

Medtronic

Engineering the extraordinary

TVT Registry Public Reporting Webinar

October 20, 2022

Moderator: Lucy Schlueter, Global Market Development Consultant, Medtronic

Faculty:

Joan Michaels, RN, MSN, CPHQ, AACC, Director of STS/ACC TVT Registry

Kristin Pasquarello, P.A., Administrative Director of the Heart Valve Center, St. Francis Hospital, Roslyn, NY

UC# 202308084 EN

October 2022

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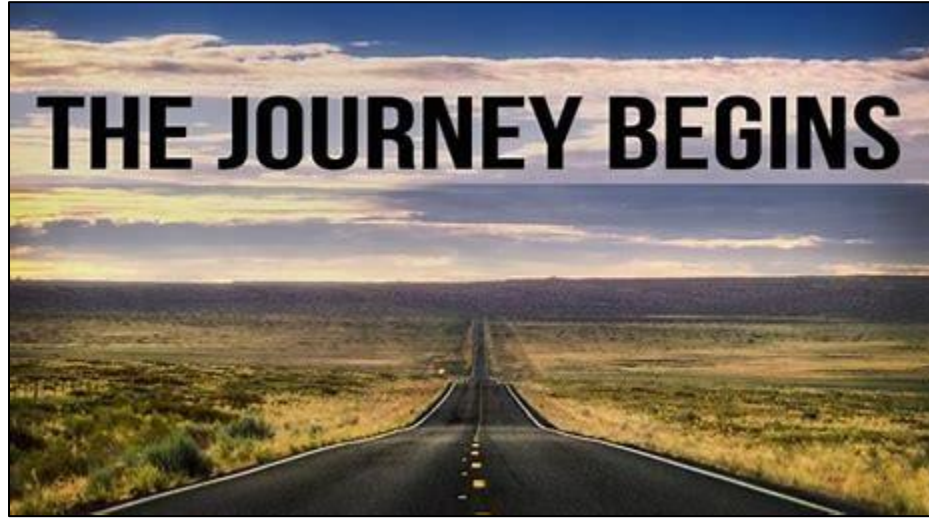
TVT Registry Quality Public Reporting

• Agenda

- 1 Joan Michaels - TVT Registry Quality Public Reporting Methodology Overview
- 2 Kristen Pasquarello – Best Practice Example of Process and deciding to Opting In
- 3 Q & A and Survey



STS/ACC TVT Registry Public Reporting



Joan Michaels



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TVT Public Reporting Building Blocks

- Sufficient Volume
- Risk Model Development
- Morbidity & Mortality Risk Model
- Public Reporting
- USNWR



Why is Public Reporting Important?

- Transparency
- Used in USNWR
- Required in California



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What Will Be Included in Public Reporting?

1. TAVR annual volume
2. TAVR 30-day mortality/morbidity composite (reported as a “site difference”)



TVT Registry Public Reporting Workgroup

- Co-Chairs:
 - Dave Shahian, MD – Massachusetts General Hospital (STS rep)
 - Ralph Brindis, MD - University of California, San Francisco (ACC rep)
- STS representatives:
 - Vinay Badhwar, MD – University of West Virginia
 - Jeff Jacobs, MD – University of Florida
- ACC representatives
 - Greg Dehmer, MD – Carilion Health
 - Jon Jennings, MBA – HCA Healthcare



TAVR Volume Metric



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TAVR Volume Metric



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



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Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume ¹ (commercial procedures only)		Distribution of Annual Hospital TAVR Volumes (Across all TVT Registry Hospitals)
	Cumulative	Annual volume (Jan 1 to Dec 31, 2019)	
Dec, 2011	750	60	

The month/year your hospital submitted your first procedure submitted to Registry (when you enrolled).

Your hospital's cumulative volume since enrollment.

Your hospital's annual volume (most recent last 4 qtrs).

Your hospital's annual volume as compared to the volume across all registry hospitals in a distribution diagram.

