American College of Cardiology/ Society of Thoracic Surgeons

TVT Registry: Updates in the Registry

April 8, 2021

Agenda

- Welcome and Introductions
- COVID-19 Data
- TAVR Minimum Dataset
- Mitral National Coverage Determination
- Public Reporting
- Q&A
  - Please use the Q&A function
  - Raise your hand if you would like to be unmuted

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COVID-19 Data

Dr. John Carroll & Dr. Vinod Thourani

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Capturing COVID in the STS-ACC TVT Registry

- COVID has disrupted call for VHD patients in many ways
- COVID may delay or prevent receiving transcatheter valve therapies
- COVID may impact on outcomes – how the patient does after receiving transcatheter valve therapy
- COVID impact on patients receiving all forms of TAVR, mitral repair, mitral replacement, and tricuspid valve therapies/

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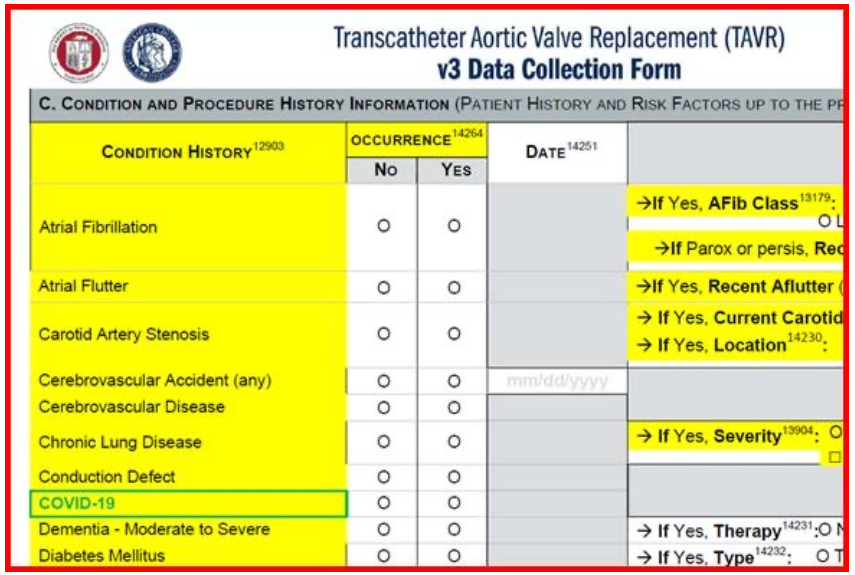
Three Opportunities to Add COVID



Transcatheter Aortic Valve Replacement (TAVR)
v3 Data Collection Form

C. Condition and Procedure History Information (Patient History and Risk Factors up to the pr

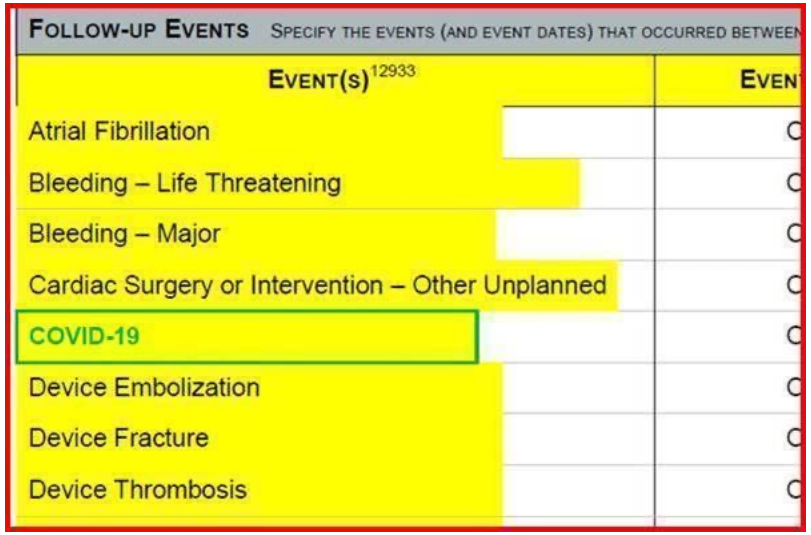
Condition History[12903]	Occurrence[14264] No	Occurrence[14264] Yes	Date[14251]	
Atrial Fibrillation	O	O		→If Yes, AFib Class[13179]: O L →If Parox or persis, Rec
Atrial Flutter	O	O		→If Yes, Recent Aflutter (
Carotid Artery Stenosis	O	O		→ If Yes, Current Carotid → If Yes, Location[14230]:
Cerebrovascular Accident (any)	O	O	mm/dd/yyyy	
Cerebrovascular Disease	O	O		
Chronic Lung Disease	O	O		→ If Yes, Severity[13904]: O
Conduction Defect	O	O		
COVID-19	O	O		
Dementia - Moderate to Severe	O	O		→ If Yes, Therapy[14231]:O N
Diabetes Mellitus	O	O		→ If Yes, Type[14232]: O T

<u>Baseline</u>
When Patient
Initially Evaluated

Post-Procedure - Intra or Post-Procedure Events (Complete for

Intra or Post Procedure Event(s)[12153]	Event(s
Annular Rupture	O No
Aortic Dissection	O No
Atrial Fibrillation	O No
Bleeding – Access Site	O No
Bleeding – Gastrointestinal	O No
Bleeding – Genitourinary	O No
Bleeding - Hematoma at Access Site	O No
Bleeding – Other	O No
Bleeding – Retroperitoneal	O No
Cardiac Arrest	O No
Cardiac Perforation	O No
Cardiac Surgery or Intervention – Other Unplanned	O No
Coronary Artery Compression	O No
COVID-19	O No
Device Embolization	O No

<u>Procedure</u>
When Patient Has
Procedure



Follow-up Events Specify the events (and event dates) that occurred between

Event(s)[12933]	Even
Atrial Fibrillation	O
Bleeding – Life Threatening	O
Bleeding – Major	O
Cardiac Surgery or Intervention – Other Unplanned	O
COVID-19	O
Device Embolization	O
Device Fracture	O
Device Thrombosis	O

<u>Follow-up</u>
30 Day
1 Year

How Will We Use The Data on COVID in the TVT Registry?

Assess COVIDs impact

Exclude those patients who developed COVID after receiving their transcatheter valve therapy from assessment of site performance and public reporting?

