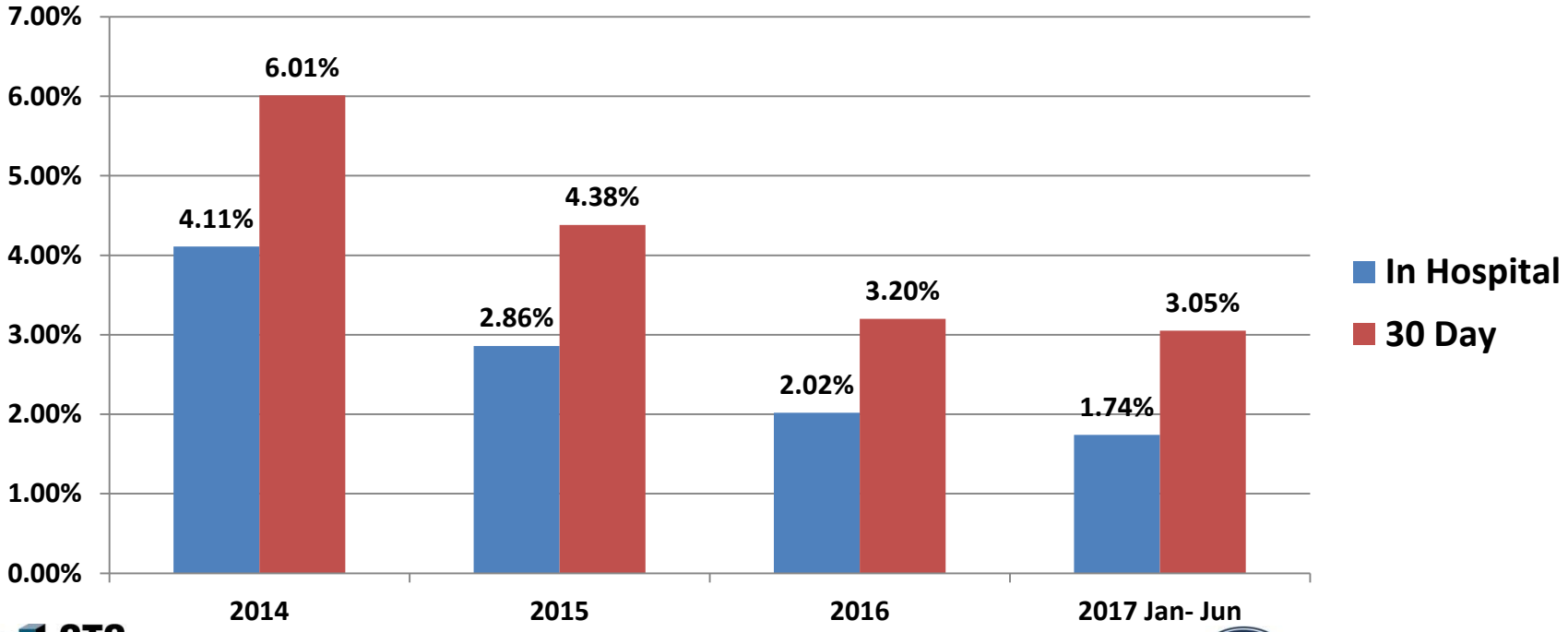
TAVR
In Hospital and 30 Day Mortality



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Source: DCRI 2017 Q3 Data Query

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Distribution of Hospital Performance
In-Hospital Risk Adjusted Mortality Rate

Percentile	10th	25th	50th (Median)	75th	90th
Reporting timeframe (based on 3 yrs.of data)	← Worse			Better →	
2012-2014	5.5%	5.1%	4.8%	4.5%	4.2%
2014 -2016	3.1%	3.0%	2.8%	2.6%	2.5%

The first risk-adjusted outcome measure developed by the TVT Registry was in-hospital mortality

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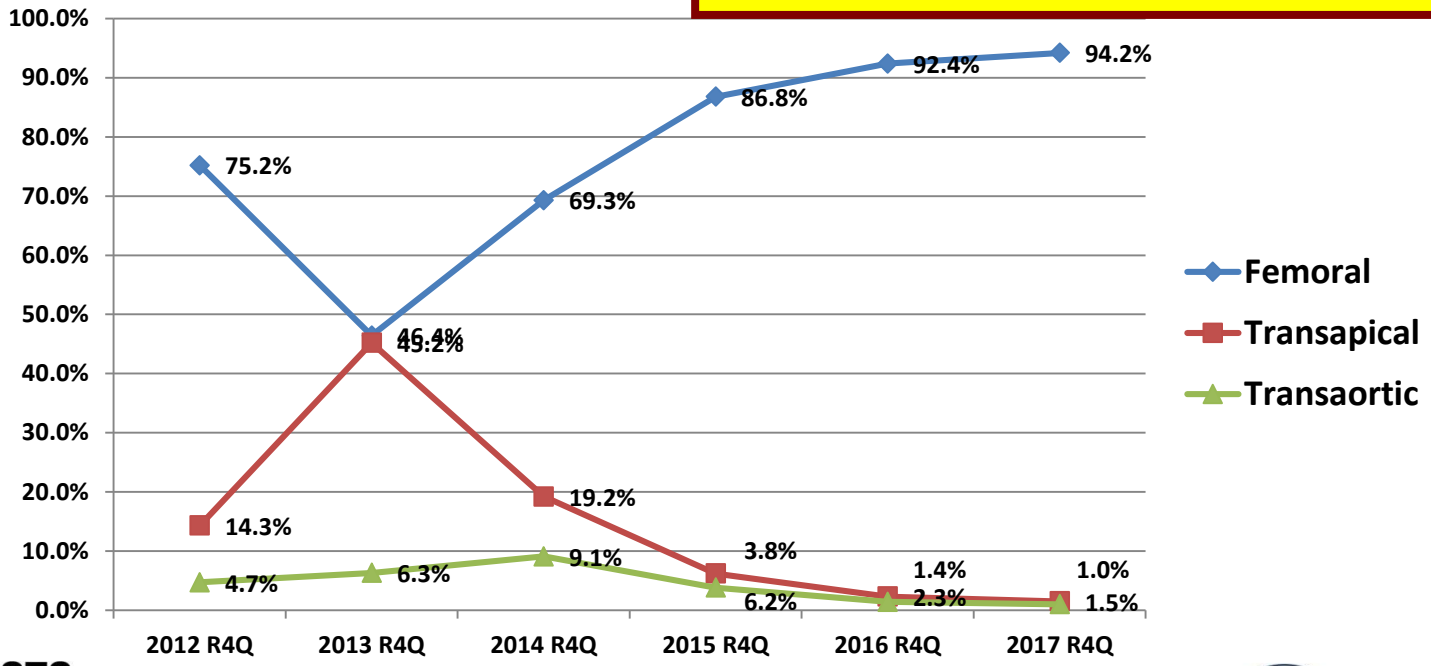
TAVR Access Site

Transfemoral access continues to increase but is plateauing. Subclavian/axillary access is now 3.0% of all TAVRs as evidence shows it is equivalent to TF for major morbidity and mortality outcomes. Gleason et al. Ann Thorac Surg 2018;105:477–83



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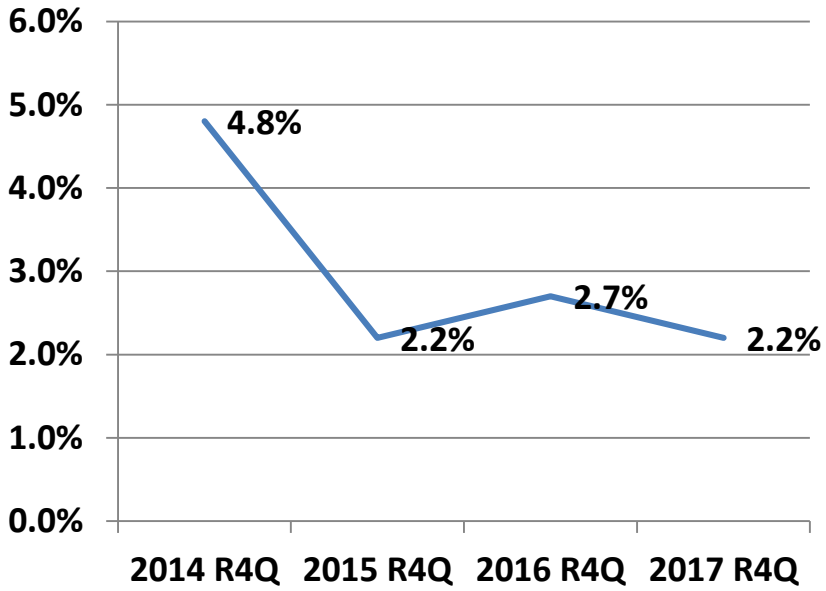
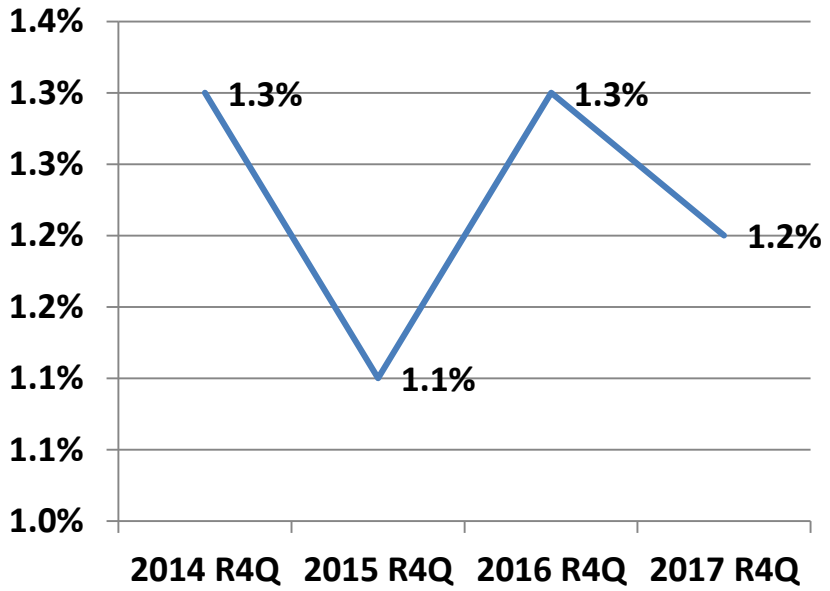
Source: STS/ACC TVT Registry Outcomes Report as of Oct 17, 2017

In-Hospital Major Outcomes

Life-Threatening Bleeding

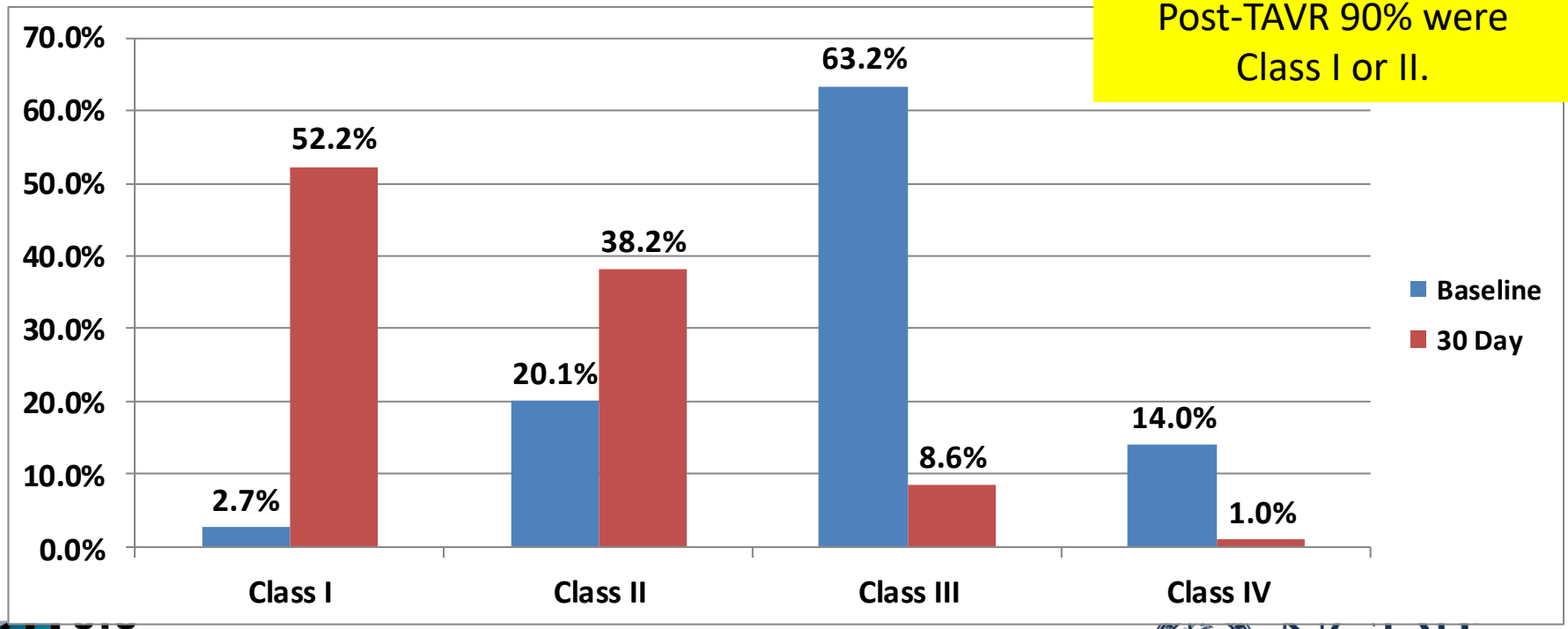


Major Vascular Complications



TAVR Procedures – NYHA 2017Q2 Data

Pre-TAVR 77% of patients were NYHA Class III-IV
Post-TAVR 90% were Class I or II.