TAVR 30-Day Mortality/Morbidity Composite



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TVT Registry Risk Model Workgroup

Risk Model Member	Representation
Nimesh Desai, Co-Chair	STS Representative
David Cohen Co-Chair	ACC Representative
David Shahian, MD	STS Representative
Vinay Badhwar, MD	STS Representative
Brian O'Neill, MD	ACC Representative
John K. Forest, MD	ACC Representative
Vinod Thourani, MD	R & P Representative*
Tsuyoshi Kaneko, MD	R & P representative *
Suzanne Arnold, MD	Analytic Center Representative*
Sreekanth Vemulapalli, MD	Analytic Center Representative*
Carole Krohn	Primary Staff Liaison (STS)*
Susan Fitzgerald	Staff Liaison (ACC)*

Circulation

ORIGINAL RESEARCH ARTICLE

Composite Metric for Benchmarking Site Performance in Transcatheter Aortic Valve Replacement

Results From the STS/ACC TVT Registry

Nimesh D. Desai¹ MD, PhD; Sean M. O'Brien, PhD; David J. Cohen² MD, MSc; John Carroll, MD; Sreekanth Vemulapalli³ MD; Suzanne V. Arnold⁴ MD, MHA; John K. Forrest, MD; Vinod H. Thourani, MD; Ajay J. Kirtane⁵ MD; Brian O'Neil, MD; Pratik Manandhar, MS; David M. Shahian, MD; Vinay Badhwar⁶ MD; Joseph E. Bavaria, MD



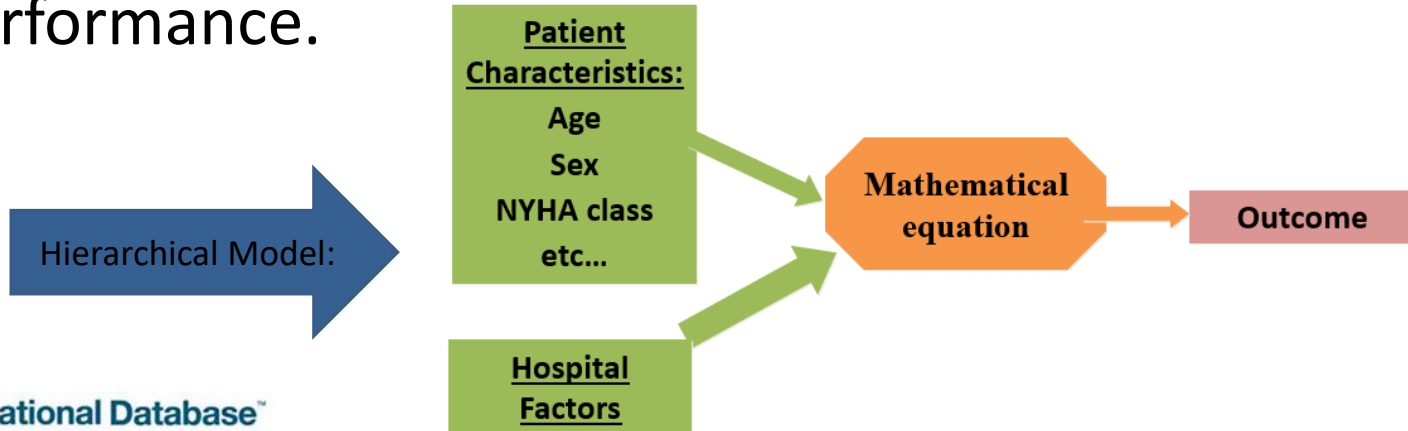
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What is it?

- The TAVR 30-day morbidity/mortality composite is a hierarchical, multiple outcome risk model that estimates risk standardized results (reported as a “site difference”) for the purpose of benchmarking site performance.





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My Hospital TAVR 30 Day Composite Site Difference ^{1,2,3} (95% Confidence Intervals)	Eligible Patients (Jan 1, 2017 –Dec 31, 2019)	Participant Rating	Distribution of Participant Estimates
0.05 (-0.15 to 0.12)	160	★★	

¹ Missing value (--) indicates that hospital does not meet eligibility criteria for reporting.

