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Cardiovascular, Spring 2021 Cycle: CDP Report

TECHNICAL REPORT
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Contents

Executive Summary

Heart disease is a significant burden in the United States (U.S.), leading to approximately 1 in 4 deaths per year.[1] In addition to being the leading cause of death in the U.S., heart disease is the highest direct health expenditure in the U.S.[2] Considering the effect of cardiovascular disease (CVD), measures that assess clinical care performance and patient outcomes are critical to reducing its negative impact.

During the spring 2021 project cycle, the Cardiovascular Standing Committee evaluated two new measures undergoing review against the National Quality Forum's (NQF) standard evaluation criteria. The Standing Committee recommended both measures for endorsement, and the Consensus Standards Approval Committee (CSAC) upheld the Standing Committee's recommendation. The endorsed measures are as listed below:

- **NQF #3610** 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR) (American College of Cardiology [ACC])
- **NQF #3613e** Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) (Centers for Medicare & Medicaid Services [CMS]/Yale Center for Outcomes Research & Evaluation [Yale CORE])

Brief summaries of the measures are included in the body of the report; detailed summaries of the Standing Committee's discussions and ratings of the criteria for these measures are in Appendix A.

Introduction

CVD is the leading cause of death in the U.S., significantly impacting most ethnic and racial groups.[1] In 2016–2017, heart disease accounted for 13 percent of healthcare expenditures and was responsible for approximately $363 billion of accrued cost annually to the U.S. healthcare system (direct costs [i.e., cost of physicians and other professionals, hospital services, prescribed medications, and home healthcare] and indirect costs [i.e., lost productivity]).[2] The American Heart Association (AHA) projects that the direct costs of heart disease will continue to increase through 2035 for patients ages 45 and older.[3]

NQF works closely with partners, stakeholders, and members to evaluate and endorse measures that assess clinical care performance and patient outcomes and reduce CVD's negative impacts on patients and healthcare systems. Measures within the NQF portfolio address primary prevention and screening, coronary artery disease (CAD), ischemic vascular disease (IVD), acute myocardial infarction (AMI), cardiac catheterization, percutaneous catheterization intervention (PCI), heart failure (HF), rhythm disorders, implantable cardioverter-defibrillators (ICDs), cardiac imaging, cardiac rehabilitation, and high blood pressure.

The Cardiovascular Standing Committee reviewed two new measures for endorsement consideration during this project cycle. The first measure, NQF #3610 *30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)*, estimates hospital risk-standardized site differences for five endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, and moderate or severe paravalvular aortic regurgitation) within 30 days following transcatheter aortic valve replacement (TAVR) using the Society of Thoracic Surgeons (STS)/American College of Cardiology's (ACC) Transcatheter Valve Therapy (TVT) Registry. The second measure, NQF #3613e *Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)*, looks at the percentage of emergency department (ED) patients with a diagnosis of ST-segment elevation myocardial infarction (STEMI) who received appropriate and timely treatment using electronic health record (EHR) data.

NQF Portfolio of Performance Measures for Cardiovascular Conditions

The Cardiovascular Standing Committee (Appendix C) oversees NQF's portfolio of Cardiovascular measures (Appendix B), which includes measures for AMI, PCI, IVD, HF, hypertension, rhythm disorders, and valvular heart disease. This portfolio contains 35 endorsed measures: 17 process measures, 13 outcome and resource use measures, and five composite measures.

Additional measures have been assigned to other portfolios. These include readmissions measures for AMI and HF (All-Cause Admissions and Readmissions), measures for coronary artery bypass graft (CABG) (Surgery), and measures for primary prevention of cardiovascular diseases (Prevention and Population Health).

Cardiovascular Measure Evaluation

On July 28, 2021, the Cardiovascular Standing Committee evaluated two new measures against NQF's standard measure evaluation criteria.

Table 1. Cardiovascular Measure Evaluation Summary

Measure Summary	Maintenance	New	Total
Measures under review	0	2	2
Endorsed measures	0	2	2

Comments Received Prior to Standing Committee Evaluation

NQF accepts comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 29, 2021, and the pre-meeting commenting closed on June 10, 2021. As of June 10, 2021, no comments have been submitted and shared with the Standing Committee prior to the measure evaluation meeting (Appendix F).

Comments Received After Standing Committee Evaluation

The continuous 16-week public commenting period with NQF member support closed on August 27, 2021. Following the Standing Committee's evaluation of the measures under review, no public or member comments were received pertaining to the draft report and to the measures under review (Appendix G).

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for each measure to inform the Standing Committee's recommendations during the commenting period. This expression of support (or not) during the commenting period replaces the member voting opportunity that was previously held after the Standing Committee's deliberations. NQF did not receive any expressions of support for the measures under endorsement consideration for the current cycle.

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Standing Committee considered. Details of the Standing Committee's discussion and ratings of the criteria for each measure can be found in Appendix A.

NQF #3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR) (ACC): Endorsed

Description: 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. This measure estimates hospital risk standardized site difference for 5 endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation) within 30 days following transcatheter aortic valve replacement. The measure uses clinical data available in the STS/ACC TVT Registry for risk adjustment for the purposes of benchmarking site to site performance on a rolling 3-year timeframe; **Measure Type**: Composite; **Level of Analysis**: Facility; **Setting of Care**: Inpatient/Hospital; **Data Source**: Registry Data

This new composite measure estimates the hospital risk-standardized site difference for five endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, and moderate or severe paravalvular aortic regurgitation) within 30 days following TAVR. The developer provided a general overview and description of the measure. The developer indicated a goal during development: respond to the Centers for Medicare & Medicaid Services' (CMS) interest regarding a 2019 coverage decision in which CMS was interested in a periprocedural composite metric that incorporated relevant patient health outcomes and might eventually replace the volume threshold in Coverage with Evidence Development (CED) for TAVR reimbursement.

The Standing Committee sought clarification as to why pacemaker was not included in the composite as one of the endpoints. The developer noted that it decided which complications to include by examining their correlation with Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, which indicate a patient's quality of life. The developer then ranked the complications by correlation and included the five with the highest correlation. Pacemaker was much lower on the list than the five indicated endpoints. A Standing Committee member made an argument for outcomes-based measures and cautioned that variability will not be as large as that which is seen in process measures, especially for a risk-standardized composite score. This Standing Committee member also noted that monitoring performance over time will be necessary to see whether the changes in the measure are meaningful because the distribution is tight. The Standing Committee questioned why the developer would not simply use the KCCQ score directly as the outcome of interest for the measure. The developer noted the challenge of combining hard outcomes, such as mortality, with quality-of-life scores, such as patient experience. The measure is meant to be interpretable for sites. The developer also had doubts about whether meaningful change would occur in the KCCQ in a 30-day measure and that six months or a year might be necessary to see meaningful change.

On March 30–31, 2021, the Scientific Methods Panel (SMP) reviewed the measure and did not have any substantial concerns regarding the scientific acceptability of this measure. The SMP rated reliability, validity, and composite quality construct as moderate. The Standing Committee reviewed the SMP's recommendations and had no concerns regarding reliability or validity. A Standing Committee member raised a concern about the composite construction and stated that sites may have a difficult time translating their score to clinical gaps due to the hierarchal construct of the different complications. The developer noted that it will include the individual component rates in its report to sites. The developer also indicated that the outcome reports have 40 detail lines, including patient drill downs. The Standing Committee asked about how the developer ensures the risk model remains well calibrated. The developer indicated that the risk model is re-estimated with each new harvest of data, which keeps it well calibrated.

The Standing Committee had no concerns with the feasibility of the measure. These data are part of routine reporting into the STS/ACC TVT Registry as a condition of CMS' coverage. The Standing Committee had no concerns regarding use or usability.

NQF #3610 has one related measure: NQF #3534 *30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR) (ACC)*. The developer indicated the two measures are closely aligned. NQF #3610 is a composite measure, and NQF #3534 is an outcome

measure of mortality. A Standing Committee member inquired whether mortality would still be reported separately on the planned website since there is no harder endpoint than mortality. This Standing Committee member also noted that at times, composite measures with softer endpoints end up overwhelming mortality. The developer indicated that the planned public reporting would only include the risk-standardized score for the overall composite. The developer felt that the public needed to be able to digest the data and that one score was clearer than the other. The same Standing Committee member further noted that from a usability standpoint, sites would need to know how they compare on components to know how to address improvements. The developer clarified that the sites would see all endpoints on their outcomes report.

Quorum was not reached during the evaluation meeting, and the Standing Committee voted using an online voting tool after the meeting ended. The measure passed on all criteria and overall suitability for endorsement. Since the measure was recommended for endorsement and no comments were received, the post-comment meeting was canceled. During the CSAC meeting on November 30, 2021, the CSAC upheld the Standing Committee's recommendation and endorsed the measure. No appeals were received.

NQF #3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) (CMS/ Yale CORE Endorsed

Description: The percentage of ED patients with a diagnosis of STEMI who received appropriate and timely treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level in a CMS accountability program, through which it may be publicly reported. **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Outpatient Services; **Data Source**: Electronic Health Records

This new electronic clinical quality measure (eCQM) assesses whether patients with STEMI in the ED receive timely, guideline-indicated reperfusion care that is appropriate for the treatment setting. The developer was unable to attend the meeting; therefore, it provided a written introduction to the measure, which Ms. Amy Moyer, former NQF senior director, read to the Standing Committee. In the written introduction, the developer indicated that CMS developed this measure for use in the Hospital Outpatient Quality Reporting (OQR) Program. The measure captures the timeliness of the three main approaches to reperfusion in STEMI patients (onsite percutaneous coronary intervention [PCI], transfer to a PCI-capable facility, and fibrinolytics) in one measure.

The lead discussant noted that the measure is supported by two guidelines: AHA and ACC Foundation (ACCF) STEMI guidelines from 2013 and the Emergency Department Management of Patients Needing Reperfusion Therapy for Acute ST-Segment Elevation Myocardial Infarction guideline released in 2017 by the American College of Emergency Physicians (ACEP). The Standing Committee had no concerns with the evidence. The lead discussant moved forward to discuss performance gap. Since this is a new measure that has not been fully implemented, performance score data were not available to assess the gap. The developer shared gap information from the literature and similar measures. The information shared demonstrated significant variability in the capability of the EDs to perform reperfusion in a timely manner. The Standing Committee noted that the information shared indicated disparities by patient gender, race, and ethnicity, and by facility rural status. Standing Committee members highlighted the

importance of stratifying results on this measure when performance results are available. A Standing Committee member noted that an advantage of this measure is the availability of race, ethnicity, and language data in the clinical record while also noting the importance of finding opportunities for improvement. A Standing Committee member asked for clarification on how to evaluate performance gap when scores are not available, and Ms. Moyer explained that using information from the literature on new measures is appropriate for new measures that have not yet been implemented.

The lead discussant moved on to scientific acceptability, noting that the developer had submitted data-element validity testing to satisfy both reliability and validity. The developer looked at data-element validity at two different hospital systems, with two different EHR systems. Standing Committee members noted that the kappa coefficients for the denominator agreement were fairly low and questioned whether this reflected a failure of the systems or a failure of the measure. They reasoned that the low agreement could reflect a system failure to diagnose and capture the relevant patient population. Standing Committee members agreed that systems need to improve data capture and performance and that all facilities should be able to achieve high performance on the measure. The Standing Committee discussed the challenge of implementing eCQMs when the data quality may not be ideal. The Standing Committee agreed that implementing the measures will provide an incentive to improve the data quality but that improvement may not occur in the absence of this incentive.

The Standing Committee questioned the feasibility of capturing door-to-balloon times, citing interoperability concerns. Frequently, the ED and catheterization lab use different software platforms. Standing Committee members stressed the importance of timely treatment and that accurately capturing door-to-balloon time is critical to assessing care quality. They stated that issues identified while implementing the measure will prompt systems to fix any data issues. The Standing Committee felt that systems would identify workflow and data issues while implementing the measure and that fixing these issues would improve documentation and patient care.

The Standing Committee had no concerns with the use criterion, given the measure's intended use in a federal program. Standing Committee members raised questions about the usability of the measure, specifically whether facilities would be able to see detailed results. Chris Millet, a consultant who works with NQF to evaluate eCQMs, clarified that the intent with using eCQMs is for systems to calculate the measure within their own systems, giving them full access to all results and data.

Lastly, the Standing Committee discussed overall suitability for endorsement and revisited the earlier discussion of existing data quality and interoperability. Standing Committee members noted that eCQMs are an important step forward in measurement and that performance measurement could not continue to set a low bar due to feasibility concerns. Standing Committee members also noted that this measure captures information about processes that are key to patient outcomes and that the results are easy to understand. They highlighted the need to push for improved data and interoperability and to overcome implementation issues with eCQMs. Mr. Millet noted that the implementation challenges being discussed are not unique to this measure and that more interoperability and application-program interfaces (APIs) will facilitate more electronic measurement. The Standing Committee agreed with the need for more APIs and electronic measurement.

NQF #3613e has two related measures: NQF #0290 *Median Time to Transfer to Another Facility for Acute Coronary Intervention* and NQF #2377 *Overall Defect-Free Care for AMI*. The Standing Committee noted that the measures capture different information and did not voice any concerns with burden or confusion.

Quorum was not reached during the evaluation meeting, and the Standing Committee voted using an online voting tool after the meeting ended. The measure passed on all criteria and overall suitability for endorsement. Since the measure was recommended for endorsement and no comments were received, the post-comment meeting was canceled. During the CSAC meeting on November 30, 2021, the CSAC upheld the Standing Committee's recommendation and endorsed the measure. No appeals were received.

References

1 Centers for Disease Control and Prevention (CDC). Heart Disease Facts | cdc.gov. Centers for Disease Control and Prevention. https://www.cdc.gov/heartdisease/facts.htm. Published September 27, 2021. Last accessed October 2021.

