Society of Thoracic Surgeons (STS) American College of Cardiology (ACC)

TAVR Update: New Insights and Perspectives from the U.S. National STS/ACC TVT Registry

Joseph E. Bavaria, MD

STS/ACC TVT Registry Steering Committee Chairman (2017-2020)

Past-President of STS (2016-17)

Roberts-Measey Professor and Vice-Chair of Cardiovascular Surgery at the University of Pennsylvania

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Disclosures

- STS-ACC Transcatheter Valve Therapy (TVT) Registry Steering Committee Chairman
- Co-Chair of the 4-Society TAVR Institutional and Operator Writing Committee (ACC/STS/AATS/SCAI)
- Site Investigator in Transcatheter Valve Trials or Consultant
  - W.L. Gore: Cardiac & Aortic Teams
  - Edwards Lifesciences: PARTNER family of Trials, Commence Trial
  - Abbott/St. Jude: Portico, Trifecta Trials
  - Medtronic: SURTAVI Intermediate Risk Trials
- Founders Shares and Equity holder in CardiAQ TMVR (sold to Edwards in Oct 2015 with no financial conflict presently)

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Disclosures

- I love TAVR!!

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

History of the TVT Registry

The **STS/ACC TVT Registry™** , created by a collaboration between the Society for Thoracic Surgeons (STS) and the American College of Cardiology (ACC), monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients.

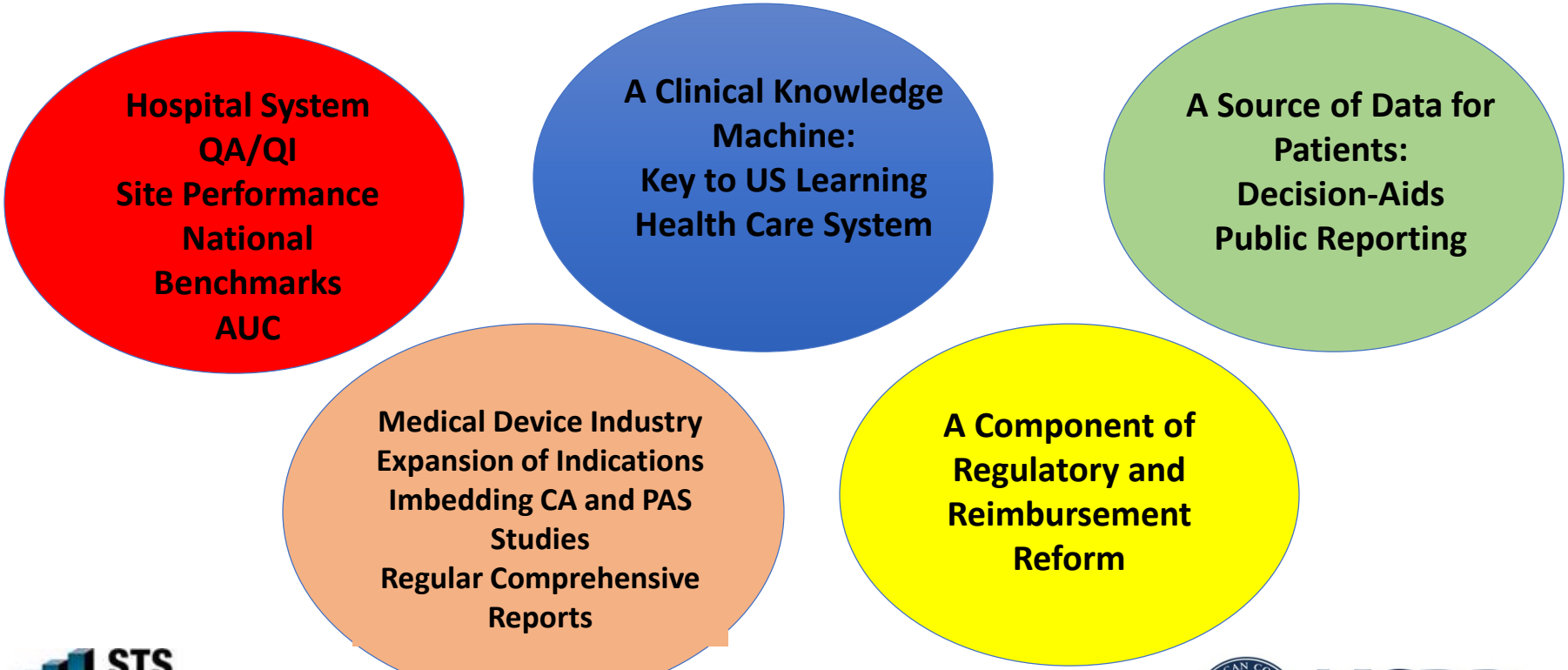
TVT = Transcatheter Valve Therapy

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

The Need for a National Clinical Registry

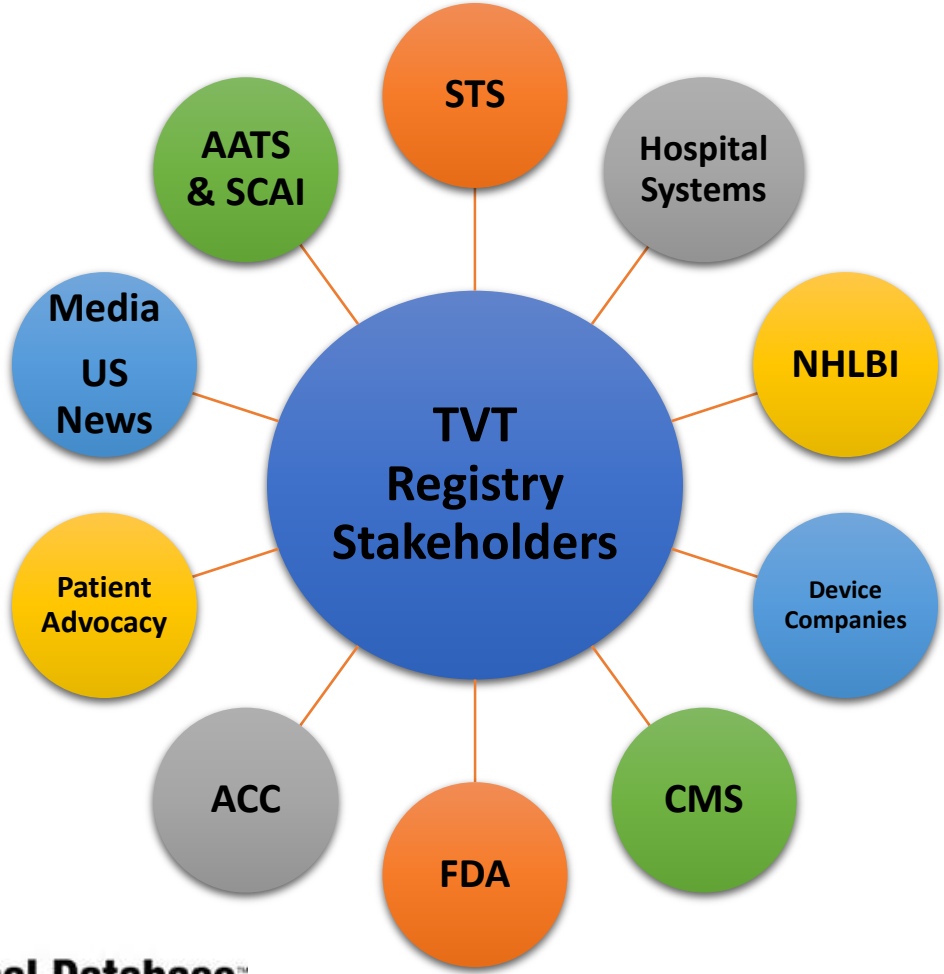
Value of TVT: The Key to Sustainability



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Multiple Stakeholders



- Professional Societies
- Government agencies
- Hospital Networks
- Device Industry
- University Analytic Centers
- Health Media

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

An Update of the Data Collected in the Three Modules

Transcatheter aortic valve replacement (TAVR)

Transcatheter mitral valve repair (MitraClip)

Transcatheter mitral valve replacement (Valve-in-Valve)

CMS Mandated

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

"**Science** tells us what we can do;

Guidelines what we should do; &

Registries what we are actually doing."

Lukas Kappenberger MD
Heart Rhythm Society Policy Conference
Washing ton DC 2005

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

An Update of the Data Collected in the Three Modules

Transcatheter aortic valve replacement (TAVR)

Transcatheter mitral valve repair (MitraClip)

Transcatheter mitral valve replacement (Valve-in-Valve)

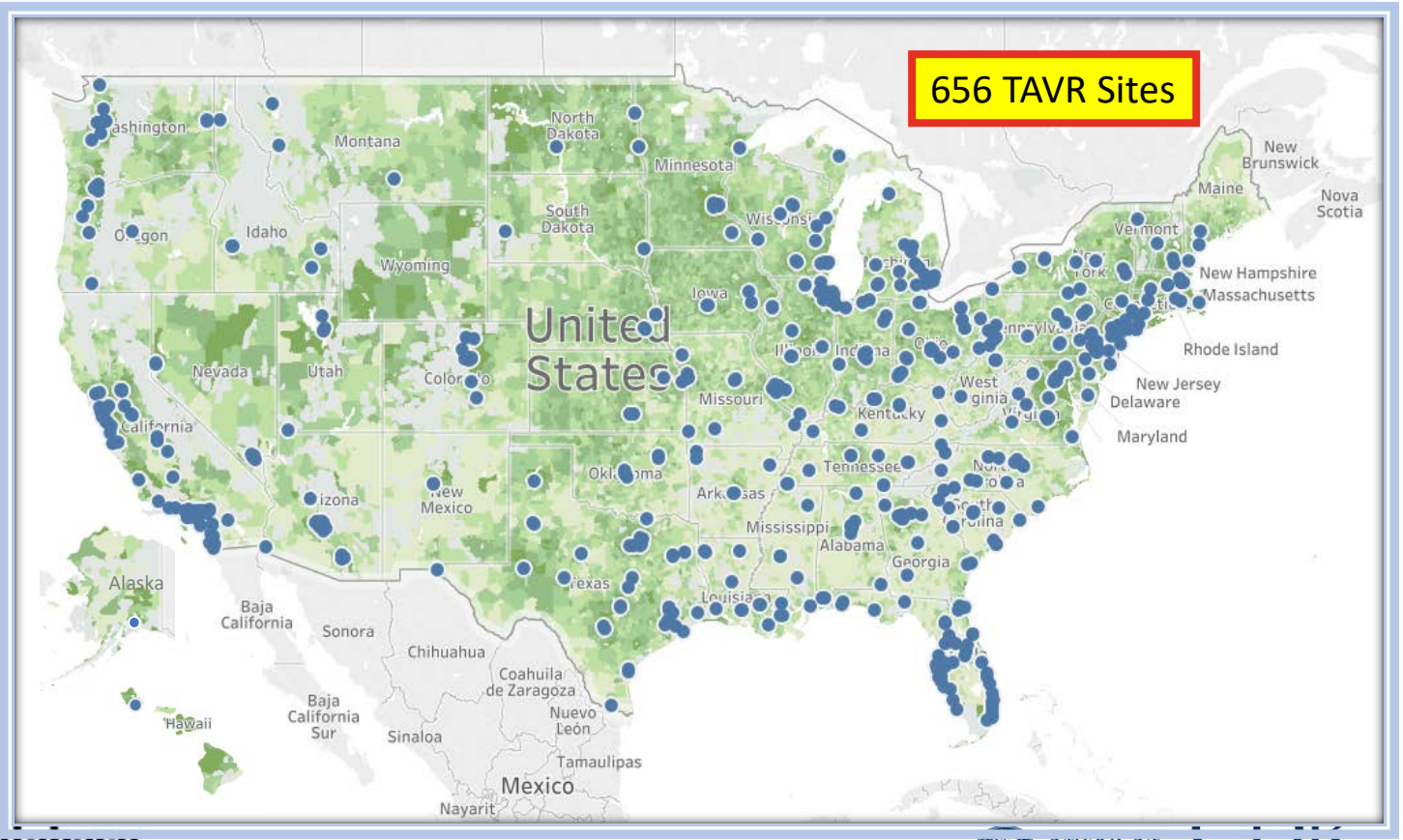
CMS Mandated

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT Registry Sites

- **Last 2 years 115 new sites**
- **New sites opening are most frequently in close proximity to existing sites**
- **Whether or not new sites meet current NCD requirements is unknown**
- **First Wyoming TAVR site to open in 2020**

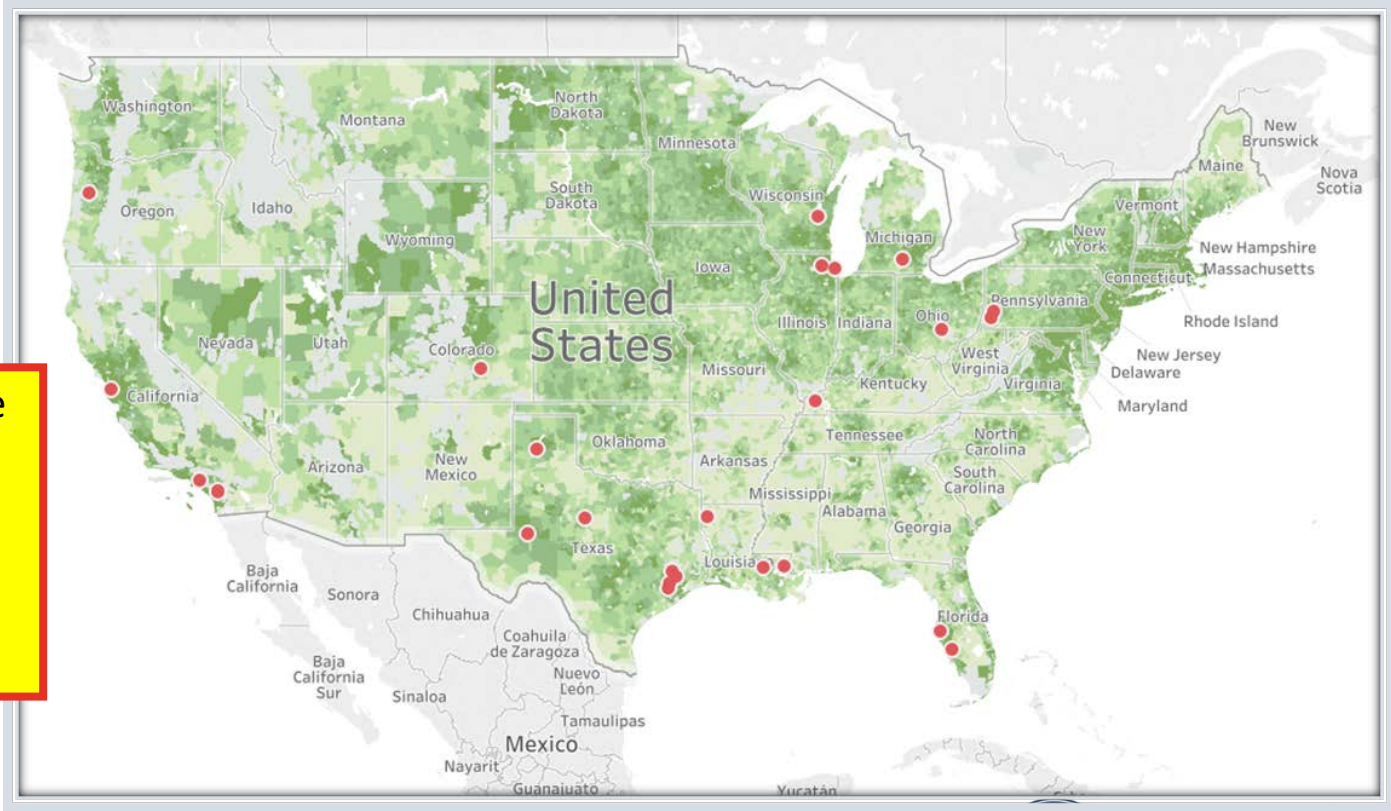


STS National Database
Using data to drive quality

Thru October 16, 2019

AMERICAN COLLEGE of CARDIOLOGY
CDR CARDIOVASCULAR DATA REGISTRY

TVT Registry Sites since new NCD

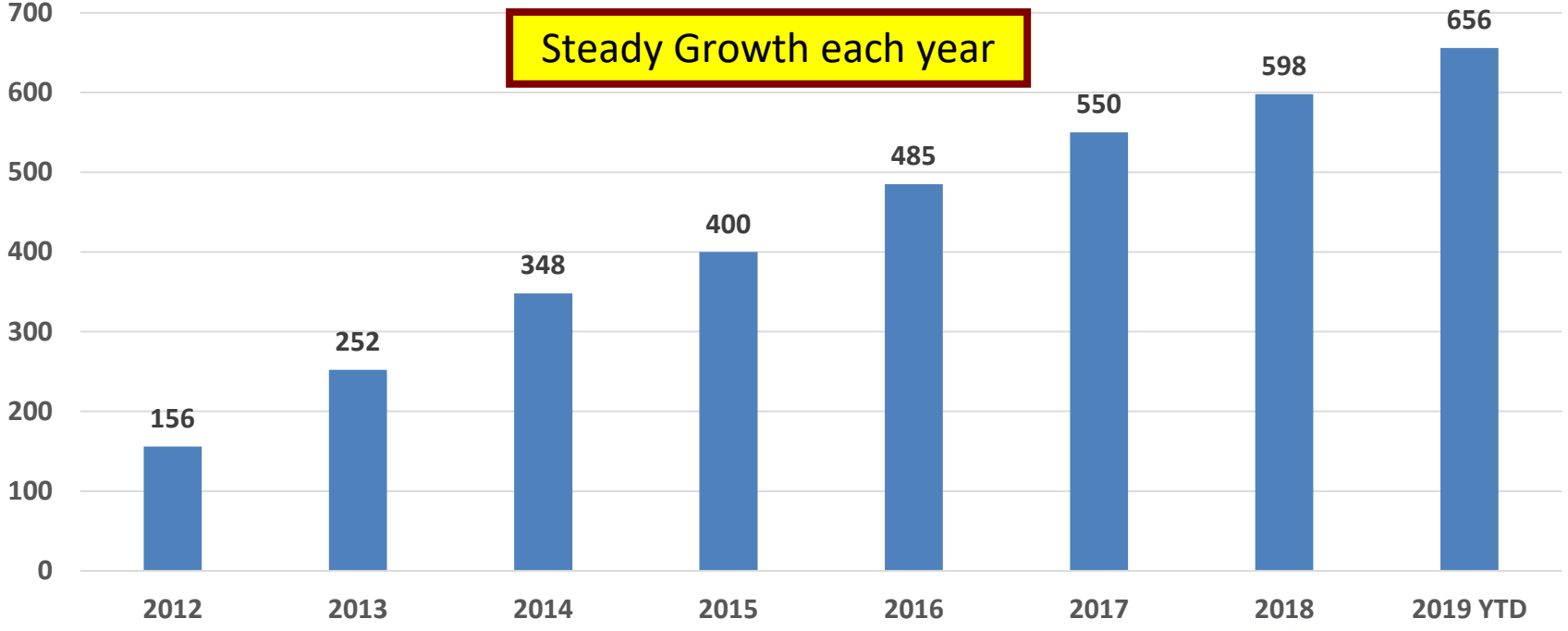


- US has 1 TAVR site for every 70,000 people over the age of 65 years. More than ANY other country

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Sites Enrolled in the TVT Registry as of October 16, 2019



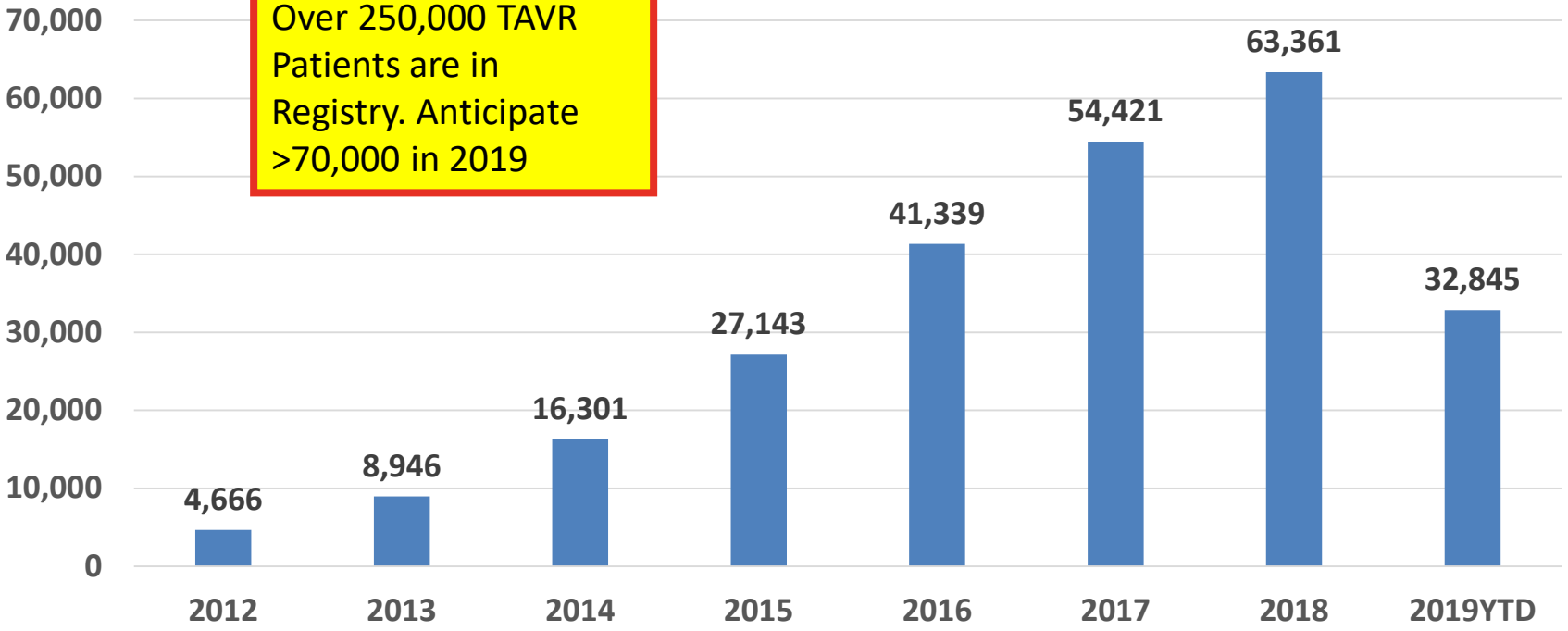
STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT National Volumes Data: Snapshot of U.S. TAVR Practice Patterns

Commercial TAVR Submitted to the TVT Registry

Over 250,000 TAVR Patients are in Registry. Anticipate >70,000 in 2019



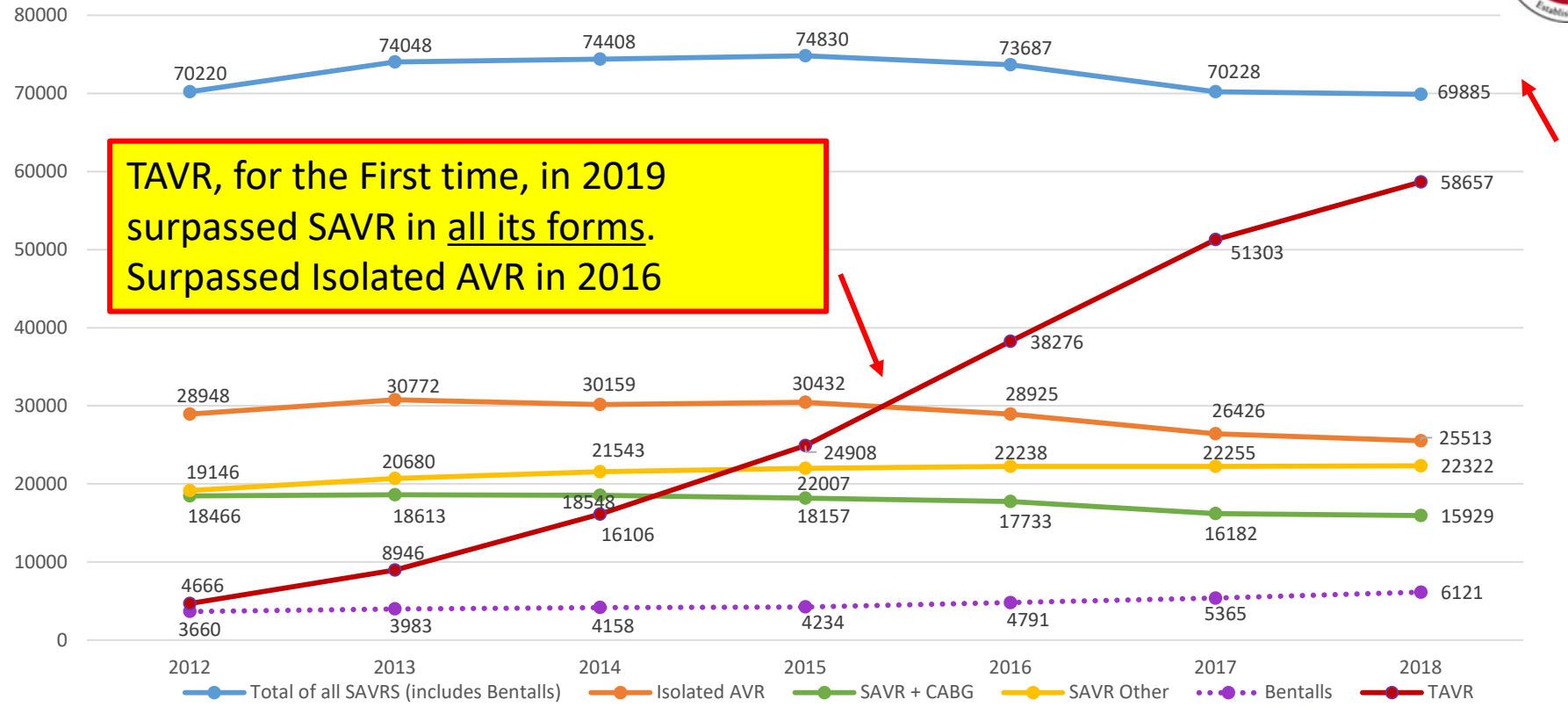
STS National Database™ Using data to drive quality