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TAVR Minimum Dataset

Dr. Sreek Vemulapalli
and
Kim Guibone

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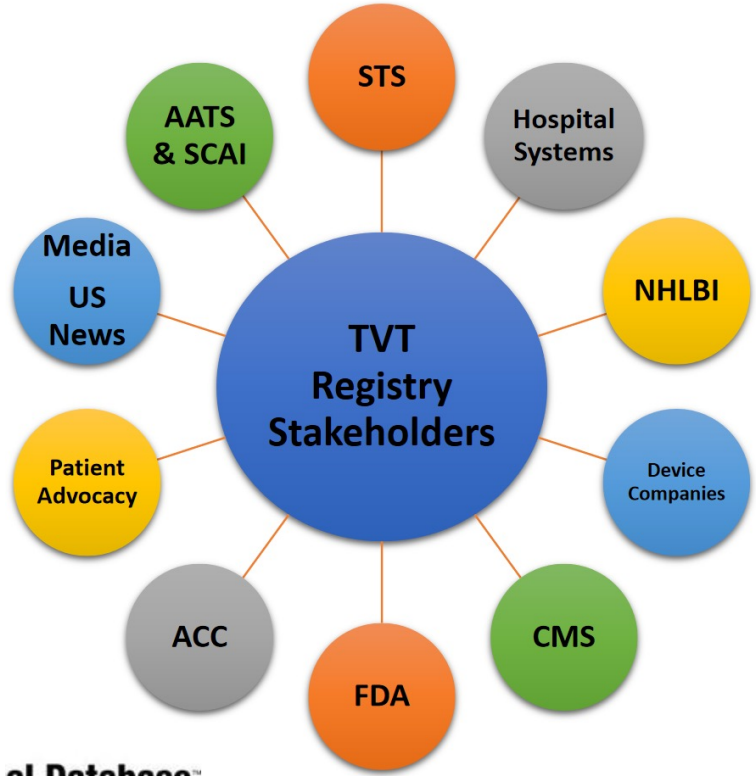
Current Functions of the TVT Registry

- Hospital Quality Feedback / Risk Models
- Appropriate Use Criteria (future)
- Fulfillment of CMS National Coverage Decision
- Post-Market Device Reporting (FDA)
- Generation of Evidence (ex. TAVR in mitral position)
- Research



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Why a change to the TAVR dataset?

- We heard feedback from you!
  - Burden of manual data element extraction

- TAVR has evolved over time
  - 2012 – High and prohibitive risk, little clinical experience
  - 2021 - All risk groups, > 275,000 commercial TAVRs

- Evolve data elements to evolving data needs→ ↑ efficiency, ↑data quality

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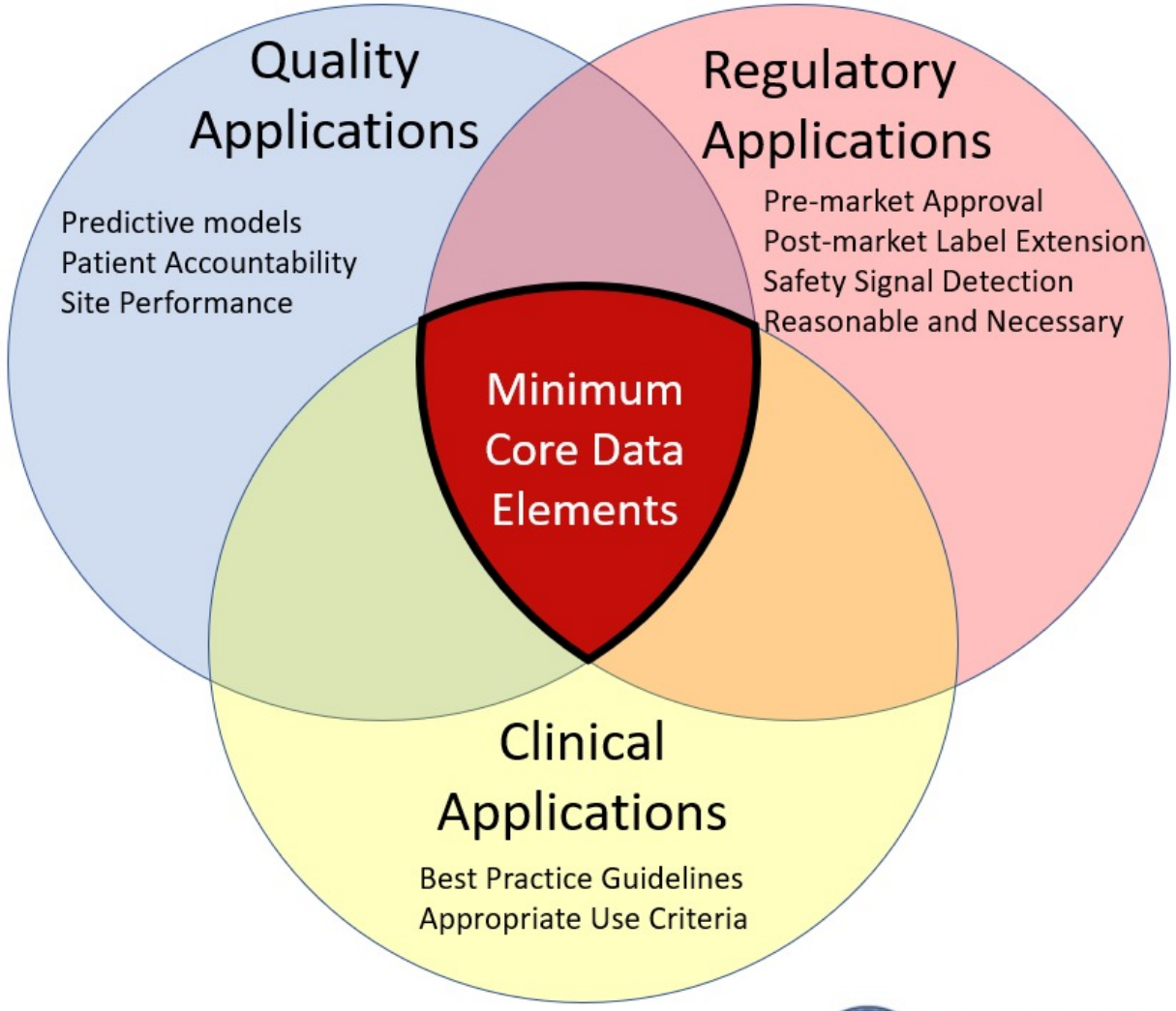
Core Minimum Dataset Concept