2 Virani S, Alonso A, Aparicio H, et al. *Heart Disease and Stroke Statistics—2021 Update | Circulation*. https://www.ahajournals.org/doi/10.1161/CIR.0000000000000950. Last accessed October 2021.

3 Virani S, Alonso A, Benjamin EJ, et al. Heart Disease and Stroke Statistics-2020 Update: A Report From the American Heart Association. *Circulation*. 2020;141(9):e139-e596.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable; **Y**=Yes; **N**=No

Vote totals may differ between measure criteria and between measures as Standing Committee members often have to join calls late or leave calls early. All voting outcomes are calculated using the number of Standing Committee members present during the meeting for that vote as the denominator. Denominator vote counts may vary throughout the criteria due to intermittent Standing Committee attendance fluctuation. The vote totals reflect members present and eligible to vote at the time of the vote. If quorum is not achieved or maintained during the meeting, the Standing Committee receives a recording of the meeting and a link to submit online votes. During the measure evaluation meeting, quorum for voting was not achieved. Therefore, the Standing Committee discussed all relevant criteria and voted after the meeting using an online voting tool.

Endorsed Measures

NQF #3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Measure Worksheet | Specifications

Description: 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. This measure estimates hospital risk standardized site difference for 5 endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation) within 30 days following transcatheter aortic valve replacement. The measure uses clinical data available in the STS/ACC TVT Registry for risk adjustment for the purposes of benchmarking site to site performance on a rolling 3-year timeframe.

Numerator Statement: A composite outcome including all-cause death, stroke, major or life-threatening bleeding, acute kidney injury, and moderate or severe paravalvular aortic regurgitation within 30 days following transcatheter aortic valve replacement (TAVR)

If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

Denominator Statement: Patients who had TAVR

Exclusions: Hospitals are excluded if they do not meet eligibility criteria noted in S.7.

Patients are excluded if any of the following occur:

1) They did not have a first-time TAVR in the episode of care (admission).
2) The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.
3) The patient is readmitted for a repeat TAVR (re-admission), and the initial TAVR was performed during the rolling three-year time frame for the measure.
4) They are in TVT Registry-sponsored research studies (identified with research study=yes and research study device used during procedure).

Adjustment/Stratification: Statistical risk model; In theory, estimates of provider-specific performance within specific disadvantaged patient populations (e.g., by race, ethnicity) could be generated by applying the measure's modeling methodology to an analysis cohort that is restricted to members of the population of interest. As a practical matter, the number of patients per provider that belong to such populations may be too small to permit a meaningful comparison of performance across providers for these groups. Outcome disparities by race and ethnicity could potentially be assessed by including race and ethnicity in the risk adjustment model and reporting their odds ratios.

Level of Analysis: Facility

Setting of Care: Inpatient/Hospital

Type of Measure: Composite
Data Source: Registry Data
Measure Steward: American College of Cardiology (ACC)
STANDING COMMITTEE MEETING 07/28/2021

1. **Importance to Measure and Report: The measure meets the Importance criteria.**
   (1a. Evidence, 1b. Performance Gap)
   1a. Evidence: **Total votes: 17; Y-17; N-0**; 1b. Performance Gap: **Total votes: 17; H-14; M-2; L-1; I-0;**
   1c. Composite – Quality Construct and Rationale: **Total votes: 17; H-2; M-15; L-0; I-0**

Rationale

- This composite measure, submitted for initial endorsement, estimates hospital risk-standardized site difference for five endpoints: (1) death from all causes, (2) stroke, (3) major or life-threatening bleeding, (4) acute kidney injury, and (5) moderate or severe paravalvular aortic regurgitation (PVL). The developers provided evidence for each outcome demonstrating actions a provider can take to achieve a change in the outcome.
- The developer also noted that the threefold goal of this outcome measure was to benchmark performance for the purpose of quality-of-care monitoring, assist patients in their healthcare choices, and respond to the Centers for Medicare & Medicaid Services' (CMS) guidance.
- The Standing Committee questioned why pacemaker was not included in the composite as one of the five endpoints. The developer explained that it decided which complications to include by examining their correlation with KCCQ scores, which indicate patient quality of life. The developer then ranked the complications by correlation and included the five with the highest correlation. Pacemaker was much lower on the list than the five indicated endpoints.
- The developer provided the distribution of site-specific composite scores based on TAVR operations performed between January 1, 2015, and December 31, 2017, from 52,561 records, from 301 hospitals (data sources is the TAVR registry). The developers reported a mean of 0.004, a standard deviation of 0.037, and an interquartile range (IQR) between -0.02 and 0.02.
- The developer also provided disparities data for individual endpoints by race and ethnicity.
- Some Standing Committee members made an argument for outcomes-based measures and cautioned that variability will not be as large as that which is seen in process measures, especially for a risk-standardized composite score.
- The Standing Committee also noted that monitoring performance over time will be necessary to see whether the changes in the measure are meaningful because the distribution is tight. The Standing Committee questioned why the developer would not simply use the KCCQ score directly as the outcome of interest for the measure.
- The developer explained the challenge of combining hard outcomes, such as mortality, with quality-of-life scores, such as patient experience. The measure is meant to be interpretable for sites.
- The Standing Committee noted that it is yet to be determined how a site would respond to and improve upon an endpoint solely based on the KCCQ score.
- The Standing Committee also raised concerns regarding the clinical consideration with using the KCCQ in a 30-day measure. They questioned whether meaningful change would occur in that period compared to six months or a year.
- Despite the concerns raised, the Standing Committee agreed that this is an important focus area of measurement and observed that the measure still has a performance gap and variation in results with room for improvement.

2. **Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.**
   (2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity)
   2a. Reliability: **Total votes: 17**; **H-0; M-17; L-0; I-0**; 2b. Validity: **Total votes: 17; H-2; M-15; L-0; I-0;**
   2c. Composite Construction: **Total votes 17; H-1; M-16; L-0; I-0**

Rationale

- The SMP reviewed this measure. It did not have any substantial concerns regarding the scientific acceptability of this measure. The SMP rated this measure as moderate for reliability (**Total votes: 8; H-0; M-7; L-1; I-0)** and validity (**Total votes 8; H-3; M-5; L-0; I-0).** A couple of SMP members questioned whether this measure represents a composite measure or a composite outcome and whether the additional complexity of this approach resulted in more precise measurement. The SMP did not have any substantial concerns regarding the scientific acceptability of this measure and passed the measure with moderate rating on composite construction (**Total votes: 8; H-3; M-3; L-1; I-1)**.
- Since voting was conducted after the meeting ended using an online voting tool, the Standing Committee voted on the scientific acceptability criteria rather than accepting the SMP's ratings.
- The developers conducted reliability testing at the measure score level.
    - The developer estimated hospital-specific performance using a hierarchical proportional odds model on 100 sets of simulated data. Then, they calculated the Pearson correlation coefficient between each hospital's calculated estimate and the simulated true value. Reliability was calculated as the average squared Pearson correlation coefficient across the 100 data sets.
    - The overall estimated reliability was 0.64, with a range from 0.65 for hospitals with at least 25 cases (n = 278) to 0.73 for hospitals with at least 200 cases (n = 96). The developer indicated that it will be using a minimum of 60 cases over a three-year period for public reporting.
    - The Standing Committee did not raise additional questions or concerns regarding the reliability of the measure.

- The developers conducted validity testing at the composite measure score and component measure score level.
    - The developer assessed the validity of the composite measure score using a known-group analysis. It divided the facilities into three levels of performance based on the global rank composite (i.e., better than expected, as expected, and worse than expected). Then, it examined the adjusted observed-to-expected (O/E) odds ratios for the individual components for each group. Sites with better-than-expected performance on the global rank composite metric showed lower O/E ratios when compared with sites that performed as expected or worse than expected. Sites that performed worse than expected showed consistently higher O/E ratios than other sites.
    - The developer assessed the validity of the component measure scores using Cox proportional hazards modeling to evaluate the associations of the components with one-year mortality and average change in KCCQ-OS. All four nonfatal complications (components) were found to be associated with increased risk of one-year mortality and patient-reported health status (assessed via KCCQ-OS score). Exclusion of hospitals with more than 10 percent missing data for the global rank endpoint, baseline Kansas City Cardiomyopathy Questionnaire 12 (KCCQ-12), or baseline five-meter walk test resulted in the exclusion of over half of the hospitals in the initial cohort (59,904 out of 114,121). Covariates for case-mix adjustment were pre-selected based on inclusion in the risk model for NQF #3534 (TAVR 30-day mortality). Covariates were retained in the model regardless of their statistical significance. The developer did not collect or analyze any variables that directly measure social risk based on the social risk analysis conducted for NQF #3534.

- The Standing Committee indicated that it might be challenging for sites to translate their score to clinical gaps due to the hierarchal construct of the different complications. The developer noted that it will be reporting to sites that will include the individual component rates in its report to sites. The developer also indicated that the outcome reports have 40 detail lines, including patient drill downs. The Standing Committee asked about the risk stratification strategy for the measure. The developer indicated that the risk model is re-estimated with each new harvest of data, which keeps it well calibrated.
- The developers provided the global ranking endpoint, which is an ordinal categorical variable that has six levels in which the first category represents the worst possible outcome (i.e., death), and the sixth category represents the best possible outcome (i.e., alive and free of major complications). Patients are classified according to the worst outcome (i.e., lowest rank score) that they experience. Endpoints were ranked in order of their decreasing hazard ratios with one-year mortality. The clinical importance of the complications was confirmed by assessing their associations with one-year mortality and one-year KCCQ-OS.
- The Standing Committee did not raise additional questions or concerns regarding the validity of the measure.

3. Feasibility: Total votes: 17; H-4; M-13; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale

- The Standing Committee had no concerns regarding this criterion. The measure uses data that are collected as part of routine reporting into the STS/ACC TVT Registry as a condition of CMS' coverage.

4. Use and Usability

(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Total votes: 17; Pass-17; No Pass-0** 4b. Usability: **Total votes: 17; H-5; M-12; L-0; I-0**

Rationale

- The developer indicated that measure results will be voluntarily publicly reported on the STS Public Reporting Page by October 2021. This measure is included in the Transcatheter Valve Certification for 2021.
- The Standing Committee had no concerns regarding this criterion.

5. Related and Competing Measures

- This measure is related to the following measures:
    - NQF #3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

- A Standing Committee member inquired whether mortality would still be reported separately on the planned website since there is no harder endpoint than mortality. The Standing Committee member also noted that at times, composite measures with softer endpoints end up overwhelming mortality.

- The developer indicated that the planned public reporting would only include the risk-standardized score for the overall composite. The developer felt that the public needed to be able to digest the data and that one score was clearer than the other.
- The same Standing Committee member further noted that from a usability standpoint, sites would need to know how they compare on components to know how to address improvements. The developer clarified that the sites would see all endpoints on their outcomes report. The Standing Committee did not raise any further concerns regarding this criterion.

6. **Standing Committee Recommendation for Endorsement: Total votes: 17; Yes-17; No-0**
7. **Public and Member Comment**
   - No public or member comments were received during the commenting period.
8. **Consensus Standards Approval Committee (CSAC) Vote: Total votes: 10; Y-10; N-0 (November 30, 2021): Endorsed**
   - The CSAC upheld the Standing Committee's decision to recommend the measure for endorsement.
9. **Appeals**
   - No appeals were received.

NQF #3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Measure Worksheet | Specifications

Description: The percentage of ED patients with a diagnosis of STEMI who received appropriate and timely treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level in a CMS accountability program, through which it may be publicly reported.

Numerator Statement: ED STEMI patients 18 years of age and older whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR non-transfer ED STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred from a non-PCI capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.

Denominator Statement: ED patients 18 years of age and older with STEMI who should have received appropriate and timely treatment for STEMI.

Exclusions: The denominator exclusions were derived from the 2013 ACC Foundation (ACCF)/American Heart Association (AHA) Guideline for the Management of STEMI (http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?download=true), which was also the basis of OP-2 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention). Denominator exclusions include the following conditions, which have to be documented as active in the patient's history at the time of the encounter: active bleeding or bleeding diathesis (excluding menses); ischemic stroke; known malignant intracranial neoplasm (primary or metastatic); known structural cerebral vascular lesion (e.g., arteriovenous malformation [AVM]); significant facial and/or closed head trauma, any prior intracranial hemorrhage, or other known intracranial pathology; suspected aortic dissection; active peptic ulcer; cardiopulmonary arrest; intubation; mechanical circulatory assist device placement; oral anticoagulant therapy prior to arrival (including streptokinase treatment); patients with advanced dementia; pregnancy; recent internal bleeding; recent major surgery; intracranial or intraspinal surgery; and severe neurologic impairment (based on Glasgow coma).

Adjustment/Stratification: No risk adjustment or risk stratification; Not applicable – this measure does not stratify its results.

Level of Analysis: Facility

Setting of Care: Outpatient Services
Type of Measure: Process
Data Source: Electronic Health Records
Measure Steward: Centers for Medicare & Medicaid Services (CMS)
STANDING COMMITTEE MEETING July 28, 2021

1. **Importance to Measure and Report: The measure meets the Importance criteria.**
   (1a. Evidence, 1b. Performance Gap)
   1a. Evidence: **Total Votes: 17; H-4; M-13; L-0; I-0;** 1b. Performance Gap: **Total votes: 17; H-5; M-11; L-0; I-1**

Rationale

- The developer provided a logic path that ties the speed of reperfusion of cardiac muscle and improved outcomes (e.g., reduced mortality, bleeding events, and reinfarction) to the provision of timely fibrinolytic therapy or PCI for STEMI within the time frame specified in the clinical practice guidelines.
- The developer cited two separate guidelines to support the development of this measure:
    - The first clinical practice guideline, released in 2013 by ACCF and AHA, evaluates the management of patients with STEMI. It provides recommendations for fibrinolytic therapy when there is an anticipated delay in performing primary PCI within 120 minutes of first medical contact. The developer provided four recommendations from this guideline to support the measure's clinical intent. All four recommendations received a Class I designation with the Level of Evidence being either A or B.
    - The second guideline, released in 2017 by the American College of Emergency Physicians (ACEP), evaluates the management of patients with STEMI. It provides recommendations for the management of ED STEMI patients in need of reperfusion therapy and provides recommendations for the treatment of STEMI. The developer provided two recommendations from this guideline to support the measure's clinical intent. Both recommendations received a Class III designation with the Level of Evidence being B.