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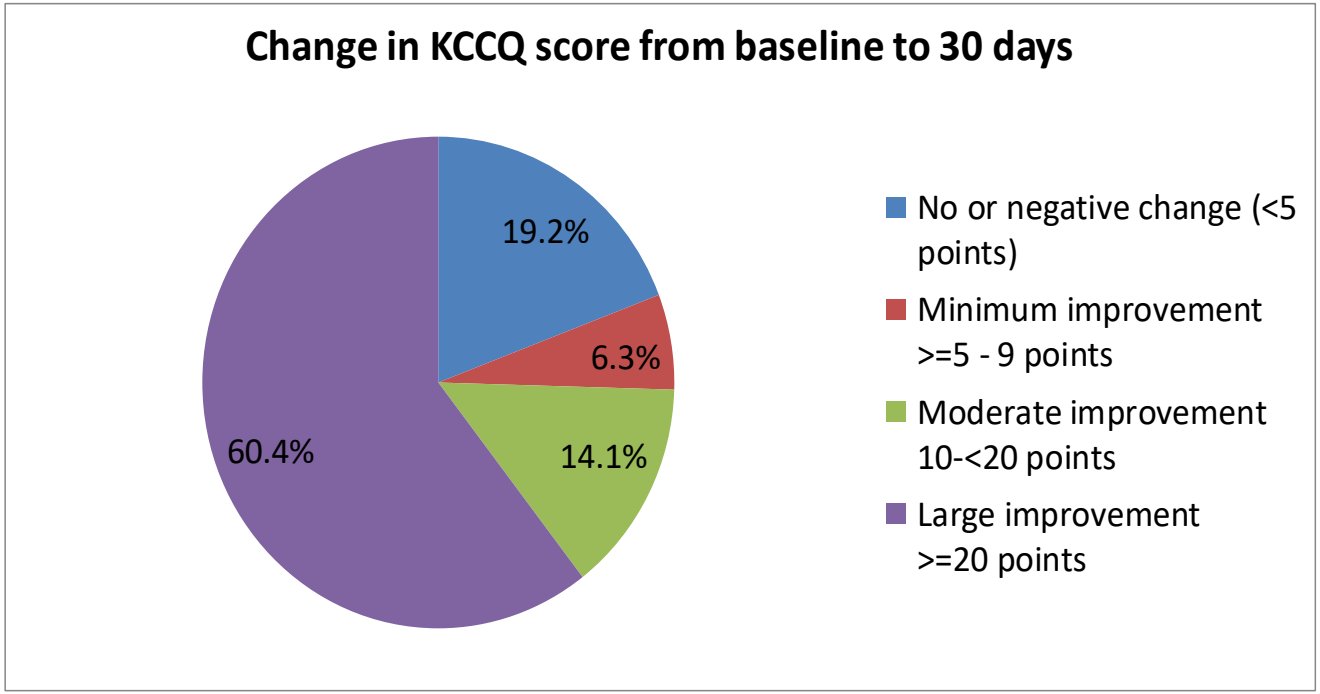
Source: STS/ACC TVT Registry Outcomes Report as of Oct 17, 2017

TAVR and KCCQ



KCCQ Data Completeness in 2017

Baseline: 93%
30 day: 88%
1 Year: 75%

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Source: STS/ACC TVT Registry Outcomes Report as of Oct 17, 2017

Quality-of-Life Outcomes Post TAVR
A Report From the STS/ACC TVT Registry

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

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

Ongoing Questions:

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

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

Volume Outcome Relationship

TVT Registry

The Best Data on the Impact of Case Volume on TAVR Outcomes

- STS/ACC TVT registry on 42,988 patients from 395 U.S. hospital sites:
  - With increasing TAVR procedural experience, there was a statistically significant and clinically important decline in the risk for major adverse outcomes for patients treated in U.S. clinical practice.
  - ***This was true after adjustment for patient factors, date of procedure, and specific procedural characteristics*** **(including device iterations).**

J Am Coll Cardiol 2017;70:29–41)

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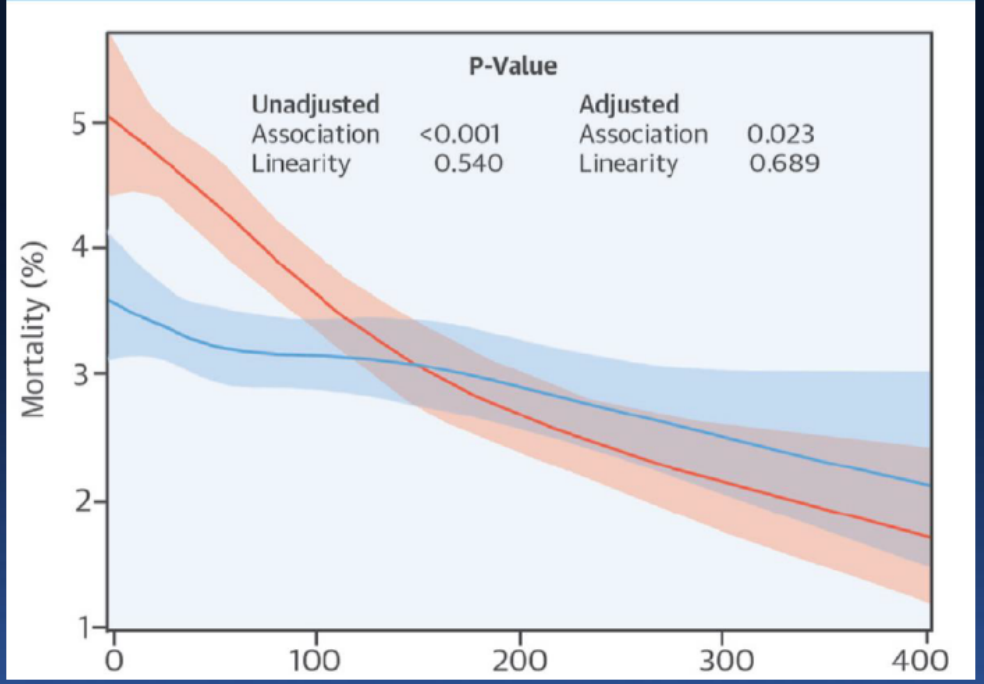
In Hospital Mortality and TAVR

TVT Registry

Dying During or Immediately After TAVR



With experience (case volume) the risk of dying is reduced from 3.57% to 2.15%.

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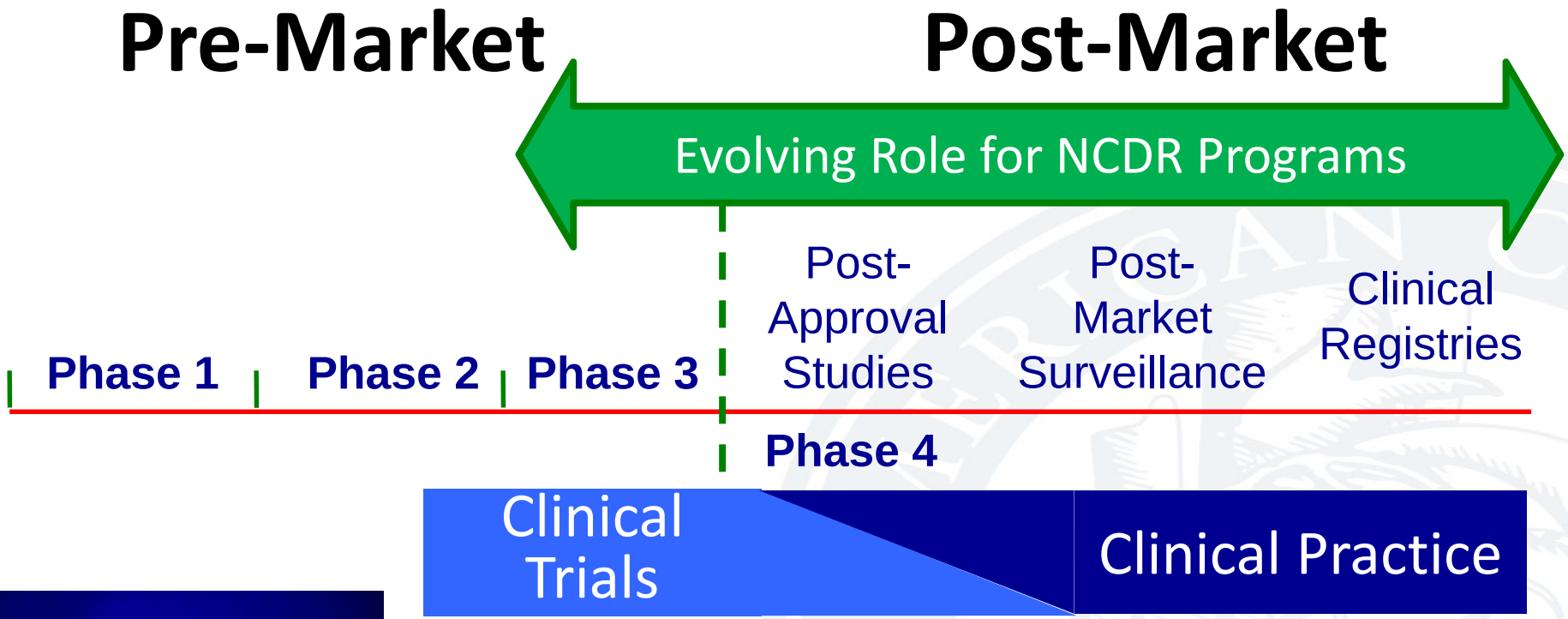
- To support CMS Coverage with Evidence Decisions
  (Implantable Cardiac Defibrillators, Transcatheter Valve Therapy, LAAO)

- To support FDA post market surveillance studies, PAS, IDE, PMAs

Registries for PMS, PAS, IDEs and PMAs



FDA

AMERICAN COLLEGE of CARDIOLOGY

ACC-NCDR - FDA - Industry Collaborations

Endorsement of the Value of Registry Utilization:

- PMS- Post Market Surveillance
- PAS- Post Approval Studies
- IDE- Investigational Device Exemptions
- and more

FDA

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Recent NCDR/Industry/FDA Collaborations