² 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:

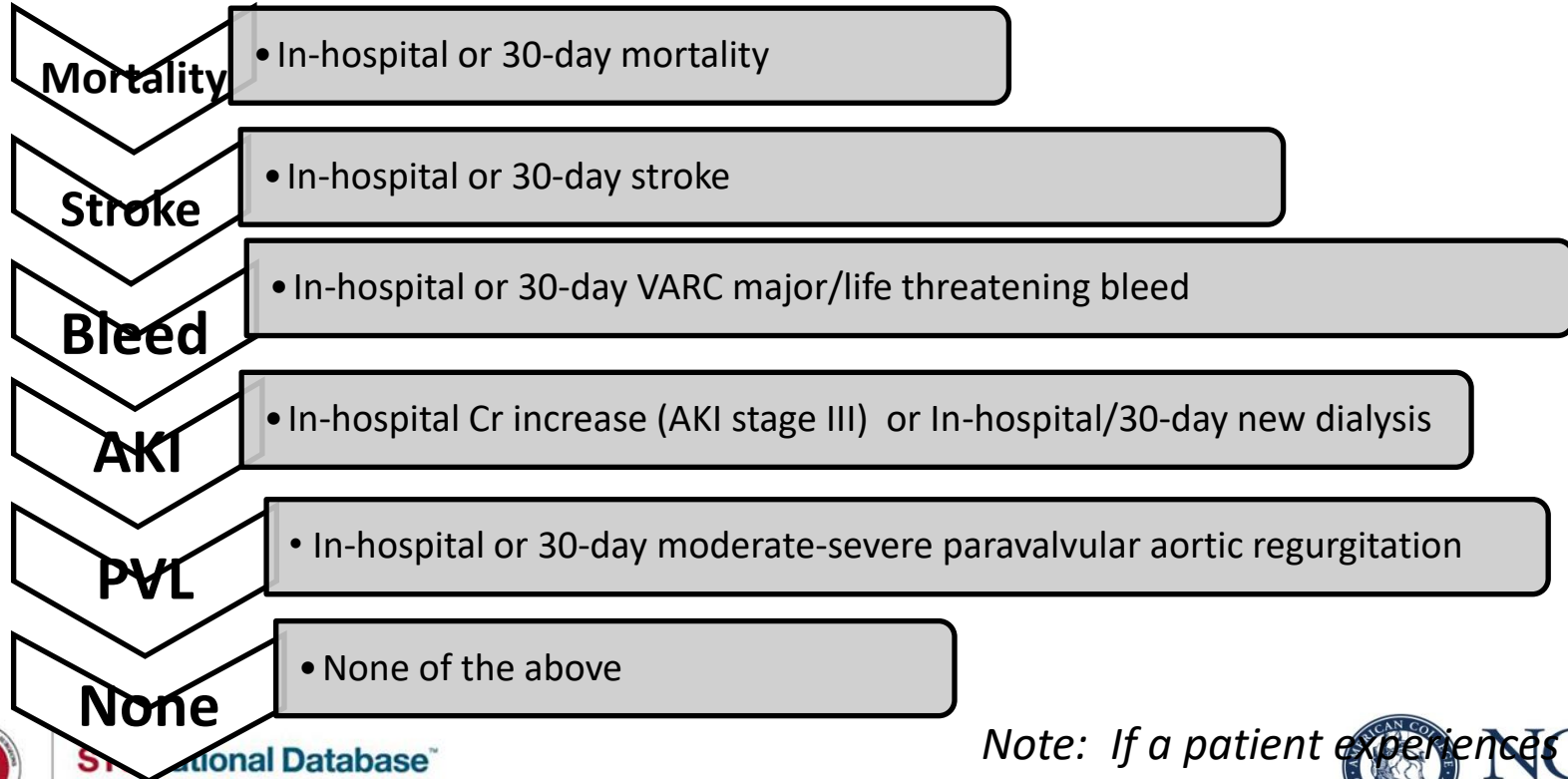
1. 30-day death
2. 30-day stroke
3. 30-day life-threatening/major bleed
4. Acute kidney injury (stage III)
5. 30-day $\geq 2+$ (mod-sev) paravalvular leak
6. None of the above

³ 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

TAVR 30-Day Morbidity/Mortality Composite Endpoints



Note: If a patient experiences multiple outcomes,



Timeframes and Inclusion Criteria

1. Timeframe: Rolling 3 years

1. Inclusion Criteria (Site Level)
 - A. $\geq 90\%$ completeness in
 - Baseline KCCQ
 - Baseline five-meter walk
 - Event status/30-day follow-up assessment completeness
 - B. Site must have enrolled prior to the rolling 3-year reporting time period
 - C. Site must have at least 60 remaining model eligible records

Note: excludes patients in research studies, subsequent TAVR and non-TAVR procedures.