- The Standing Committee had no concerns with the evidence.
- The developer noted that this new measure is not yet implemented; therefore, performance scores are not available. In lieu of performance data on this measure, the developer provided a summary of data from a data analysis performed by Lewin of the 2014 data submitted to CMS' clinical data warehouse. The analysis demonstrated variation in performance for the administration of fibrinolytics.
- The developer also cited multiple studies demonstrating disparities in the timing of PCI for STEMI. Women and African American patients were less likely to receive PCI within 90 minutes when compared to men or White counterparts. Rural facilities had door-in-door-out times significantly longer than the performance mean.
- Given the disparities demonstrated in the literature, Standing Committee members highlighted the importance of stratifying results on this measure when performance results are available. A Standing Committee member noted that an advantage of this measure is the availability of race, ethnicity, and language data in the clinical record. They also noted the importance of finding opportunities for improvement.

2. **Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.**
   (2a. Reliability precise specifications, testing; 2b. Validity testing, threats to validity)
   2a. Reliability: **Total votes: 17; H-0; M-14; L-1; I-2**; 2b. Validity: **Total votes: 17; H-0; M-13; L-3; I-1**

Rationale

- The developer stated that separate reliability testing of data elements was not conducted because NQF guidance does not require separate reliability testing if the validity of data elements is empirically tested.
- The developer noted that the machine-readable logic was used by each testing site to generate queries within their respective EHR systems. For the data validity testing, the developer compared manually abstracted EHR data against electronically abstracted EHR data for data used in the measure.
- The developer assessed and reported data element validity on five characteristics of agreement between the electronically extracted data and manually abstracted data (the gold standard), which included Cohen's kappa, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Data element validity testing was conducted with two hospital systems each using a different EHR.
- The developer reported kappa coefficients, which indicate a range of agreement across systems and data element categories, using thresholds described by Landis and Koch (1977). The developers noted that the numerator value agreements are fair for System 1 and substantial for System 2. The denominator value for System 1 indicates agreement equal to that expected by chance, and the denominator value for System 2 indicates slight agreement. Denominator exclusions values are moderate for System 1 and substantial for System 2.
- The developer highlighted that in addition to the data analyses, it conducted qualitative interviews. The interviews with staff at System 2 indicated a lack of familiarity with the Epic EHR system, to which they recently transitioned, which may have led to accuracy challenges for both the electronic extract as well as the manual abstraction.
- For exclusion analysis, the developer examined the frequency of occurrence of exclusions at each system. In addition, the developers also assessed the data element validity of individual exclusions for the manually abstracted sample of 111 randomly selected patients using the same five same characteristics of agreement (Cohen's kappa, sensitivity, specificity, PPV, and NPV). The developers reported that the frequency of occurrence for many exclusions is zero at both systems, which suggest that scores will not be substantially impacted by the exclusions.
- Standing Committee members expressed concern about the kappa coefficients for the denominator agreement, noting that the coefficients were fairly low. They questioned whether this reflected a failure of the systems or a failure of the measure. They reasoned that the low agreement could reflect a system failure to diagnose and capture the relevant patient population. Standing Committee members agreed that systems need to improve data capture and performance and that all facilities should be able to achieve high performance on the measure. The Standing Committee discussed the challenge of implementing eCQMs when the data quality may not be ideal. The Standing Committee agreed that implementing the measures will provide an incentive to improve the data quality but that improvement may not occur in the absence of this incentive. The Standing Committee did not raise any further concerns regarding this criterion.

3. Feasibility: Total votes: 17; H-5; M-10; L-2; I-0

(*3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented*)

Rationale

- Because the measure has not been implemented, no difficulties in data collection have been identified, and the developer indicated that no fees, licensure, or other requirements are necessary to use this measure.
- Using a simulated data set, the submission demonstrates that the evaluation of 100 percent of the measure logic can be automated.
- The Standing Committee questioned the feasibility of capturing door-to-balloon times, citing interoperability concerns. Frequently, the ED and catheterization lab use different software platforms. Standing Committee members stressed the importance of timely treatment and that accurately capturing door-to-balloon time is critical to assessing care quality. The Standing Committee felt that systems would identify workflow and data issues while implementing the measure and that fixing these issues would improve documentation and patient care.

4. Use and Usability

(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Total votes: 17; Pass-17; No Pass-0** 4b. Usability: **Total votes: 17; H-3; M-14; L-0; I-0**

Rationale

- The developer noted that CMS intends to use the measure in the Hospital OQR Program, where it may be publicly reported. The measure's intended audience includes healthcare consumers, ED physicians and cardiologists, ancillary medical staff, researchers, and ancillary staff (e.g., emergency medical services [EMS], 911 dispatch, administrators, and measure developers).
- The developer noted that the Measure Applications Partnership (MAP) reviewed this measure in December 2020. The Rural Health Workgroup supported the measure for use with rural providers under the Hospital OQR program. The MAP offered conditional support for rulemaking pending NQF endorsement.
- The Standing Committee had no concerns with use, given the measure's intended use in a federal program.
- The developer conducted interviews with participants from the test sites regarding the measure's usability. The participants indicated that the results would be useful to a broad range of stakeholders. Participants did not identify any potential negative unintended consequences. Participants did note that existing workflows might require changes to capture data elements in an easily extractable format.
- Standing Committee members raised questions about whether facilities would be able to see detailed results. An NQF consultant who works with NQF to evaluate eCQMs clarified that the intent with using eCQMs is for systems to calculate the measure within their own systems, giving them full access to all results and data.

5. Related and Competing Measures

- The measure is related to the following measure:
    - NQF #2377 Overall Defect-Free Care for AMI

- The developer noted that the measure specifications are harmonized to the extent possible. It added that the related measure, NQF #2377 *Overall Defect-Free Care for AMI*, stewarded by ACC, measures the proportion of AMI patients ages above 18 who receive optimal care based upon their eligibility for each performance measure. The measure concept of appropriate care for STEMI patients aligns with the STEMI eCQM concept; the measure population and settings of care, however, differ. For the STEMI eCQM, patients in the ED setting are included in the measure, whereas NQF #2377 evaluates both STEMI and non-STEMI patients in the inpatient setting. Furthermore, NQF #2377, the related measure, is a composite measure that evaluates variables beyond time to fibrinolytics and PCI.
- The Standing Committee noted that the two measures capture different information and did not voice any concern with burden or confusion.

6. Standing Committee Recommendation for Endorsement: **Total votes: 17; Yes-16; No-1**

7. Public and Member Comment

- No public or member comments were received during the commenting period.

8. Consensus Standards Approval Committee (CSAC) Vote: Total votes: 10; Y-10; N-0 (November 30, 2021): Endorsed

- The CSAC upheld the Standing Committee's decision to recommend the measure for endorsement.

9. Appeals

- No appeals were received.

Appendix B: Cardiovascular Portfolio—Use in Federal Programs*

NQF #	Title	Federal Programs (Finalized or Implemented)
0018	Controlling High Blood Pressure	None
0066	Coronary Artery Disease (CAD): Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF <40%)	Care Compare Merit-Based Incentive Payment (MIPS) Program
0067	Chronic Stable Coronary Artery Disease: Antiplatelet Therapy	Care Compare Merit-Based Incentive Payment (MIPS) Program
0068	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet	Million Hearts
0070	Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)	Care Compare Merit-Based Incentive Payment (MIPS) Program
0070e	Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)	Care Compare Merit-Based Incentive Payment (MIPS) Program
0071	Persistence of Beta-Blocker Treatment After a Heart Attack	HEDIS Quality Measure Rating System
0073	Ischemic Vascular Disease (IVD): Blood Pressure Control	None
0076	Optimal Vascular Care	None

*CMS Measures Inventory Tool Last Accessed January 26, 2022.

NQF #	Title	Federal Programs (Finalized or Implemented)
0079	Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)	None
0081	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	Care Compare Merit-Based Incentive Payment (MIPS) Program
0081e	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	Care Compare Merit-Based Incentive Payment (MIPS) Program
0083	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	Care Compare Merit-Based Incentive Payment (MIPS) Program
0083e	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	Merit-Based Incentive Payment (MIPS) Program
0133	In-Hospital Risk-Adjusted Rate of Mortality for Patients Undergoing PCI	None
0137	ACEI or ARB for Left Ventricular Systolic Dysfunction - Acute Myocardial Infarction (AMI) Patients	None
0142	Aspirin Prescribed at Discharge for AMI	None

NQF #	Title	Federal Programs (Finalized or Implemented)
0229	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization for Patients 18 and Older	Care Compare Hospital Value-Based Purchasing
0230	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older	Care Compare Hospital Value-Based Purchasing
0290	Median Time to Transfer to Another Facility for Acute Coronary Intervention	Care Compare Hospital Outpatient Quality Reporting
0535	30-Day All-Cause Risk-Standardized Mortality Rate Following Percutaneous Coronary Intervention (PCI) for Patients Without ST-Segment Elevation Myocardial Infarction (STEMI) and Without Cardiogenic Shock	None
0536	30-Day All-Cause Risk-Standardized Mortality Rate Following Percutaneous Coronary Intervention (PCI) for Patients With ST-Segment Elevation Myocardial Infarction (STEMI) or Cardiogenic Shock	None
0642	Cardiac Rehabilitation Patient Referral From an Inpatient Setting	Million Hearts

NQF #	Title	Federal Programs (Finalized or Implemented)
0643	Cardiac Rehabilitation Patient Referral From an Outpatient Setting	Care Compare Million Hearts Merit-Based Incentive Payment (MIPS) Program
0694	Hospital-Level Risk-Standardized Complication Rate Following Implantation of Implantable Cardioverter-Defibrillator	None
0964	Therapy With Aspirin, P2Y12 Inhibitor, and Statin at Discharge Following PCI in Eligible Patients	None
0965	Discharge Medications (ACE/ARB and Beta Blockers) in Eligible ICD Implant Patients	None
2377	Defect-Free Care for AMI	None
2459	Risk-Standardized Bleeding for Patients Undergoing Percutaneous Coronary Intervention (PCI)	None
2461	In-Person Evaluation Following Implantation of a Cardiovascular Implantable Electronic Device (CIED)	None
2474	Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation	Merit-Based Incentive Payment (MIPS) Program
3309	Risk-Standardized Survival Rate (RSSR) for In-Hospital Cardiac Arrest	None

NQF #	Title	Federal Programs (Finalized or Implemented)
3534	30-Day All-Cause, Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)	None
3610	30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)	None
3613e	Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)	None

Appendix C: Cardiovascular Standing Committee and NQF Staff

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Appendix D: Measure Specifications

NQF #3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

STEWARD

America College of Cardiology

DESCRIPTION

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. This measure estimates hospital risk standardized site difference for 5 endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation) within 30 days following transcatheter aortic valve replacement. The measure uses clinical data available in the STS/ACC TVT Registry for risk adjustment for the purposes of benchmarking site to site performance on a rolling 3-year timeframe.

TYPE

Composite

DATA SOURCE

Registry Data STS/ACC TVT Registry

LEVEL

Facility

SETTING

Inpatient/Hospital

NUMERATOR STATEMENT

A composite outcome including all-cause death, stroke, major or life-threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation within 30 days following transcatheter aortic valve replacement (TAVR).

If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

NUMERATOR DETAILS

The composite of outcomes are:

All-cause in-hospital or 30-day death:

1. Discharge status of deceased or
2. Follow-up status=deceased and date of difference between index procedure and death date is <=30 or
3. 30-day follow-up status=deceased, death date is missing, and difference between index procedure and follow-up assessment date is <=75 days.2

In-hospital or 30-day stroke:

1. In-hospital event=ischemic, hemorrhagic, or undetermined stroke or
2. Follow-up event= ischemic, hemorrhagic, or undetermined stroke and date of difference between index procedure and event date is <=30.

In-hospital or 30 Day VARC major or life-threatening disabling bleed:

1. In-hospital event=unplanned vascular surgery or intervention and decrease between pre procedure hemoglobin and the lowest post procedure hemoglobin is at least 3 g/dL or

2. In-hospital event=transapical related event, transaortic related event, bleeding at access site, hematoma at access site, retroperitoneal bleeding, gastrointestinal bleed, genitourinary bleed, other bleed, or hemorrhagic stroke and at least one of the following must be true:
    - **i.** Decrease between pre procedure hemoglobin and the lowest post procedure hemoglobin is at least 3 g/dL or
    - **ii.** At least 2 units of RBC/whole blood transfused.
3. Discharge status of deceased with a vascular primary cause of death or
4. Follow-up event=major bleeding event or life-threatening bleeding and date of difference between index procedure and event date is <=30 or
5. Follow-up status of deceased and difference between index procedure and death date is <=30 days (or death date is missing, documentation includes a vascular primary cause of death, and difference between index procedure and follow-up assessment date is <=75 days).

In-hospital acute kidney injury stage III (AKI) or 30-day new requirement for dialysis:

1. In-hospital minimum increase of 300% between pre procedure hemoglobin and post procedure hemoglobin or
2. In-hospital minimum of 0.5 mg/dL absolute increase between pre procedure hemoglobin and post procedure hemoglobin and a minimum 4 mg/dL post procedure creatinine or
3. In-hospital or follow-up event = new requirement for dialysis and date of difference between index procedure and event date is <=30.