TVT Registry Datamart Data as of 10/16/19

NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

Transcatheter Therapy Modules in TVT Registry	Current Number of Sites Performing Treatment	2018 Patient Volume in USA	2018 Mean Number of Procedures per Site
TAVR Native and Valve-in-Valve	642	63,361	105
Transcatheter Mitral Valve Repair (MitraClip)	355	7,230	20
Transcatheter Mitral Valve Replacement (Sapien Valve-in-Valve and Valve-in-Ring)	184	937	5
Transcatheter Tricuspid Valve Repair and Replacement (2020?)	TBD	TBD	TBD

The Aortic Valve "Universe" in the USA



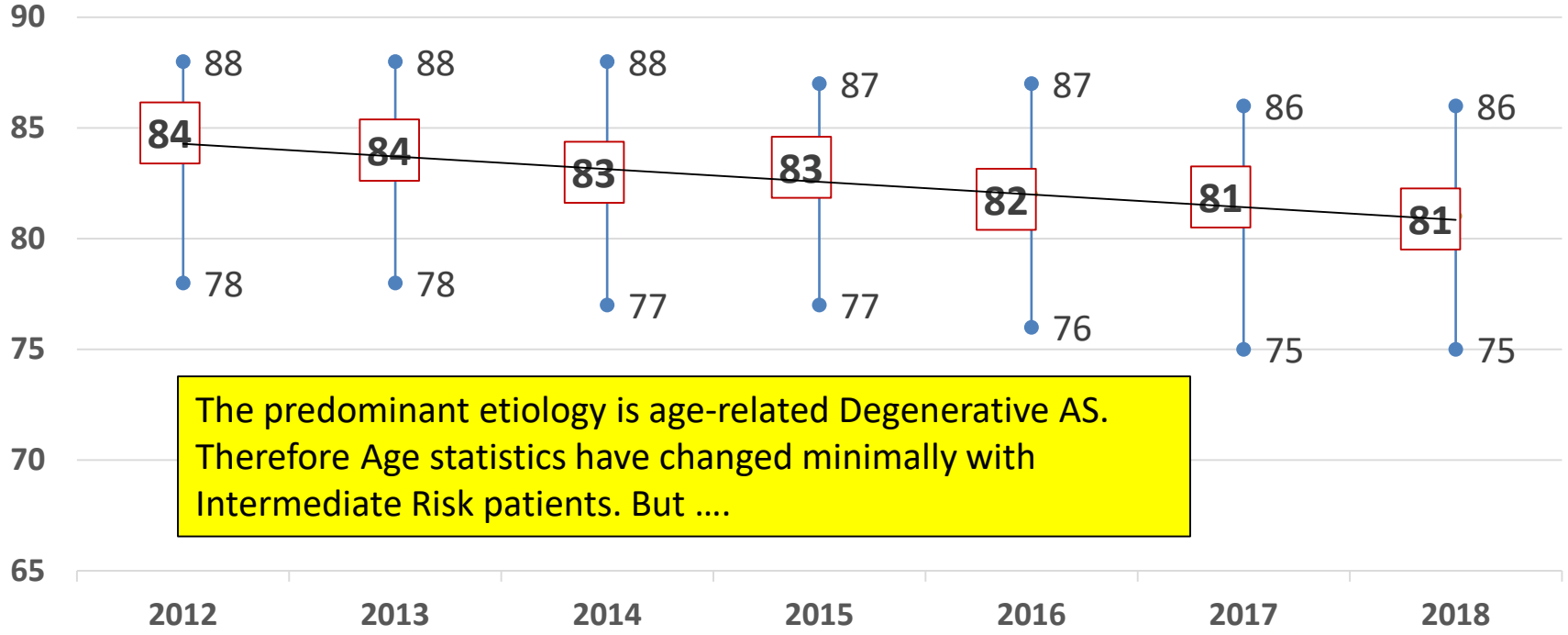
STS National Database
Using data to drive quality

Linked TVT and STS Data. From the STS/ACC TVT Steering Committee
Represents approx. 93% and 97% of SAVR and TAVR respectively

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Age

(25th and 75th percentiles)



The predominant etiology is age-related Degenerative AS. Therefore Age statistics have changed minimally with Intermediate Risk patients. But ….

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Age

(25th and 75th percentiles)

Average age of Low Risk trials = 74 years

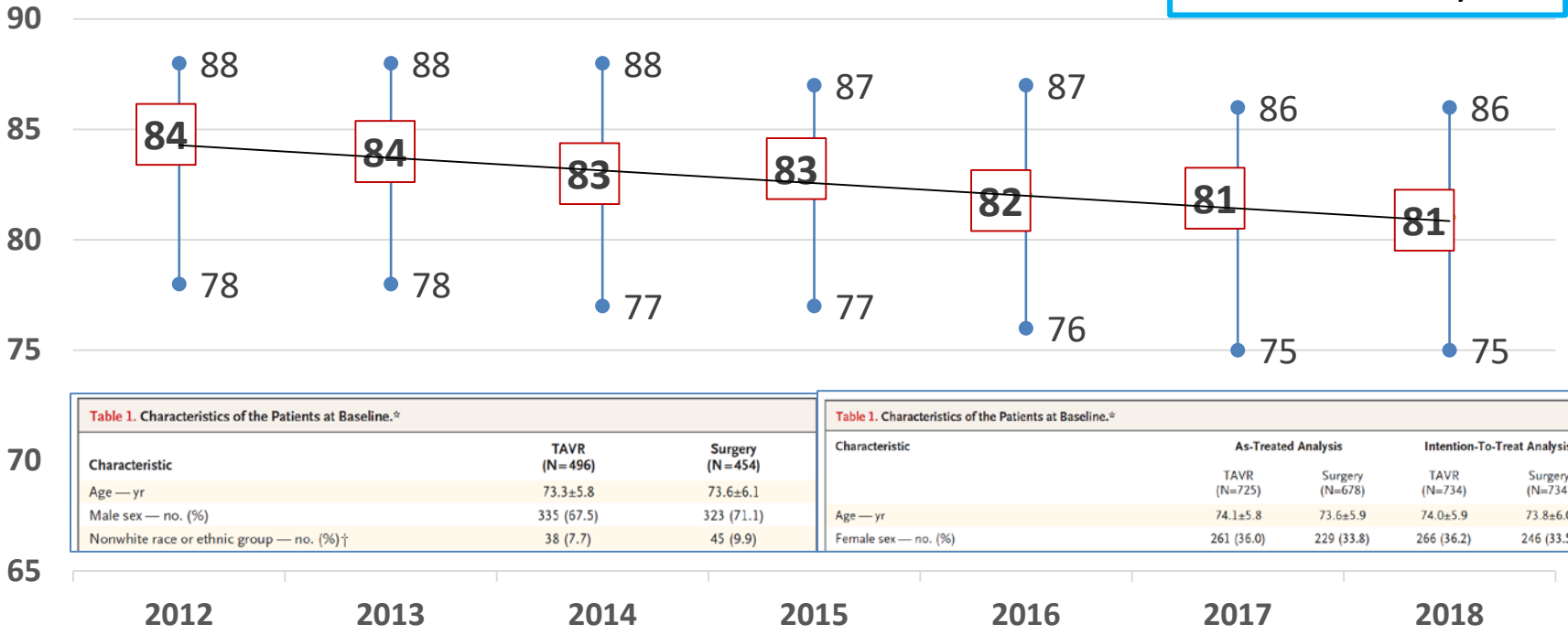


Table 1. Characteristics of the Patients at Baseline.*

Characteristic	TAVR (N=496)	Surgery (N=454)
Age — yr	73.3±5.8	73.6±6.1
Male sex — no. (%)	335 (67.5)	323 (71.1)
Nonwhite race or ethnic group — no. (%)†	38 (7.7)	45 (9.9)

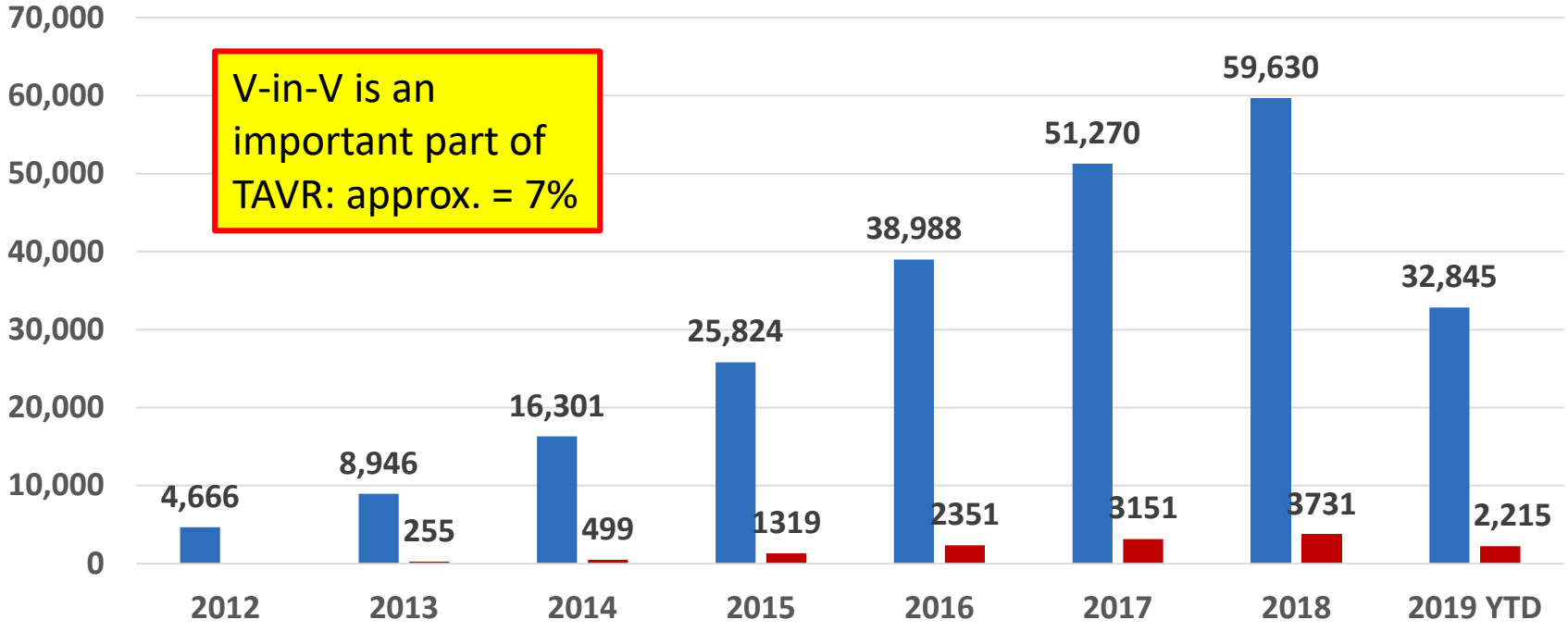
Table 1. Characteristics of the Patients at Baseline.*

Characteristic	As-Treated Analysis		Intention-To-Treat Analysis	
	TAVR (N=725)	Surgery (N=678)	TAVR (N=734)	Surgery (N=734)
Age — yr	74.1±5.8	73.6±5.9	74.0±5.9	73.8±6.0
Female sex — no. (%)	261 (36.0)	229 (33.8)	266 (36.2)	246 (33.5)

STS National Database™ Using data to drive quality

NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT Registry
TAVR and TAVR ViV Procedures



TVT Registry Datamart Data as of 10/16/19

STS National Database
Using data to drive quality

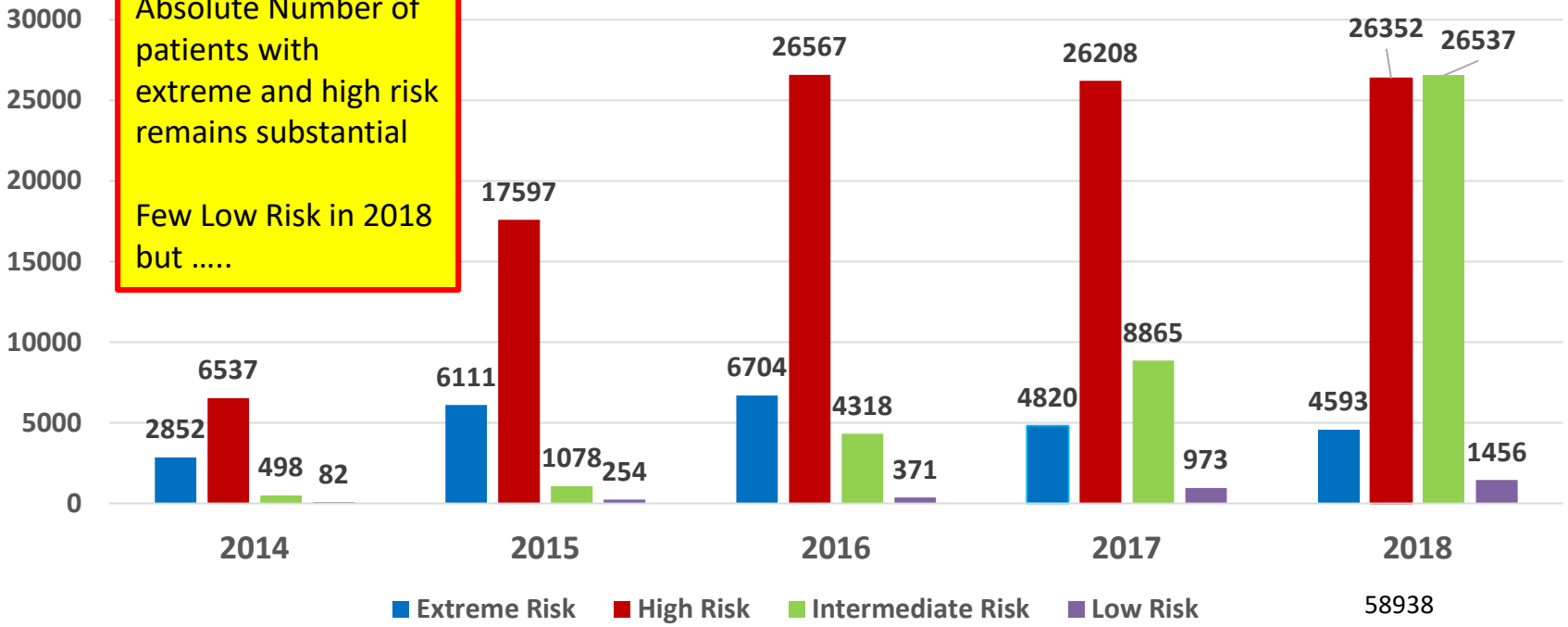
NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Records

eam Reason for Procedure

Expansion of TAVI into Intermediate Risk.
Absolute Number of patients with extreme and high risk remains substantial

Few Low Risk in 2018 but …..



58938

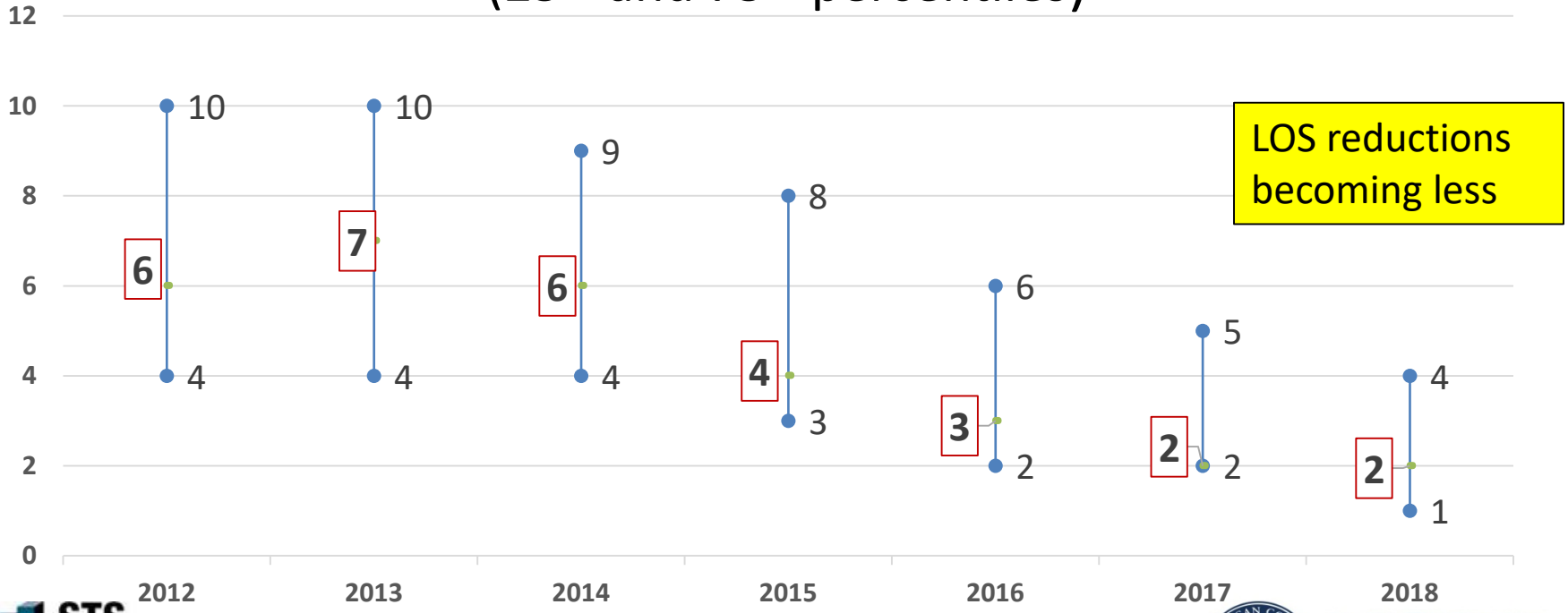
STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR

Median LOS in Days

(25th and 75th percentiles)

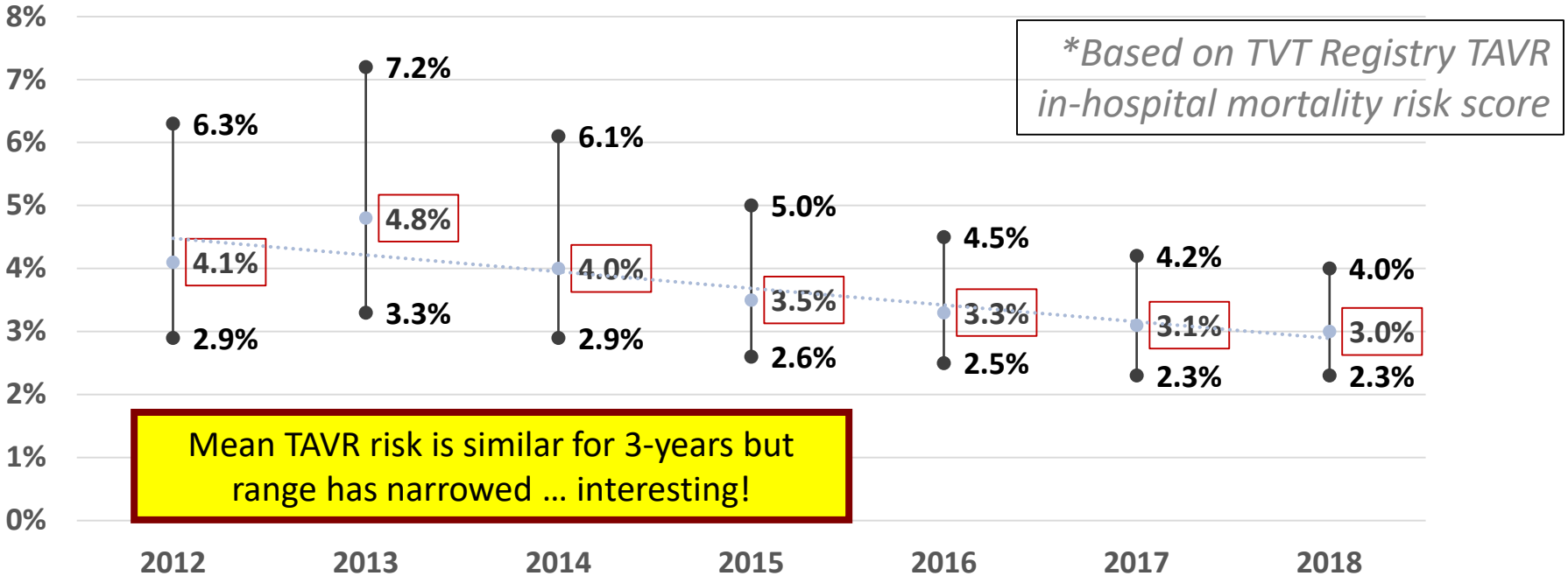


STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR In-Hospital Mortality Risk Score*

(Median, 25th and 75th %)



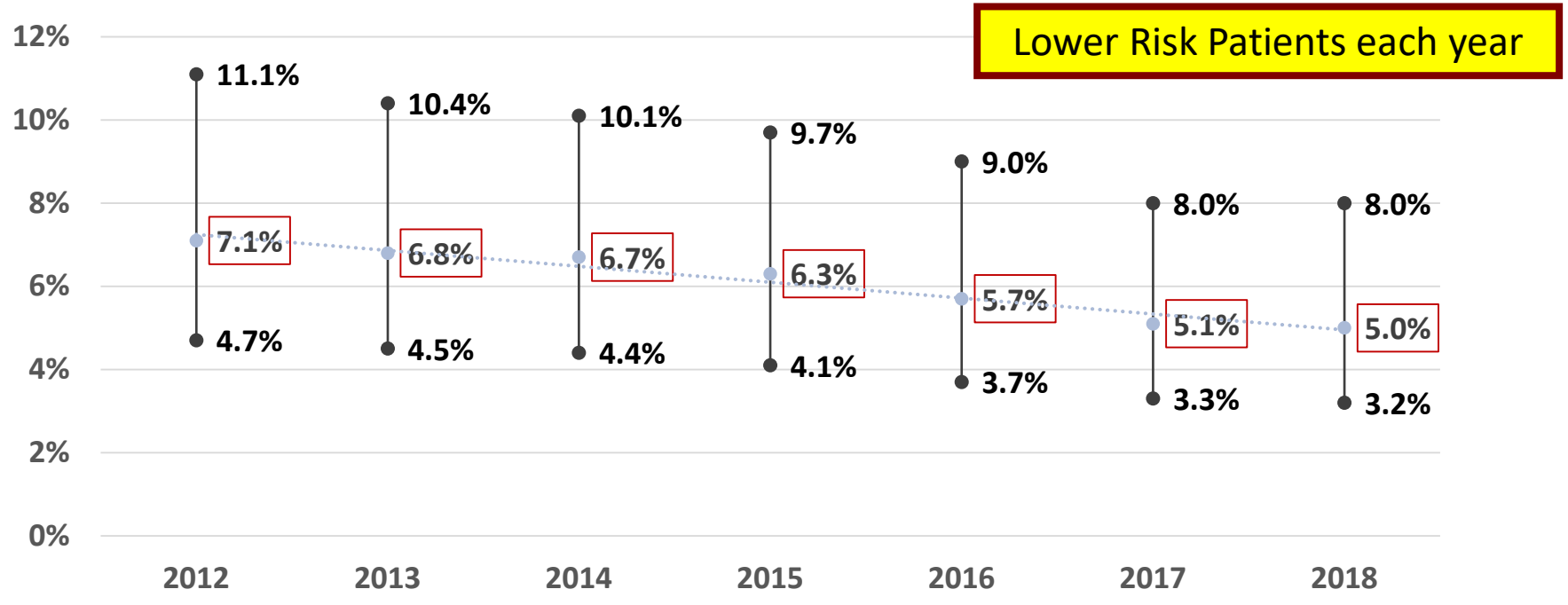
STS National Database
Using data to drive quality