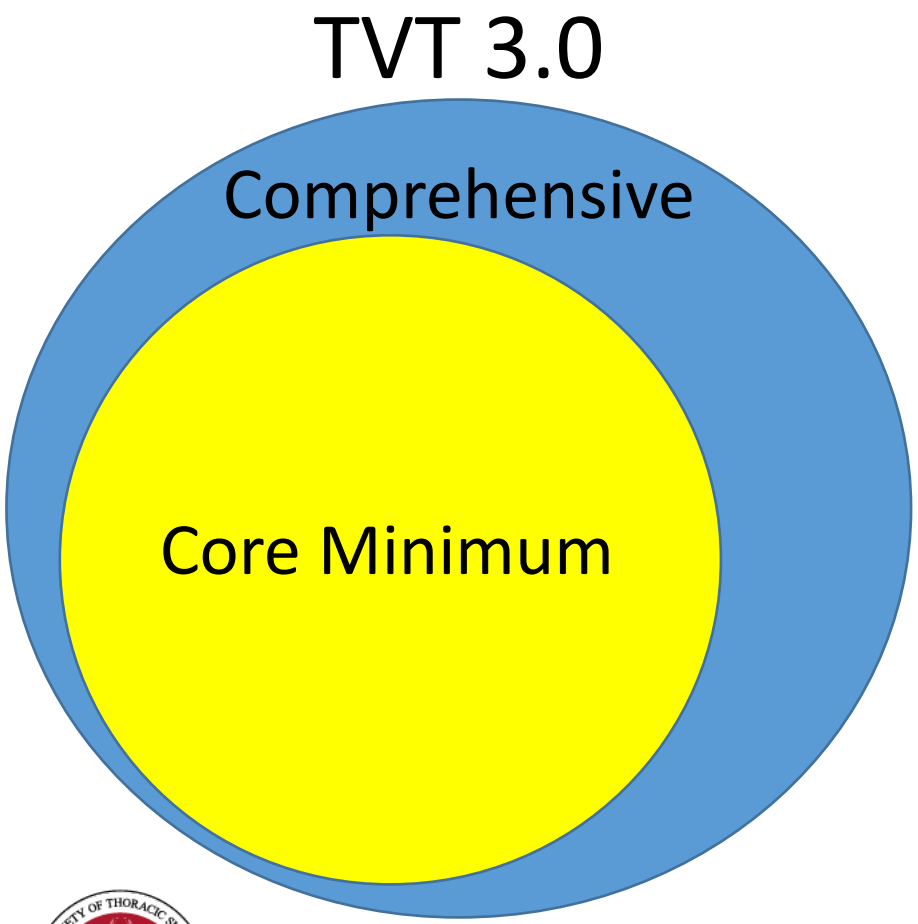
Define a core minimum dataset of essential, interoperable, re-usable data elements through unanimous consensus process

Minimum core dataset will likely require additional, more specialized modules fit for purpose to fulfill each domain

Core Minimum Dataset Applications to Evidence



Goal Data Collection State



TVT TAVR 3.0 Module

Core Minimum Dataset Pathway

Comprehensive Dataset Pathway

Minimum Core Dataset Contributors

NEST PASSION/HVC	
Name	Affiliation
Ori Ben-Yehuda, M.D.	Cardiovascular Research Foundation
Sreekanth Vemulapalli, M.D.	Duke Clinical Research Institute
Maria Alu, M.S.	Cardiovascular Research Foundation
Björn Redfors, M.D., Ph.D.	Cardiovascular Research Foundation
Flavien Vincent, M.D., Ph.D.	Cardiovascular Research Foundation
Bahira Shahim, M.D., Ph.D.	Cardiovascular Research Foundation
Matheus Simonato, M.D.	Cardiovascular Research Foundation
Mitch Krucoff, M.D.	Duke Clinical Research Institute
Changfu Wu PhD	FDA
Ted Feldman MD	Edwards Lifesciences
Kartik Sundareswaren	Abbott
Michael Mack MD	HVC
Marty Leon MD	HVC / CRF