In-hospital or 30-day moderate or severe paravalvular leak:

1. In-hospital post procedure aortic paravalvular severity is moderate or severe (and no instance of follow-up aortic valve regurgitation of none or follow-up paravalvular regurgitation is none, mild, moderate, or severe and associated with latest follow-up echocardiogram date within 25-75 days of index procedure).
2. Follow-up aortic paravalvular severity is moderate or severe and associated with latest follow-up echocardiogram date within 25-75 days of index procedure.

[1]Note: If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

[2]Note on missing date of death: The <=75-day follow-up assessment timeframe was identified to be a clinically reasonable surrogate to capture a 30-day death if 30-day follow-up date of death was missing (this occurred in 0.9% of deceased records from January 2015 to December 2017). Sometimes a status of "deceased" is known and documented but the exact date of death is not available. In addition, we validated the accuracy of 30-day mortality in the TVT Registry by comparing Registry data linked CMS claims data from 2012-2015. Across 3.5 years, 99.6% of the 29,247 patient records had no discrepancy.

DENOMINATOR STATEMENT

Patients who had TAVR.

DENOMINATOR DETAILS

Population: Patients who had TAVR.

Timeframe: Rolling three years

Eligibility:

1. Eligibility at the hospital level:
    a. Acceptable "Data Quality Report (green or yellow)" data submissions for each quarter in the reporting period.
    b. >=90% completeness of the following items for all patient records in the rolling 3-year reporting period:
        - **i.** Computed Baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND

ii. Baseline 5-meter walk test (a key model covariate), AND
iii. Event status/30-day follow-up (patients meet criteria for any endpoint or has some 30-day follow-up assessment at least 21 days after index procedure.

c. At least 60 TAVR procedures
d. Enrolled and submitted data prior to the rolling 3-year timeframe.

2. Eligibility at the patient level: Hospitalization for first-time TAVR procedure

EXCLUSIONS

Hospitals are excluded if they do not meet eligibility criteria noted in S.7.

Patients are excluded if any of the following occur:

1. They did not have a first-time TAVR in the episode of care (admission),
2. The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.
3. The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.
4. They are in TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

EXCLUSION DETAILS

1. Hospital ineligibility:
   a. Unacceptable data quality report submissions for all quarters of the reporting time-period.
   b. Hospitals who have less than 90% of patient records with respect to ANY of the following assessments in the rolling 3-year reporting period:
      i. Computed Baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND
      ii. Baseline 5-meter walk test (a key model covariate), AND
      iii. Event status/30-day follow-up (patient meets criteria for any endpoint or 30-day follow-up assessment is performed at least 21 days after index procedure).
   c. At least 60 TAVR procedures.
   d. Enrolled and submitted data prior to the rolling 3-year timeframe.
2. Patient ineligibility:
   a. They did not have a first-time TAVR in the episode of care (admission)
   b. The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.
   c. The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.
   d. The patient is in a TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

RISK ADJUSTMENT

Statistical risk model

STRATIFICATION

In theory, estimates of provider-specific performance within specific disadvantaged patient populations (e.g., by race, ethnicity) could be generated by applying the measure's modeling methodology to an analysis cohort that is restricted to members of the population of interest. As a practical matter, the number of patients per provider that belong to such populations may be too small to permit a meaningful comparison of performance across providers for these groups. Outcome disparities by race and ethnicity could potentially be assessed by including race and ethnicity in the risk adjustment model and reporting their odds ratios.

TYPE SCORE

Other (specify): Site difference better quality = higher score

ALGORITHM

The measure score is calculated based on the following steps:

1. Patient cohort is identified based on inclusion criteria for a rolling-3-year time period (see questions S.7-S11)
2. Data elements for risk adjustment variables are analyzed using the first collected value (model variables listed below)
3. Observed and expected outcomes are ascertained for each hospital.
4. A measure score is calculated with aggregated data across all included sites. Case mix adjustment is implemented using a hierarchical logistic regression model with the above covariates and a site-specific random intercept.
    a. The main summary measure of a hospital's risk-standardized outcomes performance is the hospital's estimated "site difference" which calculates the probability that a random patient at the hospital of interest would have a worse outcome at an average hospital (vs the hospital of interest) MINUS the probability that a random patient at the hospital of interest would have a better outcome at an average hospital (vs the hospital of interest).
        i. What is a Site Difference? A site difference assesses the association between risk factors and composite outcomes. It calculates the probability that a random patient at the hospital of interest would have a worse outcome at an average hospital (vs the hospital of interest) MINUS the probability that a random patient at the hospital of interest would have a better outcome at an average hospital (vs the hospital of interest).
        ii. It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus, a lower site difference (<0) implies worse-than-expected morbidity/mortality (worse quality), and a higher site difference (>0) implies better-than-expected morbidity/mortality (better quality). To assess hospital performance in any reporting period, the model re-estimates coefficients using the years of data in that period.
    b. A 95% empirical Bayes interval is estimated for each facilities performance.

Model variables include:

1. Age
2. Body surface area (BSA)
3. Sex
4. Race/ethnicity
5. Estimated glomerular filtration rate (eGFR), which quantifies kidney function
6. Left ventricular ejection fraction (LVEF)
7. Hemoglobin function
8. Platelet count
9. Procedure date
10. Dialysis
11. Left main coronary artery stenosis >=50%
12. Proximal left anterior descending coronary artery stenosis >=70%
13. Priori myocardial infarction
14. Endocarditis
15. Prior stroke or transient ischemic attack
16. Carotid stenosis
17. Prior peripheral artery disease
18. Current/recent smoker
19. Diabetes

20. Hypertension
21. Atrial fibrillation/flutter
22. Conduction defect
23. Severe chronic lung disease
24. Home oxygen
25. “Hostile” chest
26. Porcelain (severely concentrically calcified) aorta
27. Access site
28. Pacemaker
29. Previous implantable cardioverter defibrillator
30. Prior percutaneous coronary intervention
31. Prior coronary artery bypass surgery
32. # Prior cardiac operations
33. Prior aortic valve surgery/procedure
34. Prior other valve surgery/procedure (mitral, tricuspid, pulmonic)
35. Aortic valve disease etiology
36. Aortic valve morphology
37. Aortic insufficiency (moderate or severe)
38. Mitral insufficiency (moderate or severe)
39. Tricuspid insufficiency (moderate or severe)
40. Acuity status (defined by a combination of procedure status, prior cardiac arrest w/in 24 hours, need for pre-procedure inotropic medications, and use of mechanical assist device)
41. Unable to walk
42. Gait speed (via the 5-meter walk test which assesses frailty)
43. Baseline Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12, a measure of heart-failure specific health status)

References:

a. Win Ratio –An Intuitive and Easy-To-Interpret Composite Outcome in Medical Studies: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518256/
b. Finkelstein DM, Schoenfeld DA. Combining mortality and longitudinal measures in clinical trials: https://pubmed.ncbi.nlm.nih.gov/10399200/
c. Use of the Win Ratio in Cardiovascular Trials – JACC Heart Failure https://www.jacc.org/doi/full/10.1016/j.jchf.2020.02.010
d. Normand S-LT, Shahian DM, 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226. 151143

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NQF #3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

STEWARD

Centers for Medicare & Medicaid Services (CMS)

DESCRIPTION

The percentage of ED patients with a diagnosis of STEMI who received appropriate and timely treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level in a CMS accountability program, through which it may be publicly reported.

TYPE

Process

DATA SOURCE

Electronic Health Records

LEVEL

Facility

SETTING

Outpatient Services

NUMERATOR STATEMENT

ED STEMI patients aged 18 and older whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR Non-transfer ED STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred from a non-PCI capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.

NUMERATOR DETAILS

The numerator is defined by procedural, RxNorm, and SNOMEDCT codes included in the value sets for this measure; these detailed lists can be found in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for each numerator action are included, below:

Fibrinolytic Therapy within 30-minutes of ED Arrival OID: 2.16.840.1.113883.3.3157.4020

PCI within 90-minutes of ED Arrival for Non-Transfer Patients OID: 2.16.840.1.113883.3.3157.2000.5

Arrival Code

As determined by facility standard operating procedure (SOP)

Discharge to Another Facility Within 45-minutes of ED Arrival As determined by facility SOP

DENOMINATOR STATEMENT

ED patients 18 years of age and older with STEMI who should have received appropriate and timely treatment for STEMI.

DENOMINATOR DETAILS

The denominator is defined by E&M, SNOMEDCT, and ICD-10-CM diagnosis codes included in the value sets for this measure; these detailed lists can be found in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for the denominator are included, below:

Emergency Department Visit

OID: 2.16.840.1.113883.3.464.1003.101.12.1085

STEMI

OID: 2.16.840.1.113883.3.3157.4017

EXCLUSIONS

The denominator exclusions were derived from the 2013 ACCF/AHA Guideline for the Management of STEMI (http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?download=true), which was also the basis of OP-2 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention). Denominator exclusions include the following conditions, which have to be documented as active in the patient's history at the time of the encounter: active bleeding or bleeding diathesis (excluding menses); ischemic stroke; known malignant intracranial neoplasm (primary or metastatic); known structural cerebral vascular lesion (e.g., AVM); significant facial and/or closed head trauma, any prior intracranial hemorrhage or other known intracranial pathology; suspected aortic dissection;

active peptic ulcer; cardiopulmonary arrest; intubation; mechanical circulatory assist device placement; oral anticoagulant therapy prior to arrival (including streptokinase treatment); patients with advanced dementia; pregnancy; recent internal bleeding; recent major surgery; intracranial or intraspinal surgery, and severe neurologic impairment (based on Glasgow coma).

EXCLUSION DETAILS

Specific details can be referenced in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for each exclusion are included, below:

The absolute contraindication denominator exclusions:

Active bleeding or bleeding diathesis (excluding menses)
OID: 2.16.840.1.113883.3.3157.4036

Intracranial or intraspinal surgery
OID: 2.16.840.1.113883.3.3157.4056

Ischemic stroke
OID: 2.16.840.1.113883.3.464.1003.104.12.1024

Known malignant intracranial neoplasm (primary or metastatic)
OID: 2.16.840.1.113883.3.3157.4009
OID: 2.16.840.1.113883.3.3157.4010

Known structural cerebral vascular lesion (e.g., AVM)
OID: 2.16.840.1.113883.3.3157.4025

Significant facial and/or closed head trauma, intracranial hemorrhage, or other known intracranial pathology
OID: 2.16.840.1.113883.3.3157.4026

Suspected aortic dissection
OID: 2.16.840.1.113883.3.3157.4028

Active peptic ulcer
OID: 2.16.840.1.113883.3.3157.4031

Cardiopulmonary arrest
OID: 2.16.840.1.113883.3.3157.4048

For streptokinase/anistreplase: prior exposure or prior allergic reaction to these agents
OID: 2.16.840.1.113883.3.3157.4059

Intubation
OID: 2.16.840.1.113762.1.4.1045.69

Mechanical circulatory assist device placement
OID: 2.16.840.1.113883.3.3157.4052

Oral anticoagulant therapy
OID: 2.16.840.1.113883.3.3157.4045

Patients with advanced dementia
OID: 2.16.840.1.113883.3.3157.4043

Pregnancy
OID: 2.16.840.1.113883.3.3157.4055

Recent internal bleeding
OID: 2.16.840.1.113883.3.3157.4036

Recent major surgery
OID: 2.16.840.1.113883.3.3157.4056

Severe neurologic impairment (based on Glasgow coma scale)
OID: 2.16.840.1.113883.3.3157.4058

RISK ADJUSTMENT

No risk adjustment or risk stratification.

STRATIFICATION

Not applicable - this measure does not stratify its results.

TYPE SCORE

Other (specify): Percentage, Better quality = Higher score

ALGORITHM

This measure calculates the percentage of ED patients with a STEMI diagnosis who received appropriate treatment (PCI, fibrinolytic therapy, transfer to PCI-capable hospital). The measure is calculated based on EHR data, as follows:

1. System check E/M Code; if E/M code represents care provided in the ED, proceed
2. Calculate Patient Age (Outpatient Encounter Date - Birthdate)
3. Patient Age >= 18, proceed
4. System check ICD-10-CM Principal Diagnosis Code
5. Apply denominator exclusions to remove patients excluded from the measure denominator; all remaining cases are equal to the denominator count, proceed
6. System check Fibrinolytic Administration; if “Yes,” proceed; if no
7. System check PCI Received; if “Yes,” proceed; if no
8. System check Transferred for PCI; if “Yes,” proceed
9. System check Fibrinolytic Administration Date and Time; if a Non-Unable to Determine (UTD) value, proceed
10. System check Arrival Time; if a Non-UTD value, proceed
11. System calculates Time to Fibrinolysis (Fibrinolytic Administration Time minus Arrival Time)
12. System check Time to Fibrinolysis; if >= 0 min and <= 30 min, include in the numerator. If > 30 min and = 360 min or missing, proceed
13. System check PCI Received, Date and Time; if a Non-UTD value, proceed
14. System check Arrival Time; if a Non-UTD value, proceed
15. System calculate Time to PCI (PCI Procedure Time minus Arrival Time)
16. System check Time to PCI; if >=0 min and <=90 min, record as the numerator; if >90 minutes and <=360 min or missing, proceed
17. System check Transferred for PCI, check Transfer for PCI Date; if a Non-UTD value, proceed
18. System check Transfer for PCI Time; if a Non-UTD value, proceed

19. System check Arrival Time; if a Non-UTD value, proceed
20. System calculate Time to Transfer for PCI; if >=0 min and <=45 min, include in the numerator.
21. Measure = aggregated numerator counts / aggregated denominator counts [The value should be recorded as a percentage]. 121025| 150289

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Appendix E: Related and Competing Measures

Comparison of NQF #3610 and NQF #3534

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)
#3534 30 Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Steward

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

America College of Cardiology

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

American College of Cardiology

Description

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

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. This measure estimates hospital risk standardized site difference for 5 endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation) within 30 days following transcatheter aortic valve replacement. The measure uses clinical data available in the STS/ACC TVT Registry for risk adjustment for the purposes of benchmarking site to site performance on a rolling 3-year timeframe.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

This measure estimates hospital risk standardized odds ratio for death from all causes within 30 days following transcatheter aortic valve replacement. The measure uses clinical data available in the STS/ACC TVT Registry for risk adjustment. For the purpose of development and testing, the measure used site-reported 30-day follow-up data contained in the STS/ACC TVT Registry.