Company / Research Study	Registry
Edwards Lifesciences	
PARTNER PAS II (SAPIEN™)	STS/ACC TVT Registry™
SAPIEN 3i Continued Access Protocol	STS/ACC TVT Registry™
Abbott	
MitraClip® PAS I	STS/ACC TVT Registry™
MitraClip® PAS II	STS/ACC TVT Registry™
Medtronic	
CoreValve® PAS	STS/ACC TVT Registry™
Boston Scientific Corporation	
WATCHMAN™ NESTed Postmarket Surveillance	LAAO Registry™
MADIT-CRT PAS	ICD Registry™
EMBLEM S-ICD PAS	ICD Registry™

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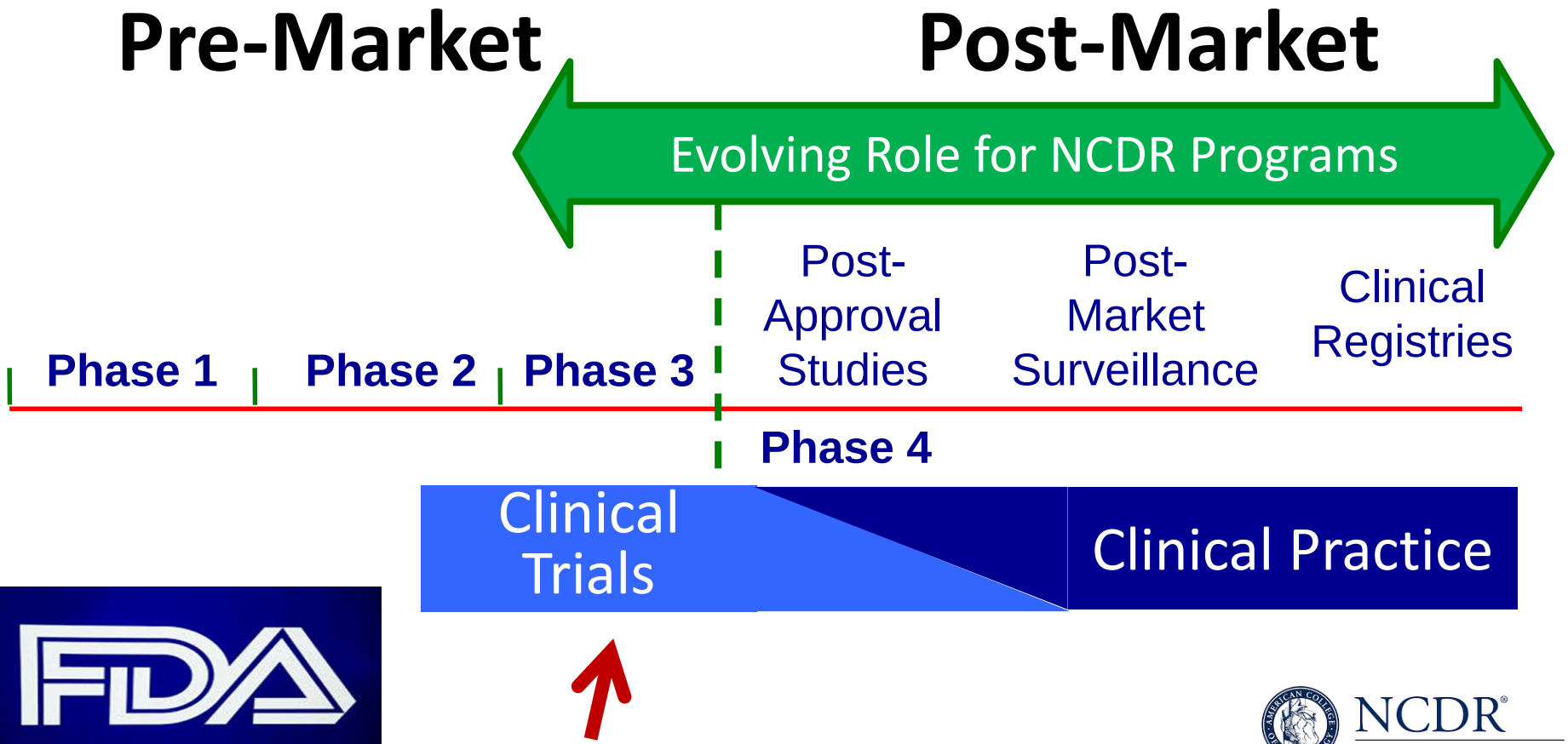
Registries for PMS, PAS, IDEs and PMAs



Registry Clinical Trial Infrastructure

CMS CENTERS for MEDICARE & MEDICAID SERVICES

FDA

National Heart Lung and Blood Institute

AMERICAN COLLEGE of CARDIOLOGY

SAFE-PCI for Women- Embedded RCT using NCDR CathPCI

In a nutshell…	Programmatic outcomes…

• NCRI proof of concept
• First multicenter randomized trial comparing radial with femoral access in U.S.
• First randomized trial comparing interventional strategies in women
• Sponsored by DCRI
• Used NCDR CathPCI Registry platform
• Estimated 65% per patient workload reduction
	• $750 per patient reimbursement
	• ~ $5 million budget
	• Study start up time cut in half
	• Included research naive sites
	• Wider enrollment spread
	  • 90% sites enrolled at least 1 patient
	  • > 70% sites enrolled at least 10 patients

SAFE-PCI
Research Implications

- As the first registry-based randomized trial in the US, the SAFE-PCI for Women trial demonstrated a new paradigm for conducting efficient pragmatic clinical trials using The National Cardiovascular Research Infrastructure
  - High quality data
  - Adjudication possible
  - CFR Part 11 compatible – IND and IDE applications
  - Faster enrollment, Reduced site workload
  - Reduced costs (total budget for SAFE-PCI for Women ~ $5 million)
- Promising approach for future clinical investigations

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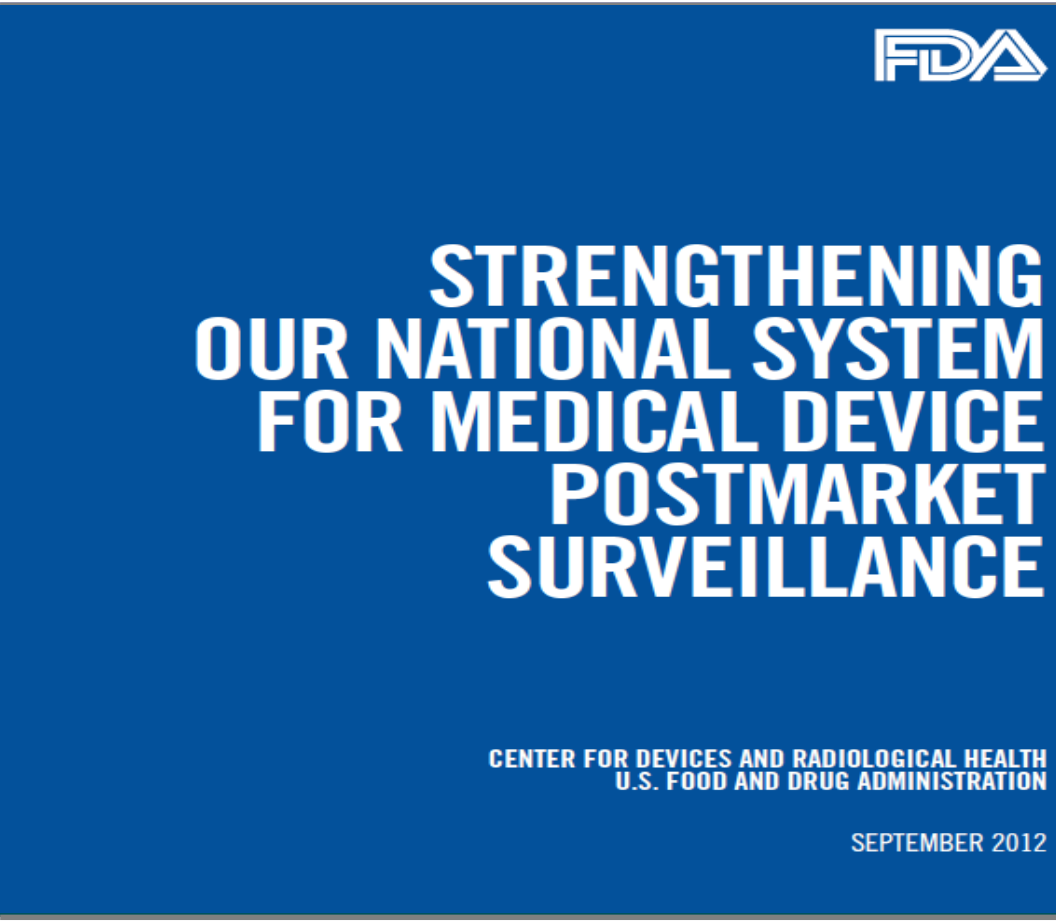


- UDI system incorporated into EHR
- **National & international device registries**
- Modernize adverse event reporting
- New methods for evidence generation, synthesis and appraisal

“You have to assess devices in the wild.”

Jeff Shuren FDA

Medial Device Innovation Consortium’s Annual Meeting 9/16

"**Randomized Clinical Trials** are the **Zoo**
While **Postmarket Surveillance** is the **Serengeti**."
FDA Staffer - Author Unknown

What Registries Offer Medical Device Evaluation: A Regulatory View

Danica Marinac-Dabic, MD, PhD
Director, CDRH Epidemiology

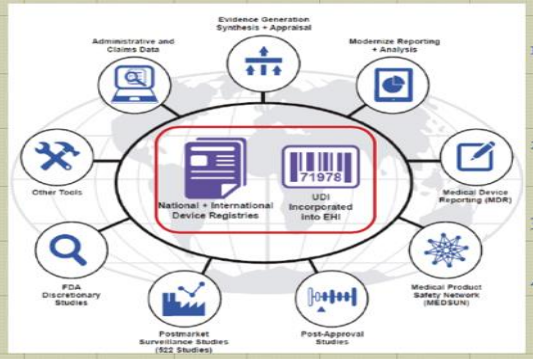
http://www.bostonadvancedanalytics.com/science-based-medicine-delta

Resnic FS, Normand SL. Postmarketing surveillance of medical devices**:** filling in the gaps. N Engl J Med 2012;366:875**–**7.

DELTA is a web-based system which imports clinical data in order to generate alerts for potentially unsafe devices or procedures.

The system began over 10 years ago as an NIH-funded research project and has been touted by the FDA as a model for how post market surveillance systems should be run.

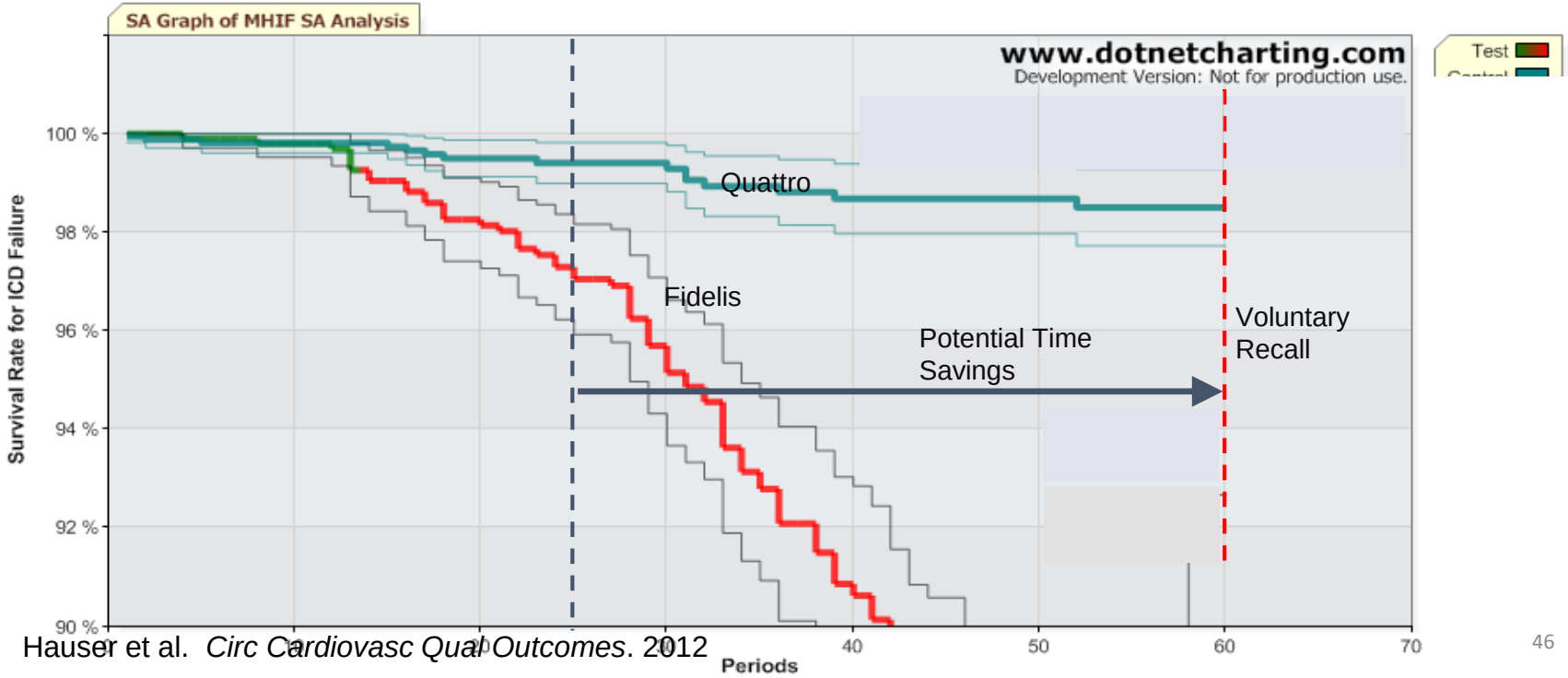
National System for Postmarket Surveillance of Medical Device