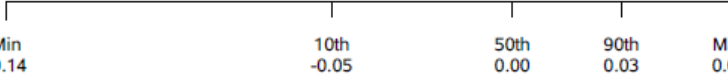


46 Variables in the Composite Risk Model

Age	Prior peripheral artery disease	# prior cardiac operations
BSA	Current/recent smoker	Prior aortic procedure
Sex	Diabetes	Prior other valve procedure
Race/ethnicity	NYHA Class	Aortic etiology
eGFR	Atrial fibrillation/flutter	Valve morphology
Dialysis	Conduction defect	Aortic insufficiency
Ejection fraction	Chronic lung disease	Mitral insufficiency
Hemoglobin	Home oxygen	Tricuspid insufficiency
Platelet count	Hostile chest	Acuity status
Procedure date	Porcelain aorta	Cardiogenic shock
LMD \geq 50%	Access site	Cardiac arrest w/in 24 hours
Proximal LAD \geq 70%	Pacemaker	Pre-procedure inotropes
Prior MI	Previous ICD	Mechanical assist device
Endocarditis	Prior PCI	Carotid stenosis
Gait speed	Prior CABG	Prior TIA/stroke
Baseline KCCQ-12		



Sites that do not meet inclusion criteria do not receive ratings on the composite model.....

My Hospital TAVR 30 Day Composite Site Difference ^{1,2,3} (95% Confidence Interval)	Eligible Patients (Jan 1, 2017 - Dec 31, 2019)	Participant Rating	Distribution of Participant Estimates
--	--	NOT RATED	

¹ Missing value (--) indicates that hospital does not meet eligibility criteria for reporting.





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0.05 (-0.15 to 0.12)			

What is a site difference?

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What is a Site Difference?

- A method to report composite outcomes (fatal and non-fatal)
- Provides a different weight for each event, based on the clinical importance and timing of the outcomes
- Is used in clinical trials that have a composite of primary endpoints
- A newer method that creates the foundation of site rankings
- Also called a “win difference” or “net benefit” in the literature



Definition of a Site Difference

Statistician:

Probability that an average patient at your hospital would have a **worse outcome** at average hospital (vs your hospital).

MINUS

Probability that an average patient at your hospital would have a **better outcome** at an average hospital (vs your hospital).

English interpretation

An average patient is better off going to YOUR hospital (vs an average hospital)

MINUS

An average patient is better off going to an AVERAGE hospital (vs your hospital)

Site Difference interpretation (note – this pivots on zero, not 1):

If an average patient is better off at your hospital (vs an average hospital): **Site Difference >0** (a positive number).

If an average patient is better off at an average hospital (not your hospital): **Site Difference <0** (a negative number).





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Your hospital's performance (median hospital is zero) and confidence intervals

Your hospital's volume (rolling 3 years of TAVRs)

Your hospital's star rating (based on 1-3 stars)

Your hospital's performance based on a distribution of all hospital's performance.



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Interpretation of Star Ratings

Site Difference w/95% Confidence Intervals as Compared to



Registry Benchmark
(Site Difference=0.00)

	*	**	***
	Outcome is statistically worse than expected (7% of sites)	Outcome is not statistically different from national benchmark (86% of sites)	Outcome is statistically better than expected (7% of sites)
Upper Probability Interval	-0.05	0.21	0.41
Lower Probability Interval	-0.19	-0.22	0.26
• Site Difference	-0.11	0.11	0.33



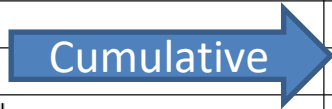
The composite details also provide the observed, expected and O/E ratio model outcomes for your hospital.

☒ Number of patients with “worst” observed outcome in each composite outcome category at your hospital

Composite Outcome Category	My Hospital		Registry	
	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 at your hospital

Composite Cumulative Outcomes	Observed (%)	Expected (%)	O / E Ratio
Death	2.5%	2.4%	1.0 (0.3-1.2)
Death or Stroke	3.1%	3.1%	1.0 (0.6-1.3)
Death or Stroke or Bleeding	8.1%	8.8%	0.9 (0.5-1.1)
Death or Stroke or Bleeding or AKI	9.4%	9.6%	1.0 (0.4-1.5)
Death or Stroke or Bleeding or AKI or PVL	11.9%	12.2%	0.9 (0.7-1.4)



• Note: O/E are not reported for each individual outcome. They are reported for cumulative outcomes.