Type

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Composite

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Outcome

Data Source

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Registry Data STS/ACC TVT Registry

Available at measure-specific web page URL identified in S.1 No data dictionary

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Registry Data STS/ACC TVT Registry

Available at measure-specific web page URL identified in S.1 Attachment TAVR_S.2b_attachment-637092425369121221.xlsx

Level

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Facility

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Facility

Setting

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Inpatient/Hospital

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Inpatient/Hospital

Numerator Statement

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

A composite outcome including all-cause death, stroke, major or life threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation within 30 days following transcatheter aortic valve replacement (TAVR).

If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

The outcome of this measure is all-cause death within 30 days following a transcatheter aortic valve replacement (TAVR).

Numerator Details

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

NUMERATOR:

The composite of outcomes are:

All-cause in-hospital or 30-day death:

1. Discharge status of deceased or
2. Follow-up status=deceased and date of difference between index procedure and death date is <=30 or
3. 30-day follow-up status=deceased, death date is missing, and difference between index procedure and follow-up assessment date is <=75 days.2

In-hospital or 30-day stroke:

1. In-hospital event=ischemic, hemorrhagic, or undetermined stroke or
2. Follow-up event= ischemic, hemorrhagic, or undetermined stroke and date of difference between index procedure and event date is <=30.

In-hospital or 30 Day VARC major or life-threatening disabling bleed:

1) In-hospital event=unplanned vascular surgery or intervention and decrease between pre procedure hemoglobin and the lowest post procedure hemoglobin is at least 3 g/dL or

2) In-hospital event=transapical related event, transaortic related event, bleeding at access site, hematoma at access site, retroperitoneal bleeding, gastrointestinal bleed, genitourinary bleed, other bleed, or hemorrhagic stroke and at least one of the following must be true:

i. Decrease between pre procedure hemoglobin and the lowest post procedure hemoglobin is at least 3 g/dL or

ii. At least 2 units of RBC/whole blood transfused.

3) Discharge status of deceased with a vascular primary cause of death or

4) Follow-up event=major bleeding event or life-threatening bleeding and date of difference between index procedure and event date is <=30 or

5) Follow-up status of deceased and difference between index procedure and death date is <=30 days (or death date is missing, documentation includes a vascular primary cause of death, and difference between index procedure and follow-up assessment date is <=75 days).

In-hospital acute kidney injury stage III (AKI) or 30-day new requirement for dialysis:

1) In-hospital minimum increase of 300% between pre procedure hemoglobin and post procedure hemoglobin or

2) In-hospital minimum of 0.5 mg/dL absolute increase between pre procedure hemoglobin and post procedure hemoglobin and a minimum 4 mg/dL post procedure creatinine or

3) In-hospital or follow-up event = new requirement for dialysis and date of difference between index procedure and event date is <=30.

In-hospital or 30-day moderate or severe paravavular leak:

1) In-hospital post procedure aortic paravalvular severity is moderate or severe (and no instance of follow-up aortic valve regurgitation of none or follow-up paravavular regurgitation is none, mild, moderate, or severe and associated with latest follow-up echocardiogram date within 25-75 days of index procedure).

2) Follow-up aortic paravalvular severity is moderate or severe and associated with latest follow-up echocardiogram date within 25-75 days of index procedure.

[1]Note: If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

[2]Note on missing date of death: The <=75 day follow-up assessment timeframe was identified to be a clinically reasonable surrogate to capture a 30 day death if 30 day follow-up date of death was missing (this occurred in 0.9% of deceased records from January 2015 to December 2017). Sometimes a status of "deceased" is known and documented but the exact date of death is not available. In addition, we validated the accuracy of 30-day mortality in the TVT Registry by comparing Registry data linked CMS claims data from 2012-2015. Across 3.5 years, 99.6% of the 29,247 patient records had no discrepancy.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

NUMERATOR:

1. Discharge status of expired or
2. Follow-up status=deceased and date difference between index procedure and death date is <=30 or
3. 30-day follow-up status=deceased, death date is missing, and difference between index procedure and follow-up assessment date is <=75 days. *

*Notes: The <=75 day follow-up assessment timeframe was identified to be a clinically reasonable surrogate to capture a 30 day death if 30 day follow-up date of death was missing (this occurred in 0.9% of deceased records from January 2015 to December 2017). Sometimes a status of "deceased" is known and documented but the exact date of death is not available.

In addition, we validated the accuracy of 30-day mortality in the TVT Registry by comparing Registry data linked CMS claims data from 2012-2015. Across 3.5 years, 99.6% of the 29,247 patient records had no discrepancy.

Denominator Statement

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Patients who had TAVR.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

The target population for the outcome is for individuals who have undergone transcatheter aortic valve replacement.

For development, reassessment and reporting of this measure, we use site reported data from the STS/ACC TVT Registry.

Denominator Details

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Population: Patients who had TAVR.

Timeframe: Rolling three years

Eligibility:

1) Eligibility at the hospital level:
   a. Acceptable "Data Quality Report (green or yellow)" data submissions for each quarter in the reporting period.
   b. >=90% completeness of the following items for all patient records in the rolling 3-year reporting period:
      i. Computed Baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND
      ii. Baseline 5-meter walk test (a key model covariate), AND
      iii. Event status/30 day follow-up (patients meet criteria for any endpoint or has some 30-day follow-up assessment at least 21 days after index procedure.
   c. At least 60 TAVR procedures
   d. Enrolled and submitted data prior to the rolling 3 year timeframe.
2) Eligibility at the patient level: Hospitalization for first-time TAVR procedure

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Measure Eligibility and Population Definition

1) Eligibility at the hospital level:
   a) Acceptable "Data Quality Report" data submissions for each quarter in the reporting period.
   b) Hospitals must have >=90% completeness of the following items for all patient records in the rolling 3-year reporting period to receive feedback on the measure:
      i) Computed baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND
      ii) Baseline 5-meter walk test (a key model covariate), AND
      iii) 30-day follow-up status =alive or dead as defined above (the outcome variable)
2) Eligibility at the patient level: Hospitalization for first-time TAVR procedure

Exclusions

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Hospitals are excluded if they do not meet eligibility criteria noted in S.7.

Patients are excluded if any of the following occur:

1) They did not have a first-time TAVR in the episode of care (admission),
2) The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.
3) The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.
4) They are in TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

1) Hospitals need to meet eligibility criteria to be included in the measure.

2) Patients are excluded if:

a) They did not have a first-time TAVR in the episode of care (admission),

b) The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.

c) The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.

d) 30-day mortality status missing.

Exclusion Details

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

1) Hospital ineligibility:

a. Unacceptable data quality report submissions for all quarters of the reporting time-period.

b. Hospitals who have less than 90% of patient records with respect to ANY of the following assessments in the rolling 3-year reporting period:

i. Computed Baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND

ii. Baseline 5-meter walk test (a key model covariate), AND

iii. Event status/30-day follow-up (patient meets criteria for any endpoint or 30-day follow-up assessment is performed at least 21 days after index procedure).

c. At least 60 TAVR procedures.

d. Enrolled and submitted data prior to the rolling 3 year timeframe.

2) Patient ineligibility:

a. They did not have a first-time TAVR in the episode of care (admission),

b. The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.

c. The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.

d. The patient is in a TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

1) Hospital ineligibility:

a) Unacceptable data quality report submissions for all quarters of the reporting time-period.

b) Hospitals who have less than 90% of patient records with respect to ANY of the following assessments in the rolling 3-year reporting period:

i) Computed baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) OR

ii) Baseline 5 meter walk test (a key model covariate), OR

iii) 30 day follow-up status =alive or dead as defined above (the outcome variable)

2) Patient Ineligibility:

a) They did not have a first-time TAVR in the episode of care (admission),

b) The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.

c) The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.

d) 30-day mortality status is missing.

Risk Adjustment

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Statistical risk model

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Statistical risk model

Stratification

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

In theory, estimates of provider-specific performance within specific disadvantaged patient populations (e.g. by race, ethnicity) could be generated by applying the measure's modeling methodology to an analysis cohort that is restricted to members of the population of interest. As a practical matter, the number of patients per provider that belong to such populations may be too small to permit a meaningful comparison of performance across providers for these groups. Outcome disparities by race and ethnicity could potentially be assessed by including race and ethnicity in the risk adjustment model and reporting their odds ratios.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

This measure will not be stratified.

Type Score

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Other (specify): Site difference better quality = higher score

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

Ratio better quality = lower score

Algorithm

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

The measure score is calculated based on the following steps:

A. Patient cohort is identified based on inclusion criteria for a rolling-3-year time period (see questions S.7-S11)

B. Data elements for risk adjustment variables are analyzed using the first collected value (model variables listed below)

C. Observed and expected outcomes are ascertained for each hospital.

D. A measure score is calculated with aggregated data across all included sites. Case mix adjustment is implemented using a hierarchical logistic regression model with the above covariates and a site-specific random intercept.

a. The main summary measure of a hospital's risk-standardized outcomes performance is the hospital's estimated "site difference" which calculates the probability that a random patient at the hospital of interest would have a worse outcome at an average hospital (vs the hospital of interest) MINUS the probability that a random patient at the hospital of interest would have a better outcome at an average hospital (vs the hospital of interest).

i. What is a Site Difference? A site difference assesses the association between risk factors and composite outcomes. It calculates the probability that a random patient at the hospital of interest would have a worse outcome at an average hospital (vs the hospital of interest) MINUS the probability that a random patient at the hospital of interest would have a better outcome at an average hospital (vs the hospital of interest).

It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus, a lower site difference (<0) implies worse-than-expected morbidity/mortality (worse quality) and a higher site difference (>0) implies better-than-expected morbidity/mortality (better quality). To assess hospital performance in any reporting period, the model re-estimates coefficients using the years of data in that period.

b. A 95% empirical Bayes interval is estimated for each facilities performance.

Model variables include:

1. Age
2. Body surface area (BSA)
3. Sex
4. Race/ethnicity
5. Estimated glomerular filtration rate (eGFR), which quantifies kidney function
6. Left ventricular ejection fraction (LVEF)
7. Hemoglobin function
8. Platelet count
9. Procedure date
10. Dialysis
11. Left main coronary artery stenosis >=50%
12. Proximal left anterior descending coronary artery stenosis >=70%
13. Priori myocardial infarction
14. Endocarditis
15. Prior stroke or transient ischemic attack
16. Carotid stenosis
17. Prior peripheral artery disease
18. Current/recent smoker
19. Diabetes
20. Hypertension

21. Atrial fibrillation/flutter
22. Conduction defect
23. Severe chronic lung disease
24. Home oxygen
25. “Hostile” chest
26. Porcelain (severely concentrically calcified) aorta
27. Access site
28. Pacemaker
29. Previous implantable cardioverter defibrillator
30. Prior percutaneous coronary intervention
31. Prior coronary artery bypass surgery
32. # prior cardiac operations
33. Prior aortic valve surgery/procedure
34. Prior other valve surgery/procedure (mitral, tricuspid, pulmonic)
35. Aortic valve disease etiology
36. Aortic valve morphology
37. Aortic insufficiency (moderate or severe)
38. Mitral insufficiency (moderate or severe)
39. Tricuspid insufficiency (moderate or severe)
40. Acuity status (defined by a combination of procedure status, prior cardiac arrest w/in 24 hours, need for pre-procedure inotropic medications, and use of mechanical assist device)
41. Unable to walk
42. Gait speed (via the 5-meter walk test which assesses frailty)
43. Baseline Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12, a measure of heart-failure specific health status)

References:

a. Win Ratio –An Intuitive and Easy-To-Interpret Composite Outcome in Medical Studies: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518256/

b. Finkelstein DM, Schoenfeld DA. Combining mortality and longitudinal measures in clinical trials: https://pubmed.ncbi.nlm.nih.gov/10399200/

c. Use of the Win Ratio in Cardiovascular Trials – JACC Heart Failure https://www.jacc.org/doi/full/10.1016/j.jchf.2020.02.010

d. Normand S-LT, Shahian DM, 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

The measure score is calculated based on the following steps:

1) Patient cohort is identified based on inclusion criteria (see questions S.7-S.11)

2) Data elements for risk adjusted are collected using the first collected value, as identified below;

3) Outcome is ascertained (see S.5)

4) Measure score is calculated with aggregated data across all included sites as described below. Risk adjustment variables include:

1. Age
2. Body surface area (BSA)
3. Sex
4. Race/ethnicity
5. Estimated glomerular filtration rate (eGFR), which quantifies kidney function
6. Hemodialysis for end-stage renal disease
7. Left ventricular ejection fraction (LVEF)
8. Hemoglobin
9. Platelet count
10. Procedure date
11. Left main coronary artery stenosis = 50%
12. Proximal left anterior descending coronary artery stenosis = 70%
13. Prior myocardial infarction
14. Endocarditis
15. Gait speed (via the 5-meter walk test which assesses frailty)
16. Baseline Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12, a measure of heart-failure specific health status)
17. Peripheral artery disease
18. Current/recent smoker
19. Diabetes
20. Atrial fibrillation/flutter
21. Conduction defect
22. Chronic lung disease
23. Home oxygen
24. “Hostile” chest
25. Porcelain (severely concentrically calcified) aorta
26. Access site
27. Pacemaker
28. Previous implantable cardioverter defibrillator
29. Prior percutaneous coronary intervention
30. Prior coronary artery bypass surgery
31. # prior cardiac operations
32. Prior aortic valve surgery/procedure
33. Prior other valve procedure surgery/procedure (mitral, tricuspid, pulmonic)
34. Aortic valve disease etiology
35. Aortic valve morphology

36. Aortic insufficiency (moderate or severe)
37. Mitral insufficiency (moderate or severe)
38. Tricuspid insufficiency (moderate or severe)
39. Acuity status (defined by a combination of procedure status, prior cardiac arrest w/in 24 hours, need for pre-procedure inotropic medications, and use of mechanical assist device)
40. Carotid stenosis
41. Prior transient ischemic attack or stroke

Case mix adjustment is implemented using a hierarchical logistic regression model with the above covariates and a site-specific random intercept. The main summary measure of a hospital's risk-adjusted outcomes performance is the hospital's estimated odds ratio, which compares the predicted odds of death of the patient population at a hospital if TAVR is performed by the hospital of interest to the predicted odds of death if TAVR were performed by an average hospital. An odds ratio greater than 1 implies higher than expected mortality and an odds ratio less than 1 implies lower than expected mortality. Each hospital's estimated odds ratio is reported along with an approximate 95% empirical Bayes interval around the estimated odds ratio.