*Based on TVT Registry TAVR in-hospital mortality risk score

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

STS SAVR Risk Score Patients Undergoing TAVR

(Median, 25th and 75th %)

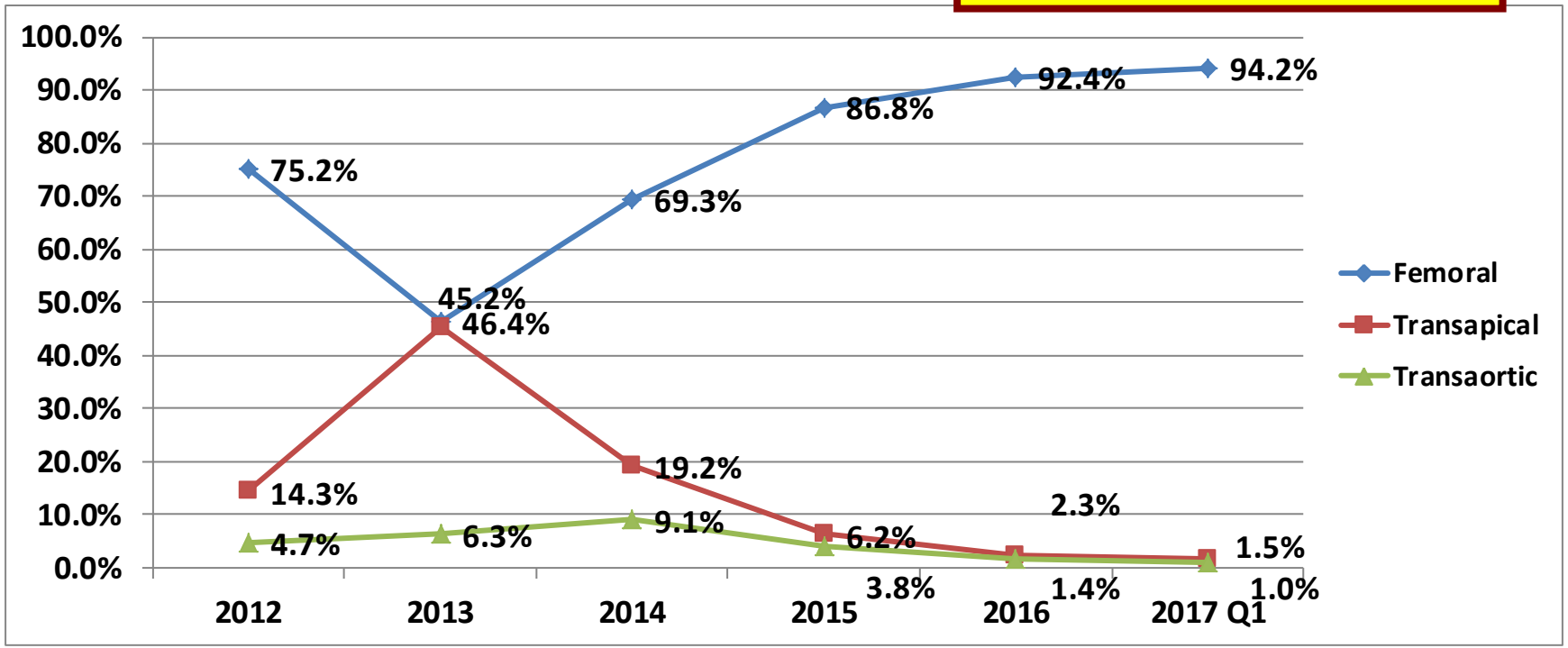


STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Access Site

TF Dominates: >95% in 2018:
Good for Patients



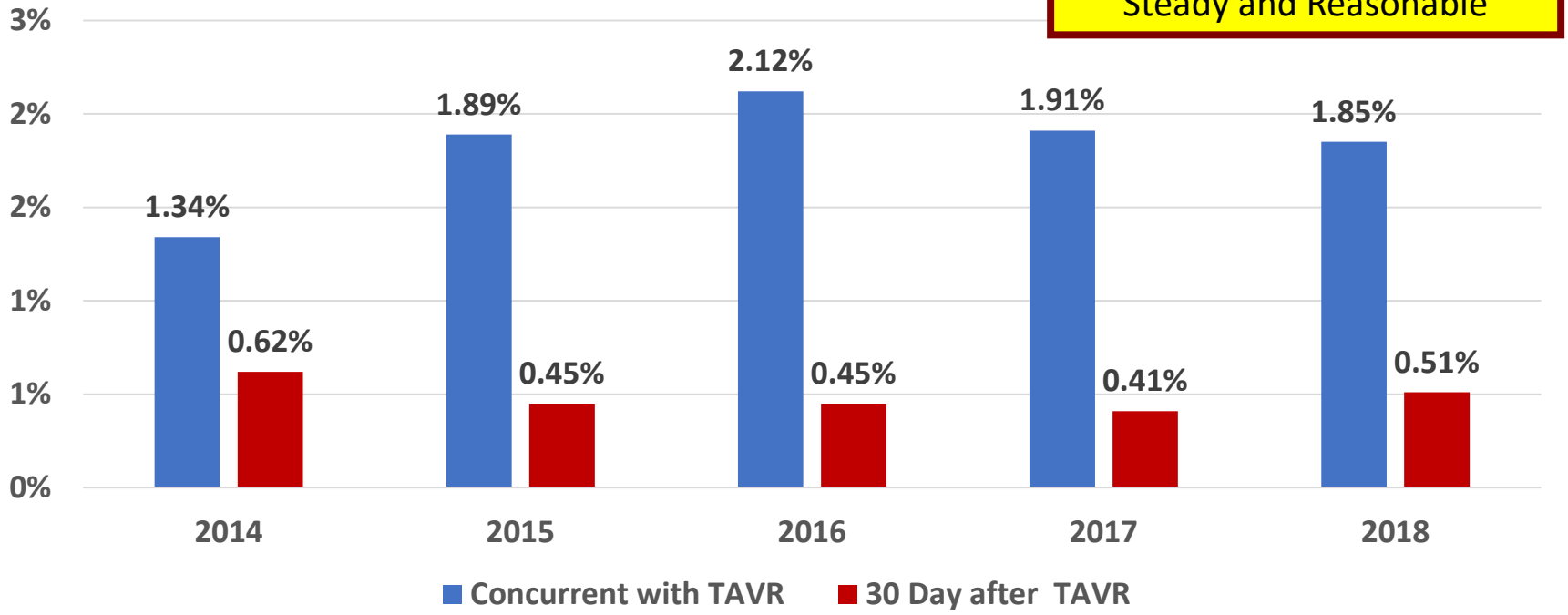
STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Source: STS/ACC TVT Registry Database.as of Jul 17,2017

Concurrent and 30-Day PCI with TAVR Procedure

Steady and Reasonable

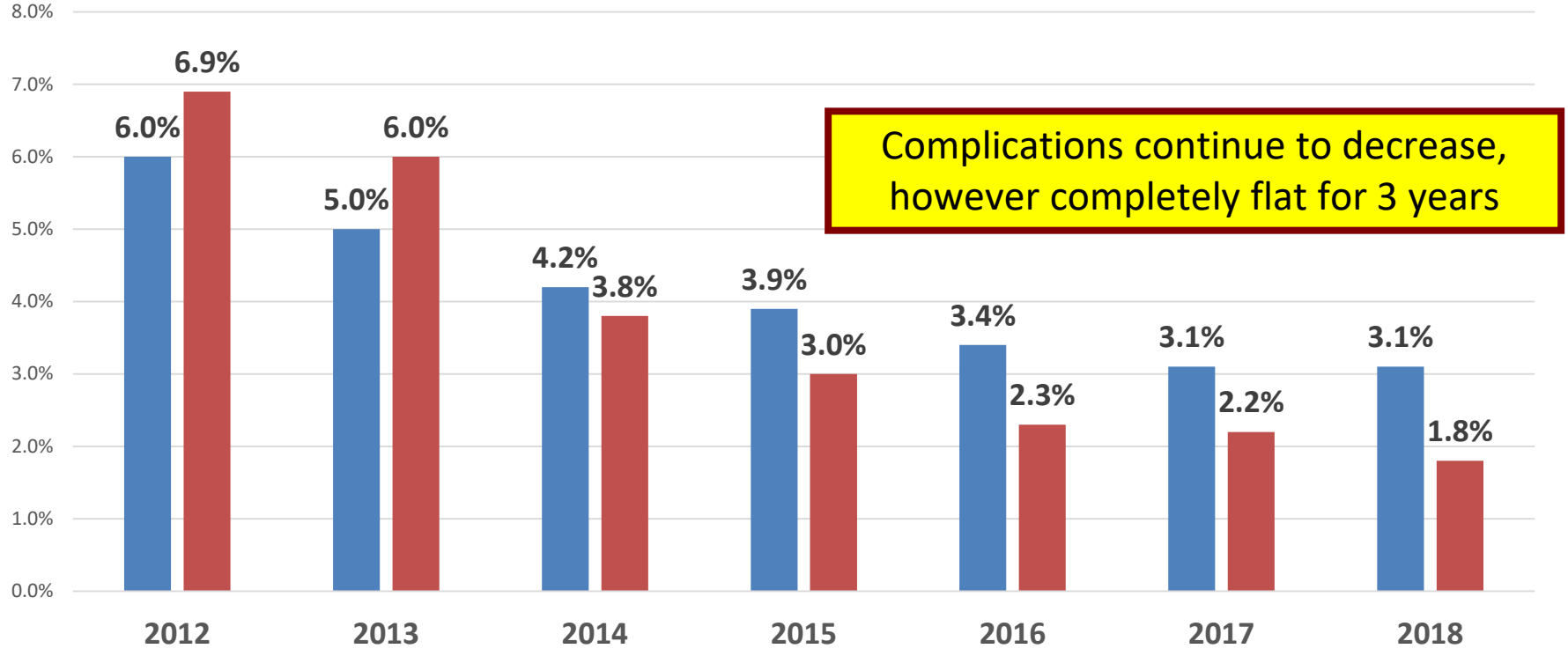


STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Real World TAVR Clinical Outcomes

TAVR: In Hospital
Major and Life-Threatening Bleed



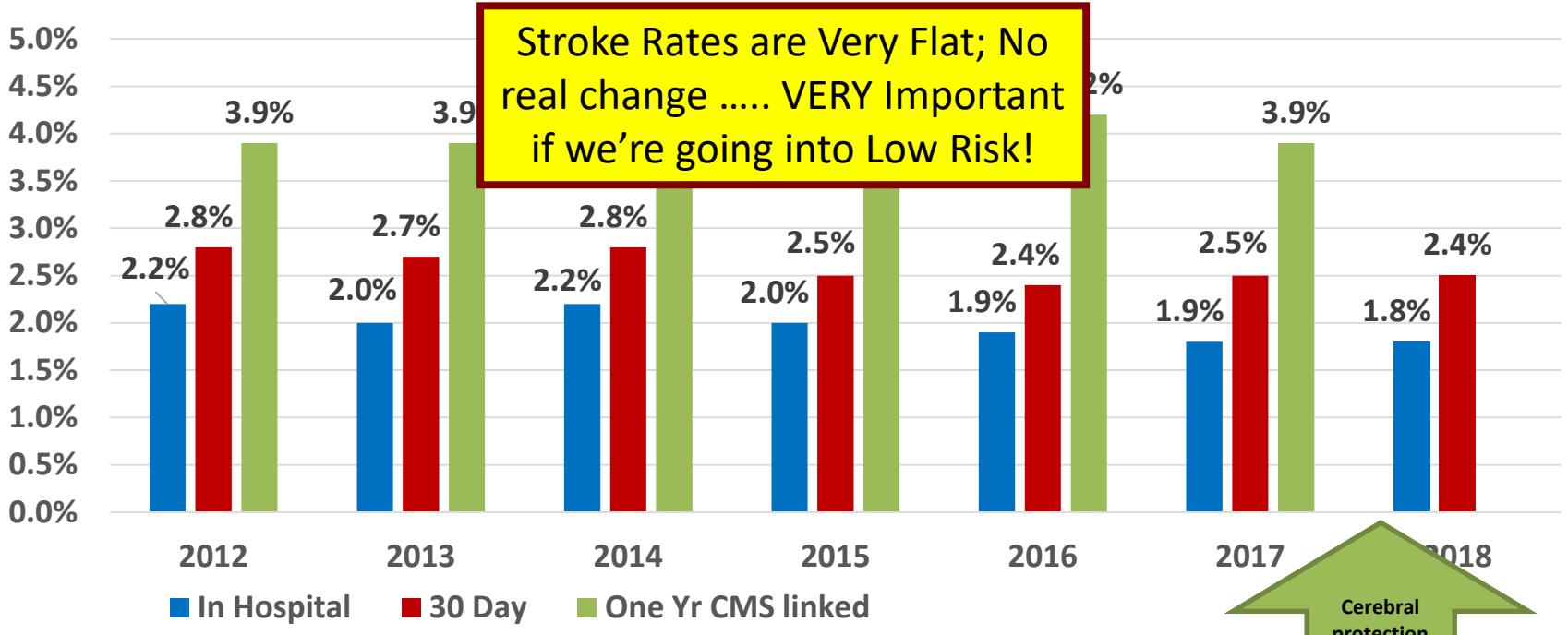
Complications continue to decrease, however completely flat for 3 years

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Stroke

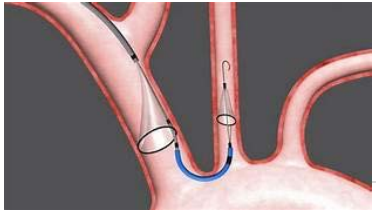
In-Hospital, 30 Day, and One Year Stroke

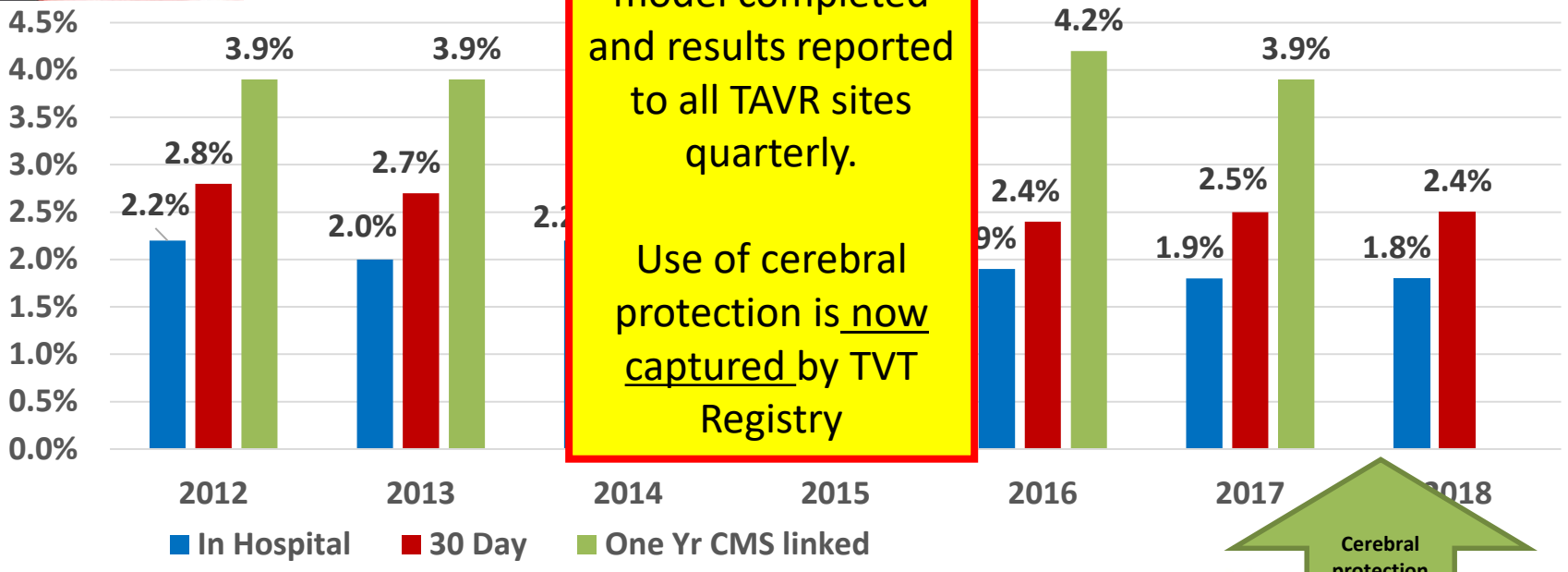


STS National Database
Using data to drive quality

NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Stroke: In-Hospital, 30 Day, and One Year Stroke





Risk-adjusted stroke model completed and results reported to all TAVR sites quarterly.

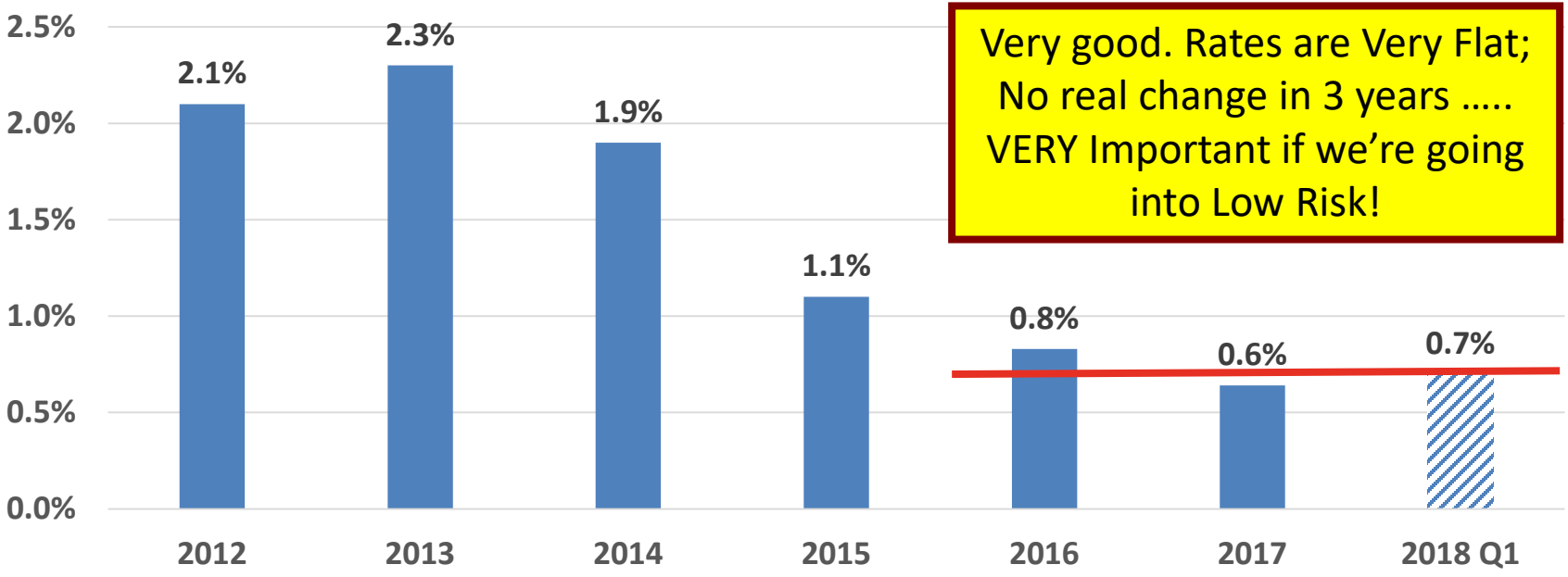
Use of cerebral protection is now captured by TVT Registry

Cerebral protection approved

STS National Database
Using data to drive quality

NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR - 30 Day Dialysis



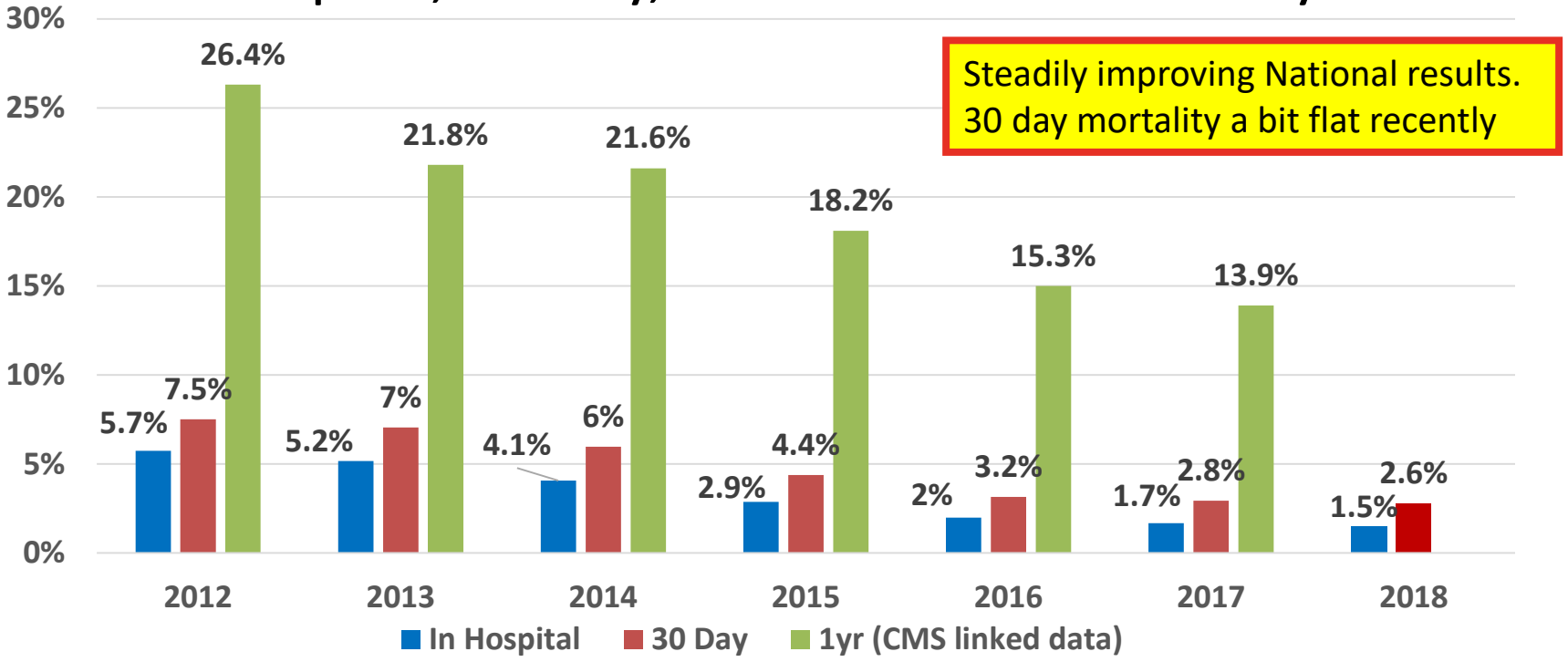
Very good. Rates are Very Flat; No real change in 3 years ….. VERY Important if we're going into Low Risk!