1. Establish a Unique Device Identification (UDI) System and Promote Its Incorporation into Electronic Health Information;
2. Promote the Development of National and International Device Registries for Selected Products;
3. Modernize Adverse Event Reporting and Analysis; and,
4. Develop and Use New Methods for Evidence Generation, Synthesis and Appraisal.

DELTA Automated Surveillance: Hospital Registries and Time Savings

Using pooled data from ***three*** **high volume centers**, DELTA performed a propensity matched analysis 0f 859 Fidelis lead implants versus traditional leads. By 25 months of analysis (dashed line) 3% of Fidelis leads had fractured (red line) whereas only 0.1% (1 of 859) alternative ICD leads had fractured.



Hauser et al. *Circ Cardiovasc Qual Outcomes*. 2012

DELTA Automated Surveillance: Hospital Registries and Time Savings

…. Those 25 months of delayed recognition led to 70,000 patients in the U.S. receiving the defective ICD lead AFTER we should have known that they were at higher risk for fracture. 70,000 people is….

ICD-DELTA Active Surveillance Study

- **The ICD-DELTA Study explores the relative safety of four commonly used ICD leads used in contemporary clinical practice during defibrillator placement.**
- Objective: validate a strategy of automated, prospective, active safety surveillance of the **NCDR ICD Registry** based on propensity matched survival analysis of contemporary high energy ICD leads.
  - The primary composite endpoint is a repeat procedure for existing lead function abnormality
  - Secondary Endpoints of lead failure of the device of interest:
    - *Lead function abnormality/ integrity failure*
    - *Defibrillation Failure*
    - *Lead Misplacement*
    - *Lead Misplacement Infection*

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The NEW ENGLAND JOURNAL of MEDICINE
October 5, 2015

ORIGINAL ARTICLE

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. de Backer, F.M. Asch, C.E. Ruiz, N.T. Olsen, A. Trento, J. Friedman, D. Berman, W. Cheng, M. Kashif, V. Jelnin, C.A. Kliger, H. Guo, A.D. Pichard, N.J. Weissman, S. Kapadia, E. Manasse, D.L. Bhatt, M.B. Leon, and L. Søndergaard

ABSTRACT

BACKGROUND

A finding of reduced aortic-valve leaflet motion was noted on computed tomography (CT) in a patient who had a stroke after transcatheter aortic-valve replacement (TAVR) during an ongoing clinical trial. This finding raised a concern about possible subclinical leaflet thrombosis and prompted further investigation.

Food and Drug Administration MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

Bioprosthetic Aortic Valves: FDA Notification - Reduced Leaflet Motion

The NEW ENGLAND JOURNAL of MEDICINE

Reduced Leaflet Motion in Bioprosthetic Aortic Valves — The FDA Perspective

October 5, 2015

John C. Laschinger, M.D., Changfu Wu, Ph.D., Nicole G. Ibrahim, Ph.D., and Jeffrey E. Shuren, M.D., J.D.

*" **The TVT Registry of the STS and the ACC** continues to play a vital role in FDA post marketing surveillance of TAVR devices and has already helped to ensure responsible adoption of TAVR therapy and measured expansion of its indications on the basis of clinical outcomes. …this resource….will become increasingly important for ensuring that newer generations of TAVR devices continue to be safe and effective throughout their total product life cycle."*

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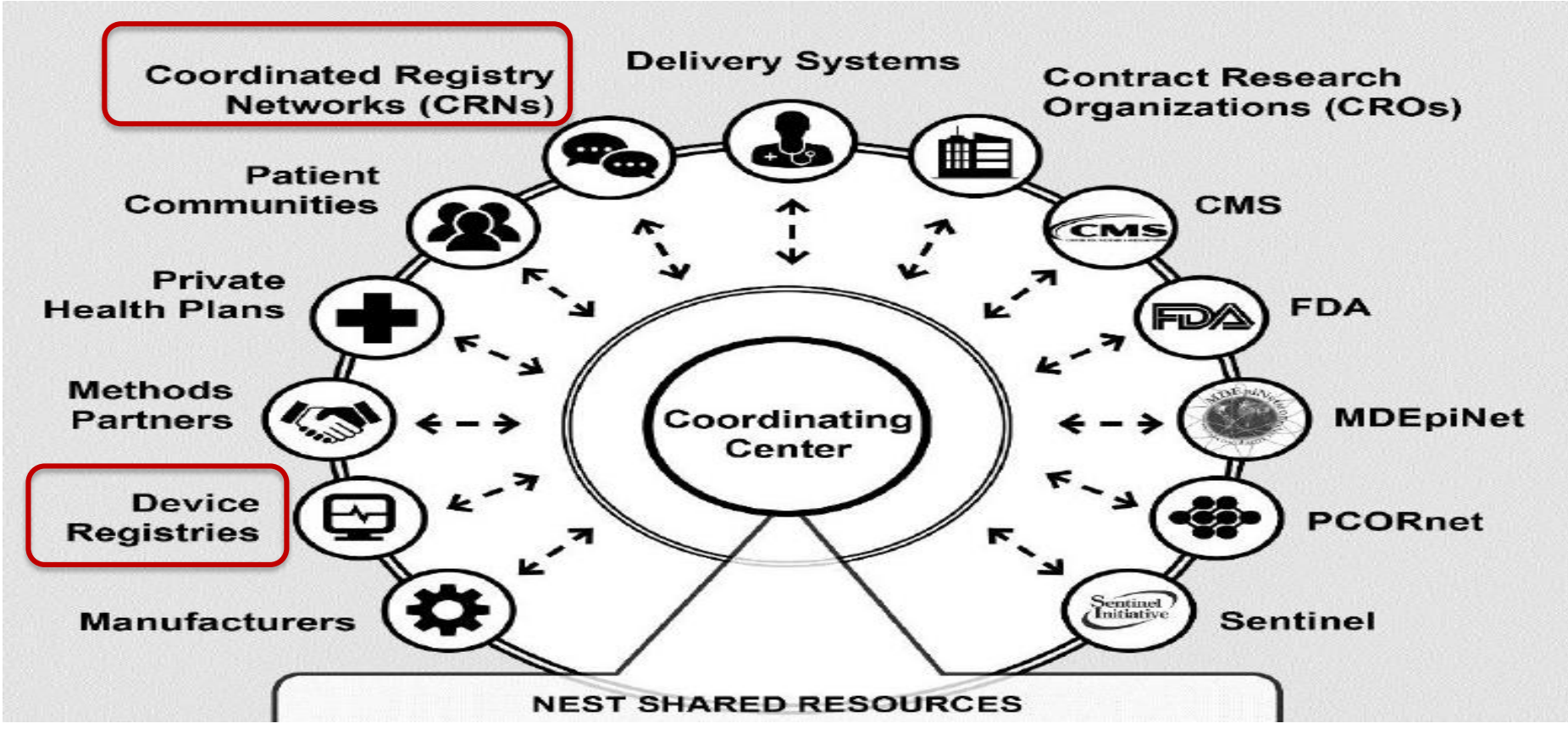
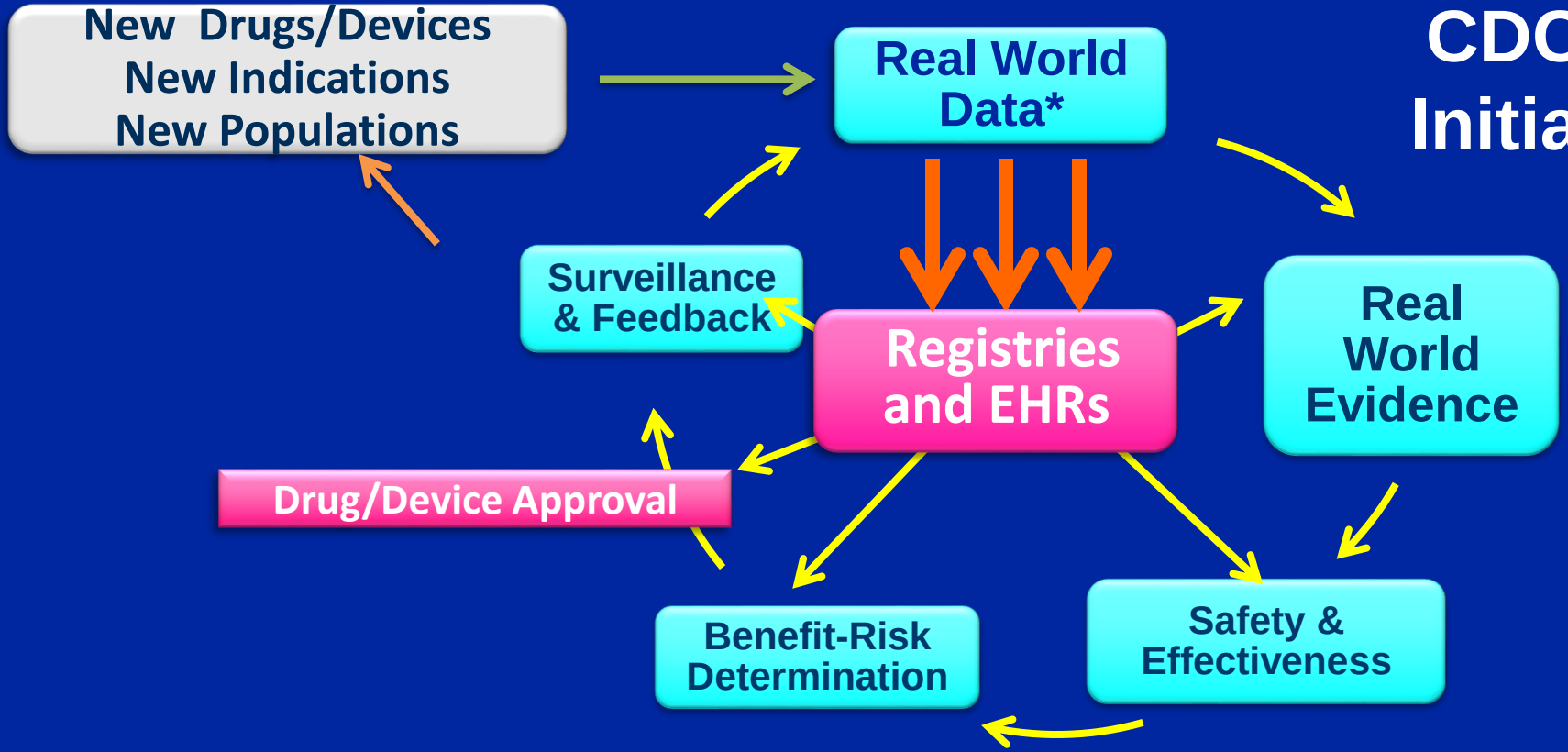
The "NEST" of the Future