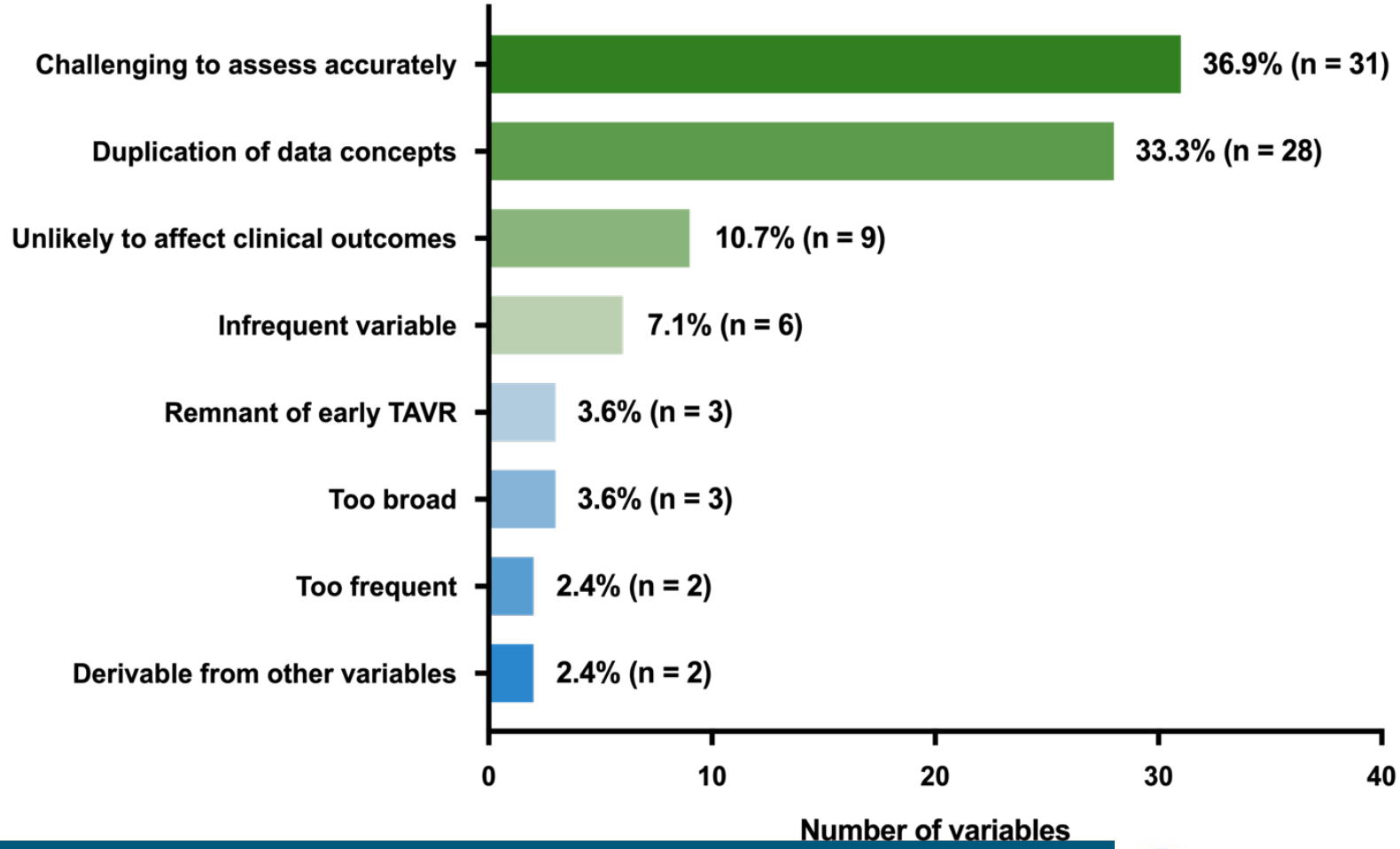
STS/ACC TVT Registry Committee	
Name	Affiliation
John Carroll, MD	University of Colorado, TVTR Co-Chair
Vinod Thourani, MD	Piedmont Heart and Vascular Institute, TVTR Co-Chair
Sreekanth Vemulapalli, MD	Duke Clinical Research Institute
Kim Guibone, DNP, ACNP-BC, FACC	Beth Israel Deaconess Medical Center
Karen Hardy	Catholic Health
Carole Krohn	Society of Thoracic Surgeons
Joan Michaels	American College of Cardiology
Susan Fitzgerald	American College of Cardiology
Bill Seward	Society of Thoracic Surgeons
Barb Christensen	American College of Cardiology

Inclusion / non-inclusion in minimum core

Reasons for Inclusion

- Quality assessment
  - 30-day composite
  - Risk-adjustment
- CMS NCD
  - KCCQ
- FDA Reporting

Reasons for Non-Inclusion



Summary of Minimum Core Elements

- Minimum Core Represent 61% of previous TVT Aortic Data Elements
- 132 total data elements
  - 45 baseline demographic / comorbidity elements
  - 16 baseline laboratory tests / imaging tests
  - 11 procedural elements
  - 48 follow-up outcomes
  - 12 follow-up laboratory / imaging tests
- 84 Comprehensive data elements

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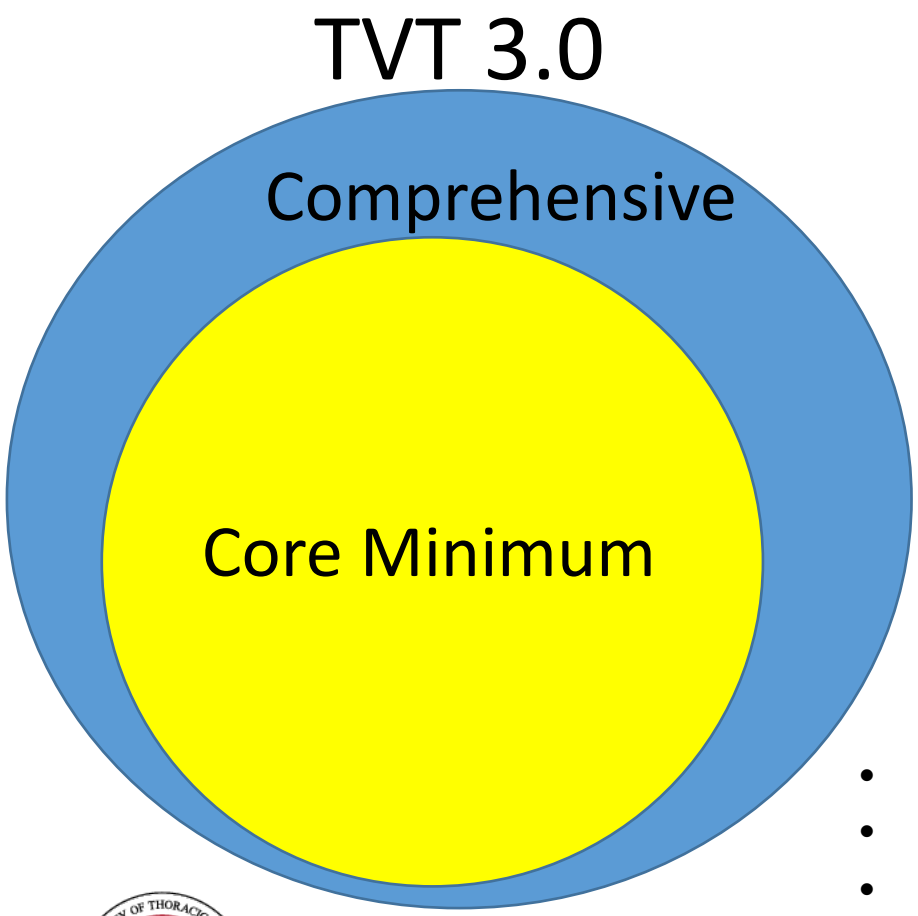
Goal Data Collection State



TVT TAVR 3.0 Module

Core Minimum Dataset Pathway

Comprehensive Dataset Pathway

- Hospital Quality Feedback / Risk Models
- Fulfillment of CMS NCD
- Post-market Device Reporting (FDA)

- Future Appropriate Use Criteria
- Regional and other Quality Initiatives
- How a Regional Collaborative of Hospitals and Physicians in Michigan Cut Costs and Improved the Quality of Care. Health Affairs. 2011

Summary: Minimum Core Dataset

- Reduce data collection burden without compromising the important and unique uses of the data and analytics from the STS-ACC TVT Registry
- Evolve data collection efforts with evolution in TAVR
- The Minimum Core Dataset is a Living Entity and Will Need to Evolve Further in the Future as TAVR Evolves.