Tips to Remember

- Site difference is calculated based on the risk profile of the patients at your hospital (e.g., age, diabetes), as well as the profile of your hospital (e.g., your hospital's procedure volume)
- Site Difference >0: your hospital's performance is better than average
- Site Difference <0: your hospital's performance is less than average
- When your site difference is <0: Look at the observed: expected (O/E) ratio for each endpoint (found in the dashboard-detail lines). Which endpoint reports a worse than expected performance (with an O/E ratio >1.0)
- Which endpoint has more weight in the model? Mortality has the highest weight, followed by stroke, etc.)
- Lower volume sites typically have wider confidence intervals because it is harder to predict the site difference with less patients.
- If the range of your confidence intervals cross zero (the registry average), you are a two-star hospital. This means your performance is as expected and you are not statistically different than the average hospital. 86% of hospitals have two stars.



STS/TVT Public Reporting Companion Guide



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STS/ACC TVT Registry™

An initiative of the STS National Database and the ACC's NCDR

Rectangular Snip

Participant Companion Guide for Public Reporting

The mission of the TVT Registry™ is to track patient safety and real-world outcomes related to transcatheter valve replacement or repair procedures. The registry is an initiative of the Society of Thoracic Surgeons (STS) and the American College of Cardiology Foundation (ACCF).



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TVT Registry

Rating Explanations

Related Resources

STS Public Reporting

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Search Site

STS/ACC TVT Reporting

The mission of the TVT Registry™ is to track patient safety and real-world outcomes related to transcatheter valve replacement or repair procedures. The registry is an initiative of the Society of Thoracic Surgeons (STS) and the American College of Cardiology Foundation (ACCF).

The TAVR 30-day morbidity/mortality composite was developed by a TVT Registry Workgroup (physician leaders of the registry and statisticians at Duke Clinical Research Institute) for the purpose of providing feedback in the institutional outcomes reports. The model is a hierarchical, multi-category risk model that estimates risk standardized results (reported as a “site difference” and including



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CardioSmart



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Search [Clear](#)

Hospital Name

Location

Cardiac Services [Services Glossary](#)

Select all services hospitals must perform

- Percutaneous Coronary Intervention
- Percutaneous Coronary Intervention
- Percutaneous Peripheral Vascular Intervention
- Transcatheter Valve Replacement

Find Your Heart a Home: For Patients

Do you or a loved one have heart disease? Deciding where to get care can be overwhelming. But it doesn't have to be.

Use the Find Your Heart a Home tool to search, compare and select the right hospital for your needs. You can search hospitals by name, location or cardiac services.

The results will list hospitals that participate in ACC's quality improvement efforts. More than 2,000 hospitals collect data about



TVT Registry Public Reporting & USNWR



USNWR Quality Indicators

Survival

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

Discharging patients directly 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.

Readmission prevention

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

Prevention of stroke

How well hospital prevents stroke from occurring on the day of the procedure. Stroke prevention is an important precaution because the procedure may put them at increased risk.

Number of patients

Relative volume of Medicare inpatients age 65 and over who had this procedure or condition over five years. Higher volume is associated with better outcomes.

Influenza immunization of workers

Percentage of healthcare personnel who received a timely vaccination during flu season.

Public transparency

Whether hospital publicly shared its TAVR data through an American College of Cardiology/Society of Thoracic Surgeons transparency program as of early 2022. Hospitals participating in transparency programs foster sharing of data and adoption of best practices.

Nurse staffing

More nursing care per patient is associated with better outcomes and better patient experience.

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.





