NATIONAL QUALITY FORUM

Memo

October 23-24, 2018

To: Consensus Standards Approval Committee (CSAC)

From: Cardiovascular Project Team

Re: Cardiovascular Spring 2018 Measure Review Cycle

CSAC Action Required

The CSAC will review recommendations from the Cardiovascular project at its October 23-24, 2018 meeting and vote on whether to uphold the Standing Committee's recommendations to endorse measure 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 (ACC).*

This memo includes a summary of the project, the recommended measure, and public and member comments. The following documents accompany this memo:

1. Cardiovascular spring 2018 cycle draft report. The draft report has been updated to reflect the changes made following public and member comments. The complete draft report and supplemental materials are available on the project webpage.
2. Comment table. This table lists the one comment received during the post-evaluation meeting comment period and the NQF and Standing Committee response.

Background

Cardiovascular disease (CVD) is the leading cause of death for men and women in the United States. It kills nearly one in four Americans and costs $312 billion per year, more than 10 percent of annual health expenditures.[1] Considering the toll of cardiovascular disease, measures that assess clinical care performance and patient outcomes are critical to reducing the negative impacts of CVD.

NQF's cardiovascular portfolio of measures is one of the largest, and it includes 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 measures. Despite the large number of endorsed measures, gaps remain in patient-reported outcomes and patient-centric composite measures.

[1] Agency for Healthcare Research and Quality (AHRQ). *2015 National Healthcare Quality and Disparities Report and 5th Anniversary Update on the National Quality Strategy*. Rockville, MD: AHRQ; 2016. http://www.ahrq.gov/research/findings/nhqrdr/nhqdr15/index.html. Last accessed March 2018.

In the 2018 spring cycle of this project, the 25-member Cardiovascular Standing Committee met virtually through one web meeting to evaluate two measures. The Committee evaluated one measure undergoing maintenance review against NQF's standard evaluation criteria and recommended that measure for endorsement. The other measure was withdrawn prior to Committee evaluation.

Draft Report

The Cardiovascular spring 2018 cycle draft report presents the results of the evaluation of one measure considered under the Consensus Development Process (CDP). The Committee recommended one measure for endorsement, and a developer withdrew one measure from endorsement consideration prior to the Committee's review.

The recommended measure was evaluated against the 2017 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	2	0	2
Measures recommended for endorsement	1	0	1
Measures withdrawn from consideration	1	0	1
Reasons for not recommending:	Importance – 0 Scientific Acceptability – 0 Use – 0 Overall Suitability – 0 Competing Measure – 0	Importance – 0 Scientific Acceptability – 0 Overall Suitability – 0 Competing Measure – 0	

Measures Recommended for Endorsement

- 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 (ACC)

  Overall Suitability for Endorsement: Yes-15; No-0

Comments and Their Disposition

NQF received one comment from one organization (an NQF member organization) pertaining to the draft report and to the measure under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Cardiovascular project webpage.

Comment Themes and Committee Responses

One commenter expressed support for the overall report and the Committee's recommendation.

Member Expression of Support

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 submitted for endorsement consideration to inform the Committee's recommendations. No NQF members provided their expression of support.

Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	No	
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	N/A	This measure was not reviewed by the Scientific Methods Panel.
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	Yes	This measure is paired with *30-Day All-Cause Risk-Standardized Mortality Rate Following Percutaneous Coronary Intervention (PCI) for Patients with ST Segment Elevation Myocardial Infarction (STEMI) or with Cardiogenic Shock*. The paired measures target different patient populations: with/without STEMI and with/without cardiogenic shock.
Were any measurement gap areas addressed? If so, identify the areas.	No	
Are there additional concerns that require CSAC discussion? If so, briefly explain.	No	

Appendix B: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

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

Submission

Description: This measure estimates hospital risk-standardized 30-day all-cause mortality rate following percutaneous coronary intervention (PCI) among patients who are 18 years of age or older without STEMI and without cardiogenic shock at the time of procedure. The measure uses clinical data available in the National Cardiovascular Data Registry (NCDR) CathPCI Registry for risk adjustment. For the purpose of development and testing, the measure used a Medicare fee-for-service (FFS) population of patients 65 years of age or older with a PCI. For the purpose of maintenance, we tested the performance of the measure in a cohort of patients whose vital status was determined from the National Death Index. As such it reflects an all-payor sample as opposed to only the Medicare population. This is consistent with the measure's intent to be applicable to the full population of PCI patients.

Numerator Statement: The outcome for this measure is all–cause death within 30 days following a PCI procedure in patients without STEMI and without cardiogenic shock at the time of the procedure.

Denominator Statement: The target population for this measure includes inpatient and outpatient hospital stays with a PCI procedure for patients at least 18 years of age, without STEMI and without cardiogenic shock at the time of procedure.

Exclusions: Hospital stays are excluded from the cohort if they meet any of the following criteria:

(1) PCIs that follow a prior PCI in the same admission (either at the same hospital or a PCI performed at another hospital prior to transfer).

This exclusion is applied in order to avoid assigning the death to two separate admissions.