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In Response to Your Feedback: Future Minimum Core Data Element Efforts

- Mitral
  - Actively evolving
    - Evolving landscape of approved devices
    - Evolving indications / populations

- Tricuspid
  - No approved devices
  - Data collection will need to be broader to assess quality due to lack of experience / knowledge

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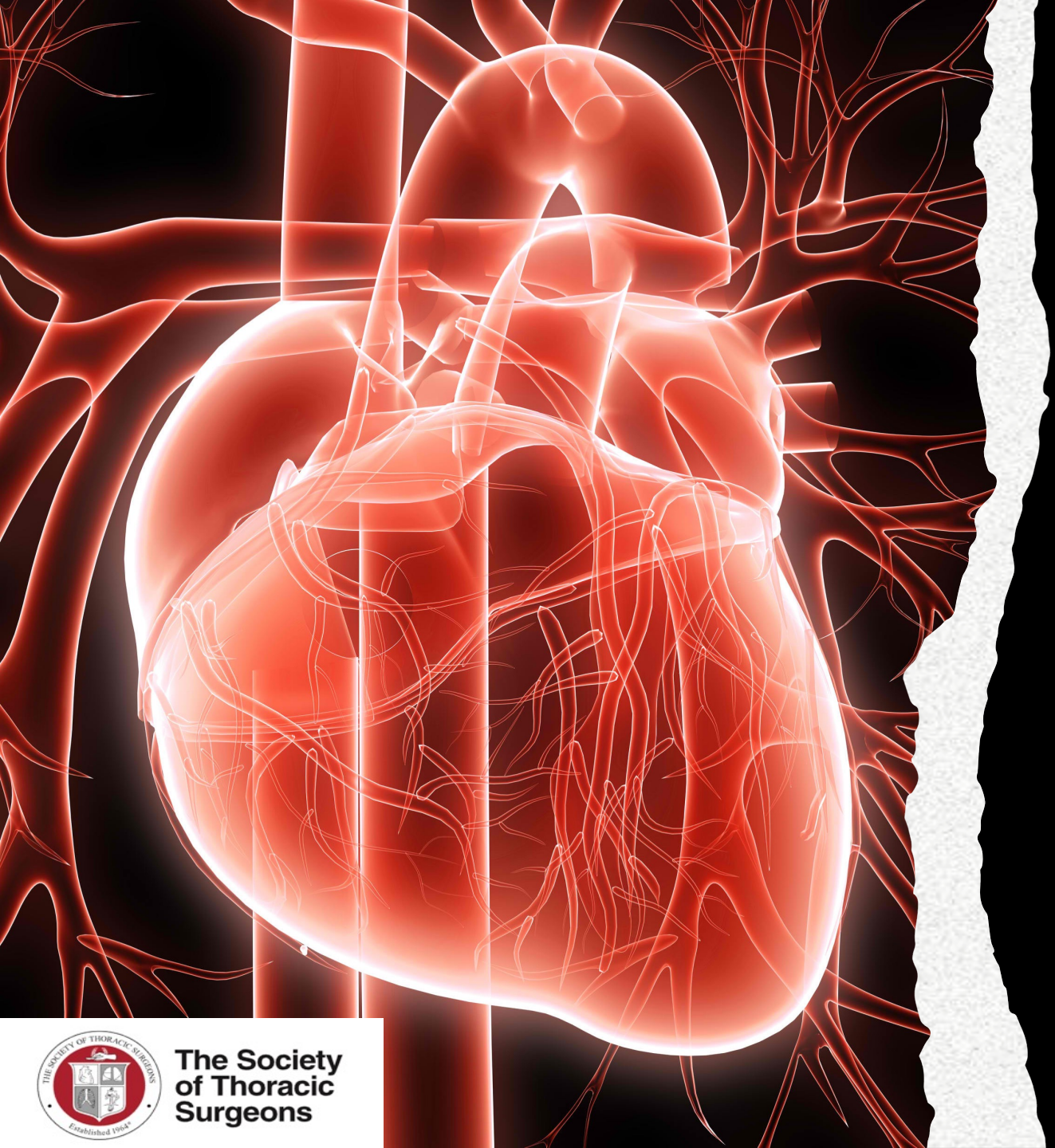

Mitral National Coverage Determination

Dr. Michael Mack

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Disclaimer

- I do not work for CMS!
- I am not an expert in health policy!