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Mortality

In-Hospital, 30 Day, and One Year Mortality



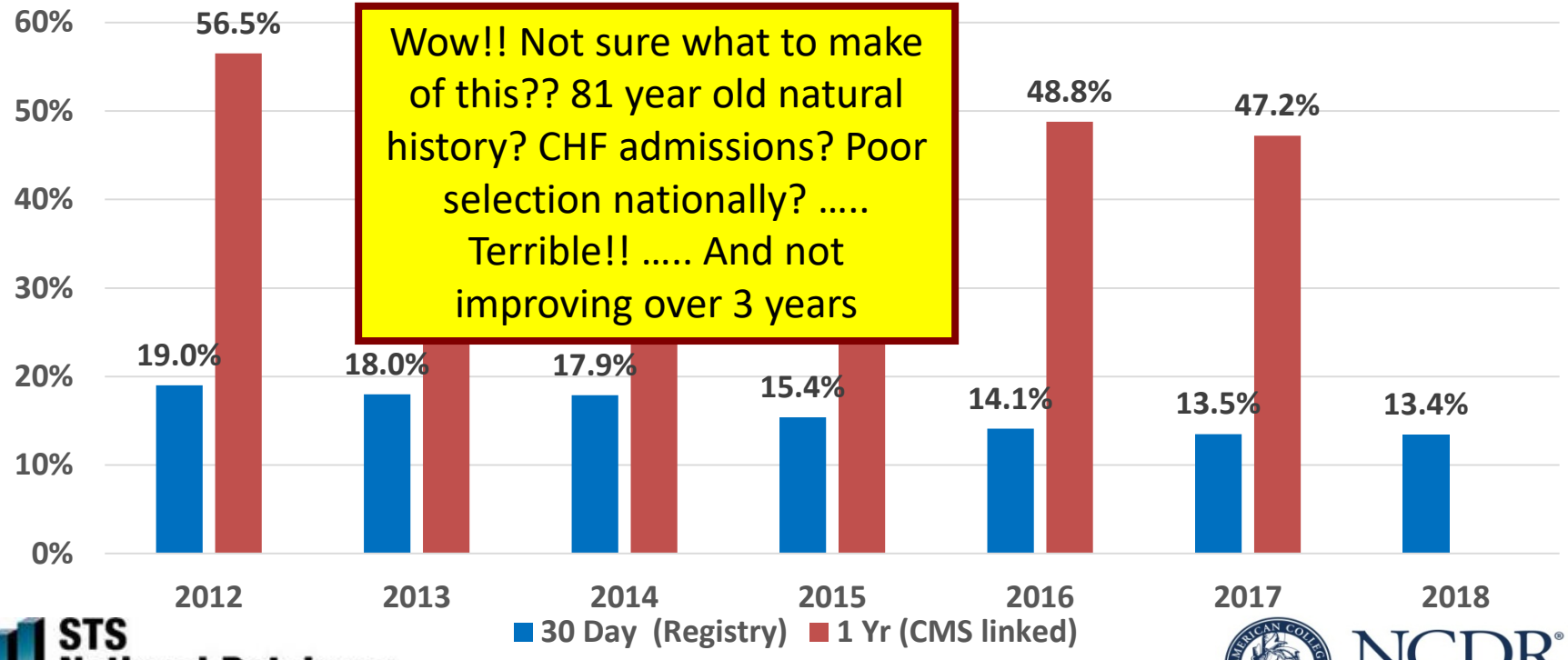
Steadily improving National results.
30 day mortality a bit flat recently

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR -All Cause Readmission

(Readmitted for any reason, valve or not valve related)

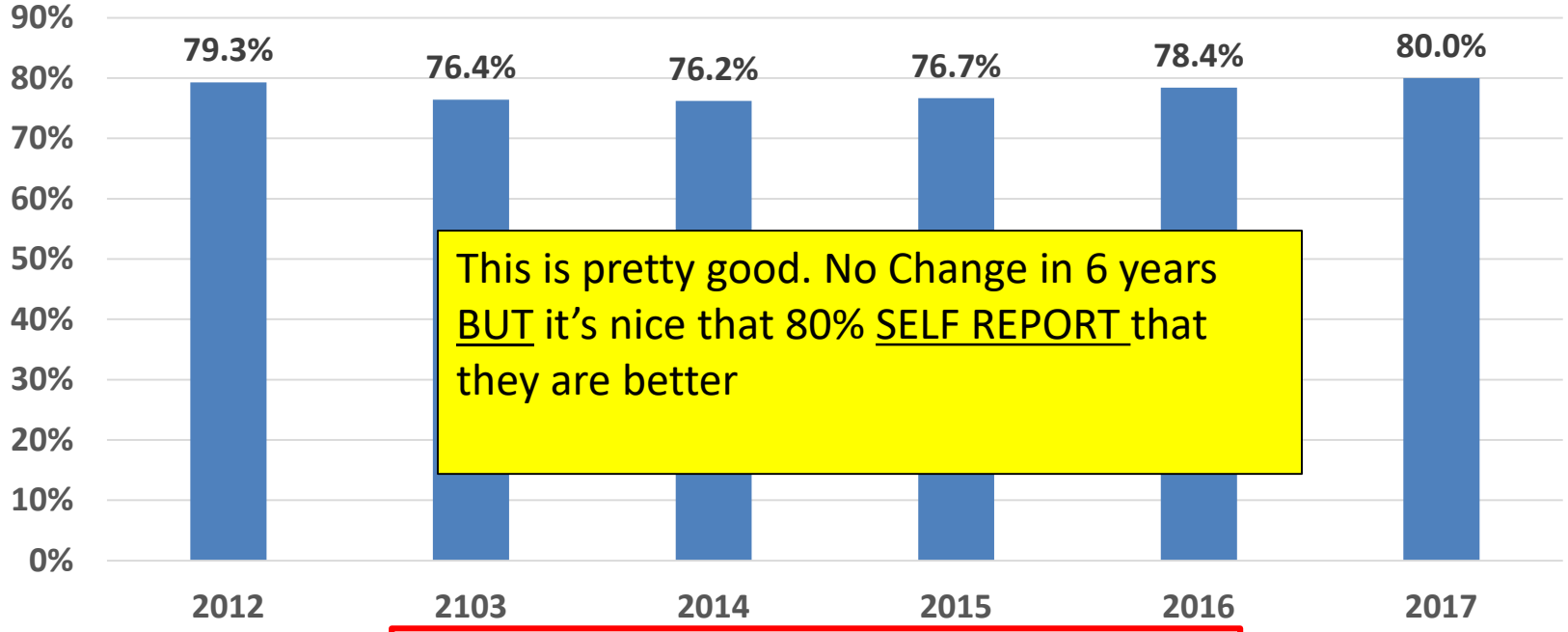


STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Alive and Well At One Year After TAVR

(among 1-year survivors with complete KCCQ*)



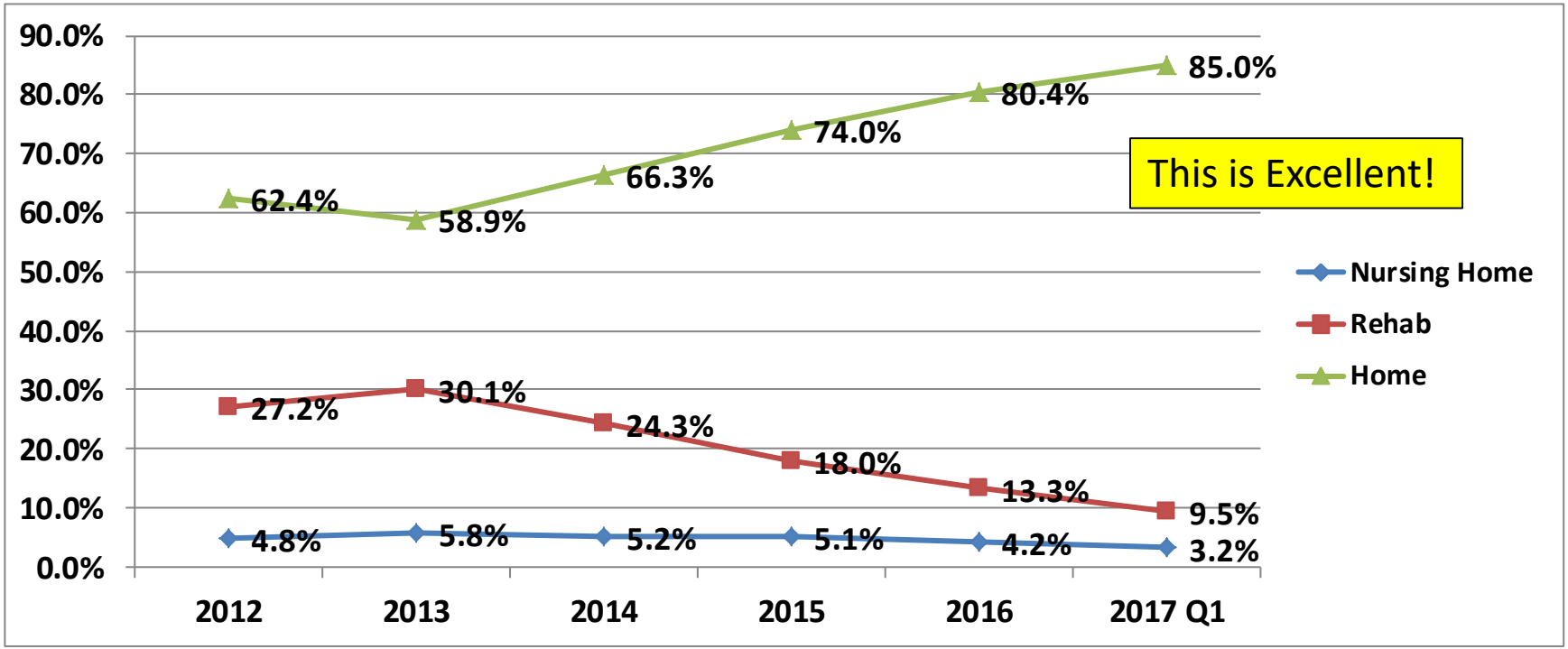
This is pretty good. No Change in 6 years BUT it's nice that 80% SELF REPORT that they are better

1-Yr KCCQ >= 60 and no more than a 10 unit decrease in KCCQ score from baseline to 1 year

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Disposition

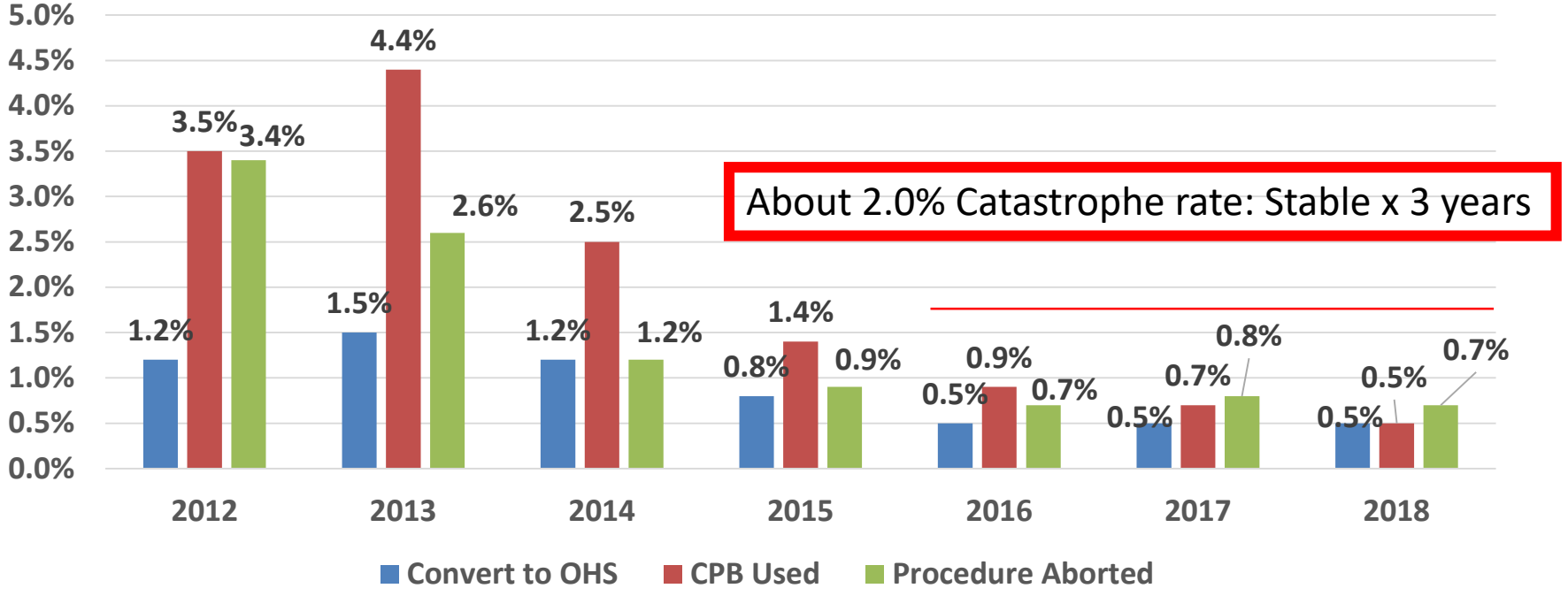


STS National Database™
Using data to drive quality

Source: STS/ACC TVT Registry Database.as of Jul 17,2017

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

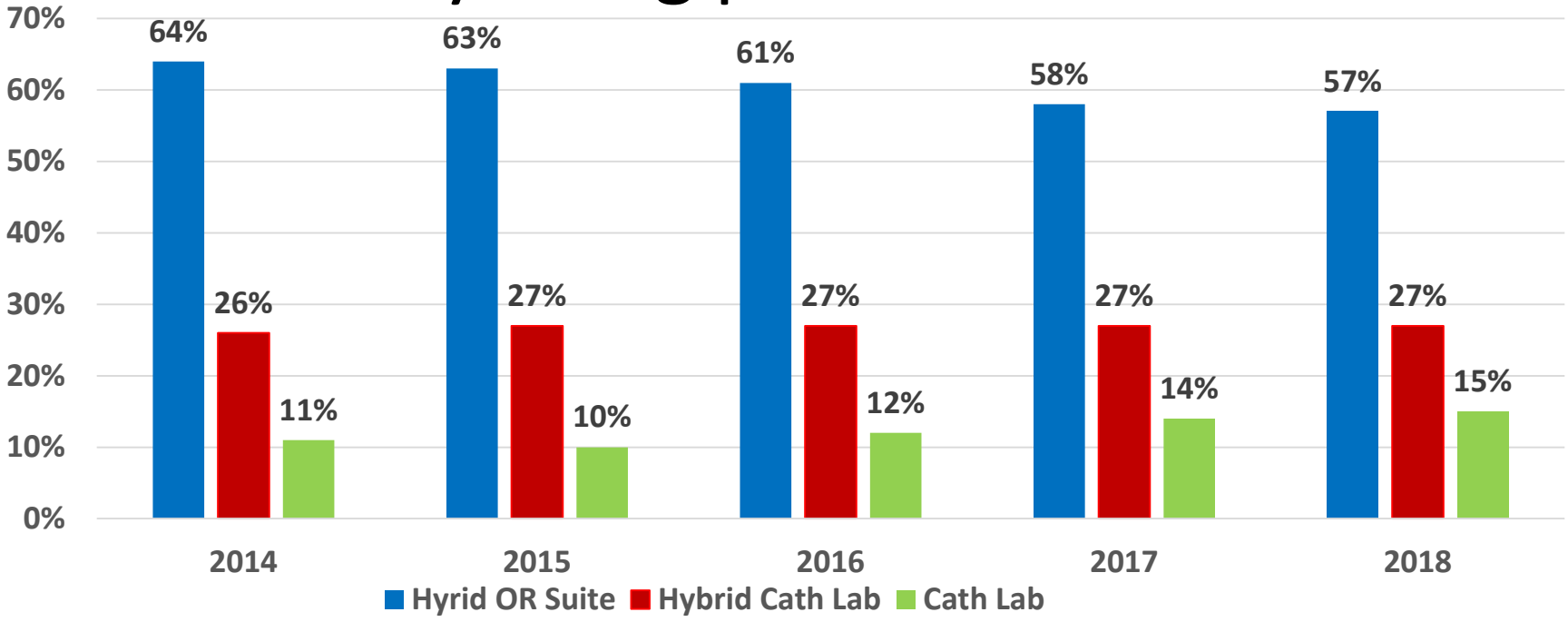
TAVR Disasters:
Three Major Procedure Events



STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Location of TAVI Procedures: where are they being performed?

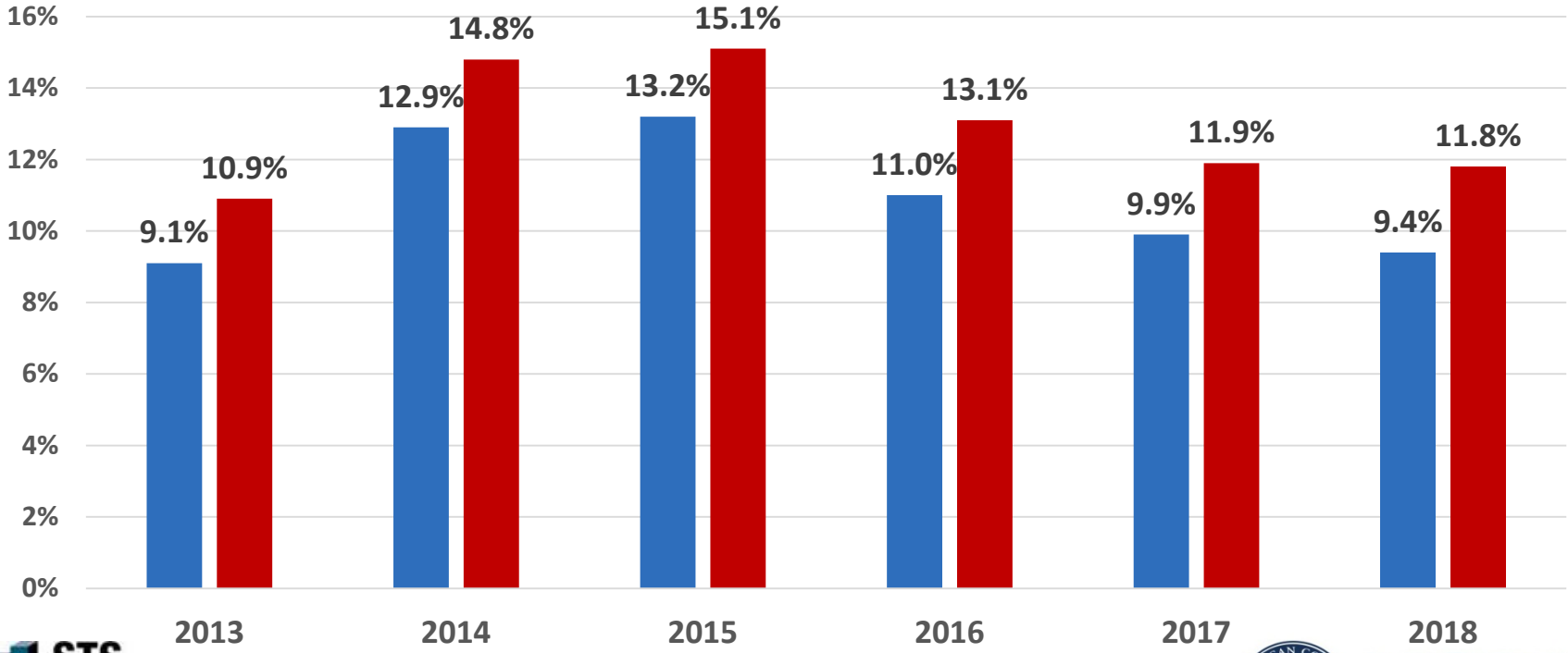


STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR

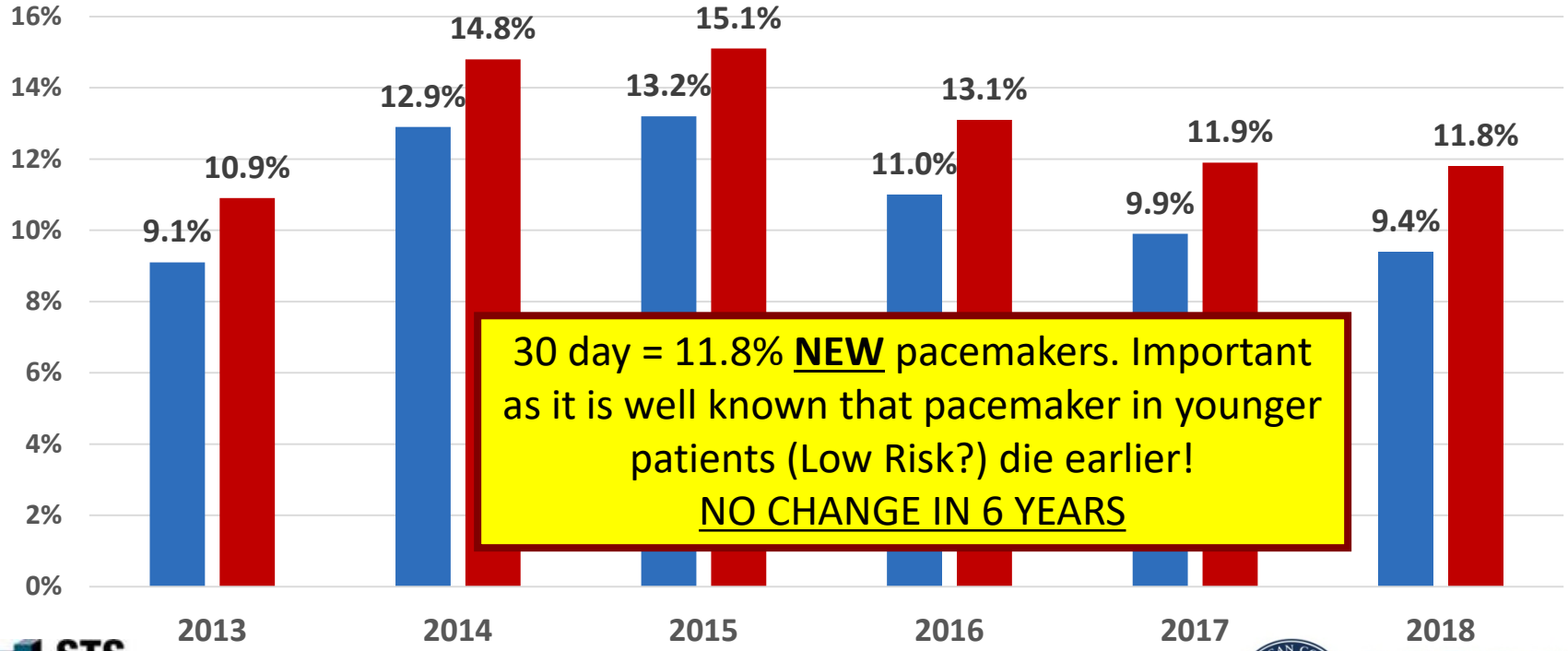
New Pacemaker after TAVR (*Excludes PPM pre TAVR*)



STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

New (excludes PPM pre TAVR)
In Hospital and 30-Day Pacemaker



30 day = 11.8% **NEW** pacemakers. Important as it is well known that pacemaker in younger patients (Low Risk?) die earlier!
NO CHANGE IN 6 YEARS

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Other Clinical Events Intermediate Risk

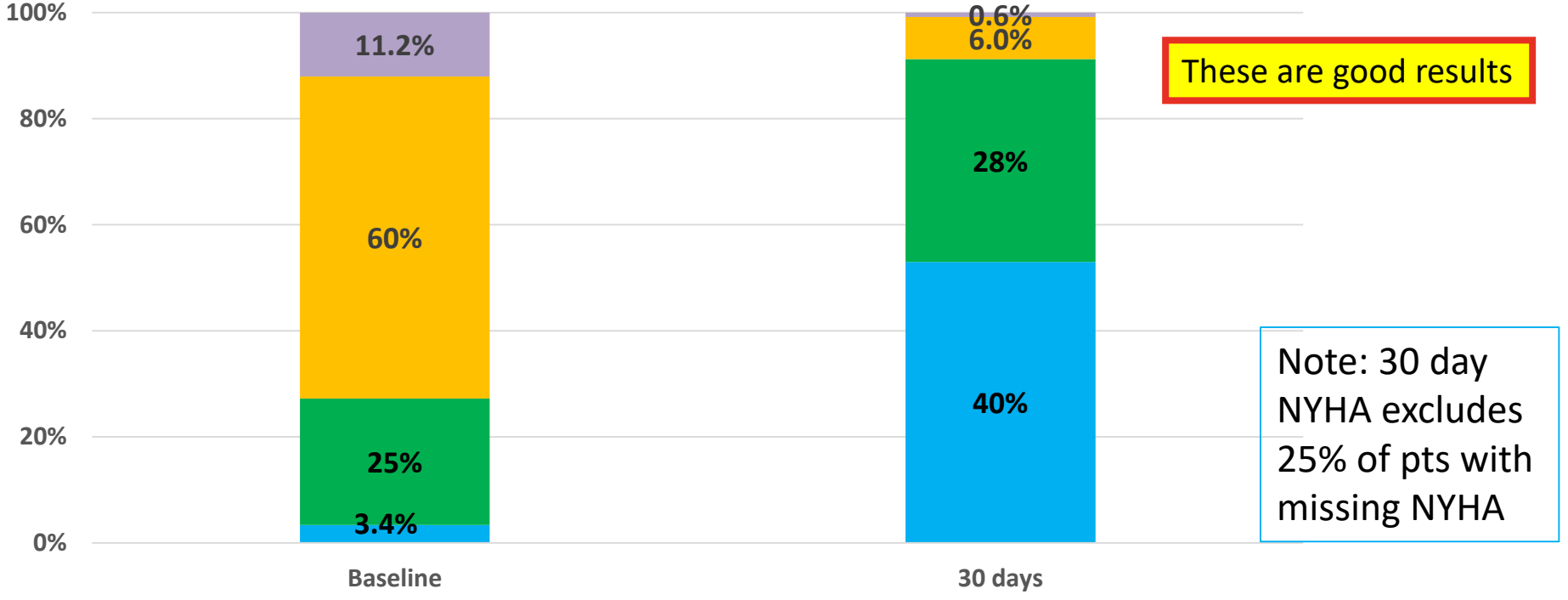
At 30 Days (As Treated Patients)

THE PARTNER II TRIAL

Events (%)	S3HR Overall (n=583)	S3HR TF (n=491)	S3HR TA/TAo (n=92)	S3i Overall (n=1076)	S3i TF (n=951)	S3i TA/TAo (n=125)
Major Vascular Comps.	5.0	5.3	3.3	5.6	5.9	3.2
Bleeding - Life Threatening	6.3	5.5	10.9	5.4	4.4	12.9
Annular Rupture					0.2	0
Myocardial Infarctions					0.3	0
Coronary Obstruction					0.4	0
Acute Kidney Injury					0.3	1.6
New Permanent Pacemaker					10.4	7.2
Aortic Valve Re-intervention	1.0	0.8	2.2	0.7	0.8	0
Endocarditis	0.2	0.2	0	0.1	0.1	0

Corroboration: TVT Data Consistent ….In the S3i TF group, the Partner 2 "BEST GROUP" = 10.4% Pacemakers - 1000 patients

TAVR: 2018 NYHA Data



These are good results

Note: 30 day NYHA excludes 25% of pts with missing NYHA

STS National Database™ Using data to drive quality

NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

National Policy Recommendations:

The Big Question in the U.S. Regarding TAVR: Is There a Significant Volume – Outcome Relationship??