Definition of Measure Score Calculation - Odds ratio: a parameter reflecting the association between risk factors and an outcome.

The Risk Standardized Odds Ratio is calculated as the odds that an outcome (e.g. 30-day mortality) will occur for patients treated at your facility compared to the “odds” that outcome will occur for patients with identical risk factors if treated by a hypothetical (average) hospital.

It conceptually allows for a comparison of a particular hospital’s performance given its case mix to an average hospital’s performance with the same case mix. Thus, a lower odds ratio implies lower-than-expected mortality (better quality) and a higher ratio implies higher-than-expected mortality (worse quality). To assess hospital performance in any reporting period, we re-estimate the model coefficients using the years of data in that period.

References:

Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226.

Arnold, S.V. et al. Measures in the Risk Adjustment of 30-Day Mortality After Transcatheter Aortic Valve Replacement: A Report From the Society of Thoracic Surgeons/American College of Cardiology TVT Registry JACC: Cardiovascular Interventions Volume 11, Issue 6, 26 March 2018, Pages 581-589

Submission Items

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

5.1 Identified measures: 3534 : 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (TAVR).

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: #2561: STS Aortic Valve Replacement (AVR) Composite Score

5b.1 If competing, why superior or rationale for additive value: 2561: STS Aortic Valve Replacement Composite Score (STS Adult Cardiac Surgery Database)

3534: 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (STS/ACC TVT Registry)

3534 is one endpoint of this new composite measure (3610). 30-day mortality has always been a key endpoint and warrants a separate measure.

2561 (STS SAVR composite score) and the TAVR 30-day composite have some overlapping endpoints (death, stroke, AKI). The SAVR and TAVR composites have the following differences:

1. Population is different (SAVR vs TAVR)
2. Some events are different. SAVR composite have events specific to surgery (deep sternal wound infection, prolonged intubation, and reoperation for bleeding) and does not include bleeding and PVL.
3. SAVR events occur prior to discharge (the TAVR composite reports events up to 30 days).
4. SAVR composite does not include the five-meter walk and health status as model variables. making 2561 and our new composite substantially different.

#3534 30-Day All-Cause Risk-Standardized Mortality Odds Ratio Following Transcatheter Aortic Valve Replacement (TAVR)

5.1 Identified measures:

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: While this measure focuses on a different population (ie those undergoing surgical AVR) and different outcomes, the current measure has been harmonized to the extent possible. Residual differences in the two models include the following:

1. Some variables are unique to each population/procedure/measure (e.g. TAVR 30-day RAM includes variables unique to the procedure such as gait speed, KCCQ, access site, porcelain aorta and aortic valve morphology).
2. The outcome of each measure is different. TAVR 30-day RAM is subset of the STS AVR Composite Score (which includes 30-day mortality as well as 5 morbidities).
3. The patient population of each measure is different. TAVR 30 day RAM is only patients who had a transcatheter aortic valve replacement procedures. STS AVR Composite is for all patients having an aortic valve replacement (which MAY include a TAVR).

5b.1 If competing, why superior or rationale for additive value: N/A

Comparison of NQF #3610 and NQF #2561

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Steward

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

America College of Cardiology

#2561 STS Aortic Valve Replacement (AVR) Composite Score

The Society of Thoracic Surgeons

Description

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

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. This measure estimates hospital risk standardized site difference for 5 endpoints (death from all causes, stroke, major or life-threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation) within 30 days following transcatheter aortic valve replacement. The measure uses clinical data available in the STS/ACC TVT Registry for risk adjustment for the purposes of benchmarking site to site performance on a rolling 3-year timeframe.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

STS AVR Composite Score comprises two domains consisting of six measures: Domain

1) Absence of Operative Mortality – Proportion of patients (risk-adjusted) who do not experience operative mortality. Operative mortality is defined as death during the same hospitalization as surgery or after discharge but within 30 days of the procedure; and Domain

2) Absence of Major Morbidity – Proportion of patients (risk-adjusted) who do not experience any major morbidity. Major morbidity is defined as having at least one of the following adverse outcomes:

1. reoperations for any cardiac reason,

2. renal failure,

3. deep sternal wound infection,

4. prolonged ventilation/intubation, and

5. cerebrovascular accident/permanent stroke. All measures are based on audited clinical data collected in a prospective registry and are risk-adjusted.

Participants receive a score for each of the two domains, plus an overall composite score. The overall composite score was created by "rolling up" the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by one star (below average performance), two stars (average performance), or three stars (above average performance). Star ratings are publicly reported on the STS website and are also currently reported on the Consumer Reports website.

Type

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Composite

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Composite

Data Source

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Registry Data STS/ACC TVT Registry

Available at measure-specific web page URL identified in S.1 No data dictionary

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Registry Data STS Adult Cardiac Surgery Database Version 2.81 (effective July 1, 2014); Version 2.9 (effective July 1, 2017)

Available at measure-specific web page URL identified in S.1 Attachment S.2b._-_S.15._Detailed_Risk_Model_Specifications.STS_AVR_Composite_Score.docx

Level

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Facility

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Facility, Clinician : Group/Practice

Setting

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Inpatient/Hospital

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Inpatient/Hospital

Numerator Statement

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

A composite outcome including all-cause death, stroke, major or life threatening bleeding, acute kidney injury, moderate or severe paravalvular aortic regurgitation within 30 days following transcatheter aortic valve replacement (TAVR).

If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Due to the complex methodology used to construct the composite measure, it is impractical to separately discuss the numerator and denominator. The following discussion describes how each domain score is calculated and how these are combined into an overall composite score.

The STS AVR Composite Score comprises two domains consisting of six individual measures:

1. Absence of Operative Mortality

   NQF # 0120 Risk-Adjusted Operative Mortality for AVR

2. Absence of Major Morbidity, scored any-or-none. The measures used are the same morbidity outcomes included in NQF #0696 STS CABG Composite Score.

   Risk-Adjusted Postoperative Stroke/Cerebrovascular Accident

   Risk-Adjusted Postoperative Surgical Re-exploration

   Risk-Adjusted Postoperative Deep Sternal Wound Infection Rate

   Risk-Adjusted Postoperative Renal Failure

Risk-Adjusted Postoperative Prolonged Intubation (Ventilation)

Participants receive a score for each of the two domains, plus an overall composite score. The overall composite score is created by “rolling up” the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by one star (below average performance), two stars (average performance), or three stars (above average performance).

Patient Population: The analysis population consists of adult patients aged 18 years or older who undergo isolated AVR surgery

Time Period: 3 years

Data Completeness Requirement: Participants are excluded from the analysis if they have fewer than 10 isolated AVR procedures in the patient population.

Technical Details

The unit of measurement for the STS AVR Composite Score can be either a participant (most often a cardiac surgical practice but occasionally an individual surgeon) or a hospital.

For the Absence of Operative Mortality domain, the NUMERATOR is:

Number of patients undergoing isolated AVR who survived until after discharge and >30 days post-surgery

For the Absence of Major Morbidity domain, the NUMERATOR is:

Number of patients undergoing isolated AVR who did not experience any of the

five specified major morbidity endpoints*

*Morbidity endpoints consist of postoperative stroke/cerebrovascular accident, surgical re-exploration, deep sternal wound infection, renal failure, prolonged intubation (ventilation). Patients with documented history of renal failure (i.e., dialysis or baseline serum creatinine of 4.0 or higher) are excluded when counting renal failure outcomes.

STS AVR risk models are used to estimate expected rates of mortality and any-or-none morbidity (Reference: O’Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2—isolated valve surgery. Ann Thorac Surg 2009;88(1 Suppl):S23–42). To enhance interpretation, mortality rates are converted to survival rates (risk-standardized survival rate = 100 – risk-standardized mortality rate), and morbidity rates are converted to “absence of morbidity” rates (risk-standardized absence of morbidity rate =100 – risk-standardized morbidity rate). Defining scores in this manner ensures that increasingly positive values reflect better performance, which is easier for consumers to interpret.

(Please see the appendix for the formula used to calculate the overall composite score.)

The method is equivalent to calculating a weighted average, with weights proportional to the inverse of the SD. In the most recent production of the STS AVR Composite Score based on data from July 2010 – June 2013, wtmort=0.79 and wtmorb = 0.21.

Star Rating: Star ratings are derived by testing whether the participant's composite or domain score is significantly different from the overall STS average. For instance, if for each of the 2 composite score domains, a participant’s estimated score is lower than the overall STS average, but the difference between the participant and STS is not statistically significant, the ratings would each be 2 stars. If however, for the overall composite, the point estimate is lower than the STS average, AND this difference is statistically significant, the overall participant star rating is 1 star. The fact that statistical significance was achieved for the composite score but not the individual domains reflects the greater precision of the composite score compared to

individual endpoints. This precision is achieved by aggregating information across multiple endpoints instead of a single endpoint.

Additional details regarding the AVR Composite Score are provided in the attached manuscript:

Shahian DM, He X, Jacobs JP, et al. The Society of Thoracic Surgeons Isolated Aortic Valve Replacement (AVR) Composite Score: a report of the STS Quality Measurement Task Force. Ann Thorac Surg 2012;94:2166-71.

Numerator Details

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

NUMERATOR:

The composite of outcomes are:

All-cause in-hospital or 30-day death:

1. Discharge status of deceased or
2. Follow-up status=deceased and date of difference between index procedure and death date is <=30 or
3. 30-day follow-up status=deceased, death date is missing, and difference between index procedure and follow-up assessment date is <=75 days.2

In-hospital or 30-day stroke:

1. In-hospital event=ischemic, hemorrhagic, or undetermined stroke or
2. Follow-up event= ischemic, hemorrhagic, or undetermined stroke and date of difference between index procedure and event date is <=30.

In-hospital or 30 Day VARC major or life-threatening disabling bleed:

1) In-hospital event=unplanned vascular surgery or intervention and decrease between pre procedure hemoglobin and the lowest post procedure hemoglobin is at least 3 g/dL or

2) In-hospital event=transapical related event, transaortic related event, bleeding at access site, hematoma at access site, retroperitoneal bleeding, gastrointestinal bleed, genitourinary bleed, other bleed, or hemorrhagic stroke and at least one of the following must be true:

i. Decrease between pre procedure hemoglobin and the lowest post procedure hemoglobin is at least 3 g/dL or

ii. At least 2 units of RBC/whole blood transfused.

3) Discharge status of deceased with a vascular primary cause of death or

4) Follow-up event=major bleeding event or life-threatening bleeding and date of difference between index procedure and event date is <=30 or

5) Follow-up status of deceased and difference between index procedure and death date is <=30 days (or death date is missing, documentation includes a vascular primary cause of death, and difference between index procedure and follow-up assessment date is <=75 days).

In-hospital acute kidney injury stage III (AKI) or 30-day new requirement for dialysis:

1) In-hospital minimum increase of 300% between pre procedure hemoglobin and post procedure hemoglobin or

2) In-hospital minimum of 0.5 mg/dL absolute increase between pre procedure hemoglobin and post procedure hemoglobin and a minimum 4 mg/dL post procedure creatinine or

3) In-hospital or follow-up event = new requirement for dialysis and date of difference between index procedure and event date is <=30.

In-hospital or 30-day moderate or severe paravavular leak:

1) In-hospital post procedure aortic paravalvular severity is moderate or severe (and no instance of follow-up aortic valve regurgitation of none or follow-up paravavular regurgitation is none, mild, moderate, or severe and associated with latest follow-up echocardiogram date within 25-75 days of index procedure).

2) Follow-up aortic paravalvular severity is moderate or severe and associated with latest follow-up echocardiogram date within 25-75 days of index procedure.

[1]Note: If a patient experiences multiple outcomes captured in the overall rank composite measure, the outcome with the highest rank is assigned.

[2]Note on missing date of death: The <=75 day follow-up assessment timeframe was identified to be a clinically reasonable surrogate to capture a 30 day death if 30 day follow-up date of death was missing (this occurred in 0.9% of deceased records from January 2015 to December 2017). Sometimes a status of "deceased" is known and documented but the exact date of death is not available. In addition, we validated the accuracy of 30-day mortality in the TVT Registry by comparing Registry data linked CMS claims data from 2012-2015. Across 3.5 years, 99.6% of the 29,247 patient records had no discrepancy.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Please see S.4 above

Denominator Statement

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Patients who had TAVR.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Due to the complex methodology used to construct the composite measure, it is impractical to separately discuss the numerator and denominator. The following discussion describes how each domain score is calculated and how these are combined into an overall composite score.

The STS AVR Composite Score comprises two domains consisting of six individual measures:

1. Absence of Operative Mortality

NQF # 0120 Risk-Adjusted Operative Mortality for AVR

2. Absence of Major Morbidity, scored any-or-none. The measures used are the same morbidity outcomes included in NQF #0696 STS CABG Composite Score.