Thank You

JANE S. DOE, MD, FACC

HEART HOSPITAL

St. Francis Hospital:

The Heart Valve Center

TVT Public Reporting

Kristin Pasquarello, MS, PA-C
St. Francis Hospital, Roslyn NY
The Heart Valve Center
Administrative Director

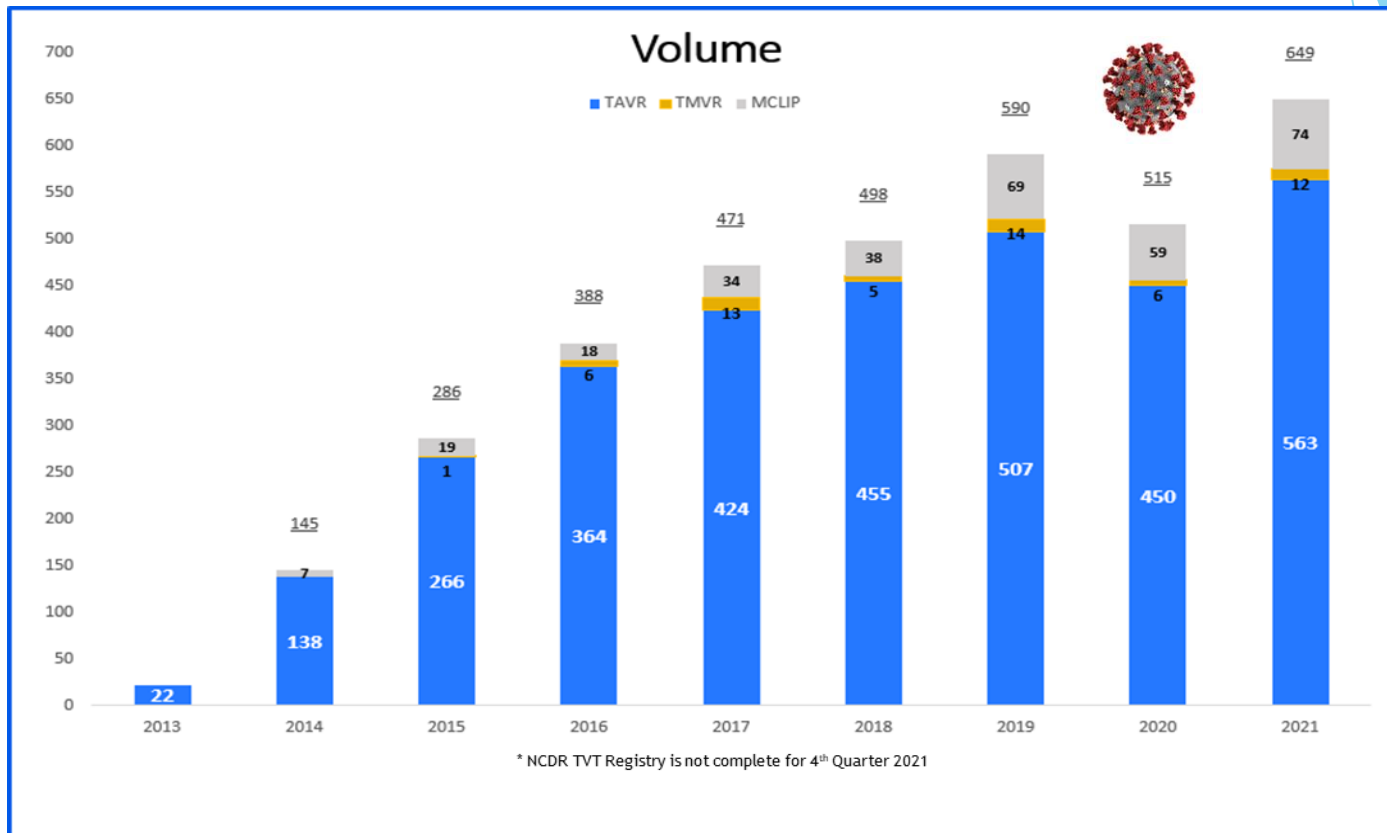


- New York State's only specialty designated cardiac center and a nationally-recognized leader in cardiac care.
- For the twelfth consecutive year, U.S. News & World Report ranked St. Francis as a Best Hospital in America.