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Post-MEDCAC Meeting:
Analyses on Volume-Outcome Relationship in TAVR

Case Volume and Outcomes After TAVR With Balloon-Expandable Prostheses

Insights From TVT Registry

Mark J. Russo, MD, MS,[a] James M. McCabe, MD,[b] Vinod H. Thourani, MD,[c] Mayra Guerrero, MD,[d] Philippe Genereux, MD,[e] Tom Nguyen, MD,[f] Kimberly N. Hong, MD,[g] Susheel Kodali, MD,[h] Martin B. Leon, MD[h]

J Am Coll Cardiol 2019;73:427–40

STS National Database™
Using data to drive quality

United States Procedure Volume and Outcomes in Transcatheter Aortic Valve Replacement

Sreekanth Vemulapalli, MD,[1,2] John D. Carroll, MD,[3] Michael J. Mack, MD,[4] David Dai, PhD,[2] Zhuokai Li, PhD,[2] Andrzej S. Kosinski, PhD,[2,5] Dharam J. Kumbhani, MD, SM,[6] Carlos Ruiz, MD,[7] Vinod H. Thourani, MD,[8] George Hanzel, MD,[9] Thomas G. Gleason, MD,[10] Howard C Herrmann, MD,[11] Ralph G. Brindis, MD, MPH,[12] Joseph E. Bavaria, MD[13]

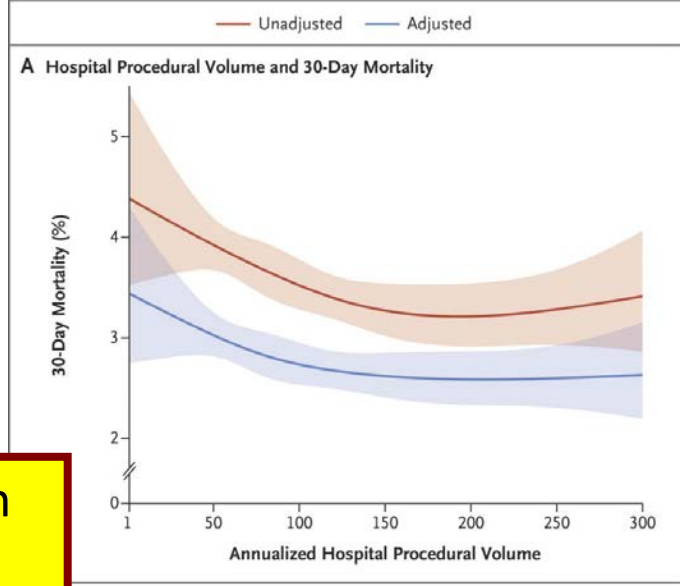
NEJM; 2019

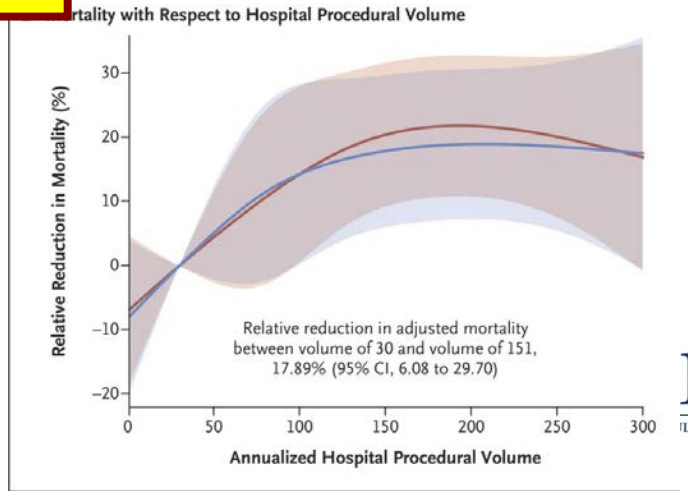
NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

United States Procedure Volume and Outcomes in Transcatheter Aortic Valve Replacement

Sreekanth Vemulapalli, MD,[1,2] John D. Carroll, MD,[3] Michael J. Mack, MD,[4] David Dai, PhD,[2] Zhuokai Li, PhD,[2] Andrzej S. Kosinski, PhD,[2,5] Dharam J. Kumbhani, MD, SM,[6] Carlos Ruiz, MD,[7] Vinod H. Thourani, MD,[8] George Hanzel, MD,[9] Thomas G. Gleason, MD,[10] Howard C Herrmann, MD,[11] Ralph G. Brindis, MD, MPH,[12] Joseph E. Bavaria, MD[13]

Approximately 27% Risk Reduction in high volume vs the lowest volume centers





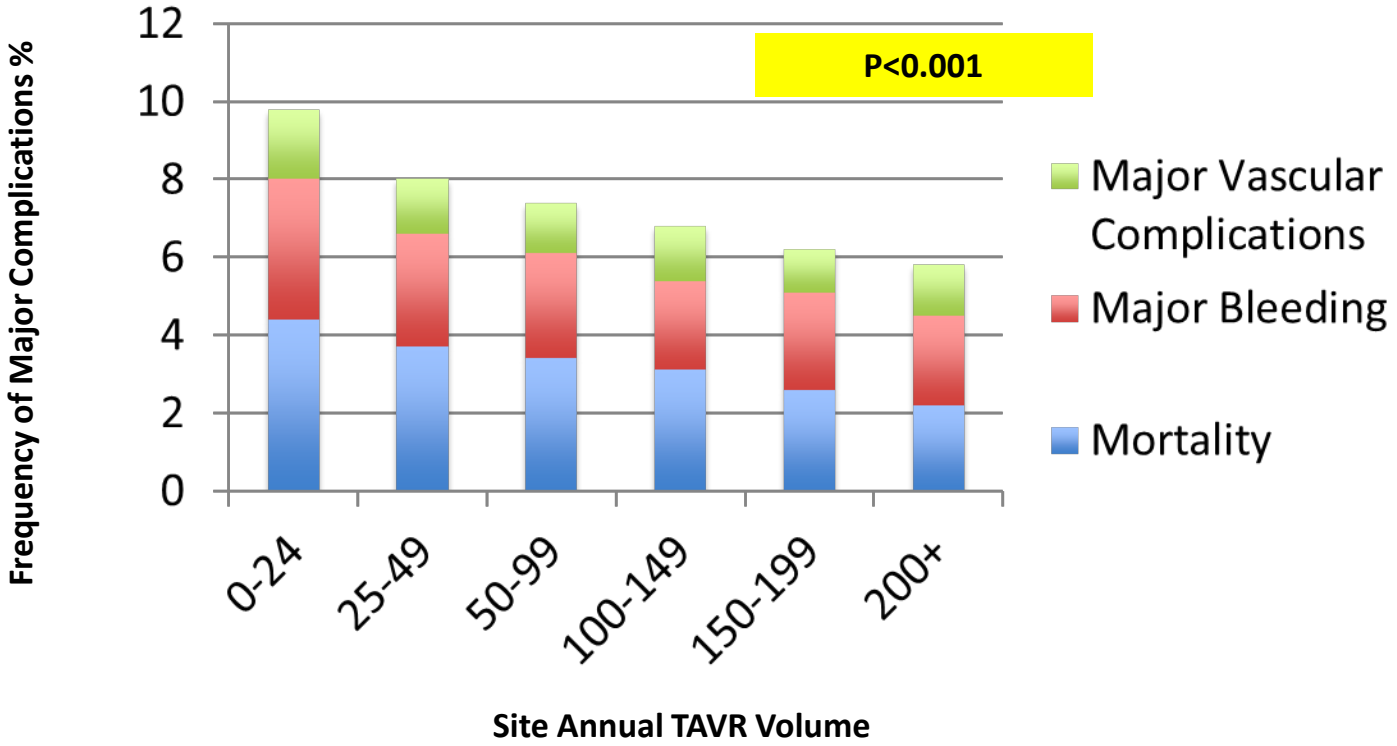
Sensitivity Analysis Excluding 12-Month Start-up Period at Each Hospital

STS National Database™
Using data to drive quality

R®
ULAR DATA REGISTRY

30 Day Composite Major Outcomes Related to Site Annual Volume

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



Is the Data any Good?
Is it Reliable?

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Is the Data any Good?

Is it Reliable?

10% of all sites are AUDITED each year per Steering Committee Resolution!

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

National Audit Program

Evaluates accuracy and reliability

- Assesses proper and complete reporting of cases
- Voluntary

2018 Results (Draft Results)

- ***Base and Follow Over Accuracy= 91.5%***
- ***Overall Follow Up Accuracy = 90.7%***
- ***30 Day Follow Up Accuracy = 92.4%***

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR Module Data Completeness

KCCQ and Follow-Up

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

DQR Submission Status

A “Red” status indicates the submission (one quarter/timeframe) is not included in the benchmark statistics. Data is not displayed in the quarterly column.

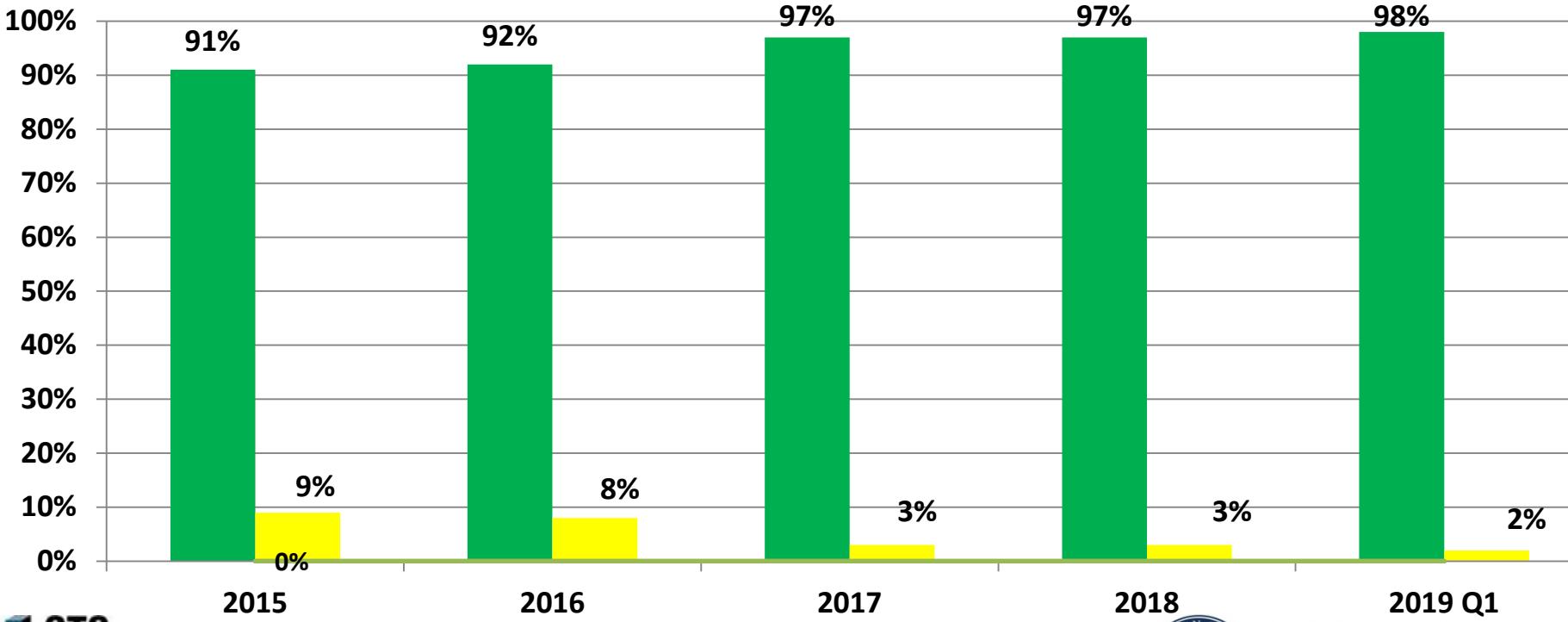
A “Yellow” status indicates the submission (one quarter/timeframe) is not included in the benchmark statistics. Data is displayed in the quarterly column, but is not included in the “My Hospital R4Q” summary. The data has not passed the overall completeness assessment checks.

A “Green” status indicates the submission (one quarter/timeframe) is included in the benchmark statistics. ***The data has successfully passed all data assessment and completeness checks.***

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

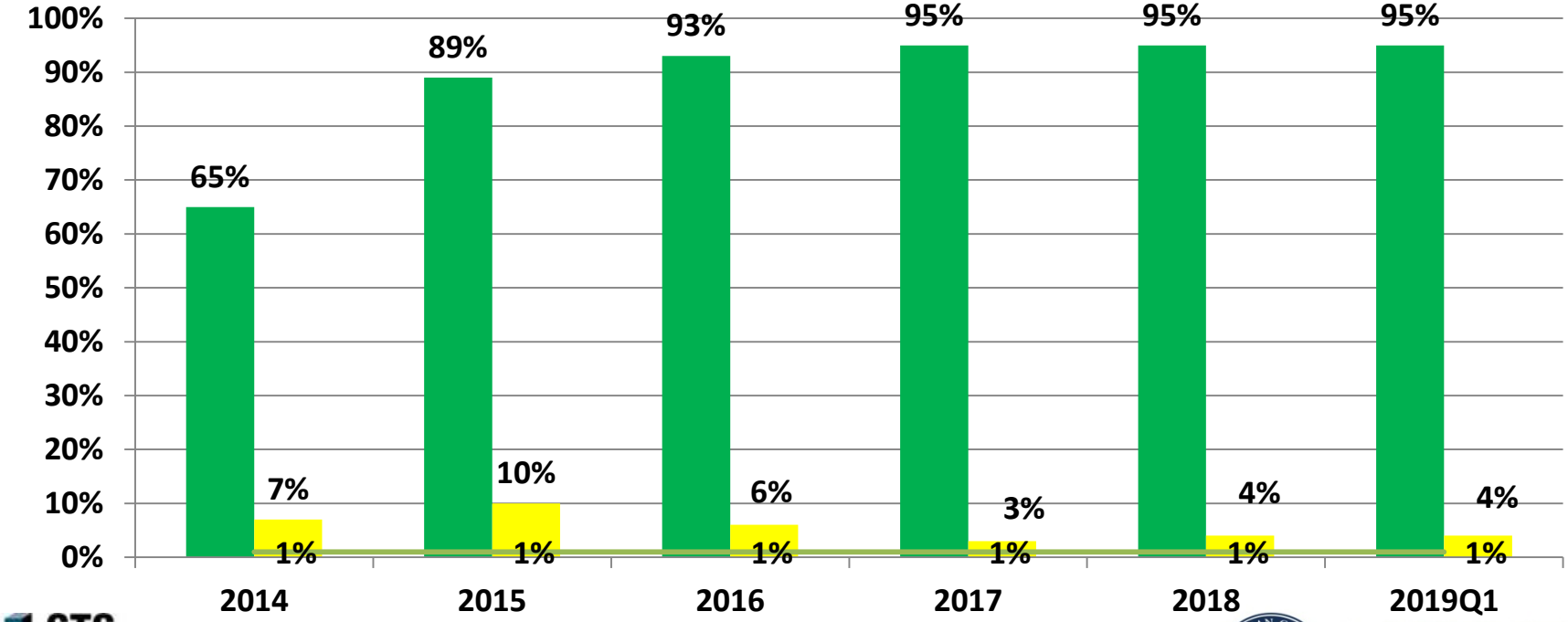
TVT Registry Base Submissions
Green Yellow Red Status
2014-2018



STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT Registry Follow Up Submissions
Green Yellow Red Status
2014-2018

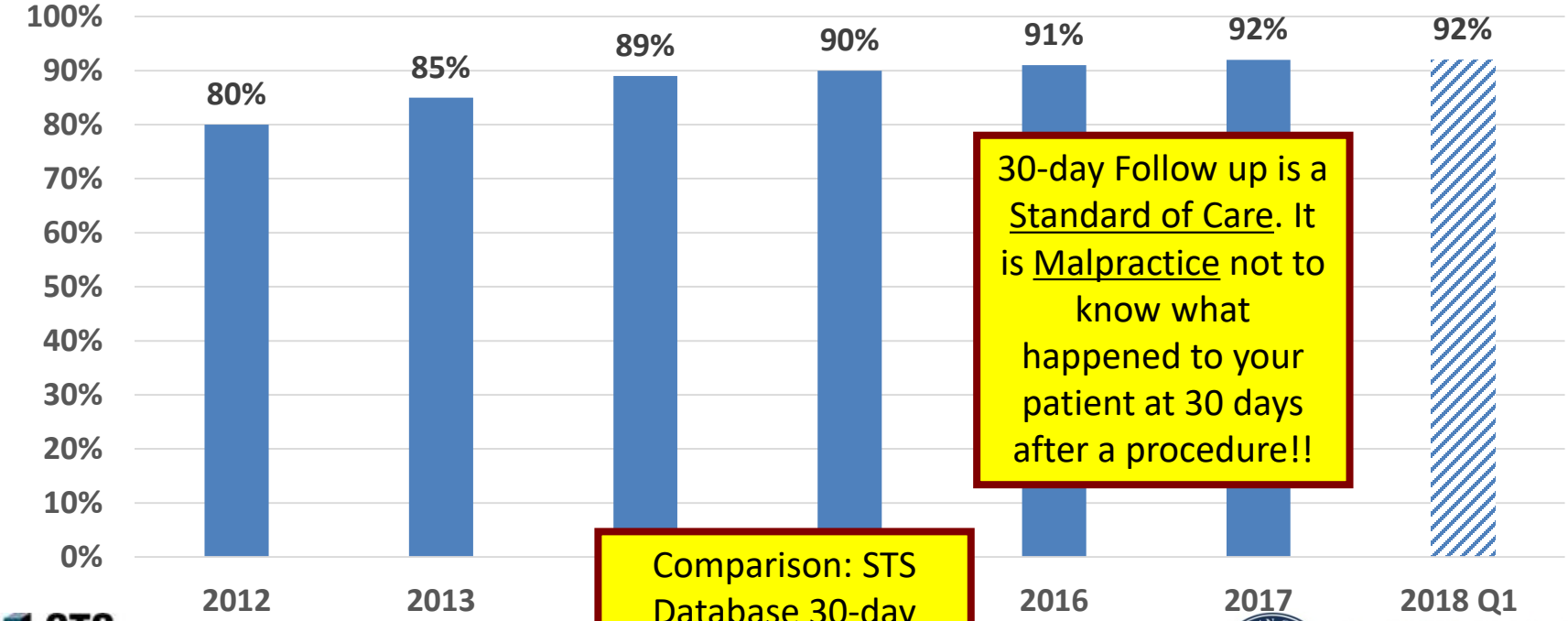


STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TAVR - 30 Day Follow Up Completed

Some follow up assessment 21-75 days after TAVR



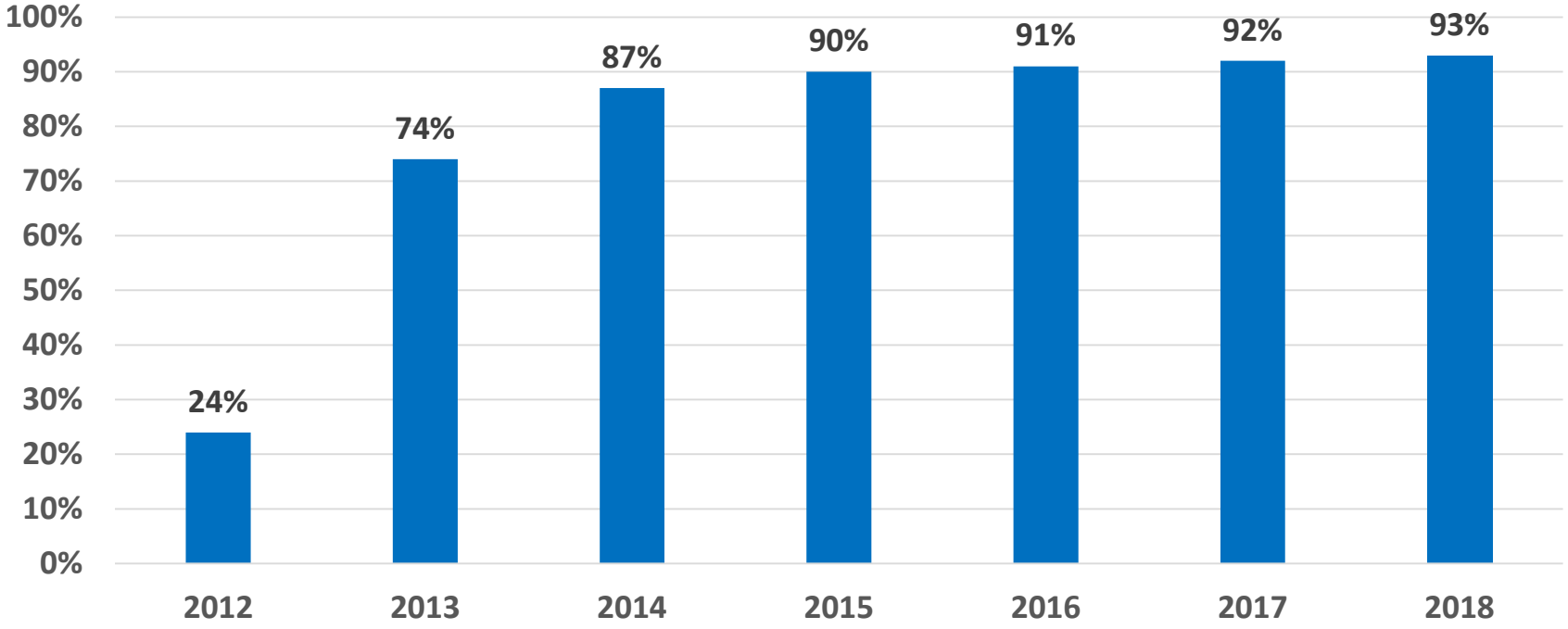
30-day Follow up is a Standard of Care. It is Malpractice not to know what happened to your patient at 30 days after a procedure!!

Comparison: STS Database 30-day mortality >98%

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

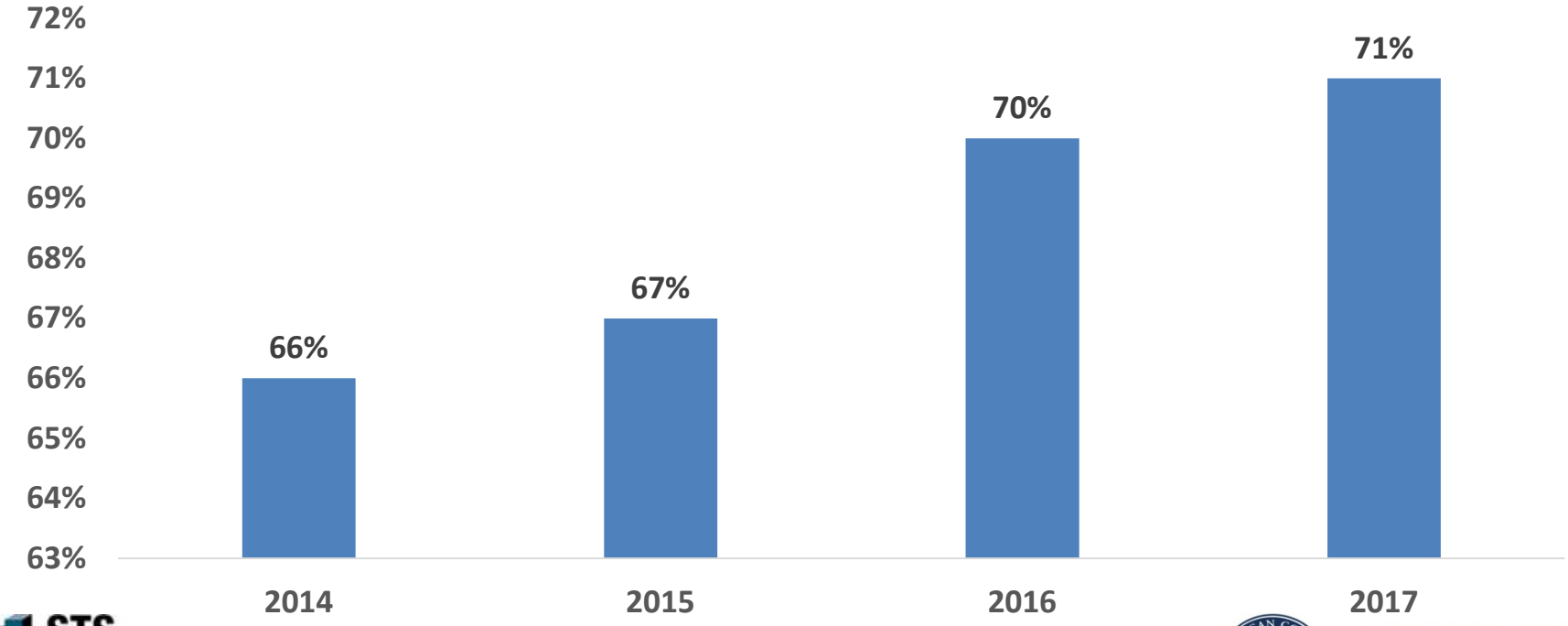
TAVR
Baseline KCCQ Completed



STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Baseline and One Year KCCQ Complete



Among One Year Survivors

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Data Completeness Becomes Essential if Institutional and Operator Volume Requirements are Replaced with Quality Metrics

Will Updated TAVR NCD Address This Problem of Sites Not Submitting Complete and Accurate Data?