Risk-Adjusted Postoperative Stroke/Cerebrovascular Accident

Risk-Adjusted Postoperative Surgical Re-exploration

Risk-Adjusted Postoperative Deep Sternal Wound Infection Rate

Risk-Adjusted Postoperative Renal Failure

Risk-Adjusted Postoperative Prolonged Intubation (Ventilation)

Participants receive a score for each of the two domains, plus an overall composite score. The overall composite score is created by "rolling up" the domain scores into a single number. In addition to receiving a numeric score, participants are assigned to rating categories designated by

one star (below average performance), two stars (average performance), or three stars (above average performance).

Patient Population: The analysis population consists of adult patients aged 18 years or older who undergo isolated AVR surgery

Time Period: 3 years

Data Completeness Requirement: Participants are excluded from the analysis if they have fewer than 10 isolated AVR procedures in the patient population.

Technical Details

The unit of measurement for the STS AVR Composite Score can be either a participant (most often a cardiac surgical practice but occasionally an individual surgeon) or a hospital.

For the Absence of Operative Mortality domain AND the Absence of Major Morbidity domain, the DENOMINATOR is:

Number of patients undergoing isolated AVR during the measurement period

STS AVR risk models are used to estimate expected rates of mortality and any-or-none morbidity (Reference: O'Brien SM, Shahian DM, Filardo G, et al. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2—isolated valve surgery. Ann Thorac Surg 2009;88(1 Suppl):S23–42). To enhance interpretation, mortality rates are converted to survival rates (risk-standardized survival rate = 100 – risk-standardized

mortality rate), and morbidity rates are converted to "absence of morbidity" rates (risk-standardized absence of morbidity rate =100 – risk-standardized morbidity rate). Defining scores in this manner ensures that increasingly positive values reflect better performance, which is easier for consumers to interpret.

(Please see the appendix for the formula used to calculate the overall composite score.)

The method is equivalent to calculating a weighted average, with weights proportional to the inverse of the SD. In the most recent production of the STS AVR Composite Score based on data from July 2010 – June 2013, wtmort=0.79 and wtmorb = 0.21.

Star Rating: Star ratings are derived by testing whether the participant's composite or domain score is significantly different from the overall STS average. For instance, if for each of the 2 composite score domains, a participant's estimated score is lower than the overall STS average, but the difference between the participant and STS is not statistically significant, the ratings would each be 2 stars. If however, for the overall composite, the point estimate is lower than the STS average, AND this difference is statistically significant, the overall participant star rating is 1 star. The fact that statistical significance was achieved for the composite score but not the individual domains reflects the greater precision of the composite score compared to

individual endpoints. This precision is achieved by aggregating information across multiple endpoints instead of a single endpoint.

Additional details regarding the AVR Composite Score are provided in the attached manuscript:

Shahian DM, He X, Jacobs JP, et al. The Society of Thoracic Surgeons Isolated Aortic Valve Replacement (AVR) Composite Score: a report of the STS Quality Measurement Task Force. Ann Thorac Surg 2012;94:2166-71.

Denominator Details

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Population: Patients who had TAVR.

Timeframe: Rolling three years

Eligibility:

1) Eligibility at the hospital level:

- **a.** Acceptable "Data Quality Report (green or yellow)" data submissions for each quarter in the reporting period.
- **b.** >=90% completeness of the following items for all patient records in the rolling 3-year reporting period:
  - **i.** Computed Baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND
  - **ii.** Baseline 5-meter walk test (a key model covariate), AND
  - **iii.** Event status/30 day follow-up (patients meet criteria for any endpoint or has some 30-day follow-up assessment at least 21 days after index procedure.
- **c.** At least 60 TAVR procedures
- **d.** Enrolled and submitted data prior to the rolling 3 year timeframe.

2) Eligibility at the patient level: Hospitalization for first-time TAVR procedure

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Please see S.6 above

Exclusions

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Hospitals are excluded if they do not meet eligibility criteria noted in S.7.

Patients are excluded if any of the following occur:

1) They did not have a first-time TAVR in the episode of care (admission),

2) The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.

3) The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.

4) They are in TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Please see S.6 above

Exclusion Details

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

1) Hospital ineligibility:

a. Unacceptable data quality report submissions for all quarters of the reporting time-period.

b. Hospitals who have less than 90% of patient records with respect to ANY of the following assessments in the rolling 3-year reporting period:

i. Computed Baseline Kansas City Cardiomyopathy Questionnaire (a key risk model covariate) AND

ii. Baseline 5-meter walk test (a key model covariate), AND

iii. Event status/30-day follow-up (patient meets criteria for any endpoint or 30-day follow-up assessment is performed at least 21 days after index procedure).

c. At least 60 TAVR procedures.

d. Enrolled and submitted data prior to the rolling 3 year timeframe.

2) Patient ineligibility:

a. They did not have a first-time TAVR in the episode of care (admission),

b. The TAVR was subsequent to another procedure in the Registry (other TAVR, Mitral Leaflet Clip and/or TMVR) during that admission.

c. The patient is readmitted for a repeat TAVR (re-admission) and the initial TAVR was performed during the rolling 3-year timeframe for the measure.

d. The patient is in a TVT Registry sponsored research studies (identified with research study=yes and research study device used during procedure).

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Please see S.6 above

Risk Adjustment

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Statistical risk model

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Statistical risk model

Stratification

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

In theory, estimates of provider-specific performance within specific disadvantaged patient populations (e.g. by race, ethnicity) could be generated by applying the measure's modeling methodology to an analysis cohort that is restricted to members of the population of interest. As a practical matter, the number of patients per provider that belong to such populations may be too small to permit a meaningful comparison of performance across providers for these groups. Outcome disparities by race and ethnicity could potentially be assessed by including race and ethnicity in the risk adjustment model and reporting their odds ratios.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

N/A

Type Score

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

Other (specify): Site difference better quality = higher score

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Rate/proportion better quality = higher score

Algorithm

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

The measure score is calculated based on the following steps:

A. Patient cohort is identified based on inclusion criteria for a rolling-3-year time period (see questions S.7-S11)

B. Data elements for risk adjustment variables are analyzed using the first collected value (model variables listed below)

C. Observed and expected outcomes are ascertained for each hospital.

D. A measure score is calculated with aggregated data across all included sites. Case mix adjustment is implemented using a hierarchical logistic regression model with the above covariates and a site-specific random intercept.

a. The main summary measure of a hospital's risk-standardized outcomes performance is the hospital's estimated "site difference" which calculates the probability that a random patient at the hospital of interest would have a worse outcome at an average hospital (vs the hospital of interest) MINUS the probability that a random patient at the hospital of interest would have a better outcome at an average hospital (vs the hospital of interest).

i. What is a Site Difference? A site difference assesses the association between risk factors and composite outcomes. It calculates the probability that a random patient at the hospital of interest would have a worse outcome at an average hospital (vs the hospital of interest) MINUS the probability that a random patient at the hospital of interest would have a better outcome at an average hospital (vs the hospital of interest).

It conceptually allows for a comparison of a particular hospital's performance given its case mix to an average hospital's performance with the same case mix. Thus, a lower site difference (<0) implies worse-than-expected morbidity/mortality (worse quality) and a higher site difference (>0) implies better-than-expected morbidity/mortality (better quality). To assess hospital performance in any reporting period, the model re-estimates coefficients using the years of data in that period.

b. A 95% empirical Bayes interval is estimated for each facilities performance.

Model variables include:

1. Age
2. Body surface area (BSA)
3. Sex
4. Race/ethnicity
5. Estimated glomerular filtration rate (eGFR), which quantifies kidney function
6. Left ventricular ejection fraction (LVEF)

7. Hemoglobin function
8. Platelet count
9. Procedure date
10. Dialysis
11. Left main coronary artery stenosis >=50%
12. Proximal left anterior descending coronary artery stenosis >=70%
13. Priori myocardial infarction
14. Endocarditis
15. Prior stroke or transient ischemic attack
16. Carotid stenosis
17. Prior peripheral artery disease
18. Current/recent smoker
19. Diabetes
20. Hypertension
21. Atrial fibrillation/flutter
22. Conduction defect
23. Severe chronic lung disease
24. Home oxygen
25. “Hostile” chest
26. Porcelain (severely concentrically calcified) aorta
27. Access site
28. Pacemaker
29. Previous implantable cardioverter defibrillator
30. Prior percutaneous coronary intervention
31. Prior coronary artery bypass surgery
32. # prior cardiac operations
33. Prior aortic valve surgery/procedure
34. Prior other valve surgery/procedure (mitral, tricuspid, pulmonic)
35. Aortic valve disease etiology
36. Aortic valve morphology
37. Aortic insufficiency (moderate or severe)
38. Mitral insufficiency (moderate or severe)
39. Tricuspid insufficiency (moderate or severe)
40. Acuity status (defined by a combination of procedure status, prior cardiac arrest w/in 24 hours, need for pre-procedure inotropic medications, and use of mechanical assist device)
41. Unable to walk
42. Gait speed (via the 5-meter walk test which assesses frailty)
43. Baseline Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12, a measure of heart-failure specific health status)

References:

a. Win Ratio –An Intuitive and Easy-To-Interpret Composite Outcome in Medical Studies: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5518256/

b. Finkelstein DM, Schoenfeld DA. Combining mortality and longitudinal measures in clinical trials: https://pubmed.ncbi.nlm.nih.gov/10399200/

c. Use of the Win Ratio in Cardiovascular Trials – JACC Heart Failure https://www.jacc.org/doi/full/10.1016/j.jchf.2020.02.010

d. Normand S-LT, Shahian DM, 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

Please see S.4 and S.6 above

Submission Items

#3610 30-Day Risk-Standardized Morbidity and Mortality Composite Following Transcatheter Aortic Valve Replacement (TAVR)

5.1 Identified measures: 3534 : 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (TAVR).

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: #2561: STS Aortic Valve Replacement (AVR) Composite Score

5b.1 If competing, why superior or rationale for additive value: 2561: STS Aortic Valve Replacement Composite Score (STS Adult Cardiac Surgery Database)

3534: 30 Day All-cause Risk Standardized Mortality Odds Ratio following Transcatheter Aortic Valve Replacement (STS/ACC TVT Registry)

3534 is one endpoint of this new composite measure (3610). 30-day mortality has always been a key endpoint and warrants a separate measure.

2561 (STS SAVR composite score) and the TAVR 30-day composite have some overlapping endpoints (death, stroke, AKI). The SAVR and TAVR composites have the following differences:

1. Population is different (SAVR vs TAVR)
2. Some events are different. SAVR composite have events specific to surgery (deep sternal wound infection, prolonged intubation, and reoperation for bleeding) and does not include bleeding and PVL.
3. SAVR events occur prior to discharge (the TAVR composite reports events up to 30 days).
4. SAVR composite does not include the five-meter walk and health status as model variables. making 2561 and our new composite substantially different.

#2561 STS Aortic Valve Replacement (AVR) Composite Score

5.1 Identified measures: 0120 : Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR)

0131 : Risk-Adjusted Stroke/Cerebrovascular Accident

0115 : Risk-Adjusted Surgical Re-exploration

0130 : Risk-Adjusted Deep Sternal Wound Infection

0114 : Risk-Adjusted Postoperative Renal Failure

0129 : Risk-Adjusted Postoperative Prolonged Intubation (Ventilation)

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: N/A

5b.1 If competing, why superior or rationale for additive value: N/A

Comparison of NQF #3613e and NQF #0290

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)
#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Steward

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Centers for Medicare & Medicaid Services (CMS)

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Centers for Medicare & Medicaid Services (CMS)

Description

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

The percentage of ED patients with a diagnosis of STEMI who received appropriate and timely treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level in a CMS accountability program, through which it may be publicly reported.

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

This measure calculates the median time from emergency department arrival to time of transfer to another facility for acute coronary intervention.

Type

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Process

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Process

Data Source

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Electronic Health Records This is not an instrument-based measure.

No data collection instrument provided Attachment STEMIeCQM_ValueSets_08262020.xlsx

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Electronic Health Records, Paper Medical Records An electronic data collection tool is made available from vendors or facilities can download the free CMS Abstraction & Reporting Tool

(CART). Paper tools for manual abstraction, which are posted on www.QualityNet.org, are also available for the CART tool. These tools are posted on www.QualityNet.org.

Available at measure-specific web page URL identified in S.1 Attachment 0290_Annual_Update_Code_Set_-2019-.xlsx

Level

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Facility

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Facility

Setting

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Outpatient Services

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Emergency Department and Services

Numerator Statement

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

ED STEMI patients aged 18 and older whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR Non-transfer ED STEMI patients who received PCI at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred from a non-PCI capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

This measure is reported as a continuous variable statement: Time (in minutes) from emergency department arrival to transfer to another facility for acute coronary intervention.

Numerator Details

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

The numerator is defined by procedural, RxNorm, and SNOMEDCT codes included in the value sets for this measure; these detailed lists can be found in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for each numerator action are included, below:

Fibrinolytic Therapy within 30-minutes of ED Arrival OID: 2.16.840.1.113883.3.3157.4020

PCI within 90-minutes of ED Arrival for Non-Transfer Patients OID: 2.16.840.1.113883.3.3157.2000.5

Arrival Code

As determined by facility standard operating procedure (SOP)

Discharge to Another Facility Within 45-minutes of ED Arrival As determined by facility SOP

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

NQF #0290 is a continuous measure; therefore, the numerator and denominator details contained in Section S.5 and S.7 are the same.

The following data elements are used to define the measure population:

- E/M Code
- ICD-10-CM Principal Diagnosis Code
- Initial ECG Interpretation
- Transfer for Acute Coronary Intervention

The measure population includes patients with a diagnosis of acute myocardial infarction (AMI) and ST-segment elevation on the electrocardiogram (ECG) performed closest to emergency department (ED) arrival who are transferred from the ED to a short-term general hospital for inpatient care, or to a federal healthcare facility specifically for an acute coronary intervention (ACI). Patients are included in the measure population if:

- Initial ECG Interpretation is equal to "Yes;" and
- Fibrinolytic Administration is equal to "No;" and
- Transfer for Acute Coronary Intervention is equal to "[1] There was documentation the patient was transferred from this facility's emergency department to another facility specifically for acute coronary intervention."