Closest TAVR Centers



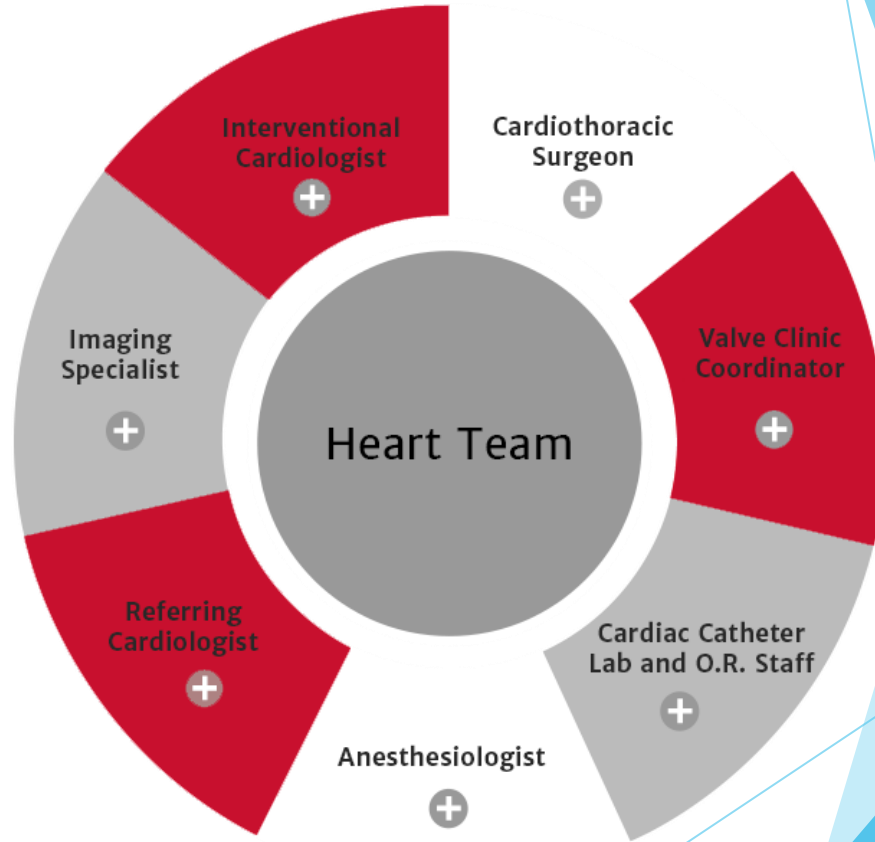
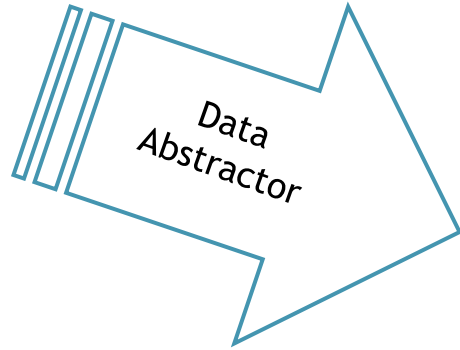
SFH Heart Valve Program



How did we start the process?

- ✓ Performance improvement team:
- ✓ Knowing the definitions
- ✓ Correct documentation in the chart
BY THE CORRECT PEOPLE!
- ✓ Knowing your outcomes
****REAL TIME**
- ✓ Getting everyone on the same page

Multi-Disciplinary Team



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Metric considerations

Optimizing your TAVR program



"Taking a multidisciplinary team approach to reviewing comprehensive data can showcase the need for change in a growing program."

- Kristin Pasquarello, P.A.,
Administrative Director
of the Heart Valve Center,
St. Francis

What could you consider tracking in your TAVR program?

These key data points can support the need for program optimization or to improve capacity, throughput, and quality within a TAVR program.

Metric/dashboard considerations to track

- Referring physician
- Referral to treatment
- Heart failure class (Pre/Post)
- Volumes (by provider/by valve type)
- Procedure times
- ICU length of stay (hours)
- Total length of stay
- Mortality (in hospital, 30 day)
- Mortality (observed/expected)
- Stroke
- Major vascular complications
- Acute kidney injury
- Pacemaker rates
- Gradients, EOA, DVI (discharge, 30 day, one year)
- Readmissions and reason for readmission (30 day/90 day)
- Quality of life KCCQ (30 day/one year)
- Patient satisfaction/HCAHPS if able to drill down to SH program

Contact your local Medtronic sales representative or program development consultant for more details.

Monthly Meeting

Invite all the players

Have the definitions, understand them!