STS/ACC TVT Registry Mortality and Morbidity Composite Risk Model for TAVR

Nimesh D. Desai MD PhD

On behalf of the TVT Risk Modeling Subcommittee

NCDR | STS National Database *Using data to drive quality*

STS/ACC TVT Registry™

TVT Risk Model: Global Rank Methodology

Death	• In-Hospital or 30-day mortality
Stroke	• In-Hospital or 30-day stroke
Bleed	• In-hospital or 30-day VARC major or longterm/disabling bleed
AKI	• In-hospital sig 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

STS/ACC TVT Registry "New Stuff"

What new ideas, devices, knowledge, and research are "informing" the TVT??

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Sapien XT™

Sapien 3™

CoreValve™

CoreValve Evolut™

Portico™

Centera

Direct Flow™

Lotus™

Accurate™

Jenavalve™

Engager™

Collecting Data on New Techniques is Becoming *Very Important* for the TVT Registry

1. Cerebral protection using one FDA approved device: Sentinel
   - to address the not "insignificant" stroke rates despite new TAVR technology and lower risk patients
2. Fracturing of sewing rings of surgically implanted prosthetic valves during V-in-V treatment for degenerated bioprosthetic valves
   - To address the problem of small surgically implanted valves/ and prosthetic-patient mismatch
3. Catheter-based electrosurgery techniques to lacerate valve leaflets and reduce risks of obstruction from TAVR and TMVR implantation
   - BASILICA: Technique applied to aortic leaflets of native and bioprosthetic valves to prevent coronary obstruction
   - LAMPOON: technique applied to anterior leaflet of mitral valve to prevent LVOT obstruction
4. Vascular Access using the transcaval (IVC to aorta) technique for TAVR

TVT Registry Updates

- Embolic protection and bioprosthetic valve fracture is captured in the device table in **v2** (current version)

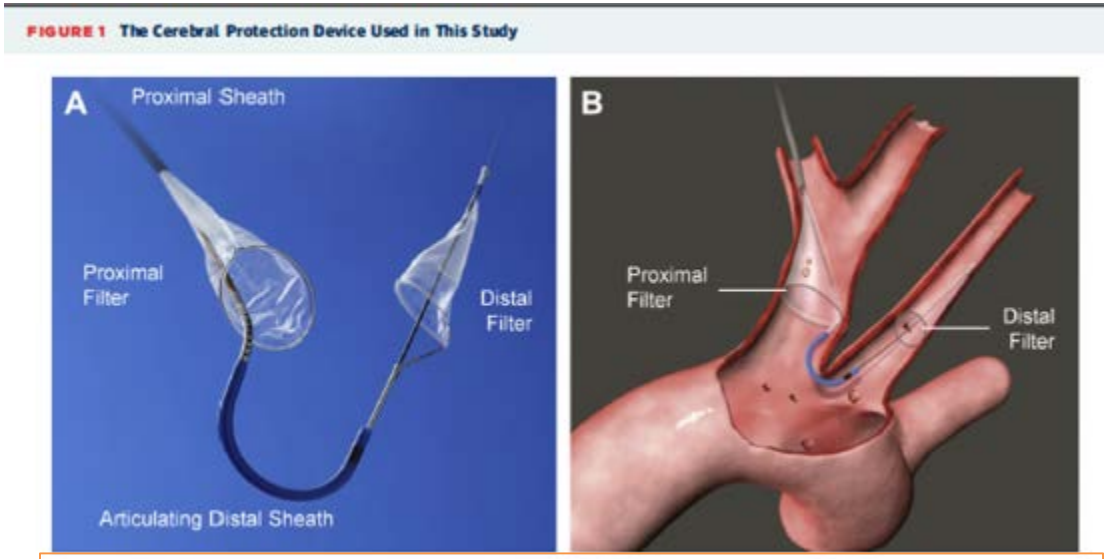
Device 1 Used[6225]:	**(Refer to Master Device List)**
Device 2 Used[6225]:	*Note: Code all valves, embolic protection, valve fracture and support devices*

STS National Database
Using data to drive quality

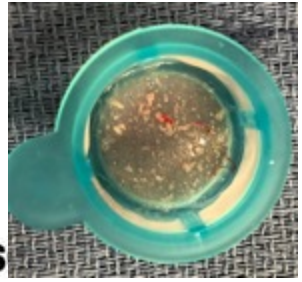
NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Cerebral Protection

- Stroke is a devastating complication of interventional procedures and surgery.
- The development of “cerebral protection” devices to capture the embolic debris released during these treatments is potentially a major advancement, but with an evidence-base that is “evolving”.
- The FDA approval of the first such device, Sentinel, has provided a unique opportunity for TVT Registry to gather clinical use.



Frerker et al. J Am Coll Cardiol Intv 2016;9:171–9.



STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Cerebral Protection and TVT Registry

- Data element added in January 2018 (Version 2).
- 3867 cases of TAVR using Sentinel performed at 82 sites have been entered into the TVT Registry.

Version 3 update will have the following data element

Embolic Protection Deployed[xxxx]: O No O Yes →**If** Yes, **EP Device**[xxxx]: _____ see device list

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Bioprosthetic Valve Fracture During Valve-in-valve TAVR: Bench to Bedside

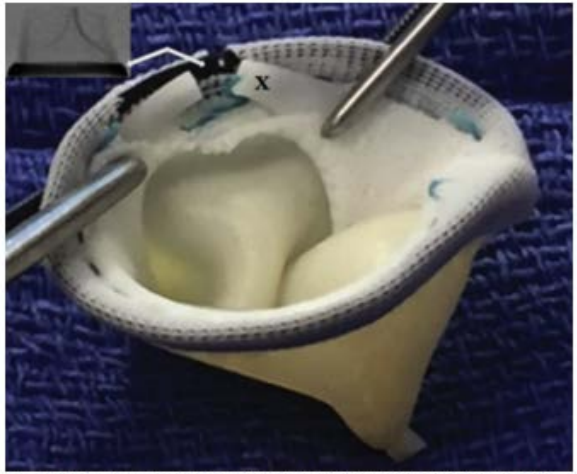
John T Saxon,[1,2] Keith B Allen,[1,2] David J Cohen[1,2] and Adnan K Chhatriwalla[1,2]

1. Saint Luke's Mid America Heart Institute, Kansas City, MO, USA; 2. University of Missouri – Kansas City, Kansas City, MO, USA

Figure 1: Technique of High-pressure Balloon Inflation to Perform Bioprosthetic Valve Fracture

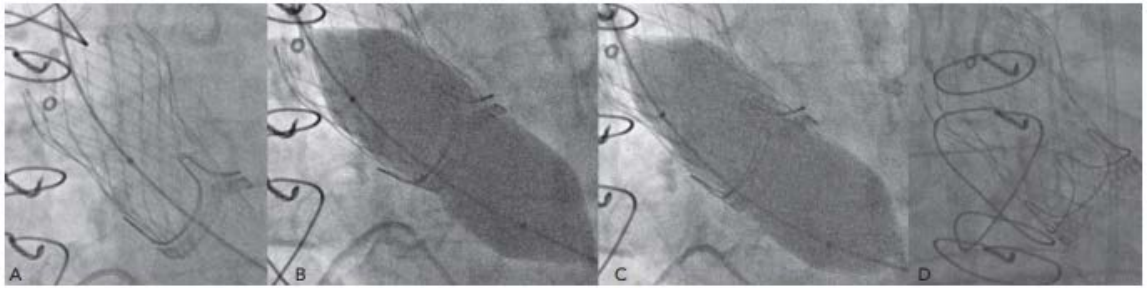
(1) A high pressure stopcock connects the valvuloplasty balloon to a syringe of dilute contrast and an indeflator. (2) The syringe is used to inflate the balloon manually. (3) The stopcock is turned so that the syringe is off and the indeflator is on. (4) The indeflator is dialed to the desired pressure, until the bioprosthetic valve fractures or the balloon ruptures.

Figure 2: Fractured 21 mm Mitroflow Bioprosthetic Valve



The Dacron sewing cuff has been partially removed to display the single separation of the polymer ring. x indicates the surgical ring which has been fractured.

Figure 3: A: Baseline Appearance of 23 mm Magna BPV after Deployment of 26 mm Medtronic Evolut R THV. B: Initial Balloon Inflation During BVF. C: Appearance of BPV and Balloon after BPV Ring Fracture. Note the Visible Release of the Balloon Waist and Expansion of BPV Compared to (B). D: Final Appearance after VIV TAVR and BVF



BVF = bioprosthetic valve fracture; BVP = bioprosthetic valve fracture; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve; VIV = valve-in-valve.

Fracturing of sewing rings of surgically implanted prosthetic valves during V-in-V treatment for degenerated bioprosthetic valves

Under-Reporting?
Efforts being made to educate site data coordinators to assess whether or not fracturing is being done.

Since 1/1/2018	num	den	prop
TAVR Procedures		54,395	n/a
Valve-In-Valve TAVR	3,766	54,395	6.9%
Among VIV TAVR, Procedures Using High Pressure Balloon for Fracturing, Pre- or Post-	52	3,766	1.4%

Data Source: TVT Registry

Inclusion:
- All Hospitals
- Submission Benchmark Code 'G' or 'Y'
- TAVR procedures

Exclusion:
- Procedures before January 1, 2018, which represents effective date of the devices being investigated

Analytic Notes:
- Valve-in-Valve TAVR qualified as [6065] ValveInValve = Yes
- Devices being investigated:

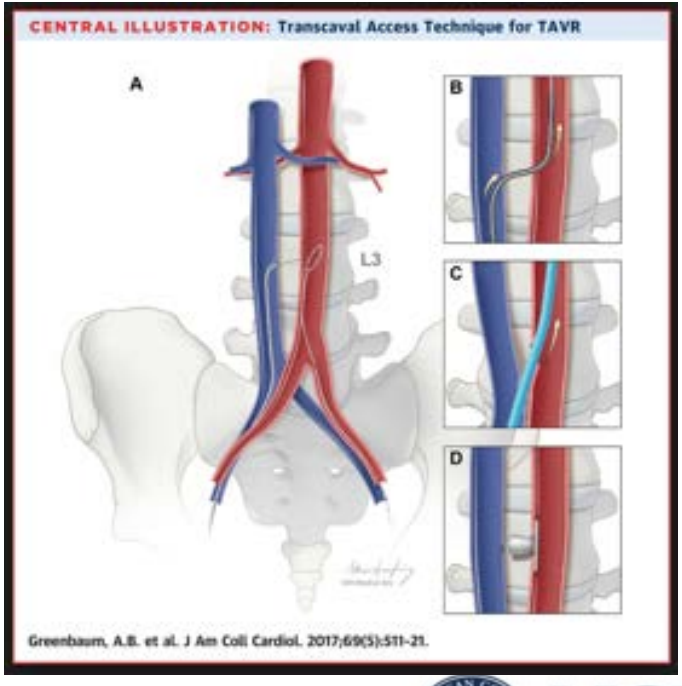
ValveDeviceID	DeviceModelName	EffectiveDate
751	High pressure balloon for bioprosthetic valve fracture (post-TAVR)	2018-01-01
750	High pressure balloon for bioprosthetic valve fracture (pre-TAVR)	2018-01-01

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

“Transcaval Access for Transcatheter Aortic Valve Replacement in People With No Good Options for Aortic Access”

- ClinicalTrials.gov Identifier: NCT02280824
- Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
- Principal Investigator: Robert J Lederman, M.D. at NHLBI



STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT Registry v3 updates

Concomitant Procedures Performed[6620]: O No O Yes

→**If** Yes, **Procedure Type(s)**[XXX]: (select the best option(s)): _____, _____, _____

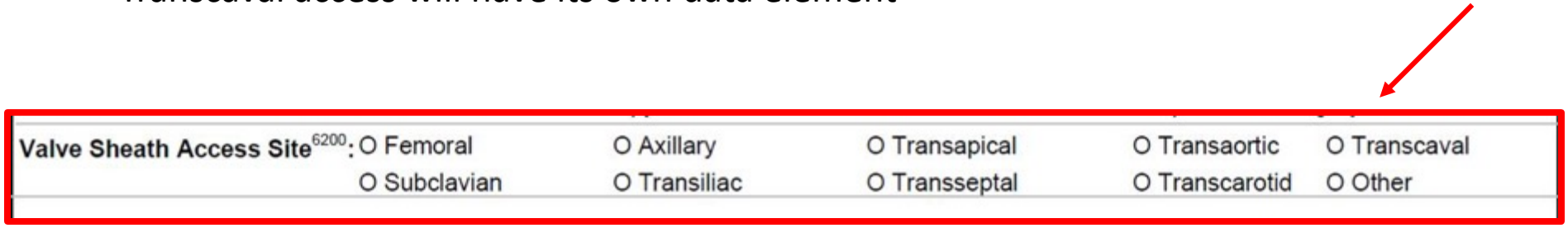
- PCI
- LAAO
- Permanent Pacer
- Mitral Valvuloplasty
- Vascular Stent
- BASILICA
- LAMPOON
- Alcohol Septal Ablation

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT Registry v3 updates

- Transcaval access will have its own data element



Valve Sheath Access Site[6200]:	O Femoral	O Axillary	O Transapical	O Transaortic	O Transcaval
	O Subclavian	O Transiliac	O Transseptal	O Transcarotid	O Other

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT Registry v3 updates

- Bioprosthetic valve fracture

Valve-in-Valve Procedure[6065]**:** O No (degenerative native valve) O Yes (degenerative bioprosthetic valve)

→**If** Yes, **BVF Attempted with High Pressure Balloon Dilation:** O No O Yes

→**If** Yes, **Timing of BVF:** ☐ Pre-implant ☐ Post- implant →**If** Yes, **Valve Observed To Be Fractured:** O No O Yes

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

STS/ACC TVT Registry Research

Over 30 Manuscripts Published and 30 in preparation

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 9, NO. 21, 2016

PUBLISHED BY ELSEVIER
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2016.07.026

FOCUS ON TAVR

Incidence, Predictors, and Outcomes of Permanent Pacemaker Implantation Following Transcatheter Aortic Valve Replacement

Analysis From the U.S. Society of Thoracic S… American College of Cardiolog… T Registr…

Opeyemi O. Fadahunsi, MBBS, MPH,[a] Abiola Olowoy…ye, … Anene…

Early pacer implantation is a common complication following TAVR.
It is associated with a higher mortality and a composite of mortality or heart failure admission at one year.

Incidence, Predictors, and Outcomes of Prosthesis-Patient Mismatch in 62,125 TAVR Patients

An STS/ACC TVT Registry Report

Presented 2018 TCT showing worse outcomes with TAVR PPM. Severe PPM in 12% of all TAVR

Howard C. Herrmann, MD
University of Pennsylvania
Philadelphia

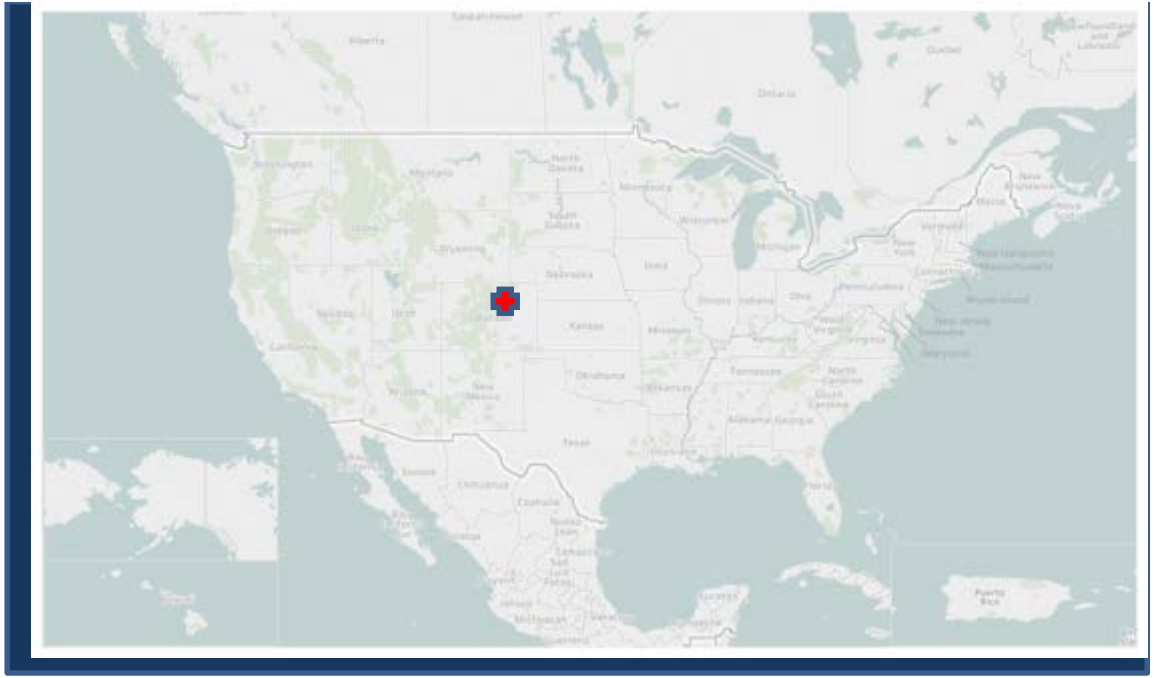
STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

The Process of Updating TVT Registry Sites of These Changes in Data Collection

- Identify changes on Data Collection Form
- Announce on TVT website
- Review at every monthly webinar.
- Place a tag line on the signature for all questions coming into TVT
- Remind valve coordinators at industry meetings
- Reinforce at National NCDR and STS AQO Meetings

TAVR – C
(What does C stand for?)
As of March 1, 2019 There is Only One TAVR – C Site in US

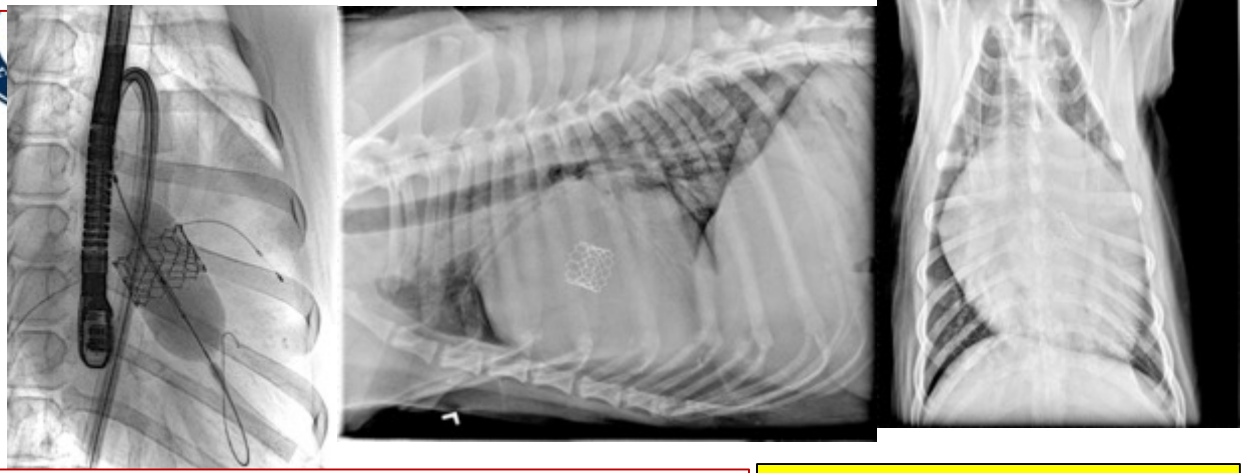


STS National Database™
Using data to drive quality

AMERICAN COLLEGE of CARDIOLOGY NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

Dog recovering after undergoing first-ever surgery at Colorado State

POSTED 10:25 PM, FEBRUARY 28, 2019, BY WEB STAFF



First Canine TAVR Performed in the World at Colorado State Ft. Collins CO with UC Health Interventional Cardiologists Drs. Justin Stroke and Brad Oldemeyer assisting Dr. Brian Scansen, a Veterinarian Interventional Cardiologist

Data not entered into TVT Registry because case lacked KCCQ results

STS National Database™
Using data to drive quality

"**Science** tells us what we can do;

Guidelines what we should do; &

Registries what we are actually doing."

Lukas Kappenberger MD
Heart Rhythm Society Policy Conference
Washing ton DC 2005

STS National Database™
Using data to drive quality

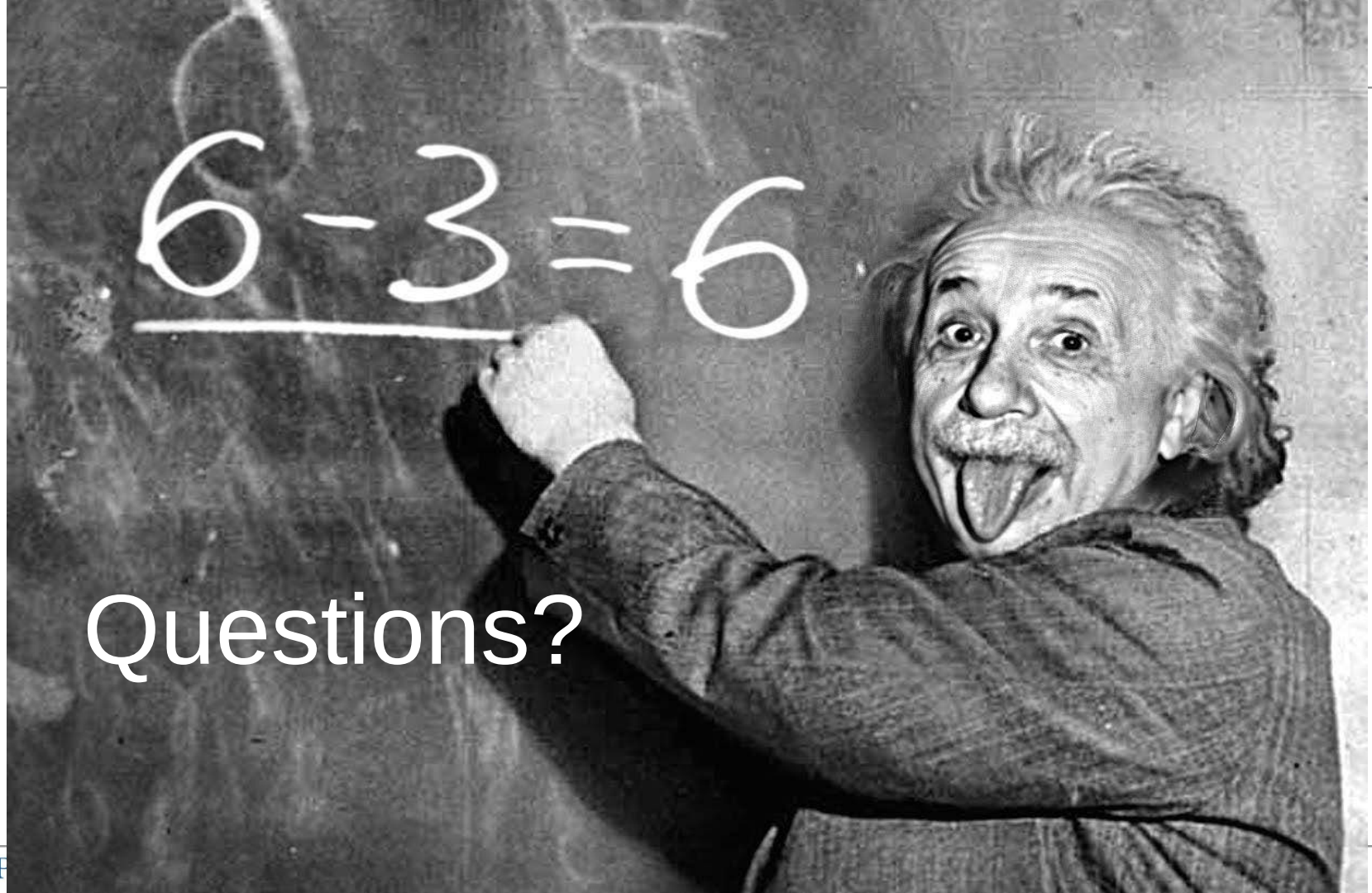
NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Conclusions

1. The National STS/ACC TVT Registry is the largest source of TAVR (and TMV repair) information in the world. … (FDA = “A National Treasure”)
2. The data from the TVT is used by multiple Stakeholders throughout the country
3. The TVT Registry continues to inform the world of “Real World” TAVR outcomes, not just trial data.
    1. Getting better in some areas
    2. Static in other areas
4. The TVT is now using the data to develop TAVR and TMVR risk models and Composite Outcome measures. These will be the basis for CMS suggested Public Reporting of Outcomes by institution and transparency.
5. The STS/ACC TVT is REALLY Big Data…. Mandated data entry by Law in the U.S. (100% participation)

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY


6-3=6
Questions?