Median times to transfer within a three-month period are aggregated, on a rolling basis, for AMI patients who are transferred for ACI.

Denominator Statement

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

ED patients 18 years of age and older with STEMI who should have received appropriate and timely treatment for STEMI.

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

This measure is reported as a continuous variable statement: Time (in minutes) from emergency department arrival to transfer to another facility for acute coronary intervention.

Denominator Details

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

The denominator is defined by E&M, SNOMEDCT, and ICD-10-CM diagnosis codes included in the value sets for this measure; these detailed lists can be found in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for the denominator are included, below:

Emergency Department Visit

OID: 2.16.840.1.113883.3.464.1003.101.12.1085

STEMI

OID: 2.16.840.1.113883.3.3157.4017

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

NQF #0290 is a continuous measure; therefore, the numerator and denominator details contained in Section S.5 and S.7 are the same.

The following data elements are used to define the measure population:

- E/M Code
- ICD-10-CM Principal Diagnosis Code
- Initial ECG Interpretation
- Transfer for Acute Coronary Intervention

The measure population includes patients with a diagnosis of acute myocardial infarction (AMI) and ST-segment elevation on the electrocardiogram (ECG) performed closest to emergency department (ED) arrival who are transferred from the ED to a short-term general hospital for inpatient care, or to a federal healthcare facility specifically for an acute coronary intervention (ACI). Patients are included in the measure population if:

- Initial ECG Interpretation is equal to "Yes;" and
- Fibrinolytic Administration is equal to "No;" and
- Transfer for Acute Coronary Intervention is equal to "[1] There was documentation the patient was transferred from this facility's emergency department to another facility specifically for acute coronary intervention."

Exclusions

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

The denominator exclusions were derived from the 2013 ACCF/AHA Guideline for the Management of STEMI (http://www.onlinejacc.org/content/accj/61/4/e78.full.pdf?download=true), which was also the basis of OP-2 (Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival) and OP-3 (Median Time to Transfer to Another Facility for Acute Coronary Intervention). Denominator exclusions include the following conditions, which have to be documented as active in the patient's history at the time of the encounter: active bleeding or bleeding diathesis (excluding menses); ischemic stroke; known malignant intracranial neoplasm (primary or metastatic); known structural cerebral vascular lesion (e.g., AVM); significant facial and/or closed head trauma, any prior intracranial hemorrhage or other known intracranial pathology; suspected aortic dissection; active peptic ulcer; cardiopulmonary arrest; intubation; mechanical circulatory assist device placement; oral anticoagulant therapy prior to arrival (including streptokinase treatment); patients with advanced dementia; pregnancy; recent internal bleeding; recent major surgery; intracranial or intraspinal surgery, and severe neurologic impairment (based on Glasgow coma).

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Excluded Populations:

- Patients less than 18 years of age; or
- Patients receiving fibrinolytic therapy administration.

Exclusion Details

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Specific details can be referenced in the value set Excel workbook attachment (see S.2b), as well as value sets published on the Value Set Authority Center (https://vsac.nlm.nih.gov/authoring). OIDs to the value sets for each exclusion are included, below:

The absolute contraindication denominator exclusions:

Active bleeding or bleeding diathesis (excluding menses)

OID: 2.16.840.1.113883.3.3157.4036

Intracranial or intraspinal surgery

OID: 2.16.840.1.113883.3.3157.4056

Ischemic stroke

OID: 2.16.840.1.113883.3.464.1003.104.12.1024

Known malignant intracranial neoplasm (primary or metastatic)

OID: 2.16.840.1.113883.3.3157.4009

OID: 2.16.840.1.113883.3.3157.4010

Known structural cerebral vascular lesion (e.g., AVM)

OID: 2.16.840.1.113883.3.3157.4025

Significant facial and/or closed head trauma, intracranial hemorrhage, or other known intracranial pathology

OID: 2.16.840.1.113883.3.3157.4026

Suspected aortic dissection

OID: 2.16.840.1.113883.3.3157.4028

Active peptic ulcer

OID: 2.16.840.1.113883.3.3157.4031

Cardiopulmonary arrest

OID: 2.16.840.1.113883.3.3157.4048

For streptokinase/anistreplase: prior exposure or prior allergic reaction to these agents

OID: 2.16.840.1.113883.3.3157.4059

Intubation

OID: 2.16.840.1.113762.1.4.1045.69

Mechanical circulatory assist device placement

OID: 2.16.840.1.113883.3.3157.4052

Oral anticoagulant therapy

OID: 2.16.840.1.113883.3.3157.4045

Patients with advanced dementia

OID: 2.16.840.1.113883.3.3157.4043

Pregnancy

OID: 2.16.840.1.113883.3.3157.4055

Recent internal bleeding

OID: 2.16.840.1.113883.3.3157.4036

Recent major surgery

OID: 2.16.840.1.113883.3.3157.4056

Severe neurologic impairment (based on Glasgow coma scale)

OID: 2.16.840.1.113883.3.3157.4058

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

The following data elements are used to define the measure exclusions:

- Birthdate
- Fibrinolytic Therapy Administration

Risk Adjustment

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

No risk adjustment or risk stratification

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

No risk adjustment or risk stratification

Stratification

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Not applicable - this measure does not stratify its results.

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Type Score

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Other (specify): Percentage better quality = higher score

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Continuous variable better quality = lower score

Algorithm

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

This measure calculates the percentage of ED patients with a STEMI diagnosis who received appropriate treatment (PCI, fibrinolytic therapy, transfer to PCI-capable hospital). The measure is calculated based on EHR data, as follows:

1. System check E/M Code; if E/M code represents care provided in the ED, proceed
2. Calculate Patient Age (Outpatient Encounter Date - Birthdate)
3. Patient Age >= 18, proceed
4. System check ICD-10-CM Principal Diagnosis Code;
5. Apply denominator exclusions to remove patients excluded from the measure denominator; all remaining cases are equal to the denominator count, proceed

6. System check Fibrinolytic Administration; if “Yes,” proceed; if no

7. System check PCI Received; if “Yes,” proceed; if no

8. System check Transferred for PCI; if “Yes,” proceed;

9. System check Fibrinolytic Administration Date and Time; if a Non-Unable to Determine (UTD) value, proceed

10. System check Arrival Time; if a Non-UTD value, proceed

11. System calculates Time to Fibrinolysis (Fibrinolytic Administration Time minus Arrival Time)

12. System check Time to Fibrinolysis; if >= 0 min and <= 30 min, include in the numerator. If > 30 min and = 360 min or missing, proceed

13. System check PCI Received, Date and Time; if a Non-UTD value, proceed

14. System check Arrival Time; if a Non-UTD value, proceed

15. System calculate Time to PCI (PCI Procedure Time minus Arrival Time)

16. System check Time to PCI; if >=0 min and <=90 min, record as the numerator; if >90 minutes and <=360 min or missing, proceed

17. System check Transferred for PCI, check Transfer for PCI Date; if a Non-UTD value, proceed

18. System check Transfer for PCI Time; if a Non-UTD value, proceed

19. System check Arrival Time; if a Non-UTD value, proceed

20. System calculate Time to Transfer for PCI; if >=0 min and <=45 min, include in the numerator.

21. Measure = aggregated numerator counts / aggregated denominator counts [The value should be recorded as a percentage].

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

Measure algorithm is available in the attached Measure Information Form. Measure algorithm is as follows:

1. Start. Run all cases that are included in the AMI Hospital Outpatient Population Algorithm and pass the edits defined in the Data Processing Flow through this measure. Proceed to Initial ECG Interpretation.

2. Check Initial ECG Interpretation.

a. If Initial ECG Interpretation is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Initial ECG Interpretation equals No, the case will proceed to a Measure Category Assignment of B. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If Initial ECG Interpretation equals Yes, the case will proceed to Fibrinolytic Administration.

3. Check Fibrinolytic Administration.

a. If Fibrinolytic Administration is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Fibrinolytic Administration equals Yes, the case will proceed to a Measure Category Assignment of B. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If Fibrinolytic Administration equals No, the case will proceed to Transfer for Acute Coronary Intervention.

4. Check Transfer for Acute Coronary Intervention.

a. If Transfer for Acute Coronary Intervention is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Transfer for Acute Coronary Intervention equals 2 or 3, the case will proceed to a Measure Category Assignment of B. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If Transfer for Acute Coronary Intervention equals 1, the case will proceed to ED Departure Date.

5. Check ED Departure Date.

a. If ED Departure Date is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If ED Departure Date equals UTD, the case will proceed to a Measure Category Assignment of Y. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If ED Departure Date equals Non-UTD Value, the case will proceed to ED Departure Time.

6. Check ED Departure Time.

a. If ED Departure Time is missing, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If ED Departure Time equals UTD, the case will proceed to a Measure Category Assignment of Y. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

c. If ED Departure Time equals Non-UTD Value, the case will proceed to Arrival Time.

7. Check Arrival Time.

a. If Arrival Time equals UTD, the case will proceed to a Measure Category Assignment of Y. Return to Transmission Data Processing Flow: Clinical in the Data Transmission Section.

b. If Arrival Time equals Non-UTD Value, the case will proceed to the Measurement Value.

8. Calculate the Measurement Value. Time in minutes is equal to the ED Departure Date and ED Departure Time (in minutes) minus the Outpatient Encounter Date and Arrival Time (in minutes).

9. Check the Measurement Value.

a. If Measurement Value is less than 0 minutes, the case will proceed to a Measure Category Assignment of X and will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Measurement Value is greater than or equal to 0 minutes, the case will proceed to Reason for Not Administering Fibrinolytic Therapy.

10. Check Reason for Not Administering Fibrinolytic Therapy.

a. If Reason for Not Administering Fibrinolytic Therapy is missing, the case will proceed to a Measure Category Assignment of X and the case will be rejected. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Reason for Not Administering Fibrinolytic Therapy equals 1, 2, or 3, the case will proceed to a Measure Category Assignment of D1, the OP-3a Overall Rate. Initialize the Measure Category Assignment for OP-3b and OP-3c equal to B. Do not change the Measure Category Assignment that was already calculated for the overall rate of OP-3a. Proceed to Reason for Not Administering Fibrinolytic Therapy.

11. Check Reason for Not Administering Fibrinolytic Therapy.

a. If Reason for Not Administering Fibrinolytic Therapy equals 1 or 2, the case will proceed to a Measure Category Assignment of D2, the OP-3c Quality Improvement Rate. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

b. If Reason for Not Administering Fibrinolytic Therapy equals 3, the case will proceed to a Measure Category Assignment of D, the OP-3b Reporting Rate. Return to Transmission Data Processing Flow: Clinical in the Data Transmission section.

Submission Threshold

In order to reduce the burden on hospitals that treat a low number of patients but otherwise meet the submission requirements for a particular quality measure, hospitals that have five or fewer cases in a quarter (both Medicare and non-Medicare) for any measure set (i.e., Stroke) will not be required to submit patient level data for the entire measure set for that quarter. (Hospital Outpatient Quality Reporting Specifications Manual, Release Notes Version: 13.0a)

Submission Items

#3613e Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

5.1 Identified measures: 0290 : Median Time to Transfer to Another Facility for Acute Coronary Intervention

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: The STEMI eCQM expands on the OP-2 (Fibrinolytic Therapy Received within 30 Minutes of ED Arrival) measure by including other forms of treatments appropriate for ED AMI patients with STEMI. OP-2 specifically measures the delivery of fibrinolytic therapy while the STEMI eCQM also captures PCI treatment and transfer. Further, while both OP-2 and OP-3 (Median Time to Transfer to Another Facility for ACI) focus on the timeliness of care, the STEMI eCQM also examines the appropriate treatments administered for STEMI patients presenting to the ED. Though the STEMI eCQM is intended to eventually replace OP-2 and OP-3, the three measures align where possible (like the interventions considered for treatment, time to treatment, and denominator exclusions). Although these measures are aligned to the extent feasible, the STEMI eCQM relies on electronic health record data that would measure all eligible STEMI patients eligible for treatment, whereas OP-2 and OP-3 are chart-abstracted measures that rely on sampled data. The related measure NQF #2377 (Overall Defect Free Care for AMI), stewarded by the American College of Cardiology, measures the proportion of acute myocardial infarction patients aged above 18 years who receive optimal care based upon their eligibility for each performance measure. The measure concept of appropriate care for STEMI patients aligns with the STEMI eCQM concept; the measure population and settings of care, however, differ. For the STEMI eCQM, patients in the ED setting are included in the measure, whereas NQF #2377 evaluates both STEMI and non-STEMI patients in the inpatient setting. Further, the related measure NQF #2377 is a composite measure that evaluates variables beyond time to fibrinolytics and PCI.

5b.1 If competing, why superior or rationale for additive value: The STEMI eCQM does not conceptually address both the same measure focus and the same target population as NQF-endorsed measure(s).

#0290 Median Time to Transfer to Another Facility for Acute Coronary Intervention

5.1 Identified measures: 0288 : Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: NQF #0290 and NQF #0288 are both in the Hospital OQR Program. These measures have the same initial patient population – patients with AMI and ST-segment elevation on the ECG performed closest to hospital arrival. While the target populations are the same, the focus of the measures is different. NQF #0288 focuses on the timely administration of fibrinolytic therapy and NQF# 0290 focuses on the timely transfer of patients who require a PCI. These two measures share several key data elements (i.e., Initial ECG Interpretation, Fibrinolytic Administration, and Arrival Time). The specifications for these two measures are generally aligned, where possible.

5b.1 If competing, why superior or rationale for additive value: No competing measures that address both the same measure focus and target population as NQF #0290 were identified.

Appendix F: Pre-Evaluation Comments

No public comments have been received as of June 10, 2021.

Appendix G: Post-Evaluation Comments

No public and member post-evaluation comments were received during the commenting period.

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