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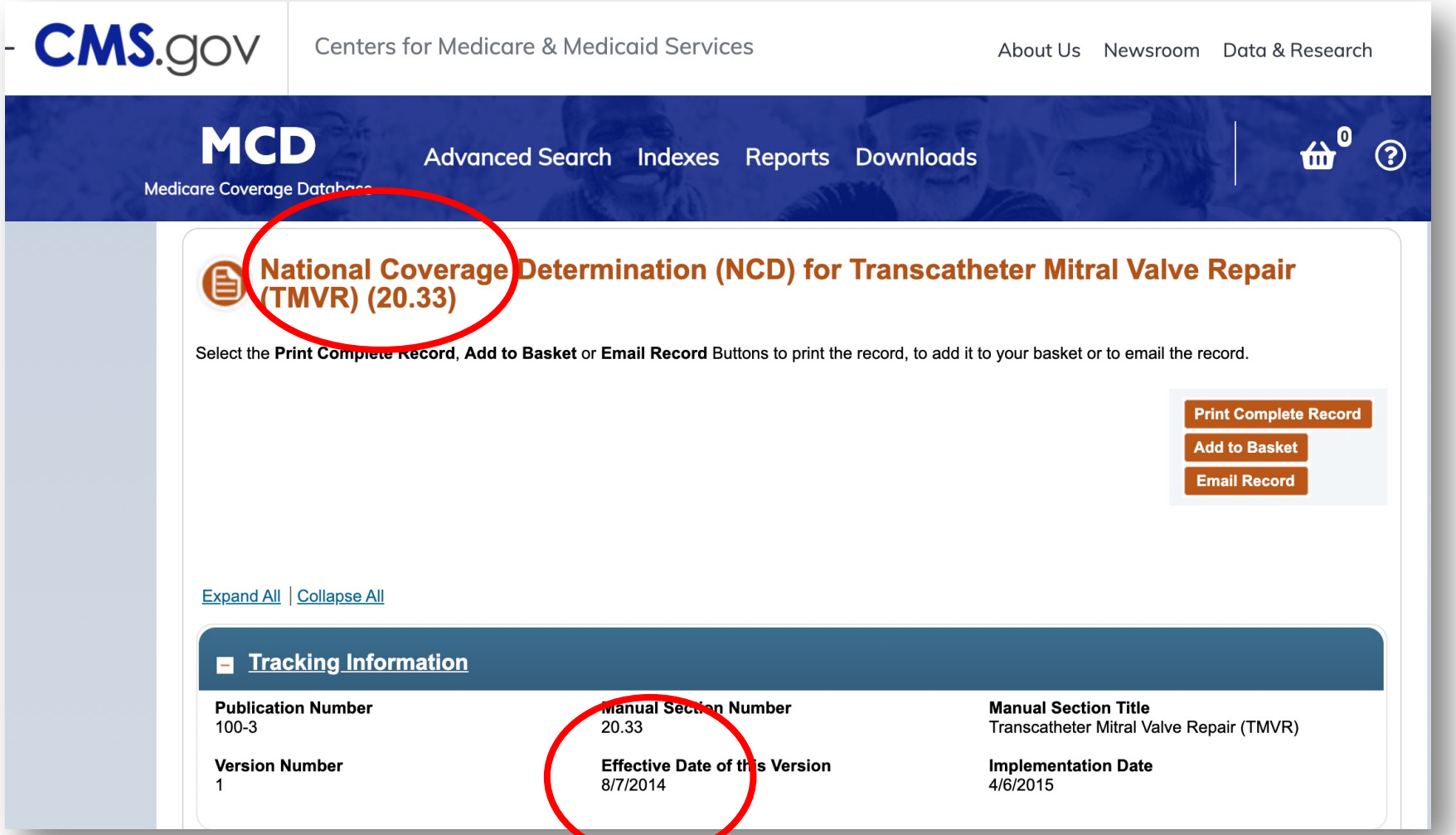
National Coverage Determination (vs. LCD)

- What does that mean?
- Procedure is approved without obtaining approval from local MAC

TMVR NCD-2014



TMVR NCD-2014

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers TMVR for MR under Coverage with Evidence Development (CED) with the following conditions:

A. Treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication and when all of the following conditions are met:

C. Nationally Non-Covered Indications

TMVR is non-covered for the treatment of MR when not furnished under CED according to the above-noted criteria. TMVR used for the treatment of any non-MR indications are non-covered.

FDA-approved Indication
High or prohibitive risk DMR

TMVR NCD-2014

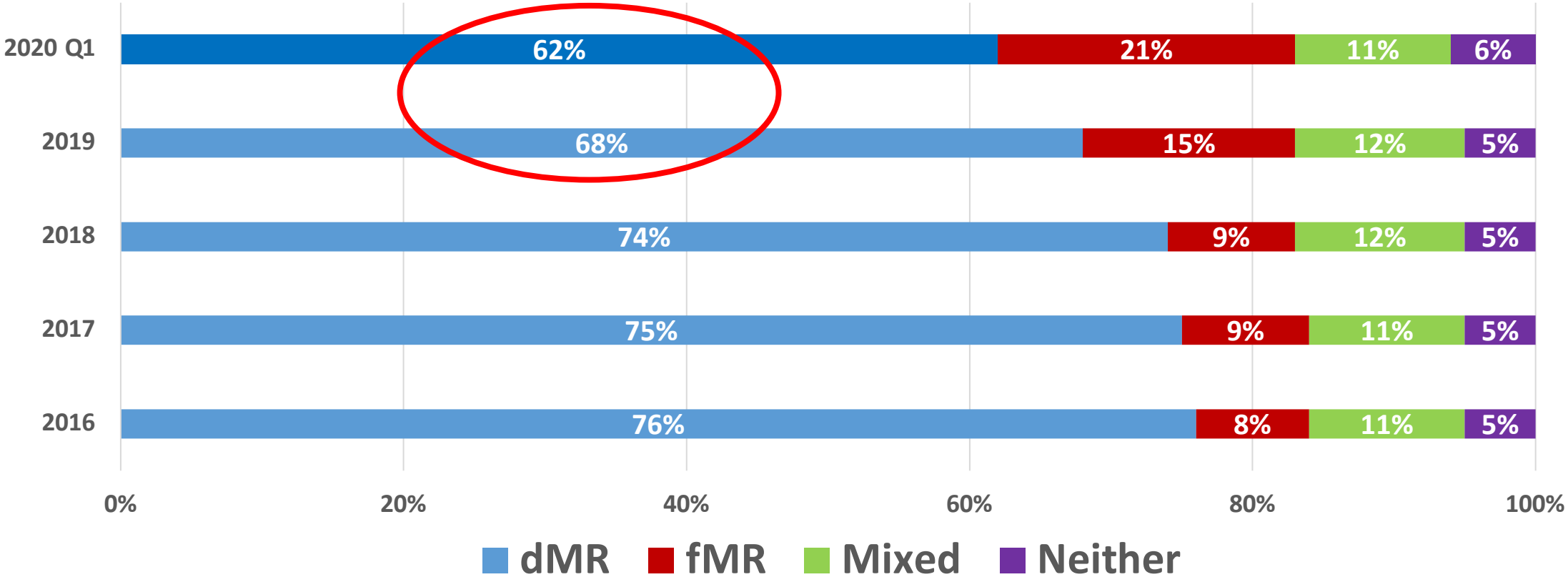
There are institutional and operator requirements for performing TMVR. The hospital must have the following:

a. A surgical program that performs ≥ 25 total mitral valve surgical procedures for severe MR per year of which at least 10 must be mitral valve repairs;
b. An interventional cardiology program that performs ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year, with acceptable outcomes for conventional procedures compared to National Cardiovascular Data Registry (NCDR) benchmarks;
c. The heart team must include:

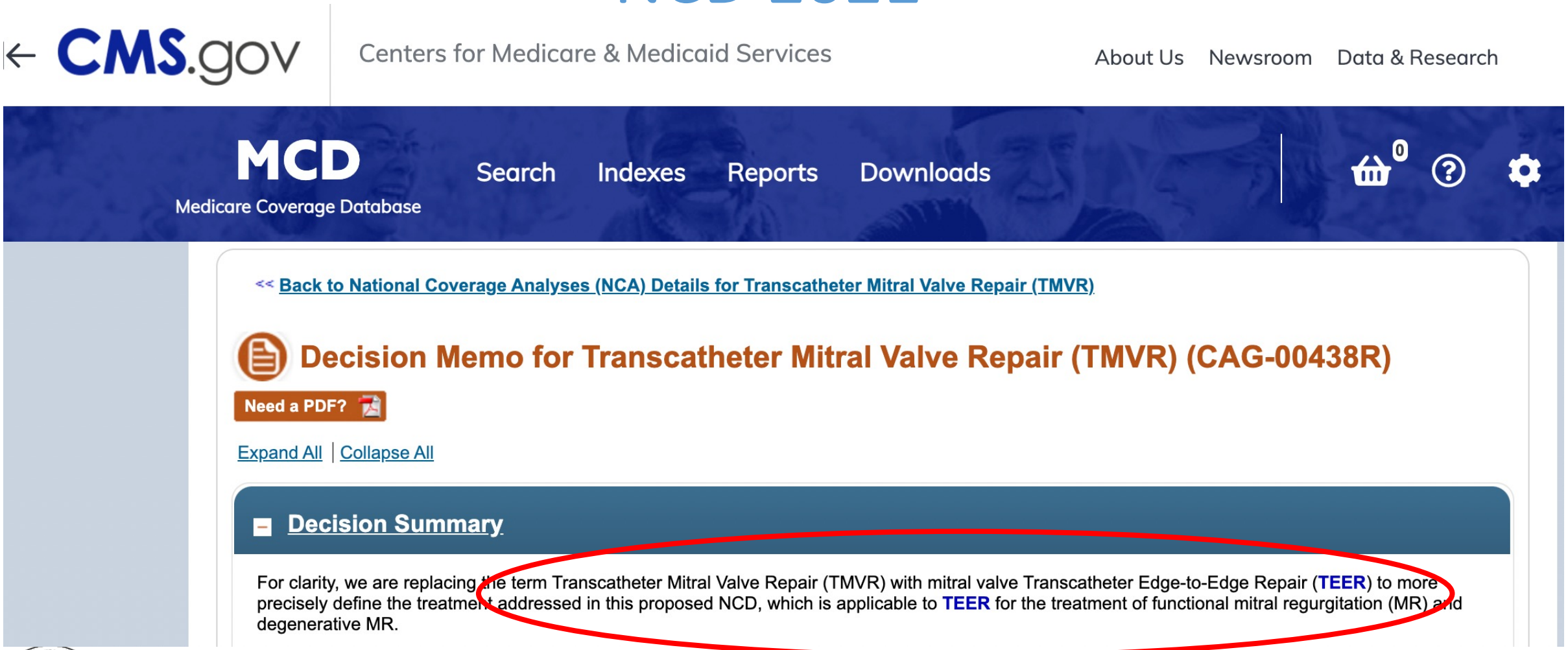
    1. An interventional cardiologist(s) who:
        - performs ≥ 50 structural procedures per year including atrial septal defects (ASD), patent foramen ovale (PFO) and trans-septal punctures; and,
        - must receive prior suitable training on the devices to be used; and,
        - must be board-certified in interventional cardiology or board-certified/eligible in pediatric cardiology or similar boards from outside the United States;
    2. Additional members of the heart team, including: cardiac echocardiographers, other cardiac imaging specialists, heart valve and heart failure specialists, electrophysiologists, cardiac anesthesiologists, intensivists, nurses, nurse practitioners, physician assistants, data/research coordinators, and a dedicated administrator;

d. All cases must be submitted to a single national database;
e. Ongoing continuing medical education (or the nursing/technologist equivalent) of 10 hours per year of relevant material;
f. The cardiothoracic surgeon(s) must be board-certified in thoracic surgery or similar foreign equivalent.

TEER- TVT Registry
MR Etiology



NCD 2021



January 19, 2021

TEER NCD

TEER of the mitral valve is covered under Coverage with Evidence Development (CED) as follows:

A. For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication and when all of the following conditions are met:

1. The procedure is furnished with a mitral valve **TEER** system that has received FDA premarket approval (PMA).

7. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions. Specifically, for the CED question d, this must be addressed through a composite metric. For the below CED questions (a-e), the results must be reported publicly as described in CED criterion k.

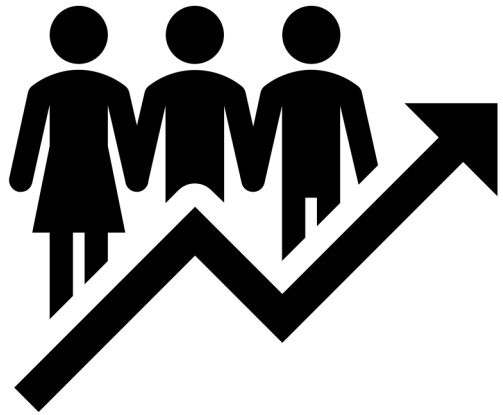
   a. When **TEER** procedures are performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
   b. How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
   c. What is the long-term (≥ 5 year) durability of the device?
   d. What are the long-term (≥ 5 year) outcomes and adverse events?
   e. How do the demographics of registry patients compare to the pivotal studies?

Summary

- FMR is now covered in an NCD
- CED (registry participation) is a requirement for coverage
- TMVR is now called **TEER**