(2) For patients with inconsistent or unknown vital status or other unreliable data (e.g. date of death precedes date of PCI);

(3) Subsequent PCIs within 30-days. The 30-day outcome period for patients with more than one PCI may overlap. In order to avoid attributing the same death to more than one PCI (i.e. double counting a single patient death), additional PCI procedures within 30 days of the death are not counted as new index procedures.

(4) PCIs for patients with more than 10 days between date of admission and date of PCI. Patients who have a PCI after having been in the hospital for a prolonged period of time are rare and represent a distinct population that likely has risk factors related to the hospitalization that are not well quantified in the registry.

Adjustment/Stratification: Statistical risk model. Results of this measure will not be stratified.

Level of Analysis: Facility, Other

Setting of Care: Inpatient/Hospital

Type of Measure: Outcome

Data Source: Claims, Other, Registry Data

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING 06/22/2018

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Accepted Prior Evaluation**; 1b. Performance Gap: **H-0; M-14; L-3; I-0**

Rationale:

- The developer referenced literature supporting an association with improved survival and the use of preprocedural clopidogrel and glycoprotein 2b/3a inhibitors; the volume of iodinated contrast; and participation in continuous quality improvement programs. The Committee agreed that the evidence behind the outcome is clear and accepted the prior maintenance evaluation without further discussion.
- The developer provided all payer and all ages (>18 years) performance data from the National Cardiovascular Data Registry (NCDR) CathPCI data linked with National Death Index (NDI) for 1,365 hospitals and 1,127,423 admissions from 2011-2014 demonstrating a variation in risk-standardized mortality rates with a mean of 1.07% and a range from 0.51% to 2.70%. The Committee noted that the interquartile range of the risk standardized mortality rate for the above data was very narrow (0.91 – 1.29 for the 2013-14 data). However, while narrow, this is clinically significant and represents a substantial number of deaths.
- The Committee discussed the performance gap data presented and expressed concern that more recent data were not presented. The developer explained that the time lapse needed to obtain and analyze the data made it difficult to get more recent data. The Committee acknowledged this challenge and agreed that there was a performance gap, despite the dated information.

---

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: **Accepted Prior Evaluation**; 2b. Validity: **Accepted Prior Evaluation**;

Rationale:

- The developer used a "test-retest" approach using Medicare FFS patients aged 65 and older by combining index admissions from two years (2010 and 2011) into a single dataset. The agreement between the two RSMRRs for each hospital was 0.256.
- Data element validity testing was done on the specified measure by comparing data elements with variables in the ACC audit program. In the audit that assessed cases submitted in 2005, the median agreement between submitted and audited values was 92%. The developer noted consistency across sites, with agreement in the lowest and highest deciles of hospitals ranging from 90% to 95%.

- This measure was not adjusted for social risk factors because they are not readily available in the clinical registry. The developer also noted that worse social risk factors might be associated with more severe illness at the time of presentation, however, incorporating detailed clinical factors in the risk-adjustment model that describe the severity of illness is a more accurate means of stratifying risk.
- The Committee accepted the developer's rationale for not including social risk factors in the risk-adjustment model and the prior reliability and validity evaluation without further discussion.

---

3. Feasibility: H-1; M-14; 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 developer stated that for clinical measures, the required data elements are routinely generated and collected during provision of care (e.g., blood pressure, lab value, diagnosis, medication order, depression score). The data are abstracted from a record by an individual other than the individual who obtained the original information (e.g., chart abstraction for quality measure/registry) and obtained from the National Death Index (NDI).
- The Committee was primarily concerned with data timeliness (the most recent data available is over 18 months old) and cost (approximately $100,000) of using National Death Index (NDI) data. The developer acknowledged these challenges and informed the Committee that the cost is borne by the developer and not the individual hospitals.
- The Committee ultimately agreed the measure is feasible despite these implementation challenges.

---

4. Usability and Use: The maintenance measure meets the Use subcriterion

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Pass-14; No Pass-1**; 4b. Usability: **H-0; M-13; L-2; I-0**

Rationale:

- This measure, similar to NQF #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*, is not publicly reported because stewardship of this measure transitioned to the American College of Cardiology (ACC) in 2014, and ACC had limited control over the public use of the measure until then. ACC has made significant effort to ensure this measure will be publicly reported, as well as used in an accountability program.
- Due to the developer's noted efforts, the Committee voted to pass this measure on use and expect the measure to be in an accountability program and publicly reported by the next maintenance review.
- The Committee noted the possible unintended consequence of case avoidance between states with and without public reporting, as well suboptimal measure performance due

to possible changes in the risk-adjustment schema based on the data. However, the Committee agreed this measure is usable, acknowledging that the unintended consequences are speculative given that the measure is not yet in use.

---

5. Related and Competing Measures

This measure is related to:

- 0229: Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization for Patients 18 and Older
- 0230: Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older
- 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

The Committee discussed these measures during previous phases of the cardiovascular project and no new information warranted further discussion.

Standing Committee Recommendation for Endorsement: Yes-15; **No-0**

6. Public and Member Comment

- No comments were received by or during the June 22 measure evaluation web meeting.
- One comment in support of the measure was received after the draft report was posted (July 31- August 29, 2018).

---

7. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Yes-X; No-X

---

8. Appeals