National Evaluation System for Health Technology



Registries

Role in Device Development and Assessment



CDCRN Initiative

Adapted from John Laschinger, FDA

*Data from diverse populations under diverse clinical circumstances

Cardiovascular Device Coordinated Registry Network: CDCRN

Proposal for Pre-Market Regulatory & Total Product Life Cycle Device Studies

- A reusable, flexible, interoperable and connective infrastructure for performance of a wide range of IDE clinical trial designs including RCT's
- Embedded patient protections including informed consent and maintenance of privacy
- Methods for identification and randomization of patients
- Follow-up that minimizes the need for Investigator-Patient contact to collect key objective data
- Clinical evidence needed for regulatory approval
- Seamless transition to long-term post-market device evaluation and surveillance throughout the TPLC
- Evidence generation necessary for device surveillance and updating of labels throughout TPLC
- Methodology necessary to facilitate and optimize use of pre/post-market balance for evidence of effectiveness for devices addressing unmet medical needs
- Appropriate data governance and data security

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Total Product Life Cycle Approach to Medical Device Development & Regulation

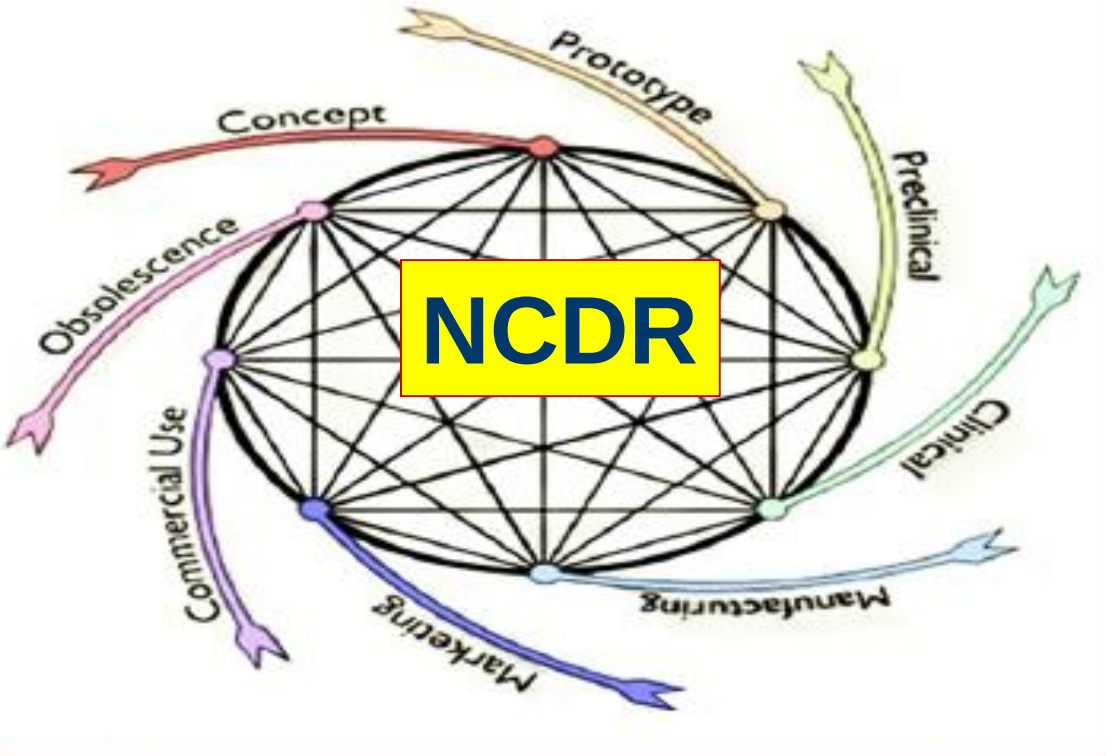


Figure 1. The Total Product Life Cycle Approach to Medical Device Development and Regulation

TAVR in >90 year Olds

Should Transcatheter Aortic Valve Replacement Be Performed in Nonagenarians?

Insights From the STS/ACC TVT Registry

Mani Arsalan, MD,[a,b] Molly Szerlip, MD,[a] Sreekanth Vemulapalli, MD,[c] Elizabeth M. Holper, MD,[a] Suzanne V. Arnold, MD,[d] Zhuokai Li, PhD,[c] Michael J. DiMaio, MD,[a] John S. Rumsfeld, MD,[e] David L. Brown, MD,[a] Michael J. Mack, MD[a]

JACC 2016;67:1387–95

TAVR in Patients > 90 years old

Conclusions

- Although 30-day and 1-year mortality rates were higher in this age group compared to <90 years old the absolute and relative differences were clinically modest.
- Nonagenarians take longer to recover their physical function and QOL than younger pts
- TAVR improved long-term QOL similarly to younger pts
- Data support both the safety and the efficacy of TAVR in select elderly patients
- TAVR should not be denied solely on basis of patient age

JACC 2016;67:1387–95

Gait Speed and 30 day TAVR Mortality

Gait Speed Predicts 30-Day Mortality After Transcatheter Aortic Valve Replacement

Results From the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

Joakim Alfredsson, MD; Amanda Stebbins, MS; J. Matthew Brennan, MD, MPH; Roland Matsouaka, PhD; Jonathan Afilalo, MD, MSc; Eric D. Peterson, MD, MPH; Sreekanth Vemulapalli, MD; John S. Rumsfeld, MD, PhD; David Shahian, MD; Michael J. Mack, MD; Karen P. Alexander, MD

Background—Surgical risk scores do not include frailty assessments (eg, gait speed), which are of particular importance for patients with severe aortic stenosis considering transcatheter aortic valve replacement.

Methods and Results—We assessed the association of 5-m gait speed with outcomes in a cohort of 8039 patients who underwent transcatheter aortic valve replacement (November 2011–June 2014) and were included in the Society of Thoracic Surg… the association between conti… ent for Society of Thoracic S… ded in-hospital mortality, blee… 75th percentile, 0.47–0.79 m/s), … making up 48%, and normal walkers (>0.83 m/s) constituting 24% of the population. Thirty-day all-cause mortality rates were 8.4%, 6.6%, and 5.4% for the slowest, slow, and normal walkers, respectively ($P<0.001$). Each 0.2-m/s decrease in gait speed corresponded to an 11% increase in 30-day mortality (adjusted odds ratio, 1.11; 95% confidence interval, 1.01–1.22). The slowest walkers had 35% higher 30-day mortality than normal walkers (adjusted odds ratio, 1.35; 95% confidence interval, 1.01–1.80), significantly longer hospital stays, and a lower probability of being discharged to home.

8039 patients from 256 centers

Circulation. 2016;133:1351-1359.

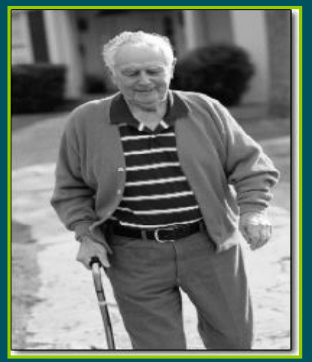
Gait Speed and 30 day TAVR Mortality

- Each 0.2-m/s decrease in gait speed corresponded to 11% increase in 30-day mortality

- The slowest walkers had 35% higher 30-day mortality than normal walkers with significantly longer hospital stays, and a lower probability of being discharged to home.

Gait Speed and 30 day TAVR Mortality

- Findings support a gait speed cutoff of <0.5 m/s as a discriminator of risk within an already frail TAVR population with severe valve disease and symptom-driven referral



Circulation. 2016;133:1351-1359.

How Can The TVT Registry Be Used to Help Patients, Families, and Clinicians in Key Patient-Centric Decisions?

Should they undergo TAVR, sAVR, or neither?

Do they have a reasonable choice between the approaches or is one treatment much better for them?

What are the patient-specific risks and benefits of different treatments?

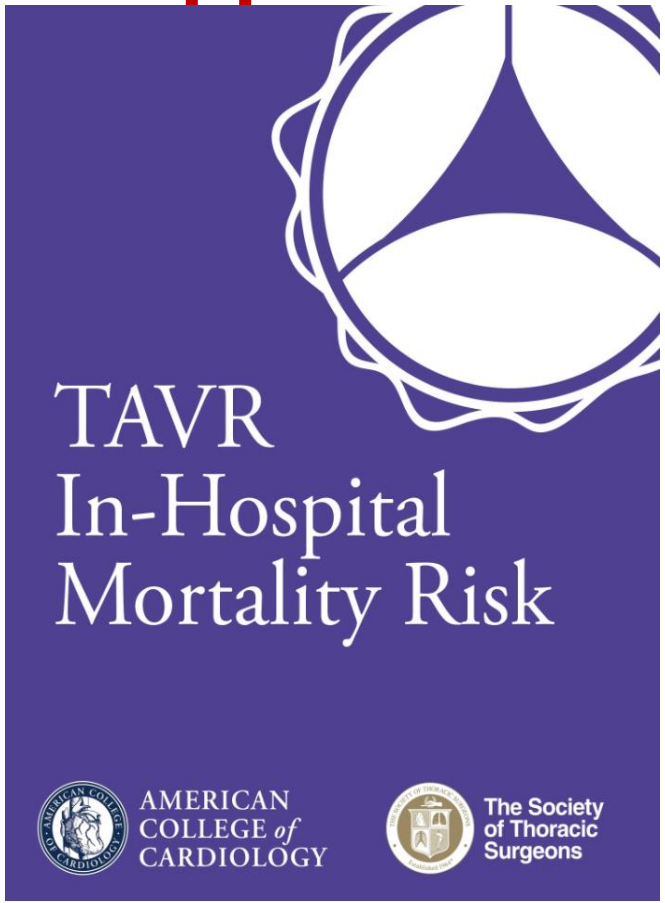
TAVR App Launch Screen

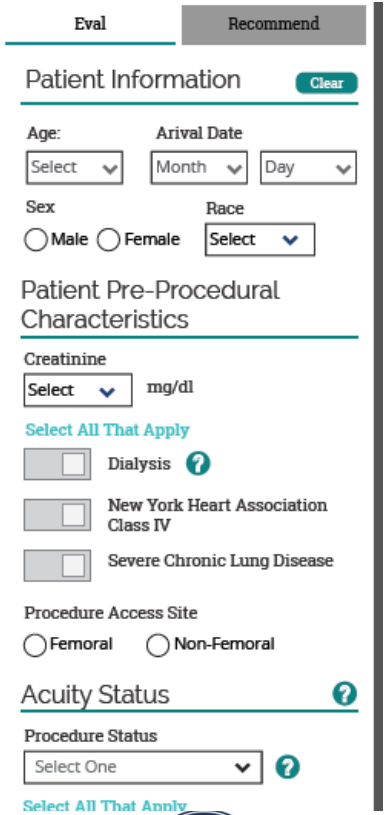
STS Risk Score:

- 30 Day

TAVR Risk Calculator:

- In-Hospital only





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Using data to drive quality

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Recommended Measures for TVT Reporting

- Volume (commercial TAVR)
- In-hospital Risk-Adjusted Mortality (TAVR)
- 30-day Risk-Adjusted Mortality (TAVR)
- Vascular access complication rate (TAVR - femoral only)

- **Timeframe for reporting:**
- Rolling 3-year period consistent with current risk-adjusted reporting

- 3 Star Rating System

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Potential Future TVT Public Reporting Measures

- TAVR outcomes composite
- Health Status (via) KCCQ
- Stroke Rate, In-hospital (TAVR)

- Movement to a One Year Risk Adjusted Mortality Model

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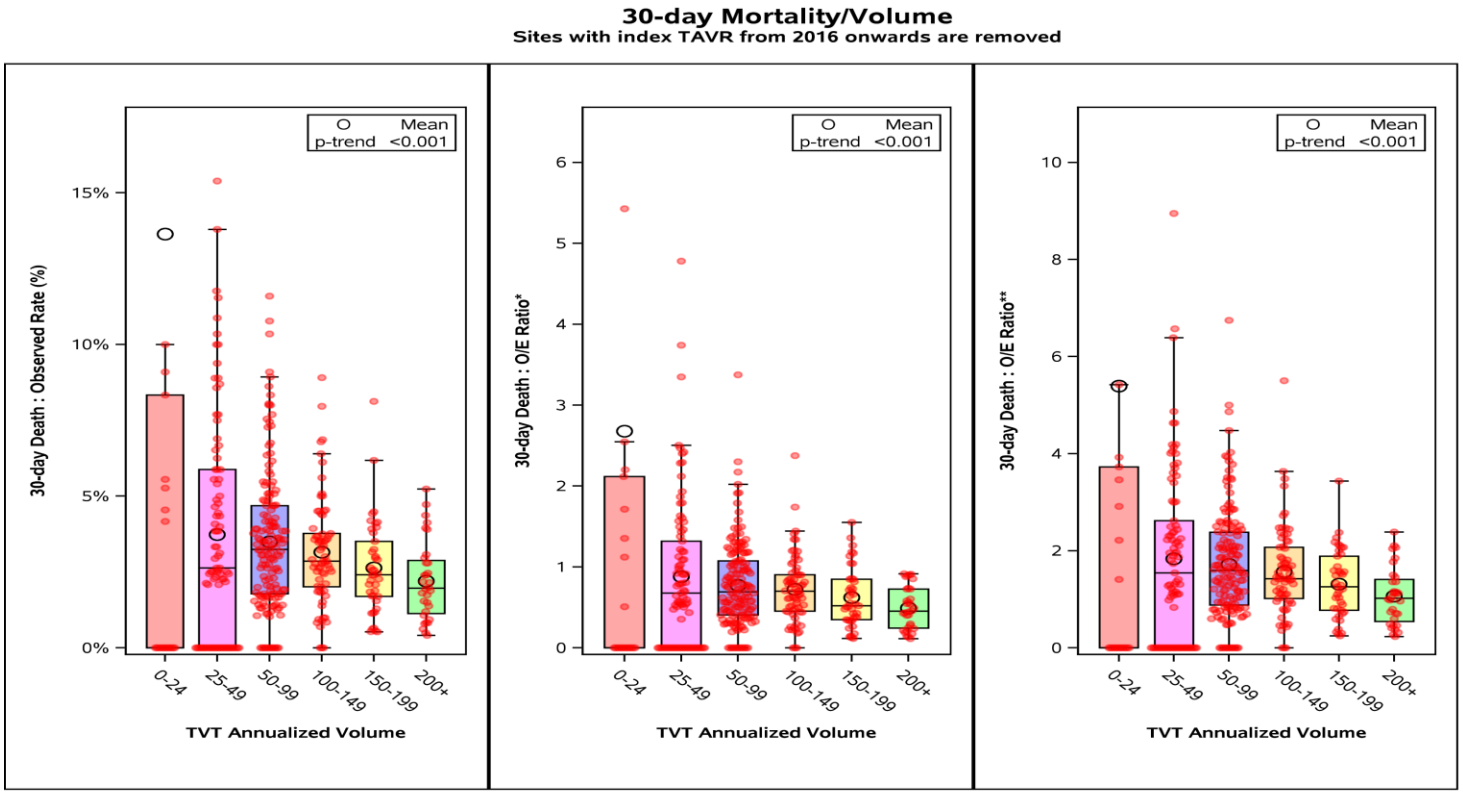
CMS MEDCAC Panel

Operator and Institutional Volume Requirements for Transcatheter Aortic Valve Replacement

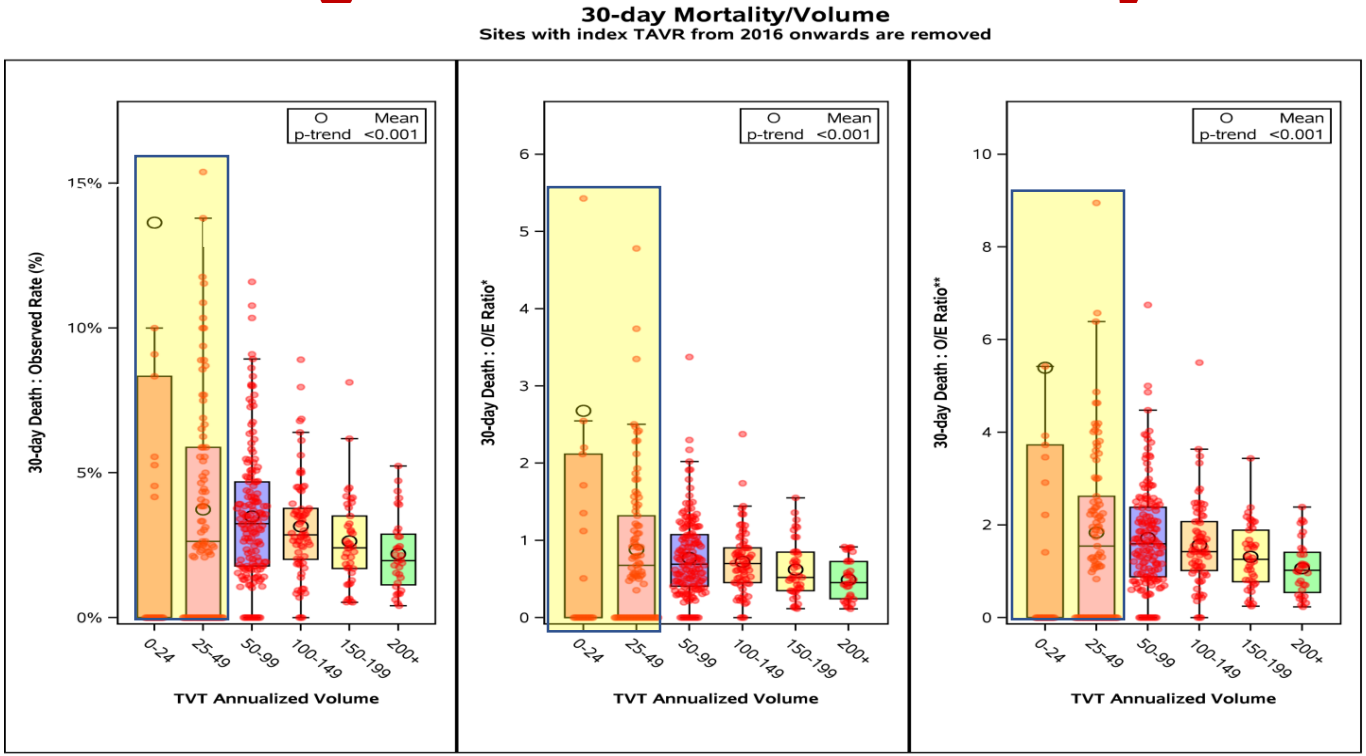
July 25, 2018

Site Variability in Quality Outcomes
Especially of Concern in Low Volume Programs



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) Signal or Uncertain Validity?



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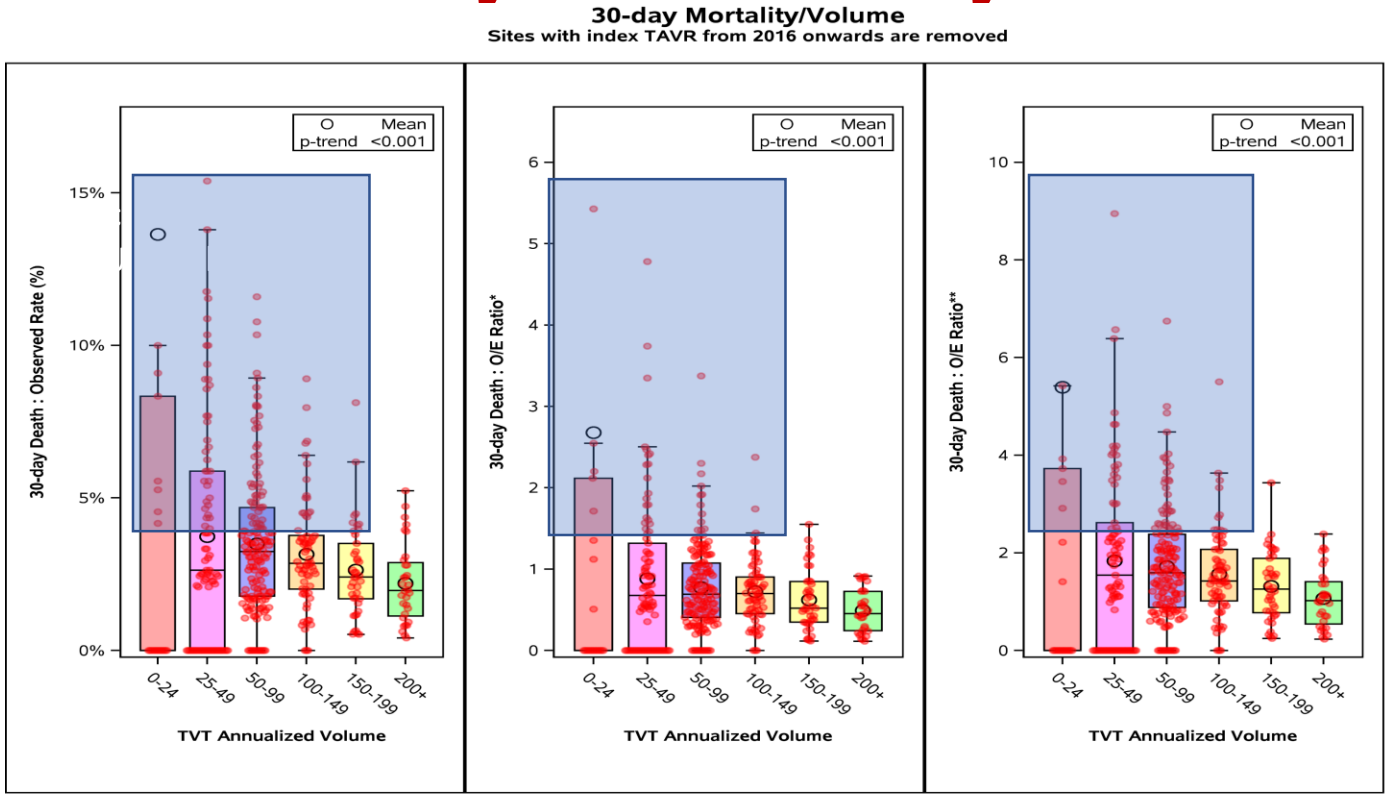
What Does A Mortality Rate > 4% Mean For Any Center? Why The Variability?



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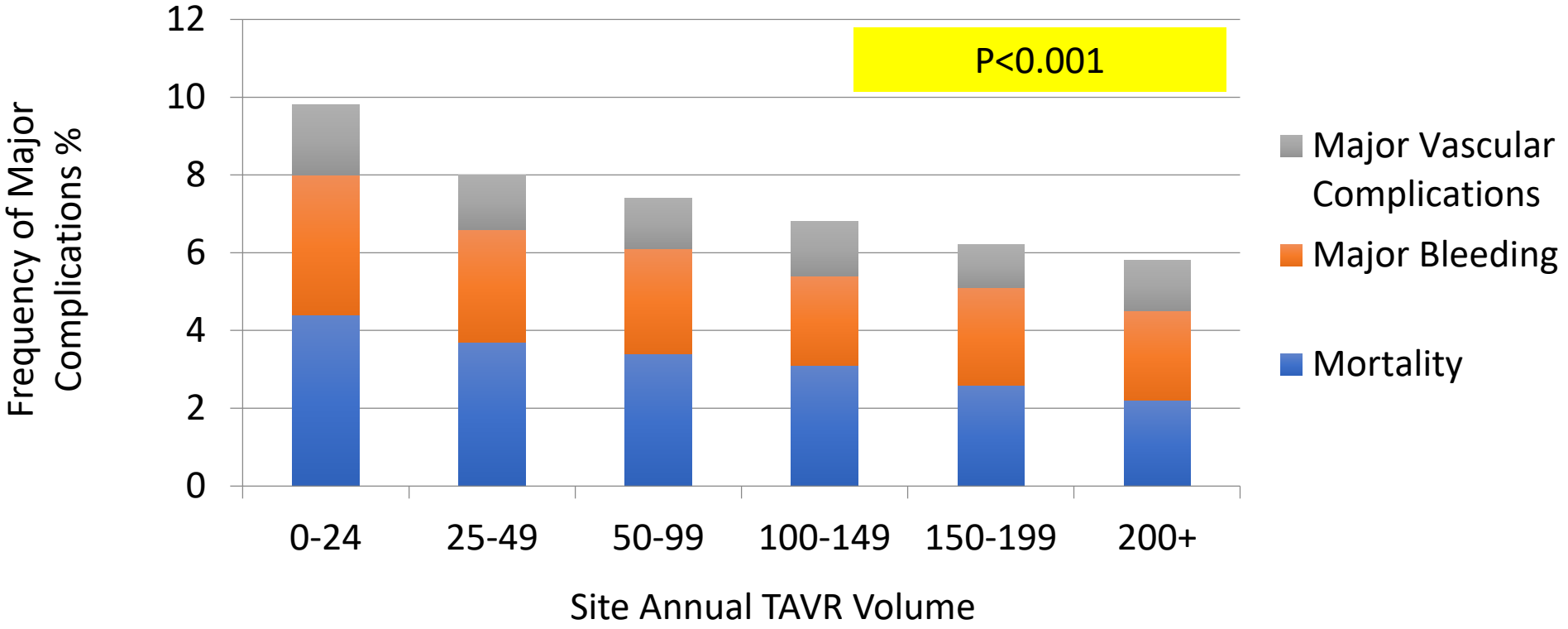
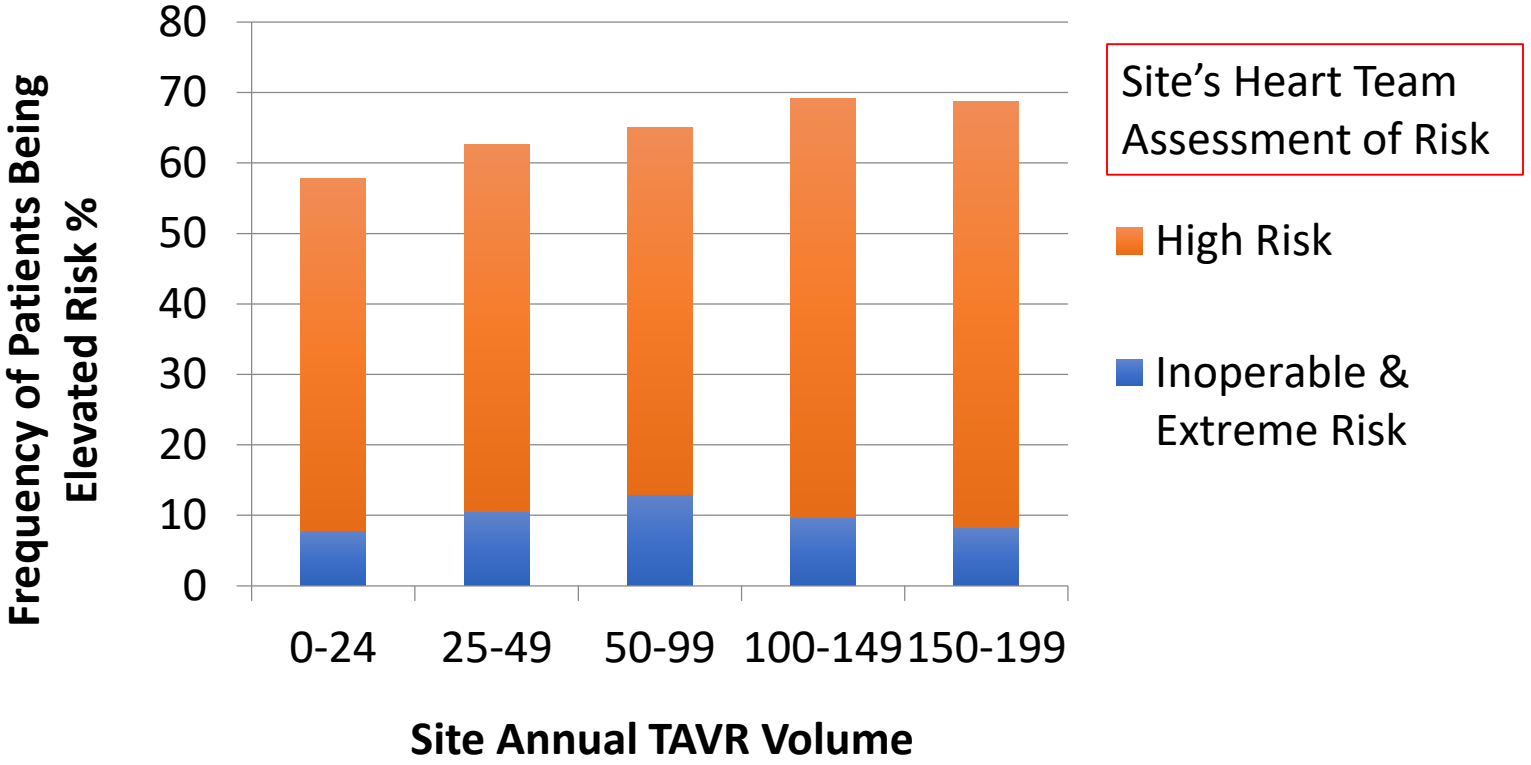
30 Day Composite Major Outcomes vs. Site Annual Volume

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

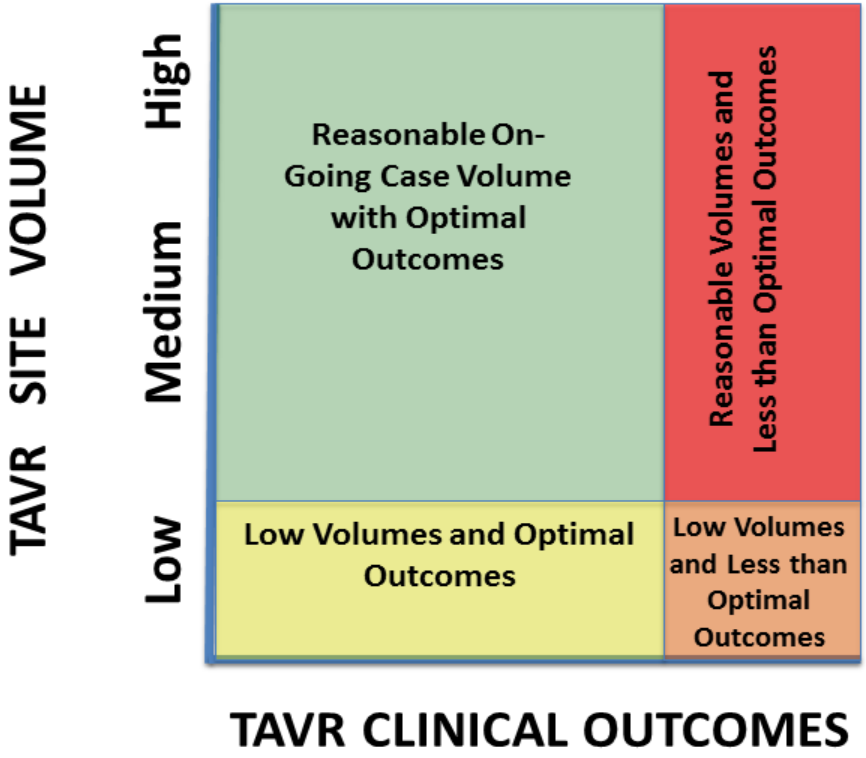


Are Lower Volume Sites Having Worse Outcomes Because They Are Treating Higher Risk Patients?

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



How to Interpret Low Volume Outcomes?



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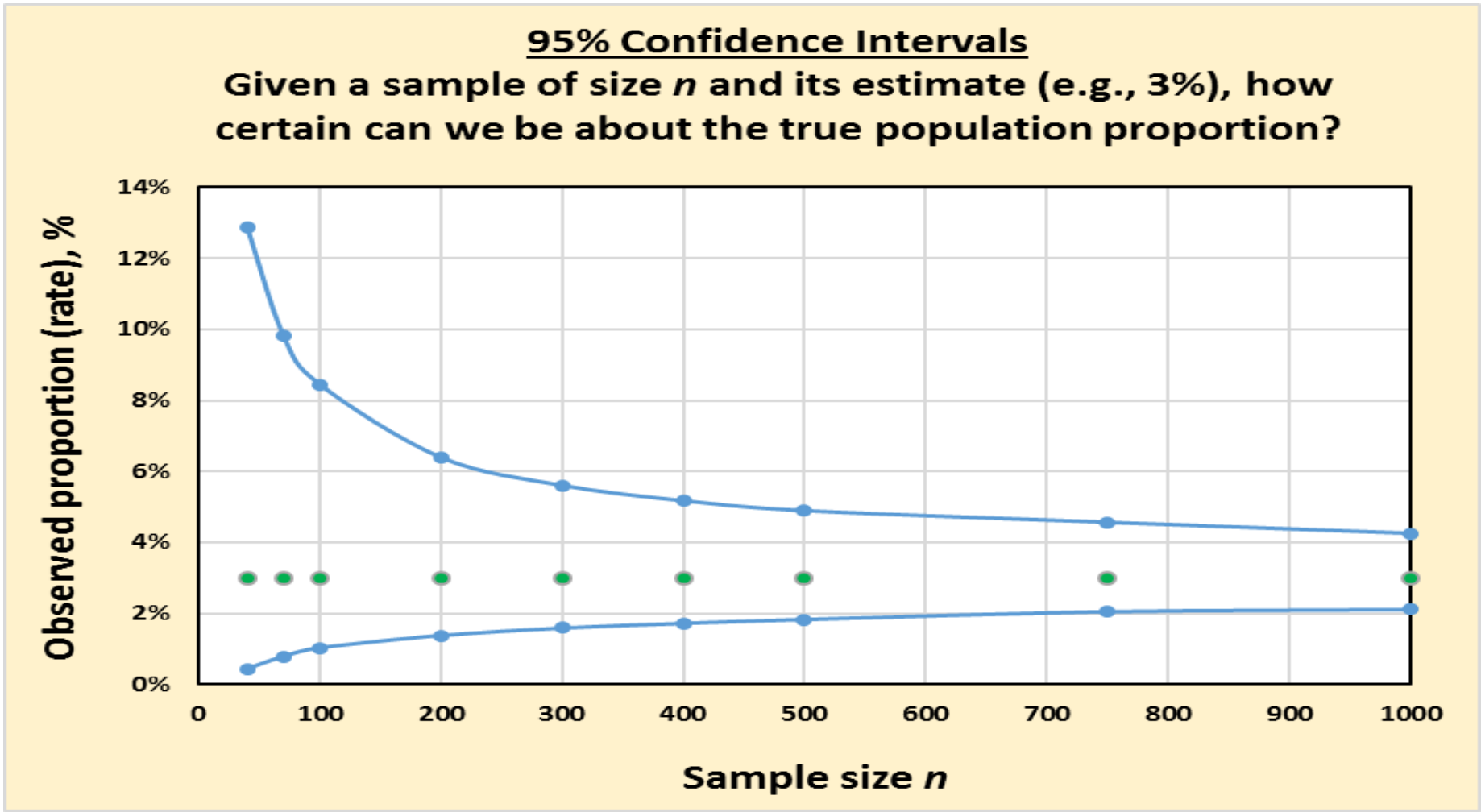
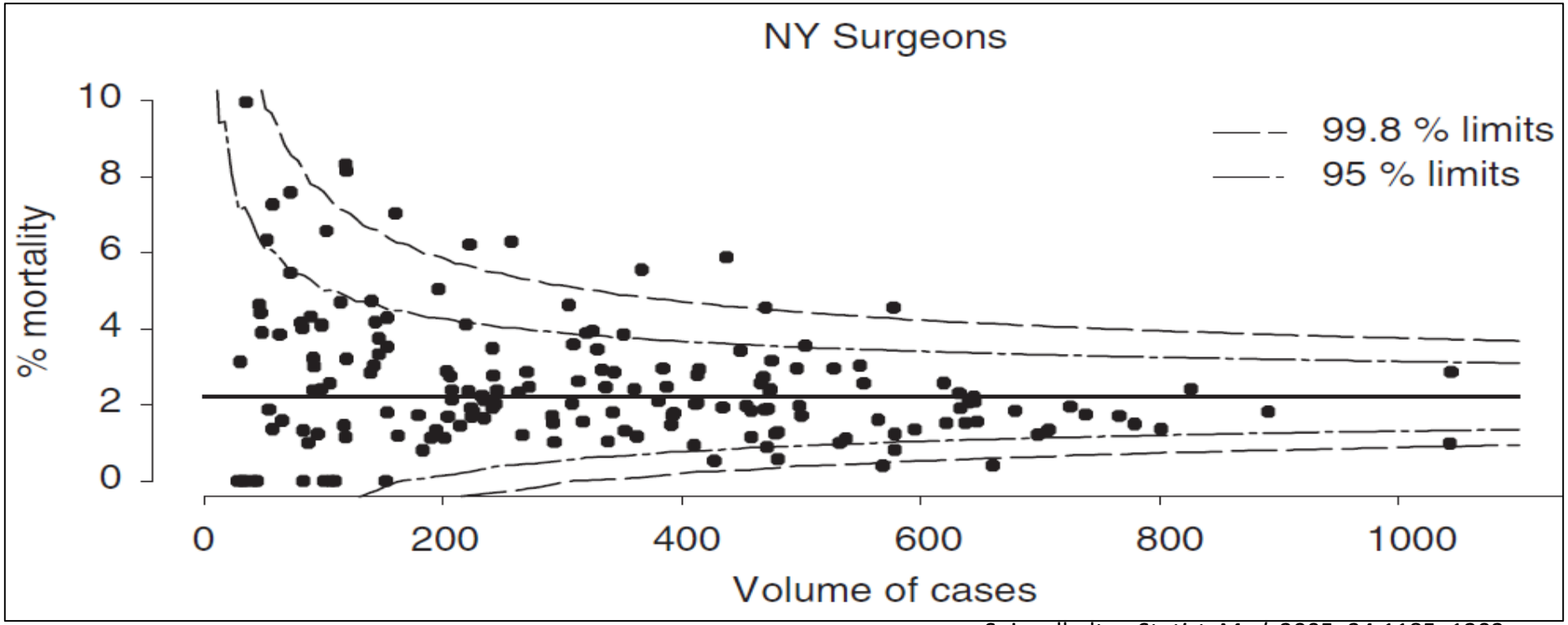
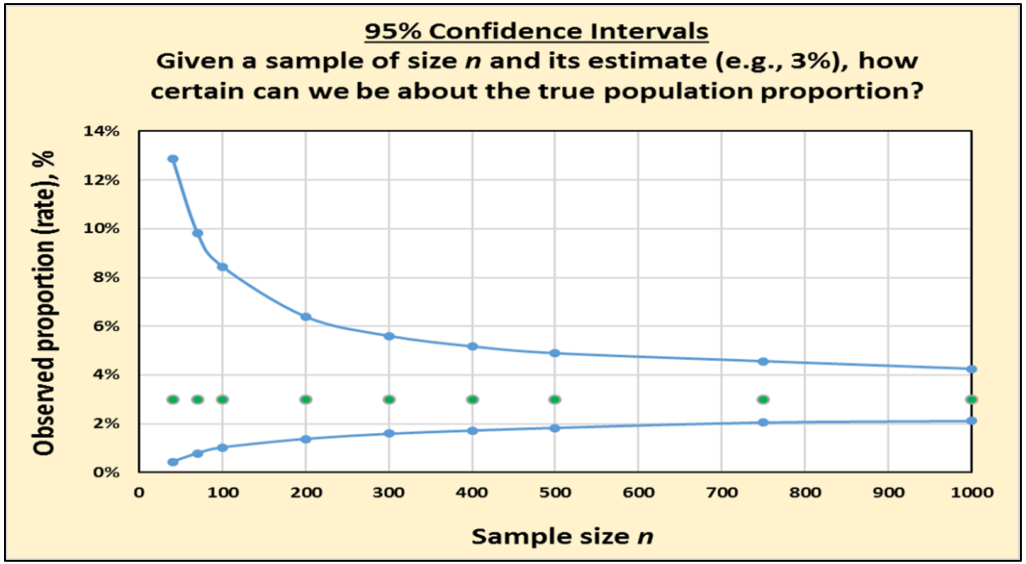

95% Confidence Intervals
Given a sample of size n and its estimate (e.g., 3%), how certain can we be about the true population proportion?
Observed proportion (rate), %
14%
12%
10%
8%
6%
4%
2%
0%
0
100
200
300
400
500
600
700
800
900
1000
Sample size n

Prediction Intervals (used for funnel plots)

Given known population parameters (mean, distribution), what can we say about estimates from future samples of size *n*?

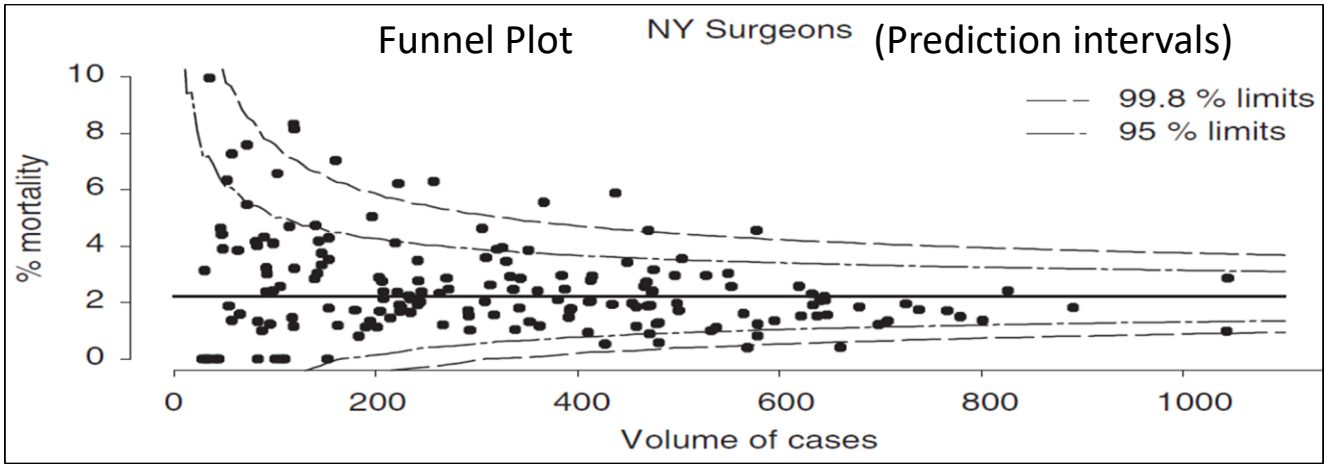


Spiegelhalter. *Statist. Med*. 2005; 24:1185–1202



Two statistical tools, same message

Estimates from small samples have substantial random variation



Statistical Power Decreases with Smaller Sample Size
Type II errors more likely

	National postoperative mortality (%)	Median annual number*	Number of procedures necessary to detect poor performance		
			60% power	70% power	80% power
Hip fracture surgery	8·4%†	31	56	75	102
Oesophagectomy or gastrectomy	6·1%‡	11	79	109	148
Bowel cancer resection	5·1%§	9	95	132	179
Cardiac surgery	2·7%¶	128	192	256	352

5% significance level. Poor performance defined as double the national overall mortality rate. *On the basis of hospital episode statistics[5] for the 3-year period from April, 2009, to March, 2012 (except for cardiac surgery, for which reported numbers[2] are used). †30-day mortality (March 1, 2010–Feb 28, 2011).[6] ‡90-day mortality (Oct 1, 2007–June 30, 2009).[7] §90-day mortality (Aug 1, 2010–July 31, 2011).[8] ¶In-hospital mortality (April 1, 2008–March 31, 2011).[9]

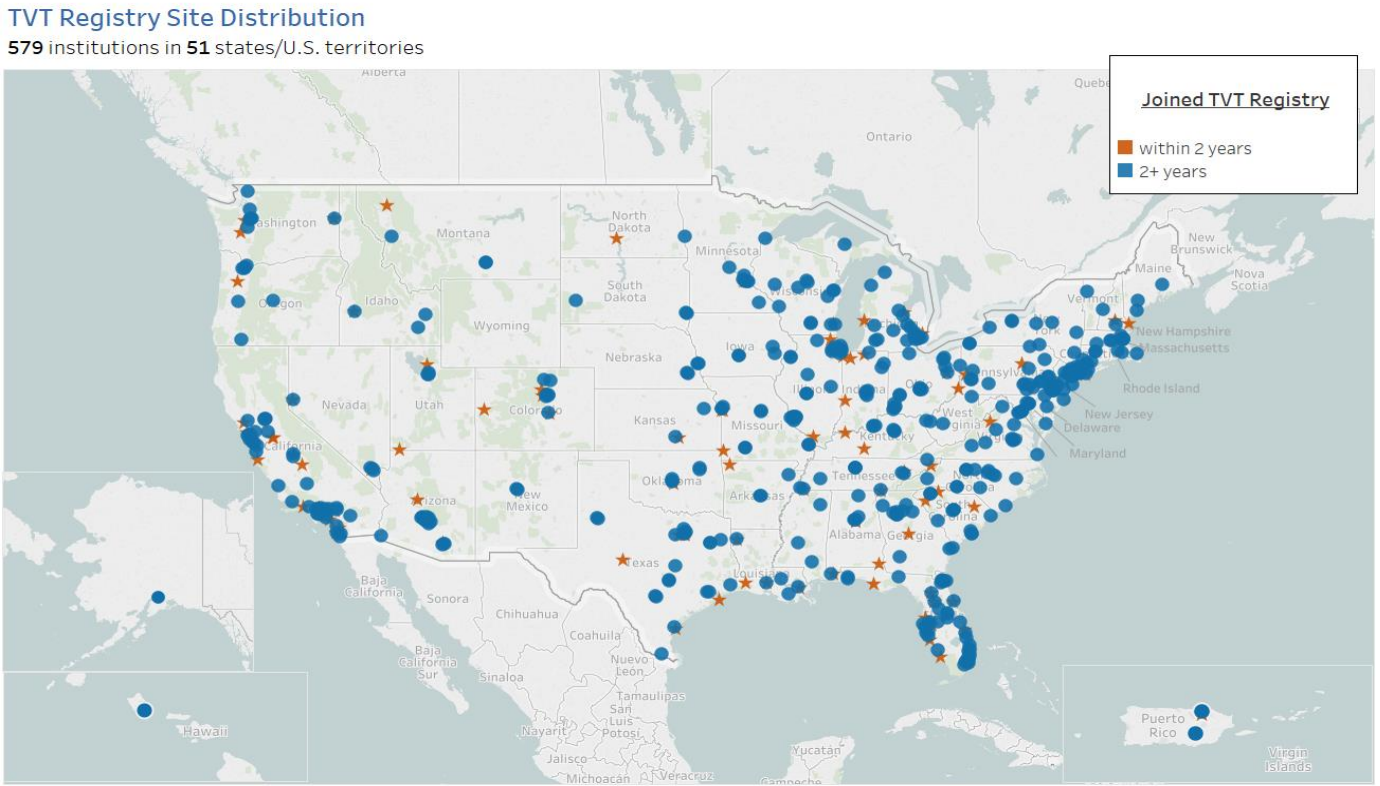
Table 1: **Mortality after four surgical procedures, the number of procedures that occur annually, and how many would be necessary to detect poor performance with different statistical powers**

Walker et al *Lancet* 2013;382(9905):1674-7

ACCESS:

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

220 TVT sites have annual TAVR Volumes < 50/cases



CED Questions

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

The 2018 Practitioner

Quality, Accountability, Transparency & Cost

Sir Luke Fildes, 1887, The Tate Museum, London

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