Document everything, appropriately

Educate other consultative services about documentation

Review your report card from the TVT registry real time

Monthly Meeting Agenda

A - Agenda:

AGENDA	ATTACHMENT	PRESENTER
I. Call to Order		C. Keeshan, RN
II. Conflict of Interest and Confidentiality		C. Keeshan, RN
III. Approve Minutes		C. Keeshan, RN
IV. SFH New Cases for discussion <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED]• [REDACTED]		C. Keeshan, RN/ L. Scheuermann, PA-C
V. GSH New Cases for discussion <ul style="list-style-type: none">• [REDACTED]• [REDACTED]• [REDACTED]		Bill DeCola, RN/ Joanne Faber, RN
VI. Open Discussion		
VII. Next Meeting & Adjournment <ul style="list-style-type: none">• October 24, 2022		C. Keeshan, RN/ L. Scheuermann, PA-C

Monthly Meeting Agenda

1	TVT Registry Patient Event List-SFH			9/26/2022	Revised 9/22/2022			
2							✓ X	
3	Name:	DOS	MRN #	Event Code:	Providers	PI Comments	Meeting comments	Complete
4	Cardullo, Biagio	6/9/2022	6399053	Stroke - Ischemic		Stroke - Ischemic: MRI-Acute posterior circulation Stroke - Ischemic: An acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of central nervous system tissue.		
5	Garda, Kathleen	7/6/2022	642005437	Bleeding - Other		Bleeding - Other: The patient experienced bleeding from a site not specified.		
6	Chico, Margaret	5/2/2022	6305049	Cardiac Arrest		Cardiac Surgery or Intervention - Other Unplanned: The patient subsequently underwent cardiocatheterization. The patient subsequently underwent cardiocatheterization that was unplanned. This does not include an intervention or procedure already identified as an adverse event in the TVT Registry (e.g. AV reintervention, other vascular surgery or intervention, pacemaker/ICD implant). Vascular Surgery or Intervention - Unplanned: The patient required unplanned vascular surgery or intervention to correct a bleeding complication or vascular related complication. Vascular Complication - Major: 1. Any aortic dissection, aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudo-aneurysm; 2. Access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, compartment syndrome, percutaneous closure device failure) leading to death, life threatening or major bleeding*, visceral ischemia or neurological impairment; 3. Distal embolization (non-cerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage; intervention associated with death, major bleeding, visceral ischemia or neurological impairment; 5. Any new ischemia documented by patient symptoms, physical exam, and/or decreased or absent blood flow on lower extremity angiogram; 6. Surgery for access site-related nerve injury; 7. Permanent access site-related nerve injury. *Refers to VARC bleeding definitions Annular Rupture: Annular rupture (or 'annulus rupture') is an umbrella term covering different procedural related injuries of the aortic root and the left ventricular outflow tract (LVOT) during transcatheter aortic valve replacement. According to the anatomical location of the injury, it can be classified into 4 types: intra-annular, subannular, supra-annular, and combined rupture Cardiac Arrest: Cardiac arrest is defined as acute cardiac event documented by one of the following: ventricular fibrillation, rapid ventricular tachycardia or bradycardia rhythms with hemodynamic compromise causing loss of consciousness, pulseless rhythms (PEA), or asystole requiring cardiopulmonary resuscitation (two or more chest compressions or open chest massage, emergency temporary pacing, pericardiocentesis, Cardiac arrest is defined as acute cardiac event documented by one of the following: ventricular fibrillation, rapid ventricular tachycardia or bradycardia rhythms with hemodynamic compromise causing loss of consciousness, pulseless rhythms (PEA), or asystole requiring cardiopulmonary resuscitation (two or more chest compressions or open chest massage, emergency temporary pacing, pericardiocentesis, institution of ECMO, or defibrillation) and without these measures death would have almost certainly resulted		
7	Reddy, Kumar	7/21/2022	63613136	Cardiac Arrest; PPM				
8	Stiprathak, Srigrana	7/13/2022	6605514	Cardiac Surgery or Intervention - Other Unplanned; Vascular Surgery or Intervention - Unplanned; Vascular Complication - Major; Annular Rupture; Cardiac Arrest; Bleeding - Other				

KNOW YOUR DATA !



**TRANSCATHETER
VALVE REPLACEMENT**



Thank You



THANK YOU

Q & A

Please type your questions in the Q&A

Complete the Survey via
QR code or Link in CHAT