Public Reporting

Dr. David Shahian



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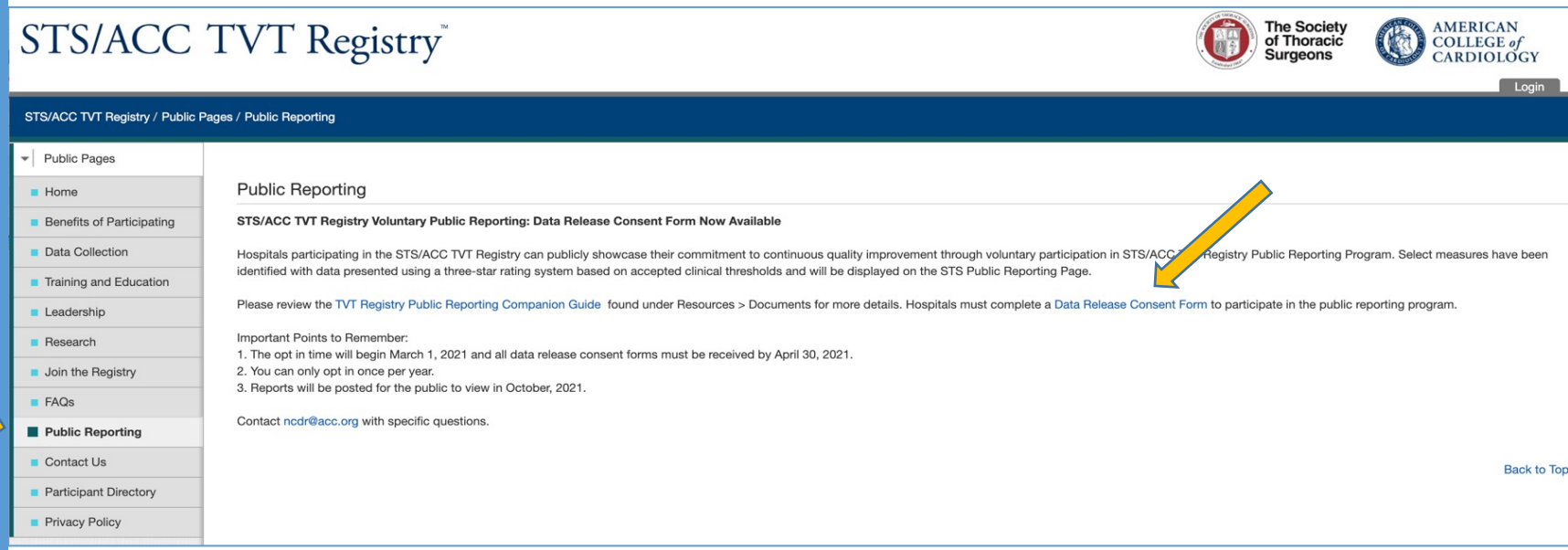
TVT Public Reporting: Current Status

- **Consenting opened on March 1, will close on April 30**
  - Sites may only consent during consenting period
    - Surgeon and Cardiologist will need to sign (e-sign is ok)
  - Consents extend indefinitely, unless revoked
  - May revoke at any time
  - Will need to reconsent if previously revoked



https://www.ncdr.com/WebNCDR/tvt/publicpage/public-reporting

TVT Public Reporting: What's Next

- Public website will be available to the public in late summer/early Fall
  - Housed on the STS Public Reporting Page
  - Links from NCDR Portal – TVT Public Reporting tab

https://publicreporting.sts.org/

TVT Public Reporting: Reporting Criteria

- Inclusion Criteria
  - Registry participation for 3-years
    - Your site must have had submitted a case to the TVT Registry prior to first date in the reporting period.
      - For example: The first reporting period will include data from October 1, 2017 to September 30, 2020. **Your site must have submitted a case prior to October 1, 2017.**
  - 60 Cases
    - Your site must have performed 60 or more TAVRs within the 36-month reporting timeframe
  - 90% or greater completeness:
    - Baseline KCCQ
    - Baseline 5-meter walk
    - Event Status/30-Day Follow-up (Mortality Status)
  - Green or Yellow 'Data Quality Report' data submission status
- Sites not meeting the 36-month time requirement, or 60 case requirement will still be able to publicly report volumes
- Sites not meeting the 90% completeness requirements or data quality submission requirements will not be able to publicly report
- Excludes patients enrolled in TVT registry-sponsored research studies

TVT Public Reporting: Reporting Metrics

- Reporting Metrics
  - Date of first TAVR performed
  - Cumulative volume since program inception
  - Average annual volume for reporting period
  - Reporting period (i.e., October 1, 2017 – September 30, 2020)
  - Number of eligible procedures for reporting period
  - TAVR 30-Day Composite Score
    - Your site's score
    - Range of achieved scores for the cohort
  - TAVR 30-Day Composite Rating
    - 1, 2, or 3 stars

Landing page

- Listing of all sites who have consented and meet reporting requirements

- Site meeting all inclusion criteria

STS/ACC TVT Public Reporting

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TVT Registry | Rating Explanations | ACC Resources | STS Resources

Search Site

General Hospital

City, State

Date of first TAVR procedure performed: MM/YYYY

TAVR Total Commercial Volume

Cumulative volume since program inception: #,###

Average annual volume for reporting period: #,###

30-Day Risk Adjusted TAVR Composite[1,2,3]

Reporting period: DD/MM/YYYY - DD/MM/YYYY

Eligible procedures in reporting period: #,###

TAVR 30-Day Composite Score* **#.##** (#.## to #.##)

TAVR 30-Day Composite Rating* ★★☆ As Expected

---

*Please view Ratings Explanation for detailed calculation and site rating information.

1. **30-Day Risk Adjusted TAVR 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 moderate to severe paravalvular leak
    6. None of the above
2. The TAVR 30-day mortality/morbidity composite score is reported as a "win difference" where:
    >0 implies "My Hospital" has better than expected performance, and
    <0 implies "My Hospital" has worse than expected performance
3. Missing value (-) indicates that the hospital does not meet eligibility criteria for reporting

Site meeting all inclusion criteria, except first case requirement

or

60 minimum cases

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TVT Registry | Rating Explanations | ACC Resources | STS Resources

Search Site

General Hospital

City, State

Date of first TAVR procedure performed: MM/YYYY

TAVR Total Commercial Volume

Cumulative volume since program inception: #,###

Average annual volume for reporting period: NA - Site did not meet three-year reporting period requirements.

30-Day Risk Adjusted TAVR Composite[1,2,3]

Reporting period: DD/MM/YYYY - DD/MM/YYYY

Eligible procedures in reporting period: NA - Site did not meet three-year reporting period requirements.

TAVR 30-Day Composite Score* NA - Site did not meet three-year reporting period requirements.

TAVR 30-Day Composite Rating* NA - Site did not meet three-year reporting period requirements.

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*Please view Ratings Explanation for detailed calculation and site rating information.

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

PLEASE USE THE Q&A FUNCTION/RAISE-HAND FUNCTION.

WE WILL ANSWER AS MANY QUESTIONS AS POSSIBLE.

WE ENCOURAGE YOUR FEEDBACK AND WANT TO HEAR FROM YOU!