Mitral Repair Module of TVT Registry

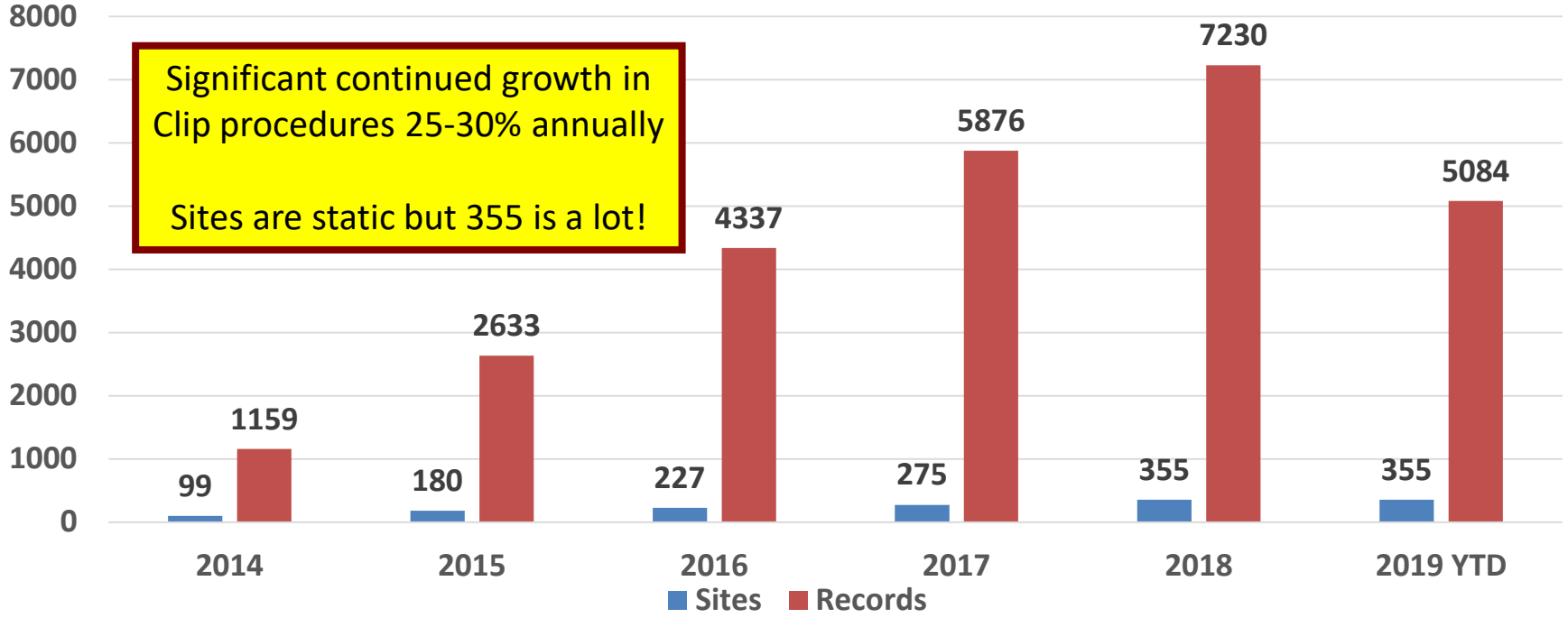
MitraClip Currently Only Technology

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

TVT National Volumes Data: Snapshot of U.S. Leaflet Clip Practice Patterns

Leaflet Clip
Sites and Records Submitted



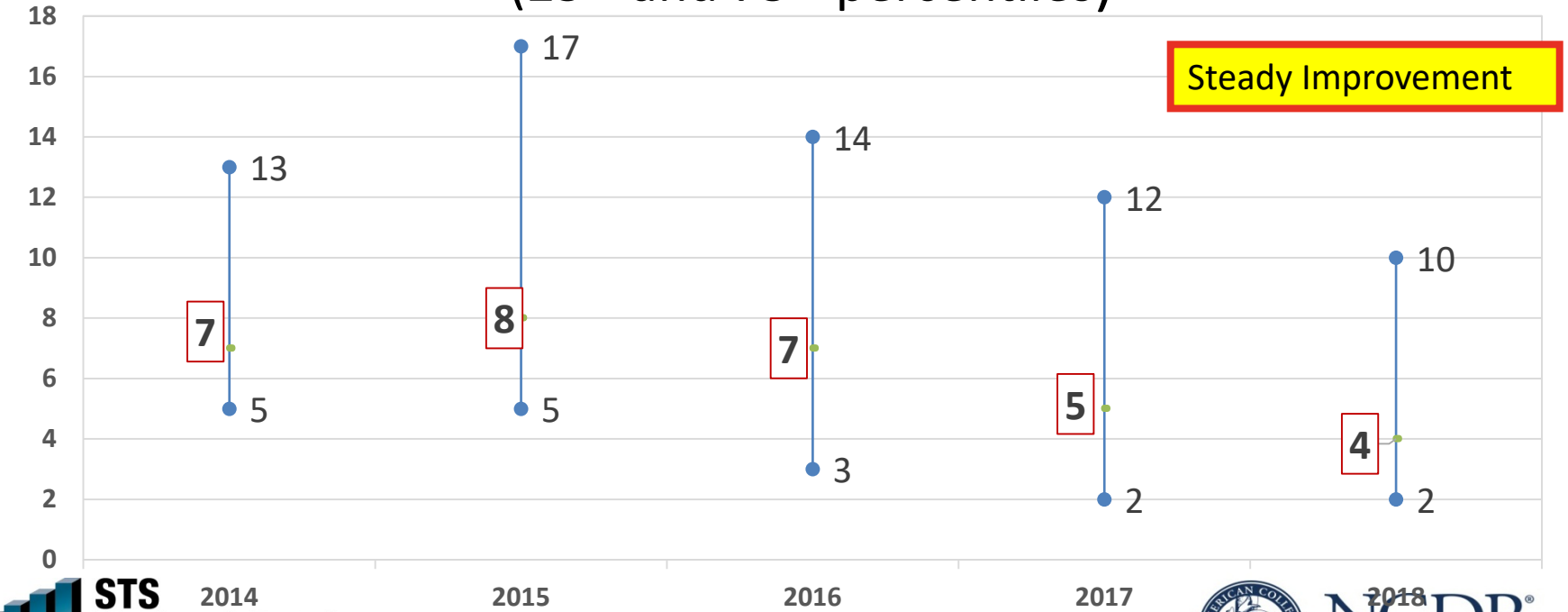
STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip

Median LOS in Days

(25th and 75th percentiles)



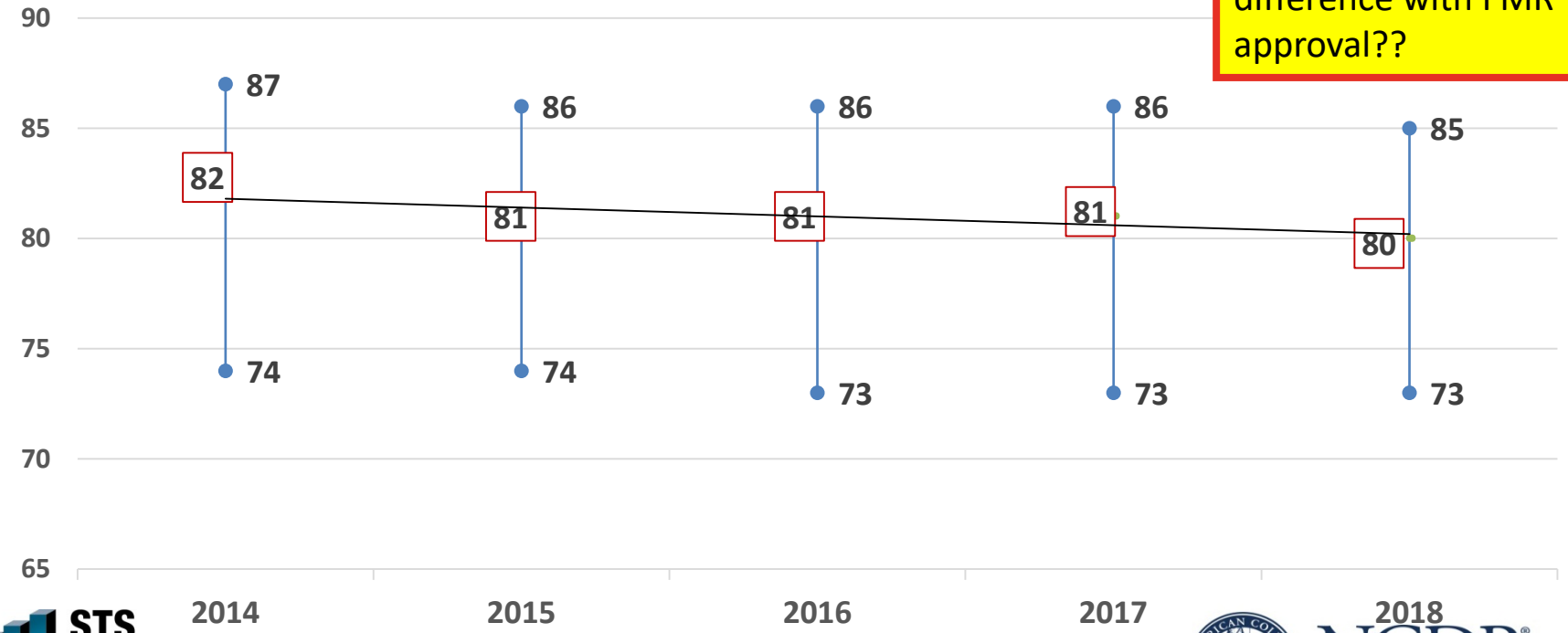
STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip Age

(25th and 75th percentiles)

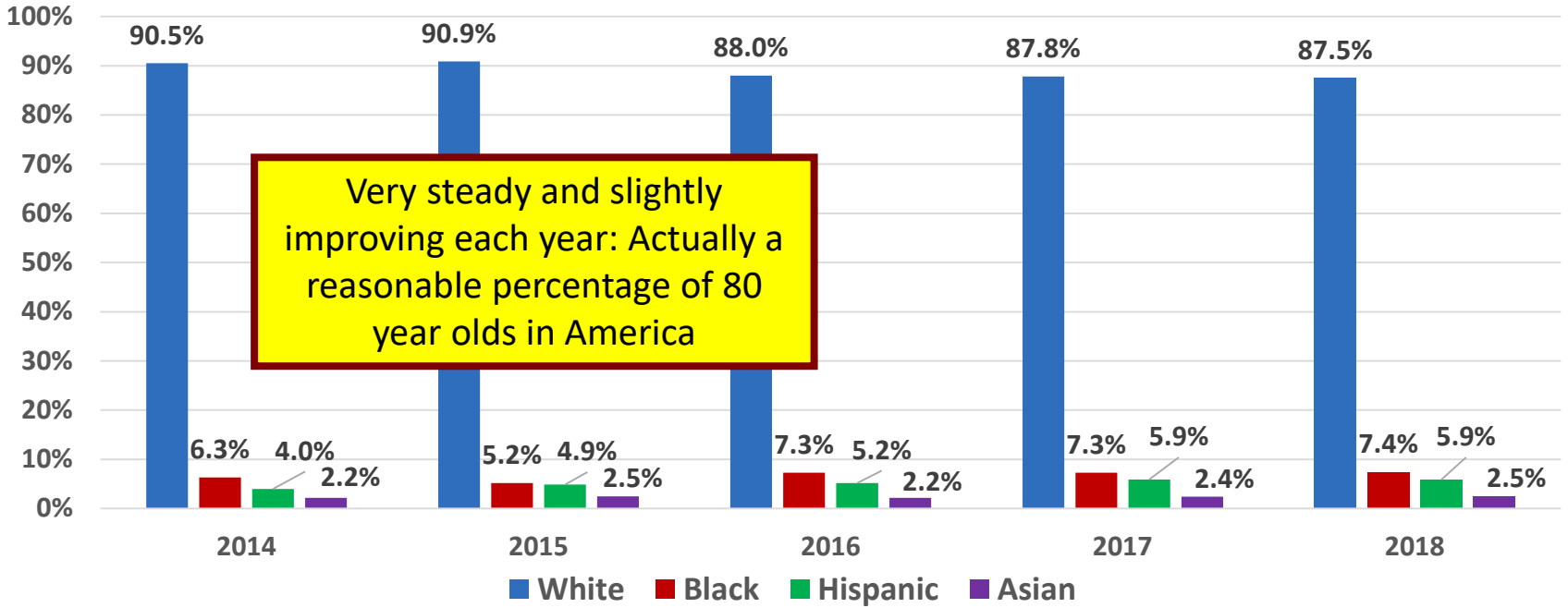
Elderly, Don't anticipate much difference with FMR approval??



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

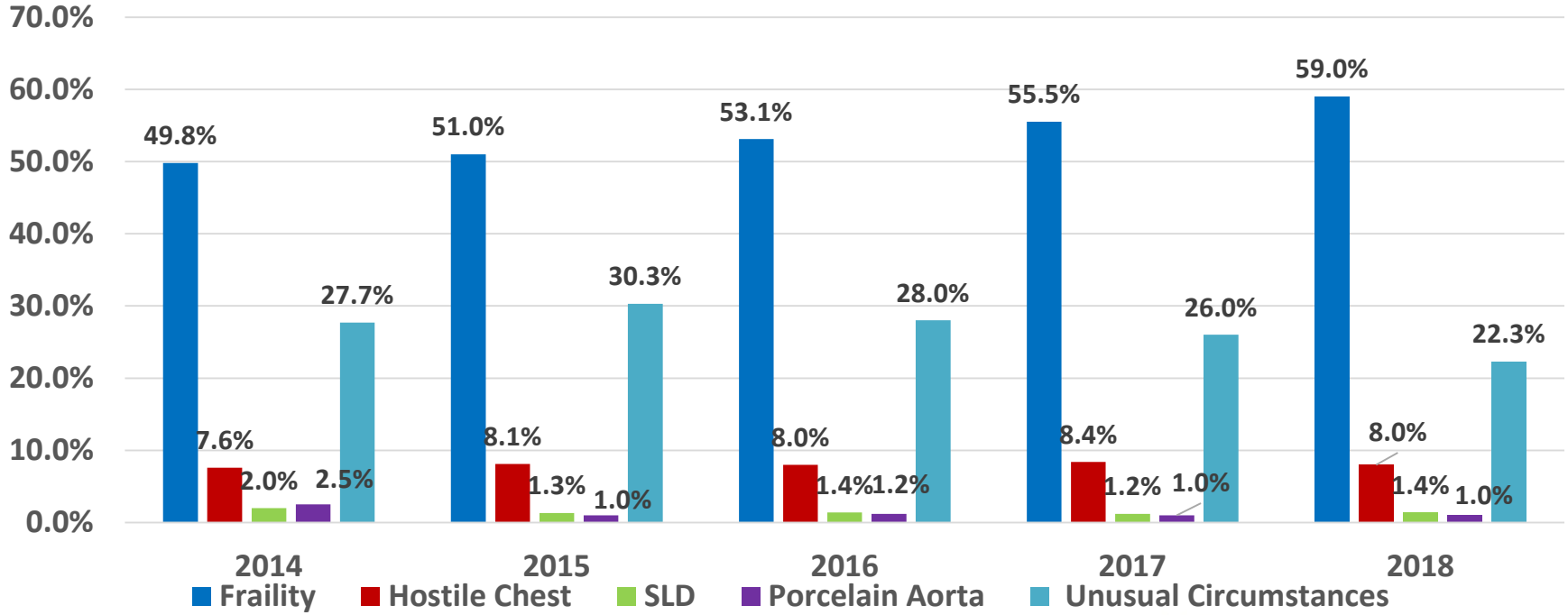
Leaflet Clip Demographics



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

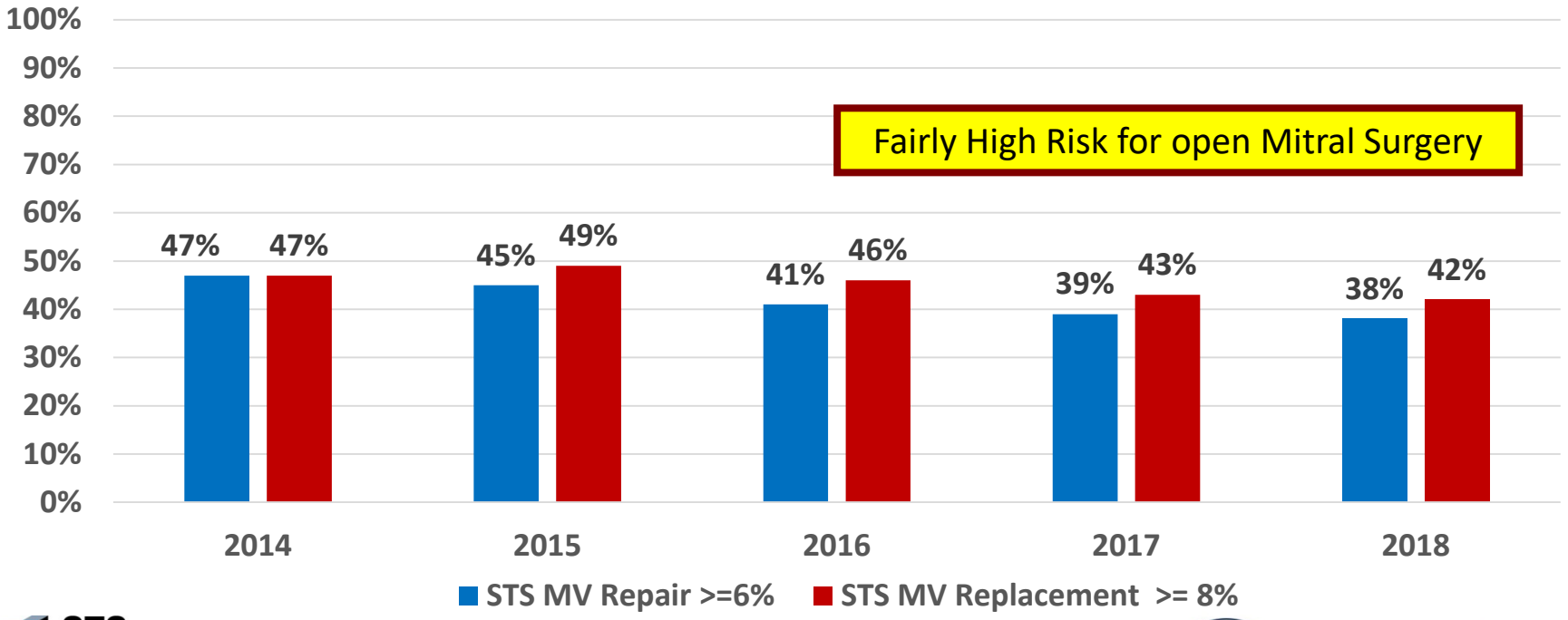
Leaflet Clip Procedure Indications
Reasons for Determination of Prohibitive Risk



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

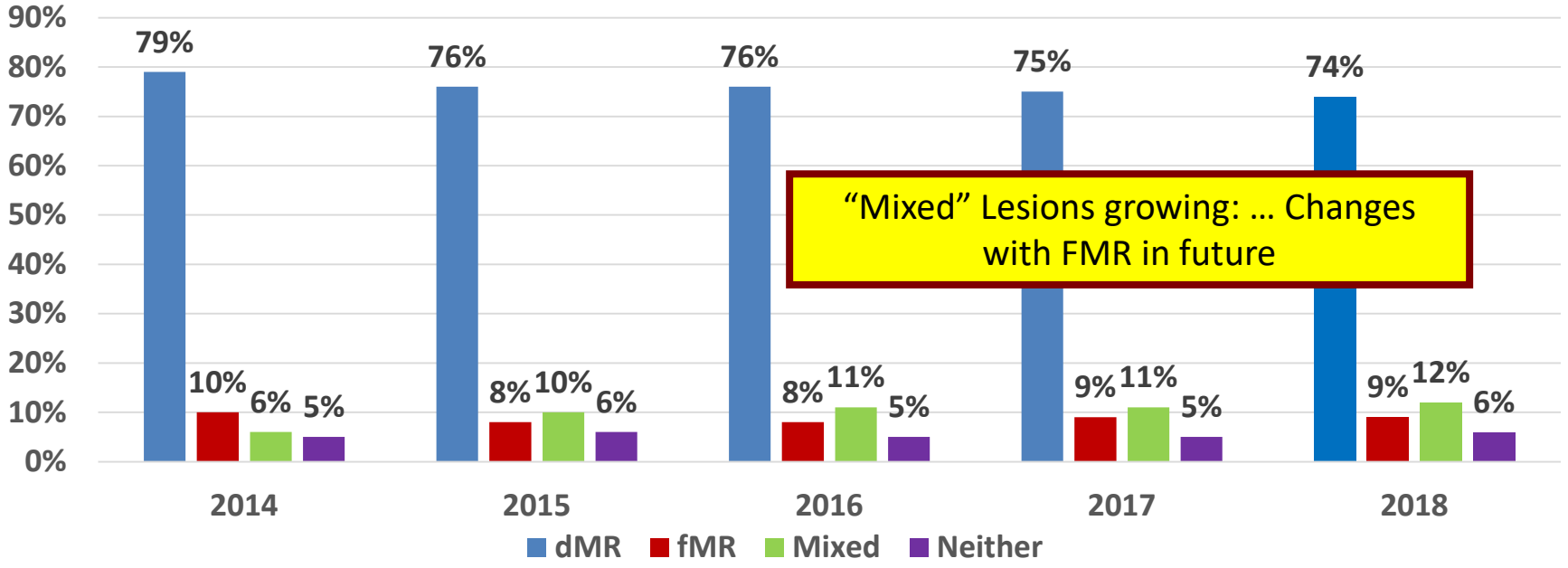
Leaflet Clip
STS Operative Mortality Risk



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip
Mitral Valve Disease Etiology



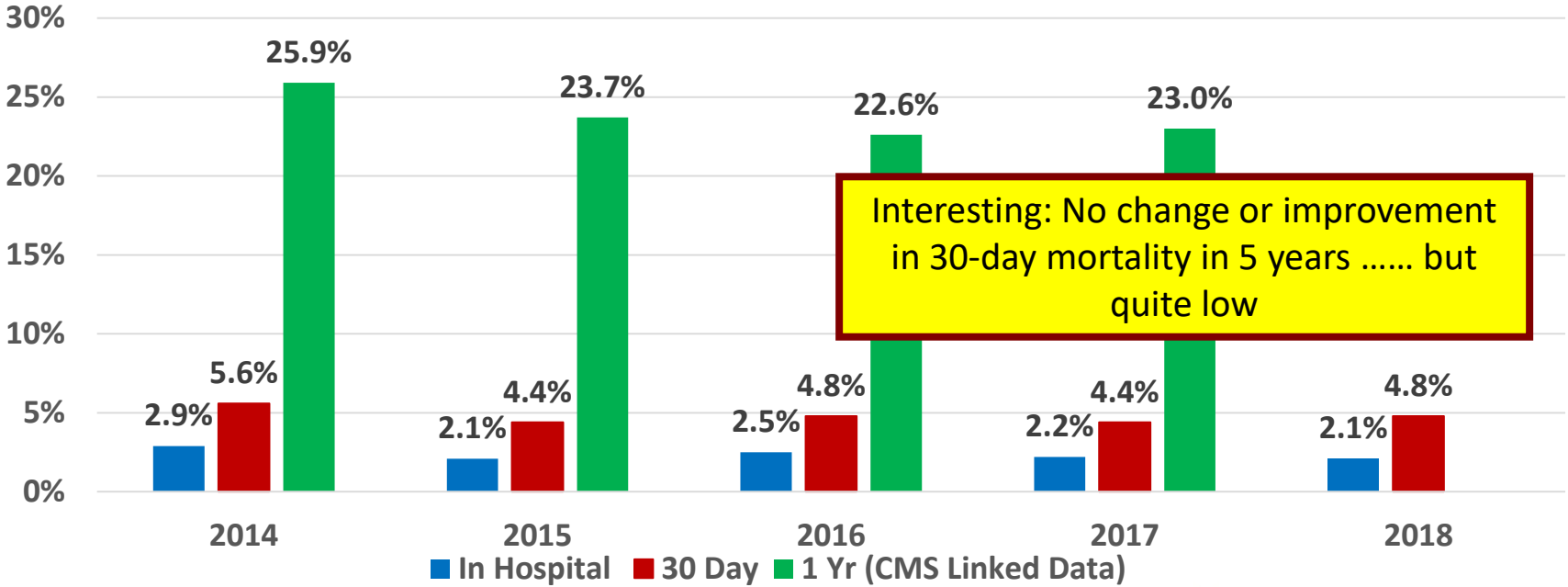
STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Real World Leaflet-Clip Repair Clinical Outcomes

Leaflet Clip Mortality

In Hospital 30 Day and One Year

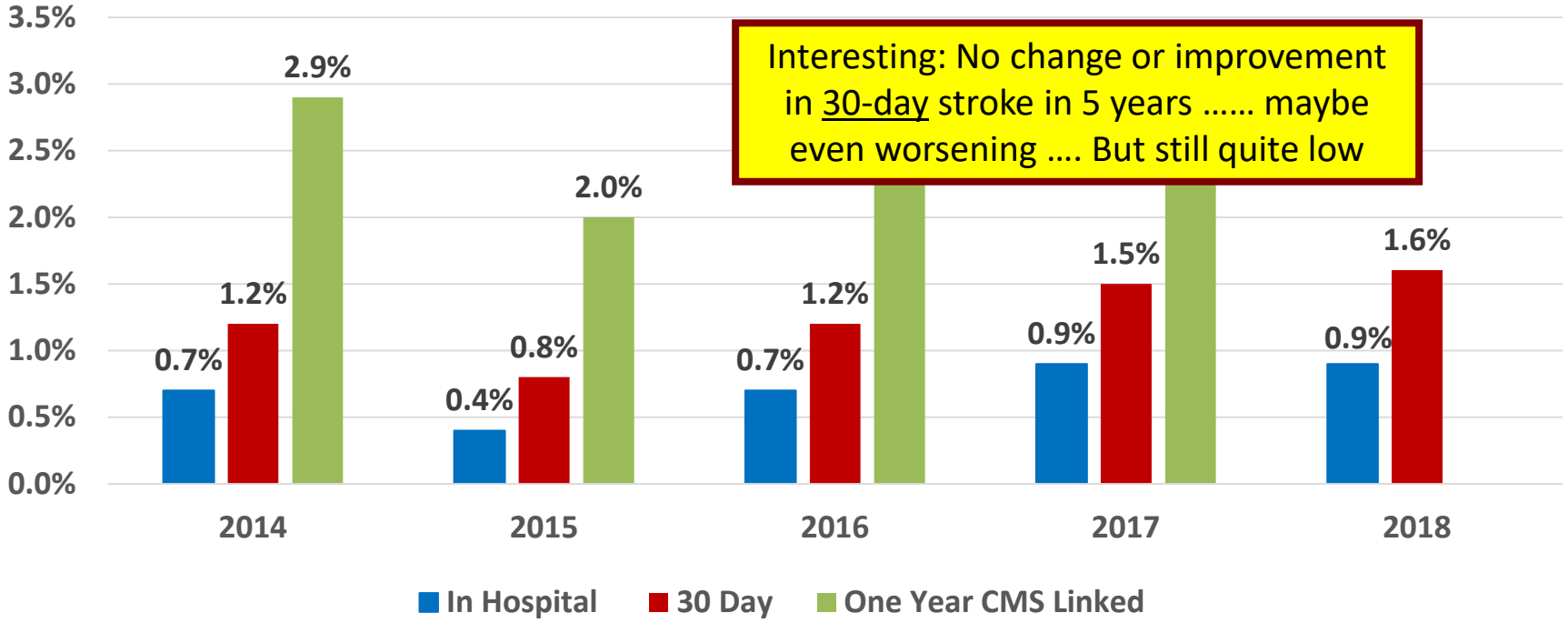


STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip Stroke

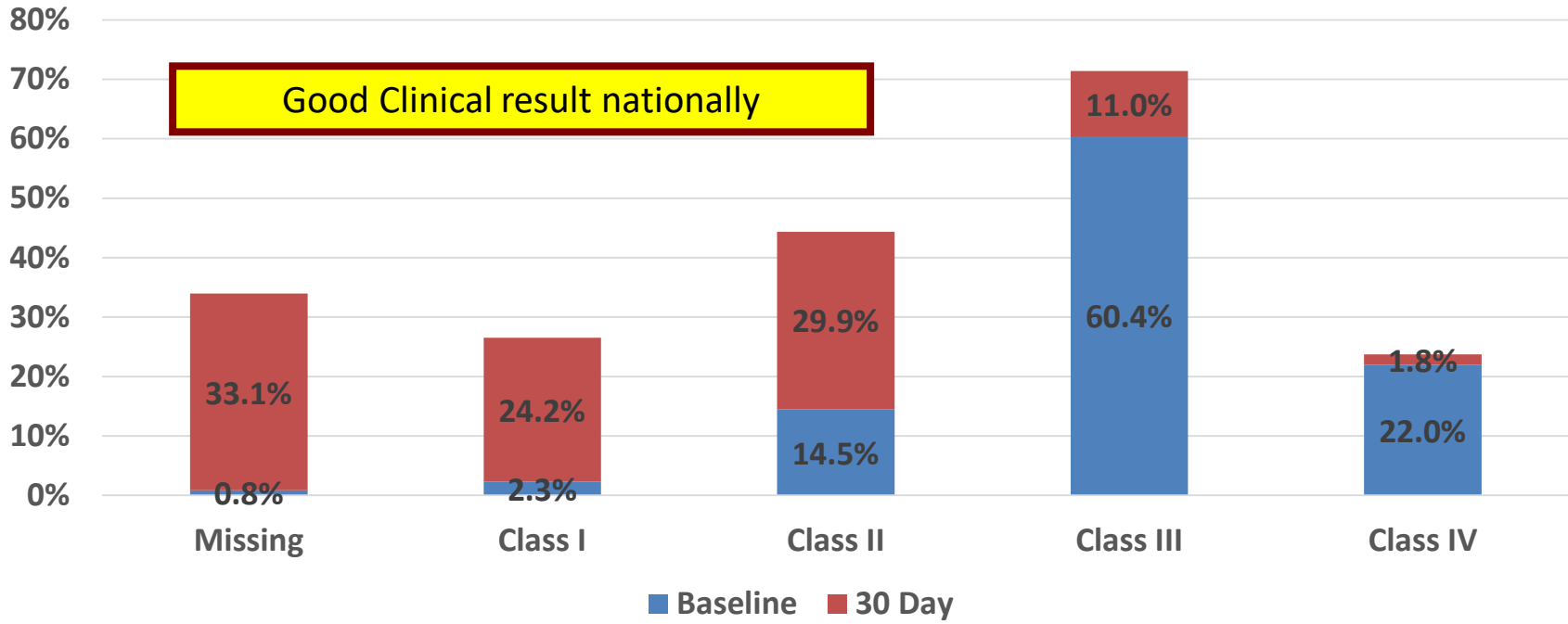
In-Hospital 30 Day and One Year Stroke



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

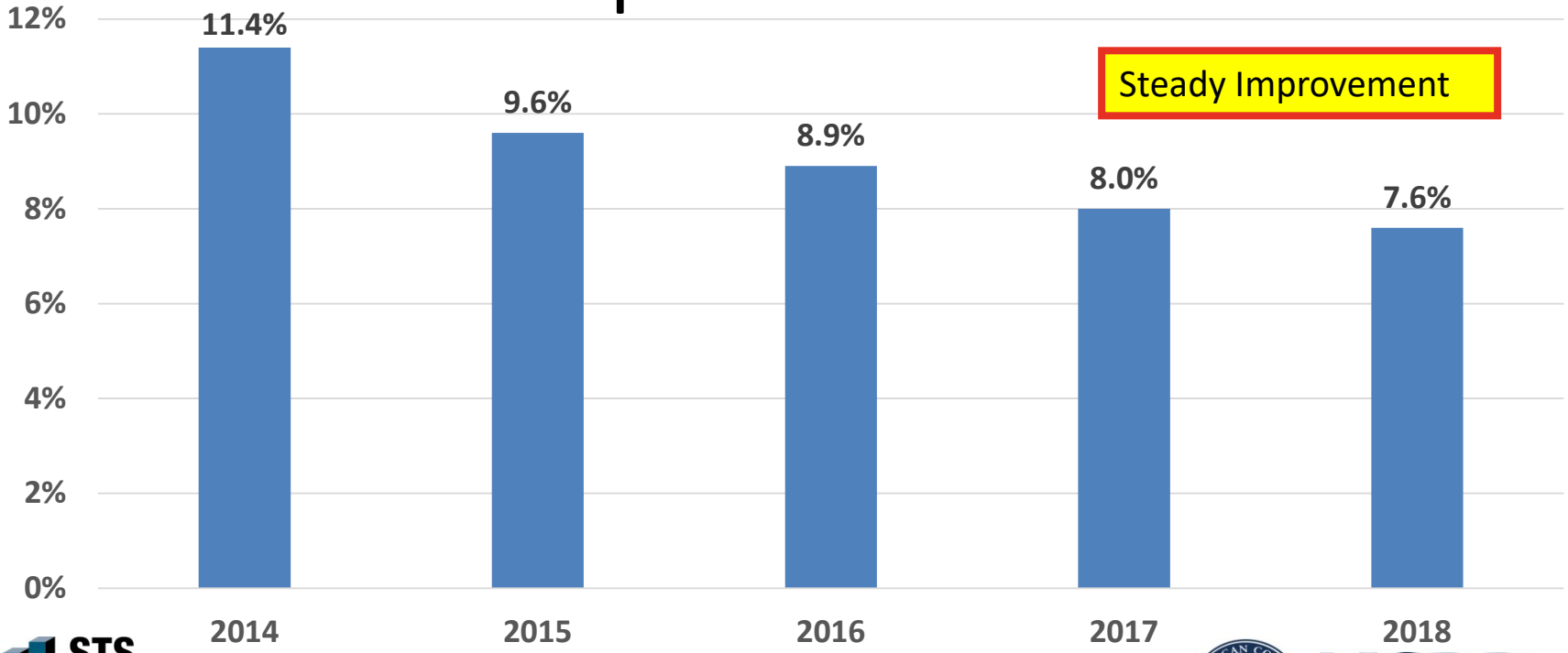
Leaflet Clip
2018 NYHA Data



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip
In Hospital Transfusions

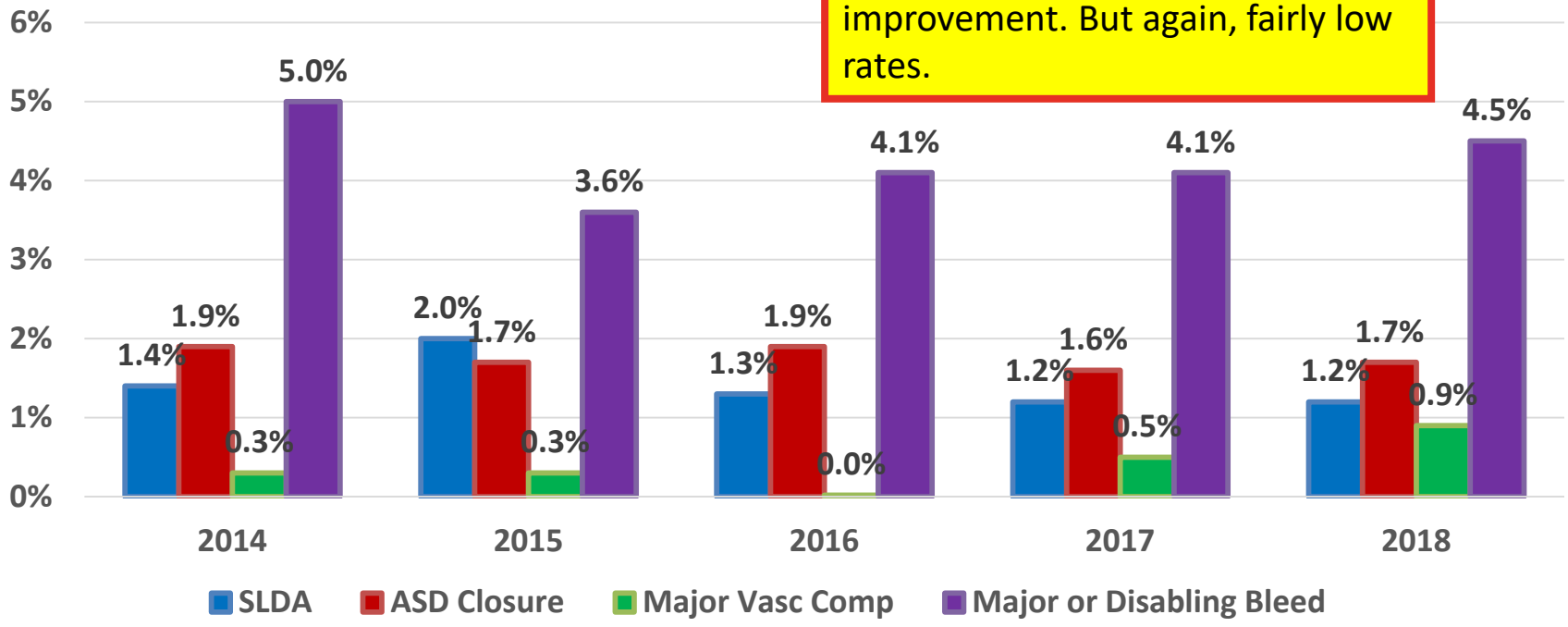


STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip Morbidity : 30 Day Outcomes

Very Steady rates of Morbidity. No improvement. But again, fairly low rates.



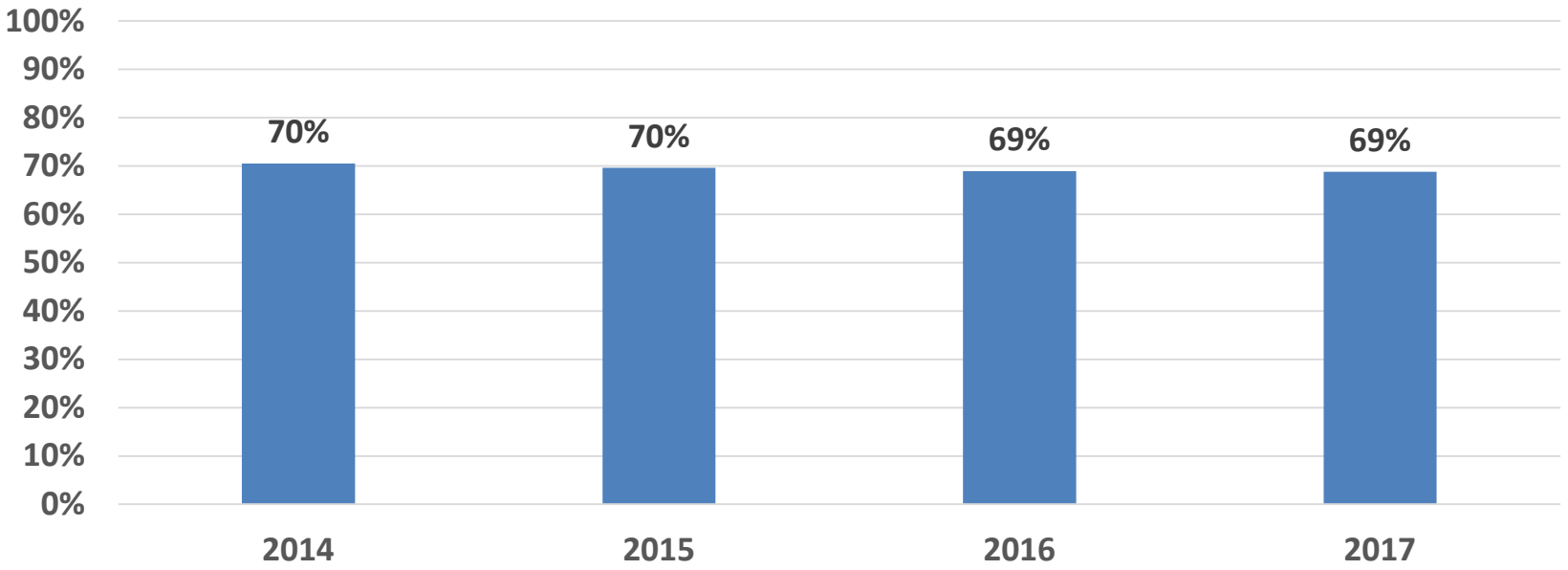
STS National Database™
Using data to drive quality

* *Among non-missing follow-up*

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Leaflet Clip – Alive and Well*

(among 1-year survivors with complete KCCQ)



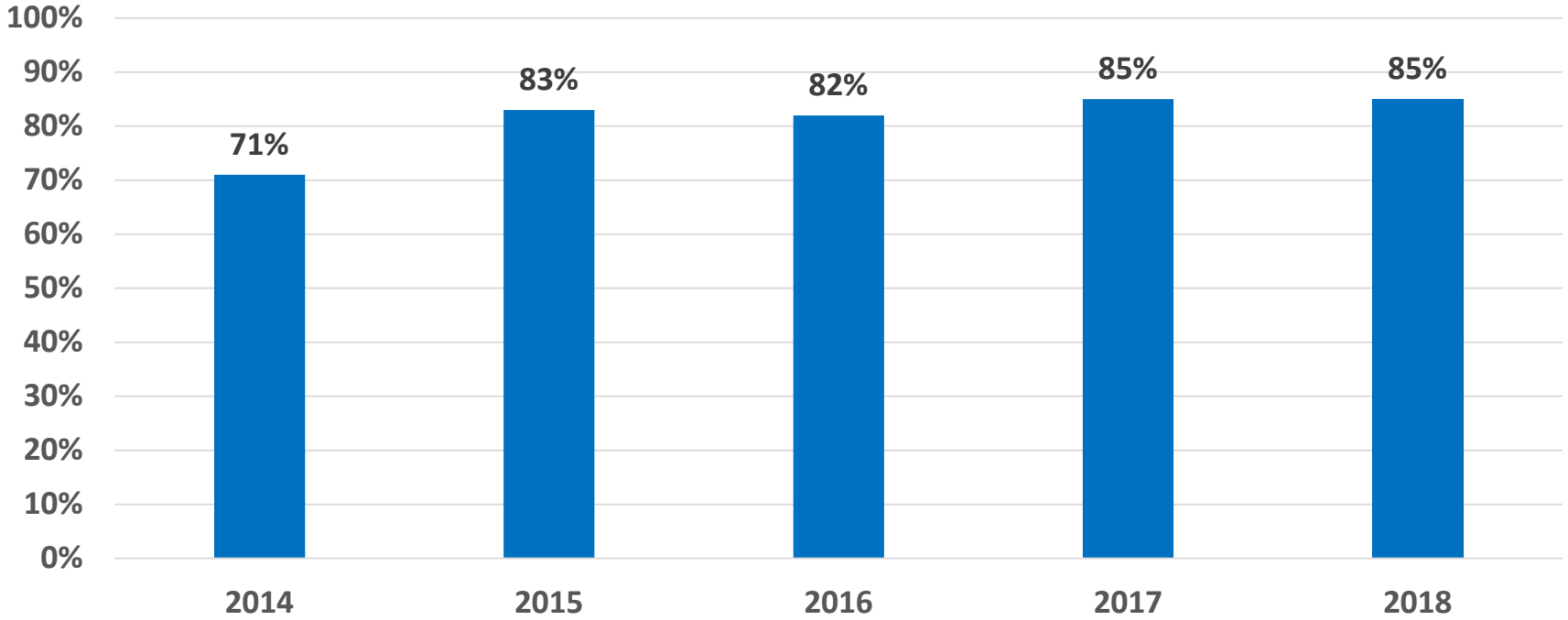
STS National Database™
Using data to drive quality

***1-Yr KCCQ >= 60 and no more than a 10 unit decrease in KCCQ score from baseline to 1 year**

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

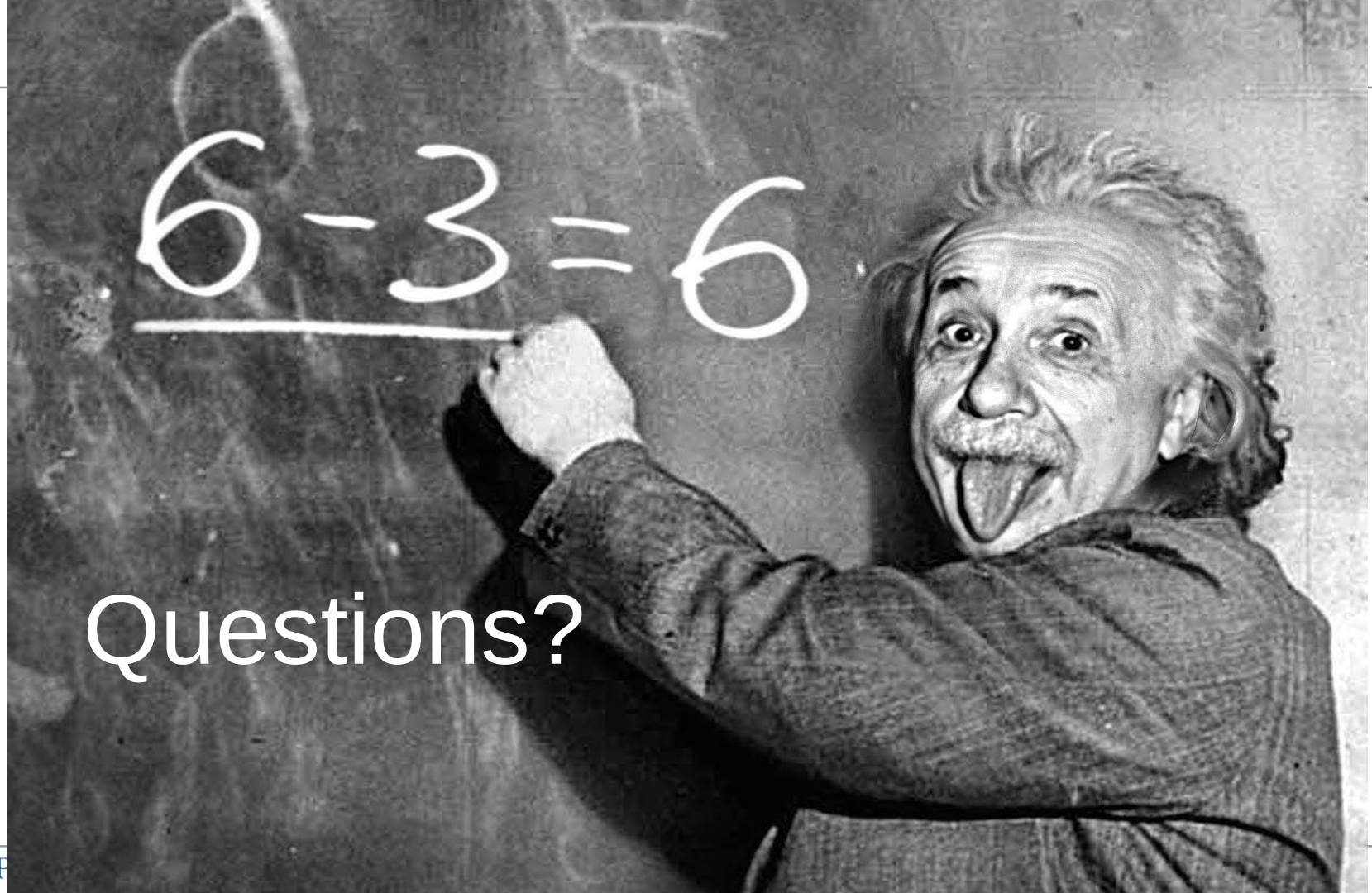
*Among 2,368 pts

Leaflet Clip
Baseline KCCQ Completed



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY



Questions?

New Techniques, Not Investigative Devices, in Transcatheter Valve Treatment

- **Physicians see first-hand problems-adverse events that arise in their patients in the trenches of clinical care.**
- The spirit of innovation is alive to come-up with solutions.
- New techniques often use existing technologies on the shelves of cath labs.
- “Beneath” the radar screen of FDA approval.
- Surgeons for years have developed new surgical techniques in such a fashion.
- These new techniques have been studied using formal research proposals, listing in ClinicalTrials.gov, and with NIH funding.
- When to add them as data elements in the TVT Registry is an important issue.
- How to add them as data elements is an additional issue.

0ther TVT Registry V3 updates

CTA Findings					
AV Annulus Size Assessment Method[5660]:	O CTA (2D)	O TTE	O TEE	O Angiography	*(note: primary documentation should be CTA)*
AV Annulus Diameter:	**Min:** _____ mm	**Max:** _____ mm	**AV Annulus Area:** _____ mm2	**AV Annulus Perimeter:** _____ mm	
AV Calcification:	O None	O Minimal	O Moderate/Severe	O Not documented	

Dobutamine stress test Findings			
Dobutamine Challenge Performed[xxx]:	O No	O Yes	
→**If** Yes, **Flow Reserve Present**[xxx]:	O No	O Yes	
→**If** Yes, **Aortic Stenosis Type**[xxx]:	O Truly severe aortic stenosis	O Pseudo-severe aortic stenosis	O Severity not documented

STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY