NATIONAL QUALITY FORUM

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Click to go to the link. ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 0964

Corresponding Measures:

De.2. Measure Title: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

Co.1.1. Measure Steward: American College of Cardiology

De.3. Brief Description of Measure:) Proportion of eligible patients = 18 years of age, who were prescribed aspirin, P2Y12 inhibitor, and statin at discharge following PCI with or without stenting.

1b.1. Developer Rationale: This measure is intended to improve rates of evidence-based medication prescribing for patients following PCI to improve outcomes associated with cardiovascular disease.

S.4. Numerator Statement: Patients who receive all medications for which they are eligible.

1. Aspirin prescribed at discharge (if eligible for aspirin as described in denominator)

AND

2. P2Y12 agent (clopidogrel, prasurgel, ticlopidine, or ticagrelor) prescribed at discharge (if eligible for P2Y12 as described in denominator)

AND

3. Statin prescribed at discharge (if eligible for statin as described in denominator)

S.6. Denominator Statement: Patients surviving hospitalization who are eligible to receive any of the three medication classes:

1) Eligible for aspirin (ASA): Patients undergoing PCI who do not have a contraindication to aspirin documented

AND

2) Eligible for P2Y12 agent (clopidogrel, prasugrel, ticlopidine, or ticagrelor): Patients undergoing PCI with stenting who do not have a contraindication to P2Y12 agent documented

AND

3) Eligible for statin therapy: Patients undergoing PCI who do not have a contraindication to statin therapy.

S.8. Denominator Exclusions: The exclusions for this measure are comprised of patients without the following: (1) a PCI during the admission , (2)discharge status of deceased (9040), and (3) discharge location of "other acute hospital, hospice, or against medical advice.

De.1. Measure Type: Composite

S.17. Data Source: Other, Registry Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Feb 05, 2013 **Most Recent Endorsement Date:** Sep 08, 2014

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a *structure, process or intermediate outcome* measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☒ **Yes** ☐ **No**
- **Quality, Quantity and Consistency of evidence provided?** ☒ **Yes** ☐ **No**
- **Evidence graded?** ☒ **Yes** ☐ **No**

Evidence Summary or **Summary of prior review in 2014**

- This composite measure has three process measure components.
- The developer provides a diagram of how the three medications are linked to patient outcomes.
- Aspirin at discharge
  - 2011 ACCF/AHA/SCAI Guideline states "After PCI, use of aspirin should be continued indefinitely. (Class 1; Level of Evidence: A)
  - 2013 JAMA systematic review included 91 publications, with priority given to data from large randomized-controlled trials, systematic reviews, and meta-analyses. The JAMA review concluded that dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor remains the main medical therapy for optimizing outcomes following PCI.

P2Y12 agent (clopidogrel, prasurgel, or ticlopidine) prescribed at discharge

- 2011 ACCF/AHA/SCAI Guideline states "In patients receiving a stent (BMS or DES) during PCI for ACS, P2Y12 inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily(570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568)". (Class I, Level of Evidence: B)
- 2013 JAMA systematic review. After consideration of the risks and benefitts, the authors of the JAMA article concluded that dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor remains the appropriate medical therapy for optimizing outcomes following PCI.

Statin prescribed at discharge

- 2013 ACC/AHA Guideline on Blood Cholesterol – guidelines for secondary prevention: "High-intensity statin therapy should be initiated or continued as first-line therapy in women and men ≤75 years of age who have clinical atherosclerotic cardiovascular disease (ASCVD*), unless contraindicated. (NHLBI Grade A, Strong; ACC/AHA Class I Level A)"
- 2013 Cochrane Review provides evidence that statins reduce total mortality, and adverse events. No QQC.
- Cholesterol Treatment Trialists Collaboration A recent meta-analysis included individual participant data from 22 trials of statin versus control and five trials of more versus less statin. The analysis concluded that statins reduce LDL cholesterol and prevent vascular events in individuals at low risk of vascular events.

Changes to evidence from last review

☒ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

Questions for the Committee:

- *The developer attests the underlying evidence for the measure has not changed since the last NQF endorsement review. Does the Committee agree the evidence basis for the measure has not changed and there is no need for repeat discussion and vote on Evidence?*
- *Is the evidence directly applicable to the processes of care being measured?*
- *Are the processes of care proximal and closely related to desired outcomes?*

Guidance from the Evidence Algorithm

Composite process measure based on a systematic review and grading of the body of evidence (box 3) → QQC presented (box 4) → Quantity, Quality, and Consistency are high (box 5) →High

Preliminary rating for evidence: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer provides performance scores from 2015-2016 (n=1633).
  - Across all hospitals: Mean= 93.6%; Median=95.8% ; Min=25.9% ; Max=100%
  - Histogram is right skewed - majority of hospitals scored between 90% to 100% on the discharged medications composite measure

Disparities

- Disparities data by multiple sub-populations is presented. However, there are no statistically significant differences within subpopulations.
- Performance rates have increased since 2011 to 2016 (89.25% to 95.06%)

Questions for the Committee:

- Based on the information provided, do you think there is enough gap in care?
- Is there a gap in care that warrants a national performance measure?
- Should this measure be stratified for disparities?

Preliminary rating for opportunity for improvement: ☐ High ☒ Moderate ☐ Low ☐ Insufficient

1c. Composite – Quality Construct and Rationale

Maintenance measures – same emphasis on quality construct and rationale as for new measures.

1c. Composite Quality Construct and Rationale. The quality construct and rationale should be explicitly articulated and logical; a description of how the aggregation and weighting of the components is consistent with the quality construct and rationale also should be explicitly articulated and logical.

- The developer provided the following rationale for the composite: "This measure focuses on processes of care that are supported by guidelines for optimal care for patients following percutaneous coronary intervention (PCI), a procedure to treat coronary artery obstructions that often includes placement of a coronary stent. Each of the components of this measure address appropriate medication prescribing at discharge for this population. Specifically, it is known that the use of statin drugs, which reduce LDL cholesterol, reduces the risk of death or future cardiovascular events in individuals with known coronary artery disease, including those who have undergone PCI. Following PCI, both aspirin use and P2Y12 inhibitors (e.g. clopidogrel or prasugrel) reduce the risk of ischemic events. This research demonstrates that this measure contributes to improved intermediate outcomes and important outcomes such as reductions in hospitalizations and mortality rates. In addition, we examined the contribution of each of the individual components to the overall composite (using r-squared analysis). We found statins had the highest explanatory value (90.5%), followed by ASA (60.4%), and P2Y12 (35.3%)".
- The developer states that a composite provides an additive value over the individual measures due to: data reduction, scope expansion, and provider performance valuation.
- Because this is an "all-or-none measure", the developer states that no empirical analyses pertinent to aggregations or weighting were conducted.

Questions for the Committee:

- Are the quality construct and a rationale for the composite explicitly stated and logical?
- Is the lack of a method for aggregation and weighting of the components explicitly stated and logical?

Preliminary rating for composite quality construct and rationale:
☒ High ☐ Moderate ☐ Low ☐ Insufficient

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence:

- The evidence for this measures is present to demonstrate that there is approriate use of aspirin and that there is a gap in care
- Evidence for this measure is well established. Need to add the 2018 cholesterol guidelines to support the statin recommendation
- This is a maintenance measure. Authors indicate that the evidence has not changed. ASA & P2Y12 use is supported by the 2011 ACCF/AHA/SCAI guideline - Class I indication; Level of Evidence:A[aspirin] & B[P2Y12] Also 2013 JAMA systematic review supports dual antiplatelet therapy that includes ASA & P2Y12; Statin use 2013 guideline and Cochrane Review
- Strong evidence in support of each component of care
- HIgh quality of evidence

- Although the individual measures have evidence, it is not clear whether there is evidence for the all-or-none measure
- Evidence is strong
- Systematic reviews support the 3 components of this measure: ASA, P2Y12 agent and statin on discharge

1b. Performance Gap:

- There is evidence of a gap and so that there is importance of this measures
- There is a high percentage of use, but this could still be improved
- Performance score are high Mean 93.6% Median 95.8%; Histogram right skewed. Approx 20% of reporting hospitals were below 90%. Analysis does not indicate disparities by sex, race/ethnicity or income (Medicaid)
- Moderate
- performance scores show a substantial variation. Little evidence of disparities.
- Tables and histograms were very helpful and demonstrated a small performance gap as well as little evidence in disparities in care
- Performance gap is real and persists despite improvement 2011-2016 (see histogram p20).
- Performance ranges from 25.9% to 100% with a mean of 93.6% and median of 95.8%. Data do not indicate disparities in performance. Performance has increased from 89.25% to 95.06% from 2011 to 2016

1c. Composite:

- This is a complex question, but the measure is logical and impacts quality. This does appear to be consistent with the intent of the measure.
- overall high level of quality construct
- Logic model provided for the composite. Rationale is reasonable.
- Given high levels of performance for each individual measure it makes sense to view as composite. Composite approach would also be patient centered
- There was no test to determine whether the all-or-non measure provided more information than any single component
- Yes
- This is an all-or-none measure, so the components are not weighted. The components are logical

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications **and** Testing

2b. Validity: Testing**;** Exclusions**;** Risk-Adjustment**;** Meaningful Differences**;** Comparability**;** Missing Data

2c. For composite measures: empirical analysis **support composite approach**

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel? ☒ **Yes** ☐ **No**

Evaluators: Lacy Fabian, Jeff Geppert, Bijan Borah, Mike Stoto, Matt Austin

Combined reviews

Evaluation of Reliability and Validity (and composite construction, if applicable):

Reliability

- Reliability testing was conducted at the measure score level using a split-sample methodology
    - Results: Pearson correlation: r=0.90

Validity

- Empirical validity testing was conducted at the measure score level. Developers also described the conduct of a face validity assessment; however, that assessment does not conform to NQF's requirements.
- Developers conducted a construct validation analysis by correlating the results of this measure with results from two measures of 30-day all-cause mortality following PCI (NQF #0536, which includes patients with STEMI/shock, and NQF #0535, which includes patients without STEMI/shock) using data from Q4 2013 to Q3 2014.
    - Developers hypothesized that providing discharge medications for PCI patients leads to better short-term outcomes.
    - Results
        - Pearson correlation coefficient between this measure and STEMI/Shock mortality measure (NQF#: 0536): -0.07465 (n=1,273)
        - Pearson correlation coefficient between this measure and NSTEMI/No Shock mortality measure (NQF#: 0535): -0.16380 (n=1,283)
        - These results supported the developers' hypothesis (i.e., better provision of discharge medications was associated with lower mortality), although the magnitude of the correlations was low.
    - Panel members were concerned about the low, albeit statistically significant correlations results. They applauded the effort to assess the association with a relevant outcome, but questioned whether mortality was the best outcome to investigate. They suggested that a more proximal outcome measure may have been more suitable.
- Additional concerns regarding validity
    - The Panel noted the overall high performance rates across facilities and questioned whether meaningful differences exist (Mean=93.58; median=95.83; 25th percentile=91.87)
    - The denominator of the P2Y12 inhibitor component is quite a bit narrower than that of the other two components (i.e., restricted to patients undergoing PCI with stenting but no contraindication to the P2Y12 inhibitor). The concern is that facility performance may be impacted not only by the performance on the components in the measure, but also on the relative frequency of PCI with and without stenting.

- Panel members noted that hospitals that do not pass the data quality review for the NCDR registry are not included in the measure.

Composite

- Developers computed hospital-level results for the three components and correlated them with the composite results (via the Pearson correlation statistic)
  - Aspirin: r=0.7774
  - P2Y12: r=0.5910
  - Statin: r=0.9508
- Panel members would have liked to have seen more analysis to support the equal-weighting decision
- Panel members expressed concern about the utility of including the aspirin and P2Y12 components in the composite

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Scientific Methods Panel **could not reach consensus** with the validity analyses for the measure. The Committee needs to discuss and vote on validity.

Questions for the Committee regarding composite construction:

- Do you have any concerns regarding the composite construction approach (e.g., do the component measures fit the quality construct and add value to the overall composite? Are the aggregation and weighting rules consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible?)?
- The Scientific Methods Panel is satisfied with the composite construction. Does the Committee think there is a need to discuss and/or vote on the composite construction approach?

Preliminary rating for reliability: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for validity: CONSENSUS NOT REACHED ☐ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Preliminary rating for composite construction: ☒ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Combined Methods Panel Scientific Acceptability Evaluation

Measure Number: 0964

Measure Title: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

Type of measure:

☐ **Process** ☐ **Process: Appropriate Use** ☐ **Structure** ☐ **Efficiency** ☐ **Cost/Resource Use**

☐ **Outcome** ☐ **Outcome: PRO-PM** ☐ **Outcome: Intermediate Clinical Outcome** ☒ **Composite**

Data Source:

☐ **Claims** ☐ **Electronic Health Data** ☐ **Electronic Health Records** ☐ **Management Data**

☐ **Assessment Data** ☐ **Paper Medical Records** ☐ **Instrument-Based Data** ☒ **Registry Data**

☐ **Enrollment Data** ☒ **Other**

Level of Analysis:

☐ **Clinician: Group/Practice** ☐ **Clinician: Individual** ☒ **Facility** ☐ **Health Plan**

☐ **Population: Community, County or City** ☐ **Population: Regional and State**

☐ **Integrated Delivery System** ☐ **Other**

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes** ☐☒ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

   PANEL MEMBER 1: None.

   PANEL MEMBER 2: None.

   PANEL MEMBER 3: The composite consists of three component measures evaluated at the patient-level (i.e. "all-or-none"). In my view, all-or-none measures are not composite measures, but rather individual measures with Boolean (and-or) logic in the numerator. Therefore the evaluation criteria are the same as an individual measure.

   In an individual measure, the denominator is the target population or the population at risk. However, here there are two different target populations. The denominator of one of the component measures (P2Y12 inhibitor) is a subset of the denominator of the other two (Patients undergoing PCI with stenting). None of the empirical testing addresses the impact of the denominator specification on the reliability or validity of the composite. An alternative would be to calculate a facility level rate among patients undergoing PCI with stenting and another among patients undergoing PCI without stenting, and then aggregating the two component performance scores into a composite using population percentages (with and without stenting) as the weights. As specified, the concern is that facility performance is impacted not only by the quality construct, but also by the relative frequency of PCI with and without stenting.

   PANEL MEMBER 4: Data source cited in S.17 (Other, Registry Data) is not clear. Perhaps this refers to data used for testing rather than for intended use. 3c.1 states "The data elements required for this measure are readily available within the patient's medical record or can be attained without undue burden within the hospital. Most data elements exist in a structured format within patient's electronic health record."

   PANEL MEMBER 5: The measure titles listed on the testing form and the MIF do not match.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level** ☒ **Measure score** ☐ **Data element** ☐ **Neither**

4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure**
   ☒ Yes ☒ No

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of patient-level data conducted?

   ☐ Yes ☐ No

   PANEL MEMBER 5: N/A

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   PANEL MEMBER 1: Split-sample methodology was adopted for reliability testing.

   PANEL MEMBER 2: Used a split sample analysis for assessing reliability.
   PANEL MEMBER 3: The developer used a split-sample methodology, which does not seem appropriate for the assessment of reliability, which is the intent to assess measurement error (i.e. noise) relative to purpose. I believe the split sample methodology only assesses the degree of signal (not signal relative to noise).
   PANEL MEMBER 4: The split sample method was appropriate. The data were from a registry, however, and it is not clear if actual operational data would perform as well.

   PANEL MEMBER 5: Used a split sample method to randomly divide data into two groups, with consistent timing.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

   PANEL MEMBER 1: The results in Section 2a2 in the testing document clearly indicates that the measure is highly reliable.

   PANEL MEMBER 2: The distribution of scores was very close to each in both samples.

   PANEL MEMBER 3: The developer reports a Pearson correlation coefficient of 0.90270 which is difficult to interpret for the reasons cited above. A more useful metric would be the percentage of measured entities that are below a threshold or above a benchmark at some probability (e.g. 80%)

   PANEL MEMBER 4: As presented, the results demonstrate considerable reliability.

   PANEL MEMBER 5: Average scores across the two random samples were not statistically different, with similar standard deviations.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒Yes

   ☐No

   ☐Not applicable (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☐Yes

   ☐No

   ☒Not applicable (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and all testing results):

    ☒High (NOTE: Can be HIGH only if score-level testing has been conducted)

☒**Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has not been conducted)

☒**Low** (NOTE: Should rate LOW if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

☐**Insufficient** (NOTE: Should rate INSUFFICIENT if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

PANEL MEMBER 1: The rationale for "High" reliability rating is based on the testing results provided. I have no further concerns.

PANEL MEMBER 2: High level of agreement between the two groups in the split sample.

PANEL MEMBER 3: Reliability is about estimation error, and the magnitude of that estimation error relative to purpose. The developer did not address the degree of estimation error relative to purpose.

PANEL MEMBER 4: As presented, the results demonstrate considerable reliability, and might have deserved a "High" rating. The data were from a registry, however, and it is not clear if actual operational data would perform as well.

PANEL MEMBER 5: Used a randomly split sample, and showed similar performance of the measure in each sample.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

Submission document: Testing attachment, section 2b2.

PANEL MEMBER 1: None.

PANEL MEMBER 2: None.

PANEL MEMBER 3: None (other than the PCI with and without stenting mentioned above)

PANEL MEMBER 4: None.

PANEL MEMBER 5: The exclusions appeared appropriate; however, wouldn't it be possible that patients who leave against medical advice should still be included in the sample as indicative of those who did still receive the prescriptions for the medication since this process measure has no assessment of actual compliance with the prescription and excluding those even more likely to be non-compliant can bias the sample?

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

Submission document: Testing attachment, section 2b4.

PANEL MEMBER 1: None.

PANEL MEMBER 2: None.

PANEL MEMBER 3: Given the concerns about reliability mentioned above, it would be difficult to establish whether the differences in performance would result in quality improvement through selection or choice.

PANEL MEMBER 4: None.

PANEL MEMBER 5: The measure shows very high scores between 90-100% with no apparent interpretation of what the clinical difference is between a score of 90 and 100 is, so it is difficult to tell if this variation is meaningful.

Similarly, the developers stratified on age, sex, race/ethnicity, and insurance. The distributions appear highly similar based on means/SD with neither p-values or clinical interpretation of differences; however, the conclusion drawn is that there is a "wide gap in performance rates" across various stratified populations.

Without p-values or clinical interpretations, there isn't enough information to conclude that meaningful differences exist; rather, given the high rates of performance and very small correlation with the outcomes, this measure does not appear to meaningfully add to the discussion of quality relative to the burden of collection/reporting/maintenance.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**

Submission document: Testing attachment, section 2b5.

PANEL MEMBER 1: N/A

PANEL MEMBER 2: Not applicable

PANEL MEMBER 3: None (the measure only uses registry data)

PANEL MEMBER 4: None.

PANEL MEMBER 5: N/A.

15. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

PANEL MEMBER 1: N/A

PANEL MEMBER 2: Not applicable.

PANEL MEMBER 3: Difficult to determine. The developer states that facilities and cases with missing data are simply excluded from the registry.

PANEL MEMBER 4: None

PANEL MEMBER 5: No concerns.

16. **Risk Adjustment**

16a. **Risk-adjustment method** ☒ **None** ☐ **Statistical model** ☒ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☒ Yes ☐ No ☒ Not applicable

16c. **Social risk adjustment:** **PANEL MEMBER 1:** (Based on 2b4)

16c.1 Are social risk factors included in risk model? ☐ Yes ☒ No ☒ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☒ Yes ☒ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☒ No

16d. **Risk adjustment summary:** **PANEL MEMBER 1:** N/A

16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

16d.5. Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e**. Assess the risk-adjustment approach**

PANEL MEMBER 1: N/A – while the risk adjustment section (2b3) is kept blank, and thus suggesting that there was no risk adjustment adopted. However, I noticed that Section 2b4 did assess the measure by different sub-groups – age, gender, race/ethnicity and insurance type. I also did not notice a justification of risk adjustment.

PANEL MEMBER 3: The composite is a process measure so risk-adjustment does not apply (although case-mix adjustment may apply for the PCI with and without stenting.

PANEL MEMBER 5: The developer did not check 2b3 .1 on the method for controlling for differences and noted N/A for subsequent questions; however, did perform stratification analyses.

VALIDITY: TESTING

17. **Validity testing level: ☒ Measure score ☐ Data element ☐ Both**
18. **Method of establishing validity of the measure score:**
    - ☒ **Face validity**
    - ☒ **Empirical validity testing of the measure score**
    - ☐ **N/A (score-level testing not conducted)**
19. **Assess the method(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.2

    PANEL MEMBER 1: As detailed in 2b1, face validity was achieved through panel of subject matter experts involved in the development of the measure. Empirical validity was assessed by determining if hospitals performed similarly on the composite discharge medication measure and 30-day mortality.

    PANEL MEMBER 2: Compared performance on the process measure to 30-day mortality.

    PANEL MEMBER 3: The developer examined the facility level correlation between the composite process measure and 30-day mortality. The only concern is that the data used for validity were older (Q4 2013 to Q3 2014) than the data used for reliability (2015-2016)

    PANEL MEMBER 4: Face validity was assessed in a formal process. Empirical testing included (a) correlating the composite with all of its components and (b) a calibration analysis with 30-day risk-standardized mortality rates (RSMR).

    PANEL MEMBER 5: Face validity was one component of validity testing. It appears that subject matter experts who also developed the measure are attributed to having achieved the face/content validity of the measure. While having such subject matter experts is one aspect to achieving face/content validity, it can be further strengthened if that initially developed measure is taken to those in the field (who are not also developing the measure) for their review and input.

    Empirical validity was the second component of validity testing as part of reendorsement. The developers correlated the score on their process/composite measure with NQF endorsed outcome measures of mortality to determine if better medication compliance was associated with reduced mortality.

20. **Assess the results(s) for establishing validity**

    Submission document: Testing attachment, section 2b2.3

    PANEL MEMBER 1: With regard to face validity, the individual components of the composite measure have bene associated with better outcomes and are considered as quality measures in the patient population. With regard to empirical validity, the strength of evidence was weak, as demonstrated by the low correlations between the composite measure and 30-day risk adjusted mortality rates.

    PANEL MEMBER 2: Weak relationship between the two measures.

PANEL MEMBER 3: The developer reports a negative but small correlation between the process and outcome. Given that the composite process measure has 2x2x2 possible values, it may be more useful to examine the outcome performance in all eight cells.

PANEL MEMBER 4: The results of all of these analyses demonstrated strong validity. The R^2 for statins (90.5% - section 1c.2), however, suggests that not much is gained by adding ASA and P2Y12.

PANEL MEMBER 5: The conclusions drawn from the face validity testing are that the measure has face validity, given consensus among experts on clinical evidence and reliability. Given the measure is up for reendorsement, it seems it would be a stronger presentation if additional face validity methods were conducted as above (21). The conclusions drawn from the empirical validity testing are that the measure is valid in that as hypothesized greater compliance was associated with reduced mortality, albeit with a very small correlation (-0.07 and -0.16).

21. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

    Submission document: Testing attachment, section 2b1.

    ☒**Yes**

    ☐**No**

    ☐**Not applicable** (score-level testing was not performed)

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?** *NOTE that data element validation from the literature is acceptable.*

    Submission document*: Testing attachment, section 2b1.*

    ☐**Yes**

    ☐**No**

    ☒**Not applicable** (data element testing was not performed)

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☒**High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☒**Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

    ☒**Low** (NOTE: Should rate LOW if you believe that there <u>are</u> threats to validity and/or relevant threats to validity were <u>not assessed OR</u> if testing methods/results are not adequate)

    ☐**Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level <u>is required</u>; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

    PANEL MEMBER 1: My "moderate" ranking on validity was based on my comment on #22.

    PANEL MEMBER 2: Appropriate method for assessing validity; do have concerns with the weak correlation found.

    PANEL MEMBER 3: Although the association is modest, this is one of the few submissions that attempts to demonstrate an empirical association between the quality construct and a material outcome.

    PANEL MEMBER 4: Methods were appropriate and results strong. My comment about the R^2 for statins addresses usefulness, not validity.

PANEL MEMBER 5: The greatest threats are with meaningful differences (see additional detail in item 13). There are also concerns that face validity could have been assessed outside of the developer expertise, given reendorsement.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

25. **What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?**

    ☒**High**

    ☒**Moderate**

    ☒**Low**

    ☐**Insufficient**

26. **Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION**

    PANEL MEMBER 1: The reason why I rank this as "moderate" is as follows. Although the measure developer offers the following justification on this issue, I don't see the correlation estimates noted there: *"The empirical validity analysis demonstrated that the individual component measures fit the overall quality construct by assessing the Pearson correlation of the discharge medications composite measure with its components, including: aspirin, P2Y12 and statins."*

    PANEL MEMBER 2: Did look at Pearson correlations between the composite measure and the individual component measures; could have done some sensitivity analyses on the decision to weight all 3 individual measures the same.

    PANEL MEMBER 3: Adding value in this context means that the user makes a better decision (is more likely to experience a better outcome) with the component than without it. That concept was not demonstrated. There was a Pearson correlation of the three components with the overall composite process measure, but that is difficult to interpret given the different denominators (PCI with and without stenting)

    PANEL MEMBER 4: Empirical testing included correlating the composite with all of its components (also part of validity testing). The R^2 for statins (90.5% - section 1c.2) suggests that not much is gained by adding ASA and P2Y12.

    PANEL MEMBER 5: The developers correlated each component of the three components with the composite value and demonstrated higher correlations, with no weighting applied.

    I'm not sure this is a composite measure. It seems more a process measure that is composed of items; rather than, a composite measure that is composed of multiple measures made up of multiple items.

ADDITIONAL RECOMMENDATIONS

27. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

    PANEL MEMBER 1: I did not see any justification for not doing risk adjustment.

    PANEL MEMBER 3: I think the question of whether an "all-or-none" composite may have material different denominators in one or more of the component measures is worthy of some discussion and empirical demonstration.

    PANEL MEMBER 4: None.

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Specifications:

- All of the elements of the mesure are part of the metrics and they make sense.
- No concerns
- Data elements (prescription of meds at discharge) are clearly identified and have been used for many years. There is no risk adjustment.
- No concerns
- clearly defined
- No Concerns
- All good for this.
- At the score level the reliability is 0.90 based on split sample. No concerns

2a2. Reliability testing:

- Yes, I have concerns about the aggregaton of the elements of the measure raise conderns over the applicability of the measure
- no concerns about reliability
- Data from the NCDR Cath-PCI 2015-2016 used Methodology - Split Sample Good correlation between samples Pearsons = 0.9027
- No
- no concerns
- no concerns
- Note scientific panel's lack of consensus on reliability. To address concerns about the relationship of the measure to "actual operational data," it would be useful for ACC to provide information on this data from the measure audits that they do. Also, given note that hospital that do not pass the NCDR quality data review are excluded, it would be good to know the fraction and characteristics of hospitals so excluded.
- No concerns

2b1. Validity testing:

- No, no concerns with the testing results for this measure
- validation testing appropriate
- Face validity by NCDR Clinical Subwork group; Empirical validity tested by comparing scoring with 30-day risk-standardized mortality - very weak correlation but in expected direction
- Testing process measure against outcomes measure, especially short term outcomes, is never a great approach, since correlations can only be expected to be weak at best.
- construct validation resulted in low correlation. They explain that this may be due to too distal of an outcome.
- The Methods Panel had concerns about the two populations that are being combined and I have the same concern. Given that the percent stenting could vary significantly across sites, a more valid approach might be to create the measures separately and then combine, as suggested by the panel
- no
- No concerns. Validity was tested against STEMI and nSTEMI shock/mortality and weak but significant negative correlations were found.

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data):

- The measure is currently being threatened because of inappropriate lower levels of care.
- No concerns based on validity testing
- No missing data per authors
- N/A
- Composite construct of the 3 medications seems appropriate as is the all-or-none construct.
- not that I can tell

- No threats
- The differences are meaningful. There were no missing data for this measure. Any hospitals with missing data were excluded from the measure as they would not have passed the NCDR data quality review. There are no significant threats to validity.

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment):

- the current process is one that does not meet the epectatiosns of people at rest
- appropriate risk adjustment discussion
- Most exclusions seemed appropriate. Not sure why transfer patients were excluded rather than being examined as discharges. No risk adjustment (process measure)
- Hospitals and practices should deliver this care 100% of time regardless of social factors, especially as it measures a hospital process.
- exclusions appropriate and minimal
- N/A
- no threats
- Exclusions are appropriate. The measure is not risk adjusted

2c. Composite:

- Yes, this part of the question is appropriate
- fits the quality construct with this composite measure
- Yes
- Yes
- no - there is no analysis to determine whether all three components are necessary
- no concerns
- There is no weighting of the components. The component measure does add value and the aggregation fits the quality construct

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- All information is obtained from the Cath PCI registry in the National Cardiovascular Data Registry (NCDR).
- The developer reports that the data are available via several methods: electronic transfer to the registry from the procedure/care setting; web-based tool for manual data entry or from an EHR.
- The developer states that the data elements captured (patient demographics, medical history, risk factors, hospital presentation, initial cardiac status, procedural details, medications, laboratory values and in-hospital outcomes) are readily available in medical records or can be attained without undue burden.
- The fees for participating in the registry: "For calendar year 2017 the annual pricing for hospitals, NCDR Analytic and Reporting Services, and licensing of measure specifications ranges from $2900-$50,000."

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?
- Would the cost of licensing put any great restrtictions on use?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility:

- feasibility is not clear as aspirin is not captured in medical economic data as aspirin in OTC
- data is readily available
- Has been used successfully for many years
- No concerns
- all data elements are defined in electronic clinical data
- no concerns
- no concerns
- The measure is based on NCDR participation and is feasible for participants

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported? ☒ **Yes** ☐ **No**

Current use in an accountability program? ☒ **Yes** ☐ **No** ☐ **UNCLEAR**

OR

Planned use in an accountability program? ☐ **Yes** ☐ **No**

Accountability program details

- Current use:
  - Quality Hospital Insight program for Anthem.
    - "Blue Distinction Centers for Cardiac Care is a national designation program that recognizes hospitals that demonstrate expertise in delivering quality specialty care, safely and effectively."
    - A total of 414 hospitals participate
  - Also, the National Cardiovascluar Data Registry, is used for public reporting and external quality Improvement with Benchmarking.
    - "ACC's National Cardiovascular Data Registry (NCDR) Voluntary Hospital Public Reporting Program: The ACC currently runs a program to give hospitals the opportunity to voluntarily publicly report their measure results based on data from the National Cardiovascular Data Registry (NCDR). Hospitals that choose to participate have their results displayed on ACC's CardioSmart."

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- Performance results are distributed to all CathPCI registry participants as part of quarterly benchmark reports. Reports include an executive summary dashboard, at-a-glance assessments, and patient level drill-downs. Registry participants also have access to an outcome report companion guide which provides common definitions and detailed metric specifications to assist with interpretation of performance rates.
- Feedback is typically obtained through monthly registry site manager monthly calls, ad hoc phone calls tracked with salesforce software, and during registry –specific break-out sessions at the NCDR's annual meeting. Registry Steering Committee members may also provide feedback during regularly scheduled calls.
- The developer states that users have not reported any issues with reporting this measure, therefore feedback has not been considered when incorporating changes to the measure.

Additional Feedback: [feedback loops]

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer states that performance rates for the composite measure have increased over time, corresponding to a growing denominator, and that these 2011-2016 rates indicate that outcomes are improving, as more patients undergoing PCI are receiving all medications for which they are eligible.

Performance Rates for Discharge Medications Composite Measure From 2011-2016

Year	Den	Num	%
2011	618146	551717	89.25
2012	627181	570435	90.95
2013	633696	586406	92.54
2014	651046	608801	93.51
2015	682385	643508	94.30
2016	703998	669255	95.06

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

- The developer states that inaccuracies may occur during the process of transmitting the information to the Cath PCI Registry, and that some site may over-code medication exclusions.
- There is the NCDR Data Quality Program in place to assess reliability of data abstraction.

Potential harms

- The developer states that there are no potential harms.

Additional Feedback:

***Questions for the Committee**:*

- How can the performance results be used to further the goal of high-quality, efficient healthcare?

Preliminary rating for Usability and use: ☒ **High** ☐ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a. Use:

- The inability of capture aspirin use makes this a non-validated measure
- Publicly reported and accountability program
- NCDR Cath-PCI registry
- No concerns
- It is used in public reporting, payment programs, and quality improvement
- no concerns
- used widely and regularly for quality improvement
- The measure is currently used by the Blue Distinction Centers for Cardiac Care. Participating centers get feedback and benchmarking

4b. Usability:

- Even if there are other measures that capture the potential for appropriate us, then there is less confibdence for use of this as a measure
- minor concern if data extracted inaccurately
- Widely utilized for public reporting and payment programs. Cost to utilize NCDR Analytic & Reporting Services $29,000 -$50,000. Larger hospitals can most likely afford but smaller ones may not.
- No concerns. No harms imagined
- No comment
- The three components should be available and easily recorded - no concerns
- none
- Benchmarking stimulates improvement. No harms are associated with thee measure

Criterion 5: Related and Competing Measures

Related or competing measures

- The developer also indicates that this measure is related to the following:
  - 0067 : Chronic Stable Coronary Artery Disease: Antiplatelet Therapy
  - 0068 : Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic
  - 0074 : Chronic Stable Coronary Artery Disease: Lipid Control

- 0118 : Anti-Lipid Treatment Discharge
- 0142 : Aspirin prescribed at discharge for AMI
- 0543 : Adherence to Statin Therapy for Individuals with Coronary Artery Disease
- 0569 : ADHERENCE TO STATINS
- 0631 : Secondary Prevention of Cardiovascular Events - Use of Aspirin or Antiplatelet Therapy
- 0639 : Statin Prescribed at Discharge

Harmonization

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing:

- No similar measures.
- numerous competing measures, but in alignment with them
- 0631 Secondary Prev - ASA or Antiplatelet RX; 0639 Statin Prescribed at Discharge others see Worksheet
- related measures for aspirin and statin at discharge exist as individual measures.
- hard to tell
- no
- There are a number of related and competing measures, but the developer makes the argument that this measure is superior to the others.

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 1/25/19

No comments or support/non-support choices have been submitted as of this date.

Brief Measure Information

NQF #: 0964

Corresponding Measures:

De.2. Measure Title: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

Co.1.1. Measure Steward: American College of Cardiology

De.3. Brief Description of Measure:) Proportion of eligible patients = 18 years of age, who were prescribed aspirin, P2Y12 inhibitor, and statin at discharge following PCI with or without stenting.

1b.1. Developer Rationale: This measure is intended to improve rates of evidence-based medication prescribing for patients following PCI to improve outcomes associated with cardiovascular disease.

S.4. Numerator Statement: Patients who receive all medications for which they are eligible.

1. Aspirin prescribed at discharge (if eligible for aspirin as described in denominator)

   AND

2. P2Y12 agent (clopidogrel, prasurgel, ticlopidine, or ticagrelor) prescribed at discharge (if eligible for P2Y12 as described in denominator)

   AND

3. Statin prescribed at discharge (if eligible for statin as described in denominator)

S.6. Denominator Statement: Patients surviving hospitalization who are eligible to receive any of the three medication classes:

1) Eligible for aspirin (ASA): Patients undergoing PCI who do not have a contraindication to aspirin documented

AND

2) Eligible for P2Y12 agent (clopidogrel, prasugrel, ticlopidine, or ticagrelor): Patients undergoing PCI with stenting who do not have a contraindication to P2Y12 agent documented

AND

3) Eligible for statin therapy: Patients undergoing PCI who do not have a contraindication to statin therapy.

S.8. Denominator Exclusions: The exclusions for this measure are comprised of patients without the following: (1) a PCI during the admission , (2)discharge status of deceased (9040), and (3) discharge location of "other acute hospital, hospice, or against medical advice.

De.1. Measure Type: Composite

S.17. Data Source: Other, Registry Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Feb 05, 2013 **Most Recent Endorsement Date:** Sep 08, 2014

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? N/A

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.***

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

0964_nqf_evidence_attachment_7.1_11.7.18_final.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

1a. Evidence (subcriterion 1a)

Aspirin prescribed at discharge

Measure Number (*if previously endorsed*)**:** 0964

Measure Title: Aspirin prescribed at discharge

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

Date of Submission: 11/8/2018

Instructions

- *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
- *Complete EITHER 1a.2, 1a.3 or 1a.4 as applicable for the type of measure and evidence.*
- *For composite performance measures:*
  - *A separate evidence form is required for each component measure unless several components were studied together.*
  - *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
- All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Contact NQF staff regarding questions. Check for resources at Submitting Standards webpage.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- Outcome: 3 Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured intermediate clinical outcome leads to a desired health outcome.

- Process: 5 a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured process leads to a desired health outcome.
- Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured structure leads to a desired health outcome.
- Efficiency: 6 evidence not required for the resource use component.
- For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- Process measures incorporating Appropriate Use Criteria: See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; AQA Principles of Efficiency Measures).

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

☐Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: Aspirin prescribed at discharge for PCI patients

☐ Appropriate use measure:

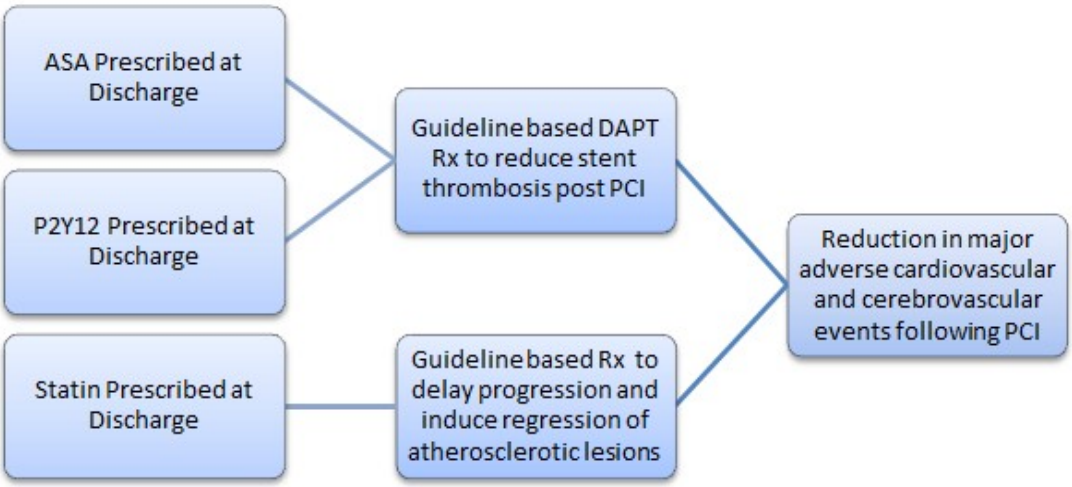
☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Intracoronary stents, either drug eluting or bare metal, are used in the treatment of the majority of patients who undergo percutaneous coronary intervention (PCI) to improve symptoms related to their obstructive coronary artery disease. These stents have a dual function; to prevent abrupt closure of the treated artery (acute stent thrombosis) and to reduce the need for repeat revascularization because of gradual recurrence of the coronary obstruction (in-stent restenosis) over time. While acute stent thrombosis is relatively uncommon, it manifests as acute myocardial infarction, usually with ST-segment elevation, and can be fatal. Recommended treatment therapy with dual antiplatelet therapy (DAPT: aspirin plus platelet P2Y12 receptor

inhibitors) markedly lowers the risk of acute stent thrombosis. Two of the three medications included in this composite medication are included for this purpose, to reduce the risk of adverse outcomes such as MI or death after stenting. The third medication included in this composite measure is the Statin class to delay progression of atherosclerosis and prevent recurrent coronary events. The use of these three medication classes is strongly endorsed by national consensus practice guidelines to reduce adverse events or death following PCI.



1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☒ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☒ Other

Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2011;58(24):e44-e122. doi:10.1016/j.jacc.2011.08.007. URL for guideline: http://content.onlinejacc.org/article.aspx?articleid=1147816
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	Page 41 of 79; e84. Section 6.1 Postprocedural Antiplatelet Therapy: Recommendations CLASS I #1. After PCI, use of aspirin should be continued indefinitely. (Level of Evidence: A) #3. Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist. (Level of Evidence: C) CLASS IIa #1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses). (Level of Evidence: B)
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	The weight of the evidence in support of most of the ACCF/AHA/SCAI recommendations included are rated as Level A, Level C and Level B respectively as noted parenthetically. Level A evidence refers to "Data derived from multiple randomized clinical trials or meta-analyses." The weight of the evidence in support of additional recommendations is rated as Level B and C. Level B evidence refers to "Data derived from a single randomized trial, or nonrandomized studies" while Level C evidence refers to "Only consensus opinion of experts, case studies, or standard-of-care."
Provide all other grades and definitions from the evidence grading system	See question above and next two questions below for more information.
Grade assigned to the **recommendation** with definition of the grade	ACCF/AHA/SCAI recommendations included have been assigned a Class I and Class IIa recommendation. Class I recommendations refer to "Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective." Class IIa recommendations refer to "Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. Weight of evidence/opinion is in favor of usefulness/efficacy."

Provide all other grades and definitions from the recommendation grading system	ACCF/AHA guideline methodology categorizes indications as class I,II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below: Classification Types Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective. Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. • IIa: Weight of evidence/opinion is in favor ofusefulness/efficacy • IIb: Usefulness/efficacy is less well established byevidence/opinion. Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective e and in some cases may be harmful. • No Benefit- Procedure/Test not helpful orTreatment w/o established proven benefit • Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful Additional detail regarding the classification of recommendation and level of evidence is provided in the following table.

Table 1:

Estimate of Certainty (Precision) of Treatment Effect	**CLASS I** **Benefit >>> Risk** **Procedure/Treatment SHOULD be performed/administered**	**CLASS IIa** **Benefit >> Risk** **Additional studies with focused objectives needed** **IT IS REASONABLE to perform procedure/administer treatment**	**CLASS IIb** **Benefit ≥ risk** **Additional studies with broad objectives needed; additional registry data would be helpful** **Procedure/Treatment MAY BE CONSIDERED**	**CLASS III *No Benefit* or CLASS III *Harm*** **Procedure/ Test** / **Treatment** COR III: No Benefit — Not Helpful — No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful — Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	▪ Recommendation that procedure or treatment is useful/effective ▪ Sufficient evidence from multiple randomized trials or meta-analyses	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Some conflicting evidence from multiple randomized trials or meta-analyses	▪ Recommendation's usefulness/efficacy less well established ▪ Greater conflicting evidence from multiple randomized trials or meta-analyses	▪ Recommendation that procedure or treatment is not useful/effective and may be harmful ▪ Sufficient evidence from multiple randomized trials or meta-analyses
Level B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	▪ Recommendation that procedure or treatment is useful/effective ▪ Evidence from a single randomized trial or nonrandomized studies	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Some conflicting evidence from single randomized trial or nonrandomized studies	▪ Recommendation's usefulness/efficacy less well established ▪ Greater conflicting evidence from single randomized trial or nonrandomized studies	▪ Recommendation that procedure or treatment is not useful/effective and may be harmful ▪ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	▪ Recommendation that procedure or treatment is useful/effective ▪ Only expert opinion, case studies, or standard of care	▪ Recommendation in favor of treatment or procedure being useful/effective ▪ Only diverging expert opinion, case studies, or standard of care	▪ Recommendation's usefulness/efficacy less well established ▪ Only diverging expert opinion, case studies, or standard of care	▪ Recommendation that procedure or treatment is not useful/effective and maybe harmful ▪ Only expert opinion, case studies, or standard of care.
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	**COR III: No Benefit** / **COR III: Harm** is not recommended / potentially harmful is not indicated / causes harm should not be performed/ administered/ other / associated with excess morbidity/ mortality is not useful/ beneficial/ effective / should not be performed/ administered/ other
Comparative effectiveness phrases[1]	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B It is reasonable to choose treatment A over treatment B		

Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	Two meta-analyses were evaluated (one collaborative meta-analysis reviewing 287 studies involving 135,000 patients in comparisons of antiplatelet therapy versus control and 77,000 in comparisons of different antiplatelet regimens and one meta- analysis of risk of bleeding complications after different doses of aspirin in 192,036 patients enrolled in 31 randomized controlled trials); one observational analysis from a double-blind, placebo-controlled, randomized trial 15,595 patients; two scientific advisory groups were consulted (the 2008 American College of Chest Physicians Evidence-Based Clinical Practice Guidelines and the 2007 Science Advisory Statement from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians); and two clinical trials were included in this body of evidence. Information regarding the overall quality of evidence across studies is not available.

Estimates of benefit and consistency across studies	Quantitative estimates of benefit of Aspirin therapy across this body of evidence are not reported.
What harms were identified?	The guidelines document addresses a post hoc analysis of the PLATO study, specifically that the based on the results in the U.S. patient cohort, a black box warning was developed stating that maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor, a P2Y12 Inhibitor, and should be avoided. After any initial dose, ticagrelor should be used with aspirin 75 mg to 100 mg per day. Ticagrelor has not been studied in elective PCI or in patients who received fibrinolytic therapy; thus, no recommendations about its use in these clinical settings can be made.
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	The ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention was most recently updated in 2011 with respect to these specific therapies as cited above.

Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	Brilakis ES, Patel VG, Banerjee S. Medical management after coronary stent implantation: a review. *JAMA.* 2013;310(2):189-198. doi:10.1001/jama.2013.7086 http://jama.jamanetwork.com/article.aspx?articleid=1710463
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	The review focused on medical therapy after percutaneous coronary intervention (PCI).
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	The authors of the systematic review did not assign a grade to the overall quality of the evidence.
Provide all other grades and definitions from the evidence grading system	The methodology for evidence review is included in the methods section of the review cited. The authors of the systematic review did not assign a grade to the overall quality of the evidence.
Grade assigned to the **recommendation** with definition of the grade	NA
Provide all other grades and definitions from the recommendation grading system	NA

Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	The systematic review included 91 publications, with priority given to data from large randomized- controlled trials, systematic reviews, and meta-analyses. The authors of the review did not provide an assessment of the overall quality of evidence across studies.
Estimates of benefit and consistency across studies	Quantitative estimates of benefit of aspirin therapy across this body of evidence are not reported.
What harms were identified?	The 2013 JAMA review considered issues surrounding appropriate dose and duration of anti-platelet drugs, drug allergies, method of administration, surgery following stent implantation, oral anticoagulation, and risk of bleeding. After consideration of the risks and benefits of therapy, the authors concluded that dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor remains the appropriate medical therapy for optimizing outcomes following PCI
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	The body of evidence is current and no additional, relevant studies have been identified.

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

The methodology for evidence review is included in the methods section of the review cited in 1a.6.1.

1a.4.2 What process was used to identify the evidence?

The authors do no provide an overall grade for the evidence.

1a.4.3. Provide the citation(s) for the evidence.

P2Y12 inhibitor prescribed at discharge

Measure Number (*if previously endorsed*)**:** 0964

Measure Title: P2Y12 inhibitor prescribed at discharge

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

Date of Submission: 11/8/2018

Instructions

- *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
- *Complete EITHER 1a.2, 1a.3 or 1a.4 as applicable for the type of measure and evidence.*
- *For composite performance measures:*
  - *A separate evidence form is required for each component measure unless several components were studied together.*
  - *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
- All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.

- If you are unable to check a box, please highlight or shade the box for your response.
- Contact NQF staff regarding questions. Check for resources at Submitting Standards webpage.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- Outcome: 3 Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured intermediate clinical outcome leads to a desired health outcome.
- Process: 5 a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured process leads to a desired health outcome.
- Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured structure leads to a desired health outcome.
- Efficiency: 6 evidence not required for the resource use component.
- For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- Process measures incorporating Appropriate Use Criteria: See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; AQA Principles of Efficiency Measures).

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

☐Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: P2Y12 inhibitors prescribed at discharge for PCI patients/prescribing optimal medical therapy at discharge for patients undergoing PCI

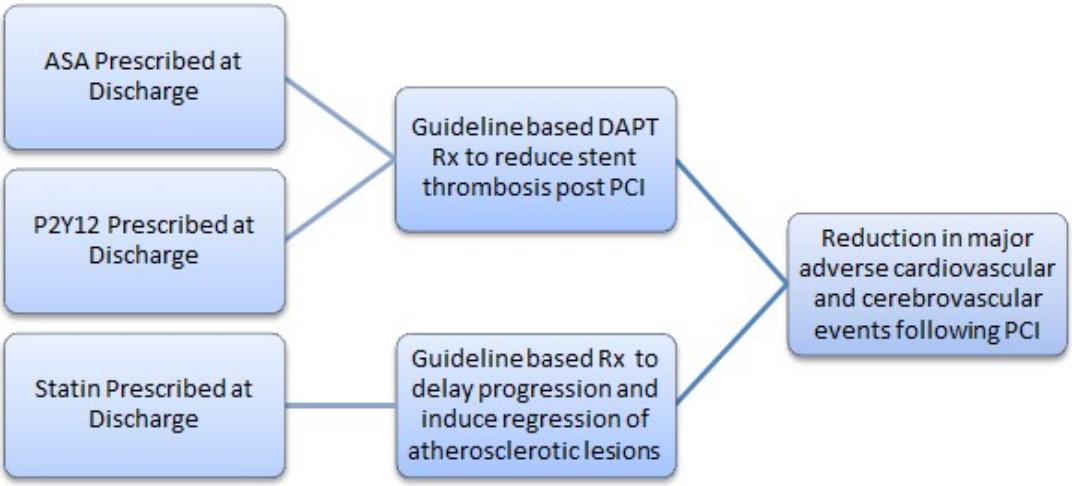
☐ Appropriate use measure:

☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Intracoronary stents, either drug eluting or bare metal, are used in the treatment of the majority of patients who undergo percutaneous coronary intervention (PCI) to improve symptoms related to their obstructive coronary artery disease. These stents have a dual function; to prevent abrupt closure of the treated artery (acute stent thrombosis) and to reduce the need for repeat revascularization because of gradual recurrence of the coronary obstruction (in-stent restenosis) over time. While acute stent thrombosis is relatively uncommon, it manifests as acute myocardial infarction, usually with ST-segment elevation, and can be fatal. Recommended treatment therapy with dual antiplatelet therapy (DAPT: aspirin plus platelet P2Y12 receptor inhibitors) markedly lowers the risk of acute stent thrombosis. Two of the three medications included in this composite medication are included for this purpose, to reduce the risk of adverse outcomes such as MI or death after stenting. The third medication included in this composite measure is the Statin class to delay progression of atherosclerosis and prevent recurrent coronary events. The use of these three medication classes is strongly endorsed by national consensus practice guidelines to reduce adverse events or death following PCI.



1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but

separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☒ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2011;58(24):e44-e122. doi:10.1016/j.jacc.2011.08.007. URL for guideline: http://content.onlinejacc.org/article.aspx?articleid=1147816
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	Page 41 of 79; e84. Section 6.1. Postprocedural Antiplatelet Therapy: Recommendations 1) The duration of P2Y12 inhibitor therapy after stent implantation should generally be as follows: a) In patients receiving a stent (BMS or DES) during PCI for ACS, P2Y12 inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily(570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568). (Class I, Level of Evidence: B) b) In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding (208,212,571). (Class I, Level of Evidence: B) c) In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (572). (Class I, Level of Evidence: B)
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	The weight of the evidence in support of the various ACCF/AHA/SCAI recommendations included in section 1a.4.2 is rated as Level B, as noted parenthetically. Level B evidence refers to "Data derived from a single randomized trial, or nonrandomized studies."
Provide all other grades and definitions from the evidence grading system	See question above and next two questions below for more information.
Grade assigned to the **recommendation** with definition of the grade	All ACCF/AHA/SCAI recommendations have been assigned a Class I recommendation. Class I recommendations refer to "Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective."

Provide all other grades and definitions from the recommendation grading system	ACCF/AHA guideline methodology categorizes indications as class I,II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below: Classification Types Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective. Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. • IIa: Weight of evidence/opinion is in favor of usefulness/efficacy • IIb: Usefulness/efficacy is less well established by evidence/opinion. Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective e and in some cases may be harmful. • No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit • Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful Additional detail regarding the classification of recommendation and level of evidence is provided in Table 1 .
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	4 randomized controlled trials, 1 observational study, and 1 science advisory statement are cited in support of the recommendation provided. The science advisory statement cites an additional 5 randomized controlled trials. Science advisory statement citation: Grines CL, Bonow RO, Casey DE Jr., et al. Prevention of premature discontinuation of dual antiplatelet therapy in patients with coronary artery stents: a science advisory from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians. J Am Coll Cardiol. 2007;49:734 –9. Information regarding the overall quality of evidence across studies is not available.
Estimates of benefit and consistency across studies	The science advisory statement includes the following summary table which includes the percentage of reported major adverse cardiovascular events in patients treated with dual antiplatelet therapy (ie, aspirin and a P2Y12 inhibitor) compared to aspirin alone or the use of aspirin and warfarin.

Table 1. After Bare-Metal Stent Placement, Aspirin Plus Thienopyridine Reduces Cardiac Events Compared with Aspirin Alone or With Oral Antithrombins

Study	No. of Pts Studied	No. of Pts Treated	MACE, %*			*P*
			ASA Thienopyridine	ASA Warfarin	ASA Alone	
ISAR	517	626	1.6	6.2	…	0.01
FANTASTIC[33]	473	485	5.7†	8.6†	…	0.37
STARS[34]	1653	1965	0.5	2.7	3.6	0.0001
MATTIS[35]	350	350	5.6	11.0	…	0.07
Hall et al[36]	226	358	0.8	…	3.9	0.1

MACE indicates major adverse cardiovascular events; Pts, patients; ASA, aspirin; ISAR, Intracoronary Stenting and Antithrombotic Regimen trial; FANTASTIC, Full ANTicoagulation versus ASpirin TIClopidine after stent implantation; STARS, STent Anticoagulation Regimen Study; and MATTIS, Multicenter Aspirin and Ticlopidine Trial after Intracoronary Stenting.

*Cardiac death, acute MI, or repeat target-vessel revascularization at 30 days (except for the FANTASTIC study).

†Death, MI, or stent occlusion at 6 weeks.

Adapted from ten Berg et al.[1]

What harms were identified?	The guidelines refer to the potential risk of morbidity from P2Y12 inhibitor therapy after stent implantation and that this may prompt the reasonable earlier discontinuation (e.g., < 12 months) of P2Y12 inhibitor therapy in some patients. The science advisory statement includes the following regarding the risk of dual antiplatelet therapy: Dual antiplatelet therapy is not without risk. Like all antithrombotic agents, both aspirin and clopidogrel increase the risk of bleeding compared with placebo. When compared with aspirin, clopidogrel may be associated with lower risk of GI bleeding. However, when clopidogrel was combined with aspirin and administered for prolonged duration (up to 28 months), randomized trials demonstrated an absolute increase (ranging from 0.4% to 1.0%) in major bleeding, compared with aspirin alone
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	The ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention has not been updated since the 2011 document referenced in the citations above PCI.

Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	Brilakis ES, Patel VG, Banerjee S. Medical management after coronary stent implantation: a revew. *JAMA.* 2013;310(2):189-198. doi:10.1001/jama.2013.7086 http://jama.jamanetwork.com/article.aspx?articleid=1710463
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	The review focused on medical therapy after percutaneous coronary intervention (PCI).
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	The authors of the systematic review did not assign a grade to the overall quality of the evidence
Provide all other grades and definitions from the evidence grading system	The methodology for evidence review is included in the methods section of the review cited. The authors of the systematic review did not assign a grade to the overall quality of the evidence

<table>
<tr><td>Grade assigned to the recommendation with definition of the grade</td><td>NA</td></tr>
<tr><td>Provide all other grades and definitions from the recommendation grading system</td><td>NA</td></tr>
<tr><td>Body of evidence:
• Quantity – how many studies?
• Quality – what type of studies?</td><td>The systematic review included 91 publications, with priority given to data from large randomized- controlled trials, systematic reviews, and meta-analyses.
The authors of the review did not provide an assessment of the overall quality of evidence across studies.</td></tr>
<tr><td>Estimates of benefit and consistency across studies</td><td>The authors of the review did The 2013 JAMA review includes the following summary table of pivotal trials of P2Y12 inhibitors following PCI which includes the event rate, point estimate, and p-value found in each trial.
Table 2. Pivotal $P2Y_{12}$ Inhibitor Trials Post-Coronary Stent Implantation
<table>
<tr><th></th><th>PCI Clopidogrel in Unstable Angina to Prevent Recurrent Events (CURE)[29]</th><th>Clopidogrel for the Reduction of Events During Observation (CREDO)[30]</th><th>TRITON-TIMI 38[31]</th><th>Study of Platelet Inhibition and Patient Outcomes (PLATO)[32]</th></tr>
<tr><td>No.</td><td>2658</td><td>2116</td><td>13608</td><td>18624</td></tr>
<tr><td>Population</td><td>Non-STEMI ACS patients</td><td>ACS (excluding STEMI) and stable angina patients</td><td>Moderate- to high-risk ACS patients with planned PCI</td><td>ACS patients treated with early invasive or conservative approach</td></tr>
<tr><td>Follow-up, mo</td><td>8</td><td>12</td><td>14.5</td><td>12</td></tr>
<tr><td>Therapy</td><td>Clopidogrel vs placebo</td><td>Clopidogrel vs placebo</td><td>Prasugrel vs clopidogrel</td><td>Ticagrelor vs clopidogrel</td></tr>
<tr><td>Ischemic end point</td><td>CV death, MI</td><td>Death, MI, stroke</td><td>CV death, MI, stroke</td><td>Vascular death, MI, stroke</td></tr>
<tr><td>Event rate, %</td><td>4.5 vs 6.4</td><td>8.5 vs 11.5</td><td>9.9 vs 12.1</td><td>9.8 vs 11.7</td></tr>
<tr><td>Point estimate (95% CI)</td><td>RR, 0.70 (0.50-0.97)</td><td>RRR, 26.9% (3.9%-44.4%)</td><td>HR, 0.81 (0.73-0.90)</td><td>HR, 0.84 (0.77-0.92)</td></tr>
<tr><td>P value</td><td>.03</td><td>.02</td><td>.01</td><td>.001</td></tr>
<tr><td>No. needed to treat</td><td>53</td><td>33</td><td>45</td><td>53</td></tr>
<tr><td>Bleeding end point</td><td>Disabling bleeding, intraocular bleeding, bleeding requiring ≥2 units of blood</td><td>TIMI major</td><td>Non-CABG-related TIMI major</td><td>Non-CABG-related TIMI major</td></tr>
<tr><td>Event rate, %</td><td>2.7 vs 2.5</td><td>8.8 vs 6.7</td><td>2.4 vs 1.8</td><td>2.8 vs 2.2</td></tr>
<tr><td>Point estimate (95% CI)</td><td>RR, 1.12 (0.70-1.78)</td><td>NR</td><td>HR, 1.32 (1.03-1.68)</td><td>HR, 1.19 (1.02-1.38)</td></tr>
<tr><td>P value</td><td>.64</td><td>.07</td><td>.03</td><td>.03</td></tr>
<tr><td>No. needed to harm</td><td></td><td></td><td>167</td><td>167</td></tr>
</table></td></tr>
<tr><td>What harms were identified?</td><td>The 2013 JAMA review considered issues surrounding appropriate dose and duration of anti-platelet drugs, drug allergies, method of administration, surgery following stent implantation, oral anticoagulation, and risk of bleeding. After consideration of the risks and benefitts, the authors concluded that dual antiplatelet therapy consisting of aspirin and a P2Y12 inhibitor remains the appropriate medical therapy for optimizing outcomes following PCI. The authors emphasized the importance of tailoring the P2Y12 treatment regimen to the patient's unique clinical profile to ensure that the drug, dose, and duration are appropriate for the individual patient's needs.</td></tr>
</table>

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	The body of evidence is current, and no additional, relevant studies have been identified.

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

The methodology for evidence review is included in the methods section of the review cited in 1a.6.1.

1a.4.2 What process was used to identify the evidence?

The authors do no provide an overall grade for the evidence.

1a.4.3. Provide the citation(s) for the evidence.

Statin prescribed at discharge

Measure Number (*if previously endorsed*)**:** 0964

Measure Title: Statin prescribed at discharge

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients

Date of Submission: 11/8/2018

Instructions

- *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*
- *Complete EITHER 1a.2, 1a.3 or 1a.4 as applicable for the type of measure and evidence.*
- *For composite performance measures:*
  - *A separate evidence form is required for each component measure unless several components were studied together.*
  - *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*
- All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Contact NQF staff regarding questions. Check for resources at Submitting Standards webpage.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- Outcome: 3 Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured intermediate clinical outcome leads to a desired health outcome.

- Process: 5 a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured process leads to a desired health outcome.
- Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence 4 that the measured structure leads to a desired health outcome.
- Efficiency: 6 evidence not required for the resource use component.
- For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- Process measures incorporating Appropriate Use Criteria: See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

3. Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) guidelines and/or modified GRADE.

5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

6. Measures of efficiency combine the concepts of resource use and quality (see NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; AQA Principles of Efficiency Measures).

1a.1.This is a measure of: (*should be consistent with type of measure entered in De.1*)

Outcome

☐ Outcome:

☐Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors. (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

☐ Intermediate clinical outcome (*e.g., lab value*):

☒ Process: Statins prescribed at discharge for PCI patients

☐ Appropriate use measure:

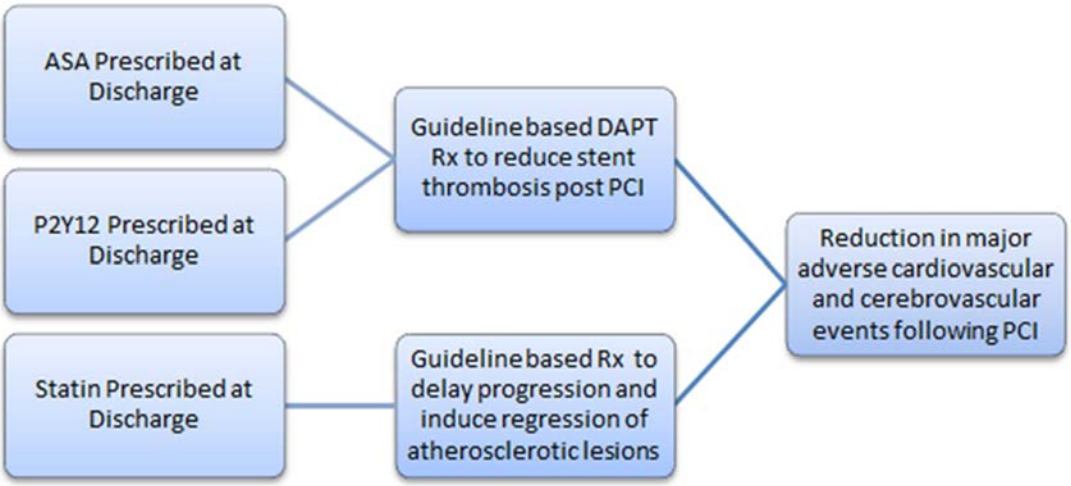
☐ Structure:

☐ Composite:

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Intracoronary stents, either drug eluting or bare metal, are deployed used in the treatment of the majority of patients who undergo percutaneous coronary intervention (PCI) to improve symptoms related to their obstructive coronary artery disease. These stents have a dual function; to prevent abrupt closure of the treated artery (acute stent thrombosis) soon after the procedure, as well as to reduce reducing the need for repeat revascularization because of gradual recurrence of the coronary obstruction (in-stent restenosis) over time compared the prevalence of repeat PCI for patients undergoing only balloon angioplasty. However, stent restenosis and stent thrombosis are potential complications of coronary artery stenting. While acute stent thrombosis is a relatively uncommon complication, it often presents as death and is almost always

accompanied by MI, it manifests as acute myocardial infarction, usually with ST-segment elevation, and can be fatal. Recommended treatment therapy with dual antiplatelet therapy (DAPT: aspirin plus platelet P2Y12 receptor inhibitors) significantly markedly lowers the risk of acute stent thrombosis. Two of the three medications included in this composite medication are included for this purpose, to reduce the risk of adverse outcomes such as MI or death after stenting. The third medication included in this composite measure is the Statin class to delay progression and induce the regression of atherosclerotic lesion in this patient population of atherosclerosis and prevent recurrent coronary events. The use of these three medication classes is guideline driven strongly endorsed by national consensus practice guidelines to reduce and guideline supported in order to reduce the adverse events or mortality death following PCI.



1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

****RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) ****

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

☒ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☒ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Source of Systematic Review: • Title • Author • Date • Citation, including page number • URL	Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013;():. doi:10.1016/j.jacc.2013.11.002. URL: http://content.onlinejacc.org/article.aspx?articleid=1770217
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	Secondary Prevention Recommendations - Page 23 Recommendation 1 - High-intensity statin therapy should be initiated or continued as first-line therapy in women and men ≤75 years of age who have clinical atherosclerotic cardiovascular disease (ASCVD*), unless contraindicated. (NHLBI Grade A, Strong; ACC/AHA Class I Level A) Recommendation 2 - In individuals with clinical ASCVD* in whom high-intensity statin therapy would otherwise be used, when high-intensity statin therapy is contraindicated† or when characteristics predisposing to statin-associated adverse effects are present, moderate-intensity statin should be used as the second option if tolerated). (NHLBI Grade A, Strong; ACC/AHA Class I Level A) *ASCVD (defined from the RCT inclusion criteria as acute coronary syndromes; history of MI, stable or unstable angina, coronary revascularization, stroke, or TIA presumed to be of atherosclerotic origin, and peripheral arterial disease or revascularization) The NHLBI initiated these guidelines by sponsoring systematic evidence reviews and collaborating with the ACC and AHA to complete and publish the guideline. Recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality, and were not formulated when sufficient evidence was not available. Each recommendation has been mapped from the NHLBI grading format to the ACC/AHA Class of Recommendation/Level of Evidence (COR/LOE) construct and is expressed in both formats. The evidence review focused on LDL–C and non-HDL–C goals for the secondary and primary prevention of atherosclerotic cardiovascular disease (ASCVD) with cholesterol-lowering drug therapy.
Grade assigned to the **evidence** associated with the recommendation with the definition of the grade	Recommendations 1 and 2 – ACC/AHA: Level A Evidence
Provide all other grades and definitions from the evidence grading system	**ACC/AHA** The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. Level B: Limited populations evaluated; Data derived from a single randomized trial or nonrandomized studies Level C: Very limited populations evaluated; only consensus opinion of experts, case studies or standard of care Specific LOE definitions are included in Table 1 below.

Grade assigned to the **recommendation** with definition of the grade	Recommendations 1 and 2 – NHLBI: Grade A, Strong Recommendation (There is high certainty based on evidence that the net benefit is substantial – ACC/AHA Class I: Procedure/Treatment should be performed/administered
Provide all other grades and definitions from the recommendation grading system	**NHLBI Grading the Strength of Recommendations** Grade B: Moderate recommendation: There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate. Grade C: Weak recommendation: There is at least moderate certainty based on evidence that there is a small net benefit. Grade D: Recommendation against. There is at least moderate certainty based on evidence that it has no benefit or that risks/harms outweigh benefits. Grade E: Expert opinion: There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends. Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Work Group thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area. Grade N: No recommendation for or against: There is insufficient evidence or evidence is unclear or conflicting. Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Work Group thought no recommendation should be made. Further research is recommended in this area ACC/AHA: Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. Class IIa: It is reasonable to perform procedure/administer treatment Class IIb: Procedure/Treatment may be considered Class III: No benefit (Not helpful or No proven benefit) Class III: Harm (Excess cost w/o benefit or Harmful to patients) Specific COR definitions are included in Table 1 below. ACC/AHA Table 1. Applying Classification of Recommendation and Level of Evidence Additional detail regarding the classification of recommendation and level of evidence is provided in the table.
Body of evidence: • Quantity – how many studies? • Quality – what type of studies?	19 Randomized Control Trials (RCT) 1 Meta-analysis – 201 Cholesterol Treatment Trialsist (CTT) The 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults does not make any qualifying statements about the overall quality of evidence across studies. The guideline states that the recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality, and were not formulated when sufficient evidence was not available.

<table>
<tr>
<td>Estimates of benefit and consistency across studies</td>
<td>The guideline Expert Panel reviewed 19 RCTs to determine the LDL–C and non-HDL–C goals for the secondary and primary prevention of atherosclerotic cardiovascular disease (ASCVD) with cholesterol- lowering drug therapy. According to the guideline, the majority of studies confirmed the
efficacy of cholesterol reduction in improving clinical outcomes in patients with clinical ASCVD using a single fixed-dose statin therapy to lower LDL–C levels.
The meta-analysis conducted by the Cholesterol Treatment Trialists (CTT) in 2010 includes percent reductions in LDL–C for a specific statin and dose calculated for the RCTs included in which statin therapy reduced ASCVD events. The CTT meta-analysis provided the following results:

<table>
<tr><th>High-Intensity Statin Therapy</th><th>Moderate-Intensity Statin Therapy</th><th>Low-Intensity Statin Therapy</th></tr>
<tr><td>Daily dose lowers LDL–C on average, by approximately ≥50%</td><td>Daily dose lowers LDL–C on average, by approximately 30% to <50%</td><td>Daily dose lowers LDL–C on average, by <30%</td></tr>
</table>

The guideline defines High- Moderate- and Low-Intensity Statin Therapy in Table 5 on page 26 of the guideline.</td>
</tr>
<tr>
<td>What harms were identified?</td>
<td>The guideline states that women and men with clinical ASCVD are at increased risk for recurrent ASCVD and ASCVD death. Evidence demonstrates that high-intensity statin therapy reduces ASCVD events more than moderate-intensity statin therapy in individuals with clinical ASCVD.
Furthermore, the guideline states that in order to optimize the safety of statins, selection of the appropriate statin and dose should be based on patient characteristics, level of ASCVD risk, and potential for adverse effects. Moderate-intensity statin therapy should be used in individuals in whom high-intensity statin therapy would otherwise be recommended when characteristics predisposing them to statin associated adverse effects are present. Characteristics predisposing individuals to statin adverse effects include, but are not limited to:
• Multiple or serious comorbidities, including impaired renal or hepatic function.
• History of previous statin intolerance or muscle disorders.
• Unexplained alanine transaminase elevations >3 times Upper Limits of Normal
• Patient characteristics or concomitant use of drugs affecting statin metabolism.
• >75 years of age.
Statins modestly increase the excess risk of type-2 diabetes in individuals with risk factors for diabetes. The potential for an ASCVD risk reduction benefit outweighs the excess risk of diabetes in all but the lowest risk individuals.</td>
</tr>
</table>

Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	A Cochrane review was carried out to assess the effects, both harms and benefits, of statins used for primary prevention in people with no history of cardiovascular disease. Reductions in all-cause mortality, major vascular events and revascularizations were found with no excess of adverse events among people without evidence of CVD treated with statins. Although this measure focuses on secondary prevention, the Cochrane review provides further evidence that statins reduce total mortality, and adverse events. Taylor F, Huffman MD, Macedo AF et al. Statins for the primary prevention of cardiovascular disease. The Cochrane database of systematic reviews 2013; Issue 1. Art. No.: CD004816. DOI: 10.1002/14651858.CD004816.pub5. A meta-analysis included individual participant data from 22 trials of statin versus control and five trials of more versus less statin. The analysis concluded that statins reduce LDL cholesterol and prevent vascular events in individuals at low risk of vascular events. Cholesterol Treatment Trialists Collaboration. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised trials. *Lancet* 2012;380:581–90

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

The methodology for evidence review is included in the methods section of the review cited in 1a.6.1.

1a.4.2 What process was used to identify the evidence?

The authors do no provide an overall grade for the evidence.

1a.4.3. Provide the citation(s) for the evidence.

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

This measure is intended to improve rates of evidence-based medication prescribing for patients following PCI to improve outcomes associated with cardiovascular disease.

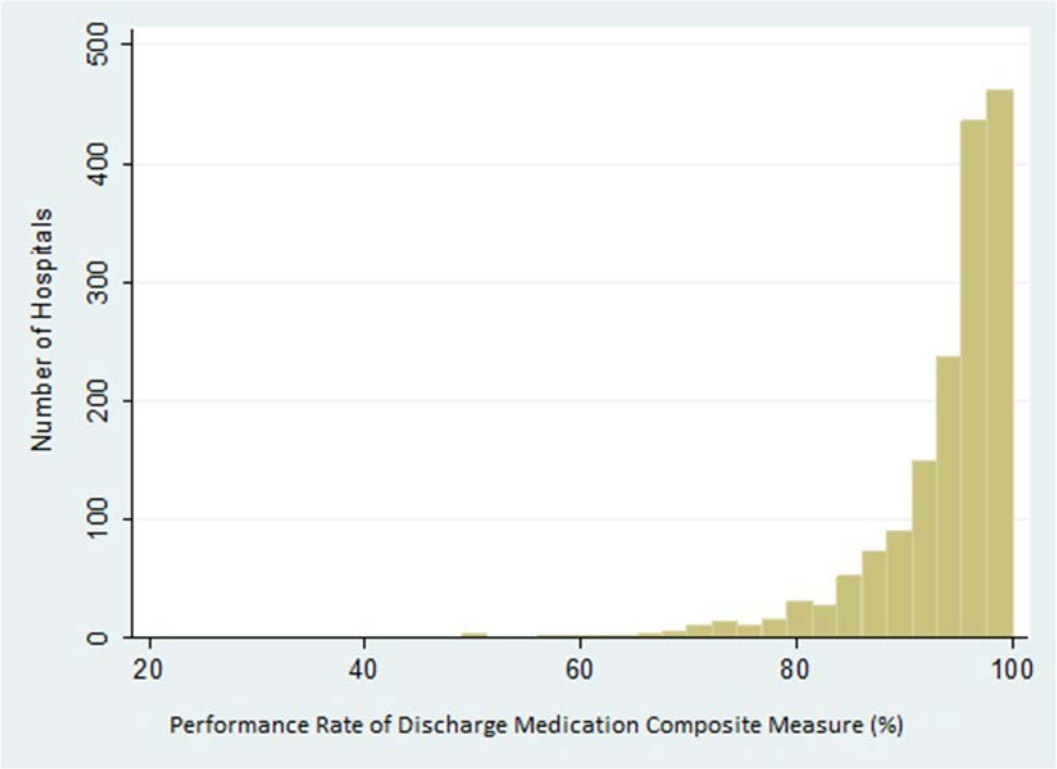
1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

The median rate of performance of the discharge medications composite across all hospitals was 95.8%. There was variation in performance, ranging from 91.9% to 98.0% for the first and third quartiles of hospitals, respectively (Table 3), and the distribution was right-skewed such that the majority of hospitals scored between 90% to 100% on the discharged medications composite measure (Figure 1).

Table 3: Distribution of Performance of the Discharge Medications Composite From 2015 - 2016 (N=1633)

		Discharge Medications Composite by Decile of Performance									
		Lowest Performing Sites							*Highest Performing Sites*		
Description	**DCM Total**	**0 - 9%**	**10 -19%**	**20 -29%**	**30 - 39%**	**40 -49%**	**50 -59%**	**60 -69%**	**70 -79%**	**80 -89%**	**90 -100%**
N	1633	163	163	164	163	164	163	163	164	164	162
Mean	93.6%	76.8%	88.1%	91.7%	94.0%	95.3%	96.3%	97.2%	98.0%	98.8%	99.7%
Std Deviation	7.2%	9.3%	1.4%	0.8%	0.5%	0.4%	0.3%	0.2%	0.3%	0.2%	0.3%
100% Max	100.0%	85.2%	90.3%	92.9%	94.6%	95.8%	96.8%	97.6%	98.4%	99.2%	100.0%
99%	100.0%	85.1%	90.3%	92.9%	94.6%	95.8%	96.7%	97.6%	98.4%	99.2%	100.0%
95%	99.7%	84.7%	90.1%	92.9%	94.5%	95.8%	96.7%	97.5%	98.4%	99.1%	100.0%
90%	99.2%	84.4%	90.0%	92.8%	94.5%	95.8%	96.7%	97.5%	98.3%	99.1%	100.0%
75% Q3	98.0%	83.2%	89.2%	92.5%	94.4%	95.7%	96.6%	97.4%	98.2%	99.0%	100.0%
50% Median	95.8%	79.9%	88.2%	91.9%	94.0%	95.4%	96.3%	97.2%	98.0%	98.8%	99.7%
25% Q1	91.9%	73.1%	86.9%	91.0%	93.6%	95.0%	96.1%	97.0%	97.8%	98.6%	99.4%
10%	85.2%	67.6%	86.0%	90.6%	93.3%	94.8%	95.9%	96.9%	97.6%	98.5%	99.3%
5%	79.9%	59.2%	85.7%	90.4%	93.1%	94.7%	95.9%	96.8%	97.6%	98.5%	99.2%
1%	67.6%	33.3%	85.4%	90.3%	93.0%	94.6%	95.8%	96.8%	97.6%	98.5%	99.2%
0% Min	25.9%	25.9%	85.2%	90.3%	93.0%	94.6%	95.8%	96.8%	97.6%	98.4%	99.2%

Figure 1: Histogram of Performance of the Discharge Medications Composite From 2015 - 2016



1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

There is a demonstration for an opportunity for improvement based on the noted performance ranges. One in five hospitals performed at rates below 90% for the composite.

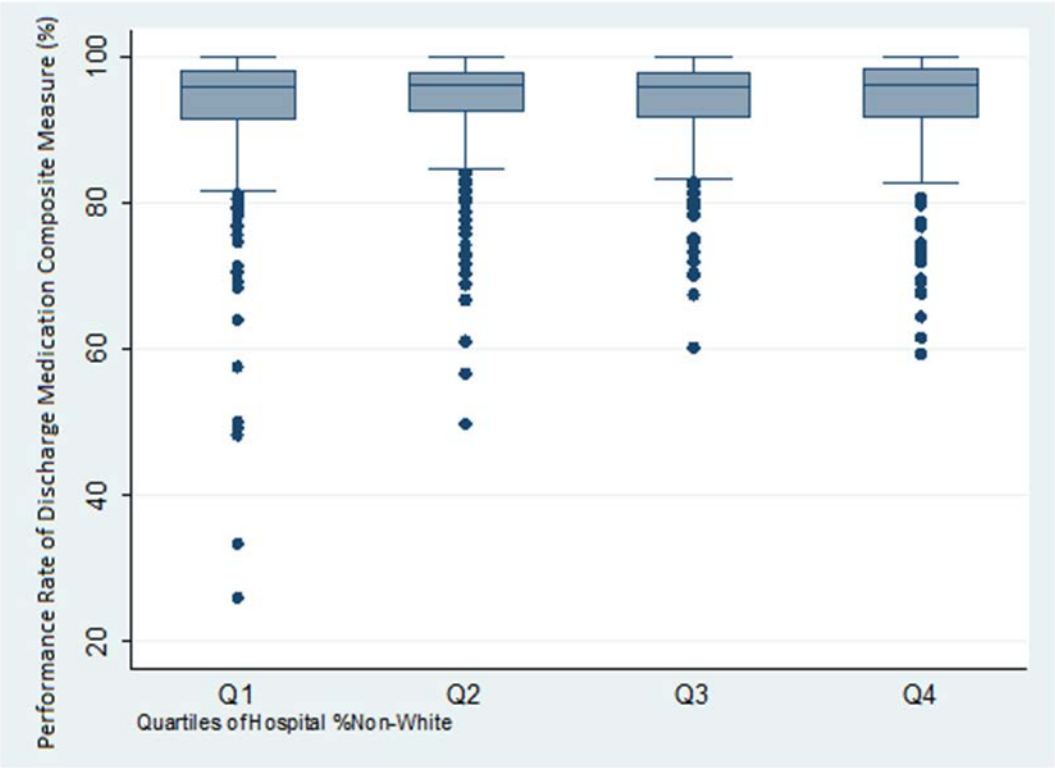
1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

We used Medicaid insurance status as an economic indicator of social risk. We also examined race/ethnicity, age, and sex to determine if there were differences in these demographic indicators of social risk.

Proportion of Non-White

Hospitals (n=1,633) were stratified into quartiles by the proportion of non-White patients (median: 9.1%, IQR: 3.9% to 19.1%). Hospital performance across quartiles was similar regardless of the proportion of non-White patients treated, with median performance ranging from 95.7% (Q1) to 96.1 (Q4)%, with those hospitals serving a higher proportion of Non-White patients performing slightly better (Figure 2).

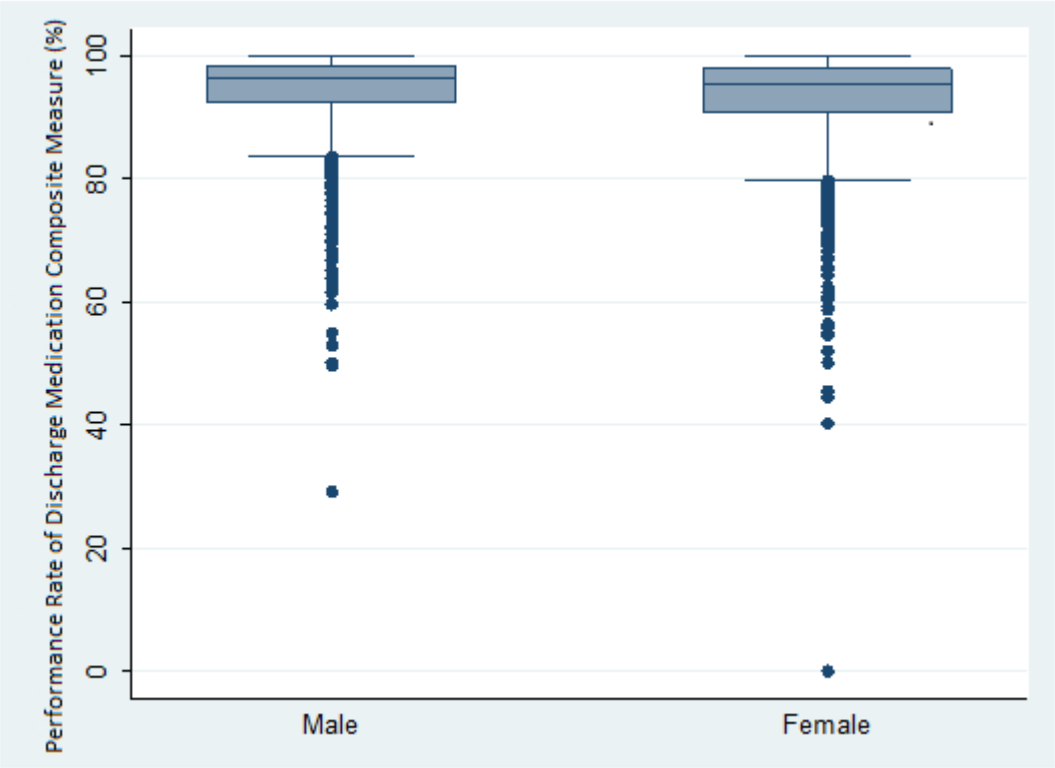
Figure 2: Distribution of the Performance for Discharge Medication Composite Measure Stratified by Quartiles of Non-White Patients at the Hospital-Level From 2015 - 2016



Gender

The median hospital performance among female patients was 95.4% while among male patients it was slightly higher at 96.2% (Figure 3).

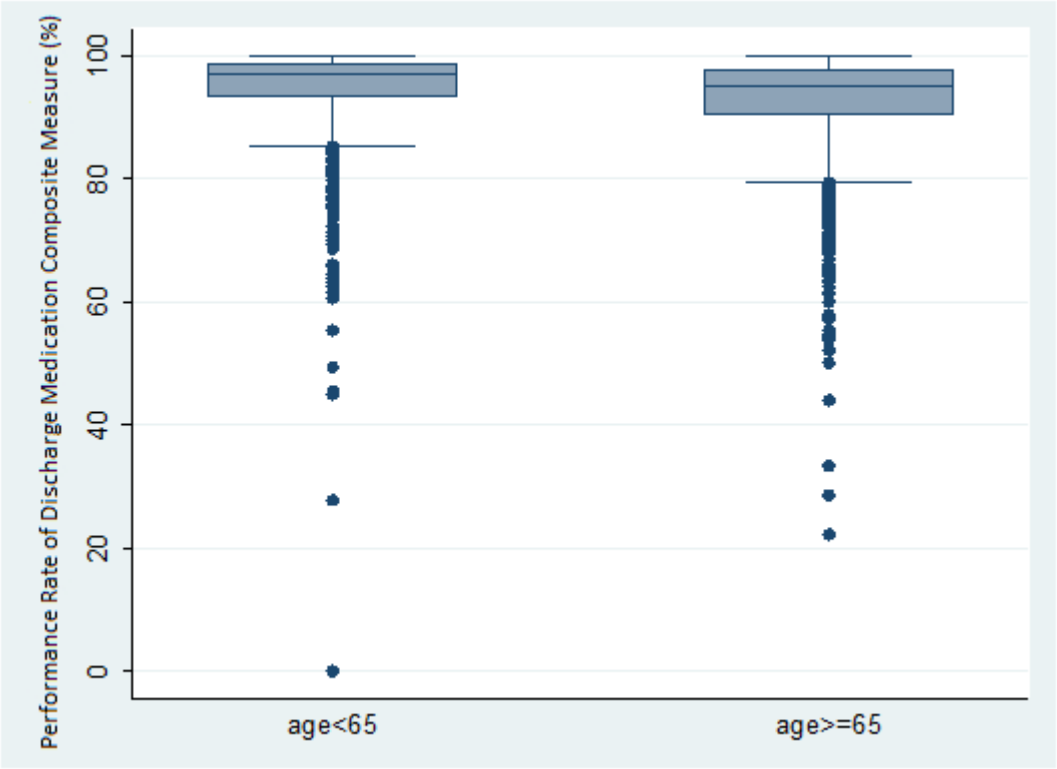
Figure 3: Distribution of the Performance of the Discharge Medication Composite Measure Stratified by Sex at the Hospital-Level From 2015 - 2016



Age

The median hospital performance among patients aged < 65 was 96.8% while that among patients ≥ 65 years of age was 95.1% (Figure 4).

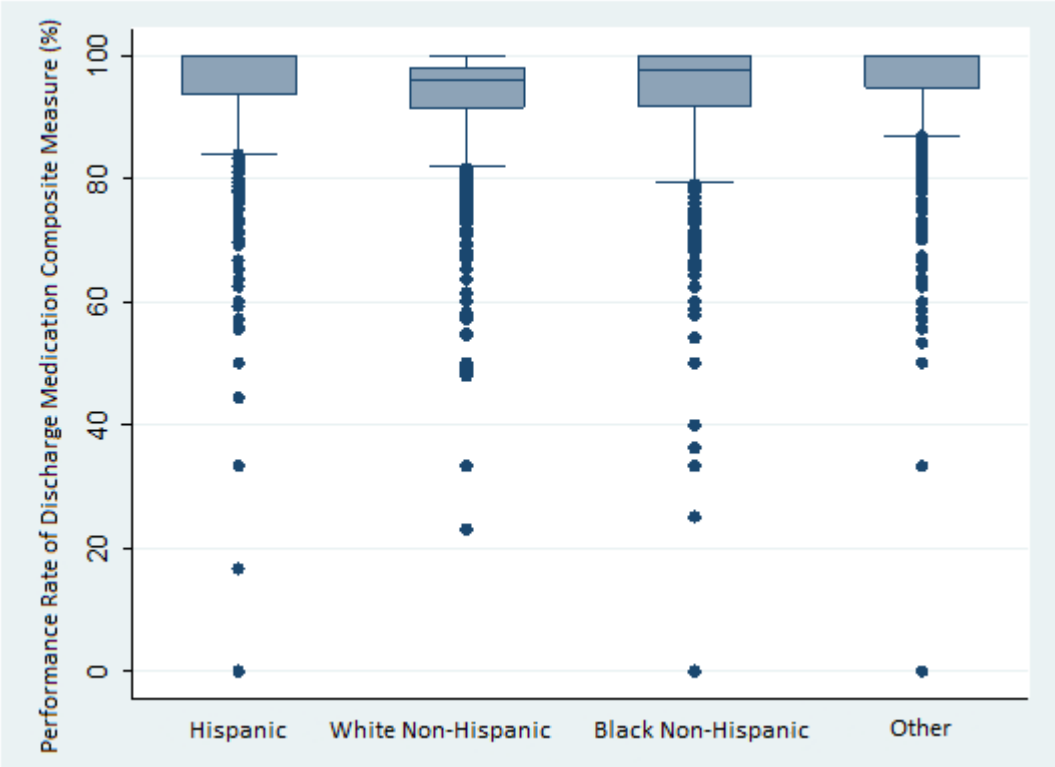
Figure 4: Distribution of the Performance for the Discharge Medication Composite Measure Stratified by Age Group at the Hospital-Level From 2015 - 2016



Race/Ethnicity

The distribution of hospital performance was examined among White (non-Hispanic), Hispanic, Black (non-Hispanic), and Other race patients. Hospitals more frequently delivered discharge medications to those of Hispanic ethnicity and Other race (median: 100%) than those of White Non-Hispanic (95.9%) and Black Non-Hispanic (97.5%) race/ethnicity (Figure 5).

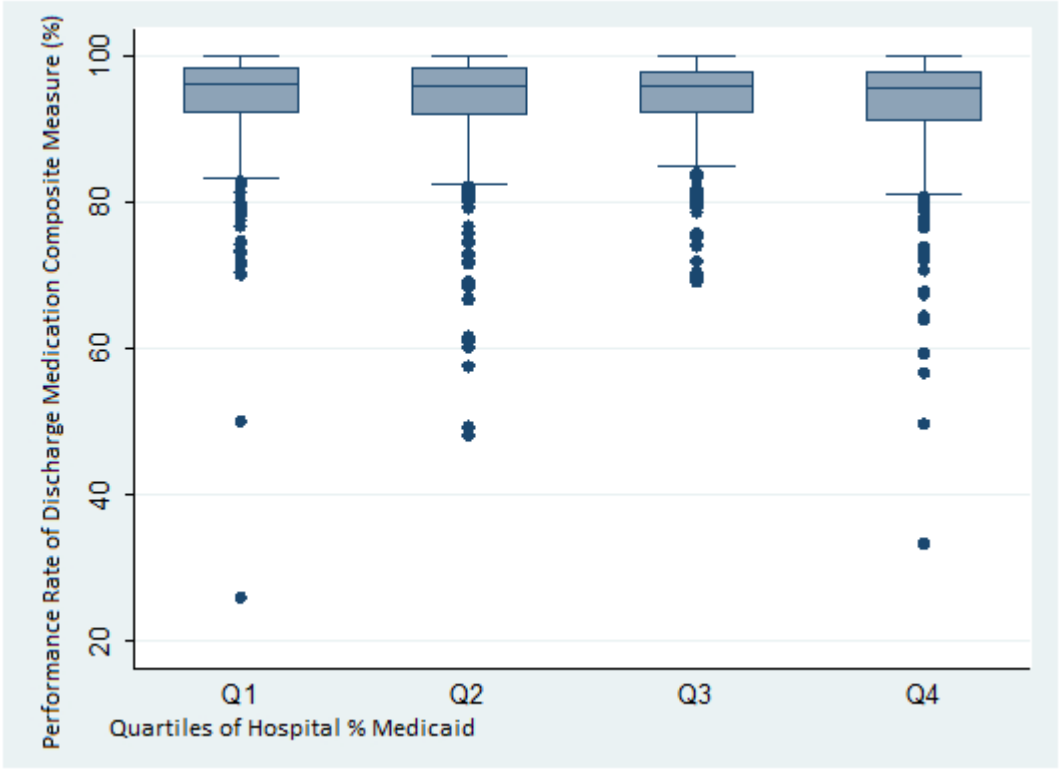
Figure 5: Distribution of the Discharge Medication Composite Measure Stratified by Race at the Hospital-Level From 2015 - 2016



Insurance

Hospitals (n=1,633) were stratified into quartiles by their proportion of patients with Medicaid as the primary insurance (median: 9.8%, IQR: 5.9% to 15.1%). Hospital performance was similar across hospitals stratified by quartile based the proportion of patients with Medicaid insurance coverage. Median hospital performance ranged from 95.6% (Quartile 4, highest proportion of Medicaid) to 96.1% (Quartile 1, lowest proportion of Medicaid) (Figure 6).

Figure 6: Distribution of the Performance for the Discharge Medication Stratified by Quartile of Hospital Percent Medicaid From 2010



1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

None

1c. Composite Quality Construct and Rationale

1c.1. A composite performance measure is a combination of two or more component measures, each of which individually reflects quality of care, into a single performance measure with a single score.

For purposes of NQF measure submission, evaluation, and endorsement, the following will be considered composites:

- Measures with two or more individual performance measure scores combined into one score for an accountable entity.
- Measures with two or more individual component measures assessed separately for each patient and then aggregated into one score for an accountable entity:
  - all-or-none measures (e.g., all essential care processes received, or outcomes experienced, by each patient);

1c.1. Please identify the composite measure construction: all-or-none measures (e.g., all essential care processes received, or outcomes experienced, by each patient)

1c.2. Describe the quality construct, including:

- the overall area of quality
- included component measures and
- the relationship of the component measures to the overall composite and to each other.

We believe the content validity of this measure has been achieved by virtue of the expertise of those individuals who developed this measure. The individual components of the composite have already shown to

influence clinical outcomes. This measure focuses on processes of care that are supported by guidelines for optimal care for patients following percutaneous coronary intervention (PCI), a procedure to treat coronary artery obstructions that often includes placement of a coronary stent. Each of the components of this measure address appropriate medication prescribing at discharge for this population. Specifically, it is known that the use of statin drugs, which reduce LDL cholesterol, reduces the risk of death or future cardiovascular events in individuals with known coronary artery disease, including those who have undergone PCI. Following PCI, both aspirin use and P2Y12 inhibitors (e.g. clopidogrel or prasugrel) reduce the risk of ischemic events. This research demonstrates that this measure contributes to improved intermediate outcomes and important outcomes such as reductions in hospitalizations and mortality rates. In addition, we examined the contribution of each of the individual components to the overall composite (using r-squared analysis). We found statins had the highest explanatory value (90.5%), followed by ASA (60.4%), and P2Y12 (35.3%).

1c.3. Describe the rationale for constructing a composite measure, including how the composite provides a distinctive or additive value over the component measures individually.

This measure is intended to assess the extent to which eligible patients receive evidence-based medications that are indicated at hospital discharge following PCI.

Composite performance measures have a variety of uses.

Data reduction. A large and growing array of individual indicators makes it possible for users to become overloaded with data. A composite measure reduces the information burden by distilling the available indicators into a simple summary.

Scope expansion. The information in a composite measure is highly condensed, making it feasible to track a broader range of metrics than would be possible otherwise. Composite measures have been described as a tool for making provider assessments more comprehensive

Provider performance valuation. Performance indicators are used for various decisions about providers, including the allocation of pay-for-performance incentives, designation of preferred provider status, and assignment of letter grades and star rating categories. If a decision is to be based on multiple indicators instead of a single indicator, a method of translating several variables into a single decision is needed. Composite measures serve this function by assigning providers to 1 position on a scale of

better-to-worse performance.

Given all these uses, NCDR believes that while we will continue to report these measures at the individual level there is a distinctive value of having a composite measure endorsed at NQF.

1c.4. Describe how the aggregation and weighting of the component measures are consistent with the stated quality construct and rationale.

This is an all-or-none composite, thus no empirical analyses pertinent to aggregations or weighting were conducted. The components mentioned throughout the application are part of the composite measure indicator definition, not the composite of different measures.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Cardiovascular, Cardiovascular : Coronary Artery Disease (PCI)

De.6. Non-Condition Specific*(check all the areas that apply):*

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Populations at Risk

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

ACC does not have a measure specific webpage. However more information about the clinical registry that the measure is included in can be found at: https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-registry.

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

Attachment **Attachment:** CathPCI_v4_CodersDictionary_4.4-635230042811280622-636329455190369406.pdf

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

N/A

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Patients who receive all medications for which they are eligible.

1. Aspirin prescribed at discharge (if eligible for aspirin as described in denominator)

AND

2. P2Y12 agent (clopidogrel, prasurgel, ticlopidine, or ticagrelor) prescribed at discharge (if eligible for P2Y12 as described in denominator)

AND

3. Statin prescribed at discharge (if eligible for statin as described in denominator)

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

If eligible for Aspirin (9505) and prescribed (9510), then code "Yes"

If eligible for Aspirin (9505) and not prescribed (9510), then code "No"

If eligible for P2Y12 (9505) and prescribed (9510) , then code then "Yes"

If eligible for P2Y12 (9505)and not prescribed (9510), then code "No"

If eligible for statin (9505) and prescribed (9510) , then code "Yes"

If eligible for statin (9505) and not prescribed (9501) given, then code "No"

If any "No, not prescribed" present, then performance not met. Else, performance met.

Note: Contraindicated and those participating in blinded studies are also considered as exceptions and performance met if patient is eligible for at least one medication (aspirin or statin or P2Y12).

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Patients surviving hospitalization who are eligible to receive any of the three medication classes:

1) Eligible for aspirin (ASA): Patients undergoing PCI who do not have a contraindication to aspirin documented

AND

2) Eligible for P2Y12 agent (clopidogrel, prasugrel, ticlopidine, or ticagrelor): Patients undergoing PCI with stenting who do not have a contraindication to P2Y12 agent documented

AND

3) Eligible for statin therapy: Patients undergoing PCI who do not have a contraindication to statin therapy.

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The following patients are included in the denominator:

1. Patients 18 years of age or older (2050)
2. Patients undergoing PCI during the episode of care (5305)
3. PCI patients who are eligible for at least one of the following medications: aspirin, statin, and P2Y12 (7155, 9505, 9510)

Note:

- Eligibility for measures is determined by whether the PCI procedure included a stent (aspirin, statin, and P2Y12) or no stent (aspirin and statin) and whether patient had contraindication or was blinded to the medication
- All data element numbers listed above are included in the attach data dictionary which includes more detailed definitions for the above elements.

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

The exclusions for this measure are comprised of patients without the following: (1) a PCI during the admission, (2) discharge status of deceased (9040), and (3) discharge location of "other acute hospital, hospice, or against medical advice.

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

The exclusions for this measure include:

1. Patients without a PCI during the admission (5305)
2. Patients with a discharge status of deceased (9040),
3. Patients with a discharge location of "other acute hospital, hospice, or against medical advice (9405).

NCDR distinguishes between absolute "Exclusions" (e.g., death, transfer) and relative "Exceptions", (e.g., contraindications). Patients with exclusions are always automatically removed from the denominator and numerator; exceptions allow clinicians the opportunity to identify an intervention/process/medication as not clinically indicated based on the individual circumstances.

Each of the three medications incorporated into this composite may be coded as Yes (medication prescribed), No (medication not prescribed), Blinded (pt. involved in a clinical trial, medication type unavailable for data entry), and Contraindicated.

With respect to exceptions, patients are removed from the denominator if they have contraindication or are blinded across ALL medications that they are eligible for.

S.10. Stratification Information *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

1) Remove patients whose discharge status is deceased
2) Check if given patient is eligible for 1 of the 3 medication therapies.
3) If eligible for at least 1 medication, then keep this patient.

4) If not eligible for any of the 3 medications, then patient is removed from eligibility.

5) If eligible for Aspirin and given, then code "Yes"

If eligible for Aspirin and not given, then code "No, not given"

If eligible for Aspirin but contraindicated, then code "contraindicated/blinded"

If eligible for P2Y12 and given, then code then "Yes"

If eligible for P2Y12 and not given, then code "No, not given"

If eligible for P2Y12 but contraindicated, then code "contraindicated/blinded"

If eligible for statin and given, then code "Yes"

If eligible for statin and not given, then code "No, not given"

If eligible for statin but contraindicated, then code "contraindicated/blinded"

6) If any "No, not given" present, then performance not met. Else, performance met.

S.15. Sampling *(If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)*

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A

S.16. Survey/Patient-reported data *(If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)*

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source *(Check ONLY the sources for which the measure is SPECIFIED AND TESTED).*

If other, please describe in S.18.

Other, Registry Data

S.18. Data Source or Collection Instrument *(Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)*

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

National Cardiovascular Data Registry (NCDR®) CathPCI Registry®

S.19. Data Source or Collection Instrument *(available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)*

Available at measure-specific web page URL identified in S.1

S.20. Level of Analysis *(Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)*

Facility

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Inpatient/Hospital

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

N/A

2. Validity – See attached Measure Testing Submission Form

0964_testing_form_20180730_FINAL_Method_Panel_8.16.18FINAL-636700325254407268.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Composite Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 0964
Composite Measure Title: CathPCI: Therapy with aspiririn, P2Y12 inhibitor, and statin at discharge composite following PCI
Date of Submission: 8/1/2018

Composite Construction:

☐Two or more individual performance measure scores combined into one score

☒ All-or-none measures (e.g., all essential care processes received or outcomes experienced by each patient)

Instructions: Please contact NQF staff before you begin.

- If a component measure is submitted as an individual performance measure, the non-composite measure testing form must also be completed and attached to the individual measure submission.
- Measures must be tested for all the data sources and levels of analyses that are specified. *If there is more than one set of data specifications or more than one level of analysis, contact NQF staff* about how to present all the testing information in one form.
- Sections 1, 2a2, 2b1, 2b2, and 2b4 must be completed.
- For composites with outcome and resource use measures, section 2b3 also must be completed.
- If specified for multiple data sources/sets of specificaitons (e.g., claims and EHRs), section 2b5 also must be completed.
- Respond to all questions as instructed with answers immediately following the question. All information on testing to demonstrate meeting the subcriteria for reliability (2a2) and validity (2b1-2b6) and composites (2c) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 25 pages (*incuding questions/instructions;* minimum font size 11 pt; do not change margins). *Contact NQF staff if more pages are needed.*

- Contact NQF staff regarding questions. Check for resources at Submitting Standards webpage.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for version 7.1 of the Measure Testing Attachment. and the 2017 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a2. Reliability testing 10 demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing 11 demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure; 12

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately). 13

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration

OR

- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponses) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2.the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(*if not conducted or results not adequate, justification must be submitted and accepted)*

Notes

10. Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

11. Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples

of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

12. Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

13. Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

14. Risk factors that influence outcomes should not be specified as exclusions.

15. With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing,(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the sources of data specified and intended for measure implementation.* ***If different data sources are used for different components in the composite, indicate the component after the checkbox. If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (*must be consistent with data sources entered in S.17*)	**Measure Tested with Data From:**
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☒ registry	☒ registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☒ other: American Hospital Association	☒ other: American Hospital Association

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

We used a clinical registry, namely the American College of Cardiology National Cardiovascular Data Registry's CathPCI Registry. This is a national quality improvement registry in which over 1500 hospitals participate. Some states and healthcare systems mandate participation in the registry. Rigorous quality standards are applied to the data and both quarterly and ad hoc performance reports are generated for participating sites to track and improve their performance.

1.3. What are the dates of the data used in testing? 01/2015-12/2016

Discharges between January 2015 to December 2016 were used. Hospital information about the proportion of patients with a primary payer source of Medicaid are derived from American Hospital Association 2010 data.

1.4. What levels of analysis were tested? (*testing must be provided for <u>all</u> the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (*must be consistent with levels entered in item S.20*)	**Measure Tested at Level of:**
☐ individual clinician	☐ individual clinician
☐ group/practice	☐ group/practice
☒ hospital/facility/agency	☒ hospital/facility/agency
☐ health plan	☐ health plan
☐ other:	☐ other:

1.5. How many and which <u>measured entities</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

The overall measured entities, following the application of exclusion criteria, are as follows:

Table 1: Entities Evaluated by Level of Analysis

Level of Analysis	Variable	Data Source	Number
Patient	Patient Hospital Stay	NCDR CathPCI Registry	1,386,383
Hospital	Facilities	NCDR CathPCI Registry	1633

1.6. How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

For all the descriptive statistics, we used data collected by the CathPCI Registry between January 2015 and December 2016. Descriptive statistics about the patients included in this dataset are provided below (Table 2):

Table 2: Selected Characteristics by Calendar Year

Description	Total		Year				P
			2015		2016		
	#	%	#	%	#	%	
ALL	1,386,383	100.00	682,385	100.00	703,998	100.00	
Age≥65							0.0000
No	642,720	46.36	319,872	46.88	322,848	45.86	
Yes	743,663	53.64	362,513	53.12	381,150	54.14	
Sex							0.1300
Male	955,318	68.91	469,800	68.85	485,518	68.97	
Female	431,065	31.09	212,585	31.15	218,480	31.03	
Race							0.0000
Hispanic	84,349	6.08	40,550	5.94	43,799	6.22	
White non-Hispanic	1,124,342	81.10	554,961	81.33	569,381	80.88	
Black non-Hispanic	118,374	8.54	58,512	8.57	59,862	8.50	
Other	59,318	4.28	28,362	4.16	30,956	4.40	
Insurance							0.0000
Medicare	744,534	53.70	363,056	53.20	381,478	54.19	
Medicaid or not private	103,128	7.44	50,685	7.43	52,443	7.45	
Private	475,450	34.29	236,654	34.68	238,796	33.92	
None	63,271	4.56	31,990	4.69	31,281	4.44	
Composite Measure Performance							0.0000
Not Meeting	73,620	5.31	38877	5.70	34743	4.94	
Meeting	1,312,763	94.69	643,508	94.30	669,255	95.06	

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

The datasets, dates, number of measured entities, and number of admissions for all forms of reliability and validity testing were from an uninterrupted 2-year period: 01/2015-12/2016

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

We attributed social risk factors at the hospital-level for the purposes of this analysis. We used Medicaid insurance status as an economic indicator of social risk. We also examined race/ethnicity, age, and sex to determine if there were differences in these demographic indicators of social risk.

2a2. RELIABILITY TESTING

***Note**: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)

***Note**: Current guidance for composite measure evaluation states that reliability must be demonstrated for the composite performance measure score.*

☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. Describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

Split Sample Methodology

For the performance rates and social risk data, raw rates were calculated and a Pearson correlation coefficient was computed.

2a2.3. What were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Split Sample Methodology:

The split samples were calculated during the same timeframe to mitigate confounding factors based on time differences. The cohort was split into two random samples to compare measure scores. The distribution of hospital performance was similar in the two samples (Tables 4 and 5), and there was an extremely high correlation between hospital performance assessed in the two samples (Pearson correlation coefficient: 0.90270).

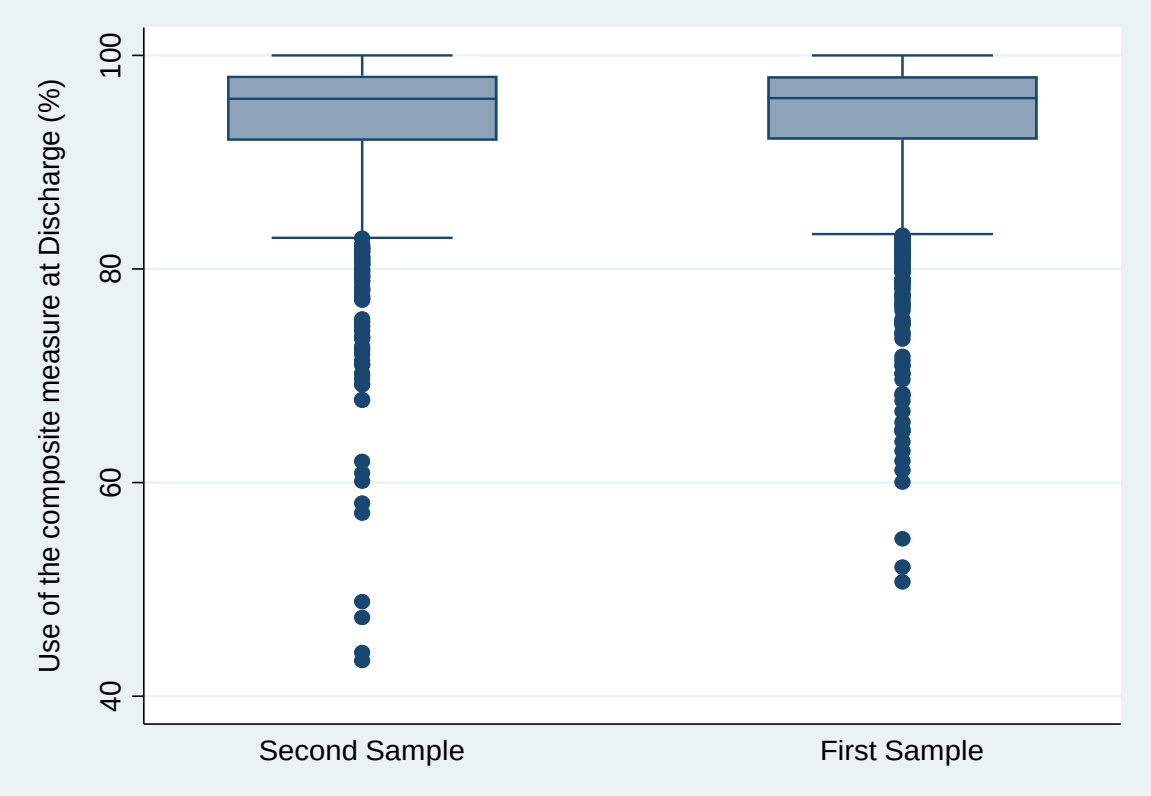
Table 4: Split Sample Composition (i.e. Number/proportion of Patients in each sample by Year)

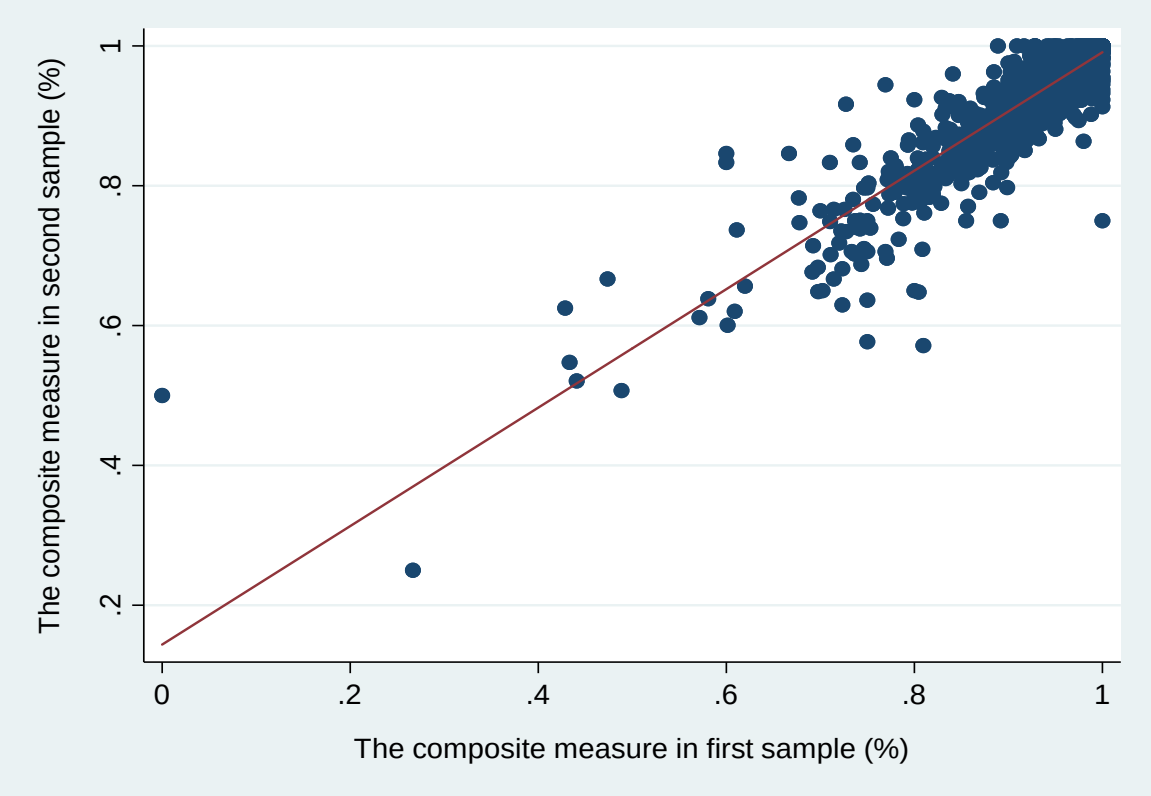
Description	Total		Year				P-value
			2015		2016		
	#	%	#	%	#	%	
Random Splitting Samples							0.0831
First	693881	50.05	342042	50.12	351839	49.98	
Second	692502	49.95	340343	49.88	352159	50.02	

Table 5: Distribution of Performance for the Discharge Medication Composite Stratified by the Randomly Split Samples

Description	Randomly Split Samples	
	First (RAND=1)	Second (RAND=0)
N	1631	1632
Mean	93.62%	93.57%
Std Deviation	7.16%	7.55%
100% Max	100.00%	100.00%
99%	100.00%	100.00%
95%	100.00%	100.00%
90%	99.38%	99.29%
75% Q3	98.07%	98.12%
50% Median	95.92%	95.84%
25% Q1	91.70%	91.68%
10%	85.05%	85.01%
5%	80.00%	79.80%
1%	64.86%	67.71%
0% Min	25.00%	0.00%

Figure 1. Distribution of Performance for the Discharge Medication Composite Stratified by Randomly Split Samples (Top) and by Split Sample Correlation (Bottom)





2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Split Sample Methodology

The box and whisker plot of the distribution of hospital performance for CathPCI composite measure at discharge shows that hospitals were stratified by randomly split samples. These results show a similar percentage of use of the composite measure at discharge for both samples which demonstrates that this is a very reliable measure. Figure 1 shows a strong positive association between both samples (r=0.90270).

_____

2b1. VALIDITY TESTING

Note*: Current guidance for composite measure evaluation states that validity should be demonstrated for the composite performance measure score. If not feasible for initial endorsement, acceptable alternatives include assessment of content or face validity of the composite OR demonstration of validity for each component. Empirical validity testing of the composite measure score is expected by the time of endorsement maintenance.*

2b1.1. What level of validity testing was conducted?

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☒ **Composite performance measure score**

☒ **Empirical validity testing**

☒ **Systematic assessment of face validity of performance measure score as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

☐ **Validity testing for component measures** *(check all that apply)*

Note*: applies to ALL component measures, unless already endorsed or are being submitted for individual endorsement.*

☐ **Endorsed (or submitted) as individual performance measures**

☐ **Critical data elements** (*data element validity must address ALL critical data elements*)

☐ **Empirical validity testing of the component measure score(s)**

☐ **Systematic assessment of face validity of component measure score(s) as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*)

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)*

Face Validity (initial measure testing of this measure):

Face validity was achieved through having subject matter experts assist in the development of this measure. For this particular topic those individuals who were involved in identifying the key attributes and variables for this process measure were leaders and experts in the field of interventional cardiology. Serial phone calls were held to both define the eligible population. These clinical leaders are noted below.

The NCDR Clinical Subworkgroup was a designated set of experts that oversaw the original NQF application. Prior to submission, this group ensured there is variation in care, disparities data, and that the measure is a true These members included Drs. Jeptha Curtis (Chair), Frederick Masoudi, John Rumsfeld, Issam Moussa, and David Malenka.

The NCDR Scientific Quality and Oversight Committee served as the primary resource for crosscutting scientific and quality of care methodological issues. These members included Drs. Frederick Masoudi (Chair), David Malenka, Thomas Tsai, Matthew Reynolds, David Shahian, John Windle, Fred Resnic, John Moore, Deepak Bhatt, James Tcheng, Jeptha Curtis, Paul Chan, Matthew Roe, and John Rumsfeld.
Lastly the 16 member NCDR Management Board and 31 member ACCF Board of Trustees reviewed and approved this measure for submission to NQF.

The face/content validity of this measure has been achieved by virtue of the noted expertise of those individuals who developed this measure.

Empirical Validity (Re-endorsement testing):

Empirical analysis was tested by determining if hospitals performed similarly on the composite discharge medications measure and 30-day mortality. The testing focused on construct validation which tested the hypothesis that following the provision of discharge medications for patients who underwent a PCI may lead to better short-term outcomes. This was achieved by examining the distribution and correlation of the discharge medications composite score and the 30-day risk-standardized mortality rates (RSMR) for PCI based on indication (STEMI/Shock or NSTEMI/No Shock) from date of procedure to 30-days. We used the NQF-endorsed 30-day PCI mortality measure for STEMI/Shock (NQF#: 0536) and No STEMI/No Shock (NQF#: 0535) to ascertain RSMR rates. For this specific analysis, the study period was Q4 2013 to Q3 2014 as this encompassed the latest NDI-CathPCI linked data available at the time of the analysis.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

Face Validity

Face validity was achieved through reaching consensus that the measure had strong clinical evidence and was reliable. Specifically, it is known that reducing LDL-c is associated with a decrease in mortality and morbidity for patients with coronary artery disease. Lipid-lowering therapy can reduce the risk of cardiovascular outcomes. Following PCI, both aspirin use and P2Y12 inhibitors, including clopidogrel and prasugrel, reduce the risk of ischemic events. This research demonstrates that this measure contributes to improved intermediate outcomes and important outcomes such as reductions in hospitalizations and mortality rates.

Empirical Validity

Below are the results achieved from the empirical validity testing by indication (Table 6):

Table 6: Distribution of Performance Rate for Discharge Medications Composite Measure and RSMR in the Time Period 2013Q4 to 2014Q3 (N=1633)

Description	Discharge Medications Composite Performance rate (%)	RSMR Performance rate (%)
Mean	95.4%	8.8%
Std Deviation	8.0%	1.7%
100% Max	100.0%	20.1%
99%	100.0%	14.0%
95%	100.0%	11.8%
90%	100.0%	10.9%
75% Q3	100.0%	9.6%
50% Median	97.7%	8.5%
25% Q1	94.2%	7.6%
10%	88.5%	6.9%
5%	83.3%	6.5%
1%	62.5%	5.8%
0% Min	0.0%	4.5%

Pearson correlation coefficient between DCM and STEMI/Shock RSMR: -0.07465 (N=1273)

Description	Discharge Medications Composite Performance rate (%)	RSMR Performance rate (%)
Mean	91.7%	1.2%
Std Deviation	8.4%	0.3%
100% Max	100.0%	2.6%
99%	100.0%	2.1%
95%	100.0%	1.7%
90%	99.1%	1.5%
75% Q3	97.2%	1.3%
50% Median	94.0%	1.1%
25% Q1	88.8%	1.0%
10%	82.2%	0.9%
5%	76.1%	0.8%
1%	57.1%	0.7%
0% Min	9.5%	0.5%

Pearson correlation coefficient between DCM and NSTEMI/No Shock RSMR: -0.16380 (N=1283)

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)

Face validity: The individual components have been associated with better outcomes and are accepted quality measures in patient populations.).

Empirical validity: The median rate of delivering defect free care for STEMI/Shock and NSTEMI/No Shock was 97.7% (IQR: 94.2% to 100.0%) and 94.0% (IQR: 88.8% to 97.2%), and the median mortality rate at 30 days was 8.5% (IQR: 7.6% to 9.6%) and 1.1% (IQR: 1.0% to 1.3%), respectively (Table 6). There was a similar distribution of hospitals by volume across both measures. The negative correlation coefficient was significant and in the hypothesized direction, such that a higher group of patients receiving discharge medications was associated with lower mortality rates. Yet, the correlation is relatively low for STEMI/Shock (-0.07) and NSTEMI/No Shock (-0.16), which is not surprising when comparing a process of care measure to an outcome measure. The low correlation may be explained by the fact that there are a number of other unmeasured factors that could contribute to 30-day mortality rates beyond whether medications were prescribed at discharge (e.g., unsuccessful procedure, lack of follow-up, poor medication adherence or access to care). Further, the 30-day time period started at the date of the procedure thus the rates also accounted for in-hospital mortality. In sum, the empirical validation demonstrates there is a relationship, albeit statistically a small one, between discharge medications and short-term mortality.

2b2. EXCLUSIONS ANALYSIS

Note: *Applies to the composite performance measure, as well all component measures unless they are already endorsed or are being submitted for individual endorsement.*

NA ☐ no exclusions — *skip to section* 2b4

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

The exclusions for this measure comprised: patients without a PCI during the admission, discharge status of deceased, discharge location of "other acute hospital, hospice, or against medical advice". With the exception of excluding patients who did not undergo a PCI procedure during the admission, these exclusions were relatively rare and firmly supported by clinical rationale.

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

Table 7 below provides information about how the final sample was derived. Excluding those who died during the hospital stay or were discharged under other circumstances only accounted for 3.5% of hospital stays. It is unlikely that this would impact performance measures in any meaningful way, and these patients ought to be excluded from this measure as it is not possible to ascertain discharge medication status on patients who were not discharged from the index hospital or died during the admission. Those who were "not eligible for the composite measure" included those with contraindications or those individuals enrolled in clinical trial studies.

Table 7: Exclusions Summary Results

Exclusions	Number of Hospital Stay	Number of Facilities
	#	#
Initial Sample	11,029,164	1,763
Discharges not between Jan 2015 and Dec 2016	- 8,020,033	82
Remaining	3,009,131	1681
Without PCI during the admission	-1,572,462	48
Remaining	1,436,669	1633
Discharge Status: not alive	-25,878	0
Remaining	1,410,791	1633
Discharge Location: Other acute care hospital	-15,574	0
Remaining	1,395,217	1633
Discharge Location: Hospice	-3,498	0
Remaining	1,391,719	1633
Discharge Location: Left against medical advice	-4,549	0
Remaining	1,387,170	1633
Discharge Location: Unknown	-507	0
Remaining	1,386,663	1633
Not eligible for the composite measure	-280	0
Study Sample	**1,386,383**	**1633**

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. Note: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

Importantly, there are no 'discretionary' exclusions. All exclusions are necessary for the accurate calculation of performance on the composite measure. For example, patients need to survive to discharge to be eligible for the measure. Similarly, it would be inappropriate to calculate the measure among patients discharged to another acute care facility or those who left the hospital against medical advice. In light of the lack of randomized trials designed to evaluate the efficacy of clopidogrel (P2Y12 receptor blockers) in addition to aspirin compared to aspirin alone in STEMI patients treated with primary PCI, we feel no additional patients should be excluded from the composite measure. The value of including these patients and the potential for evaluating their outcomes in our bleeding and mortality measures outweighs the burden of increased data collection and analysis.

Indirect evidence of long-term benefit exists from trials PCI-CURE, CREDO, and CURE (Lancet. 2001;358(9281):527, J Am Coll Cardiol. 2006;47(5):939, N Engl J Med. 2001;345(7):494) of patients with non- STEMI in which P2Y12 receptor blockers were continued for 9 to 12 months. At 30 days after PCI, clopidogrel therapy was associated with a significant reduction in the primary endpoint of cardiovascular death, MI, or stroke (3.6 versus 6.2 percent, adjusted odds ratio 0.54, 95% CI 0.35-0.85).

Accordingly, we do not believe additional testing is necessary.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

Note: *Applies to all outcome or resource use component measures, unless already endorsed or are being submitted for individual endorsement.*

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4**.**

2b3.1. What method of controlling for differences in case mix is used? *(check all that apply)*

☐ **Endorsed (or submitted) as individual performance measures**

☐ **No risk adjustment or stratification**

☐ **Statistical risk model with _risk factors**

☐ **Stratification by_ risk categories**

☐ **Other,**

2b3.1.1 If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

2b3.2. If an outcome or resource use component measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

N/A

2b3.3a. Describe the conceptual/clinical and statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion;** for example, are social risk factors added after all clinical factors?

N/A

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☐ **Other (please describe)**

2b3.4a. What were the statistical results of the analyses used to select risk factors?

N/A

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors (e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.) Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.

N/A

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to 2b3.9

N/A

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**

N/A

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

N/A

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

N/A

2b3.9. Results of Risk Stratification Analysis:

N/A

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for the test conducted*)

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)

_____

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

Note: *Applies to the composite performance measure.*

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*

We examined variation in hospital performance for the composite measure based on overall performance, and stratified by subgroups of sex, age, race/ethnicity, and the proportion of patients who are insured through Medicaid to identify if there were meaningful differences in social risk.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., *number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)

Overall

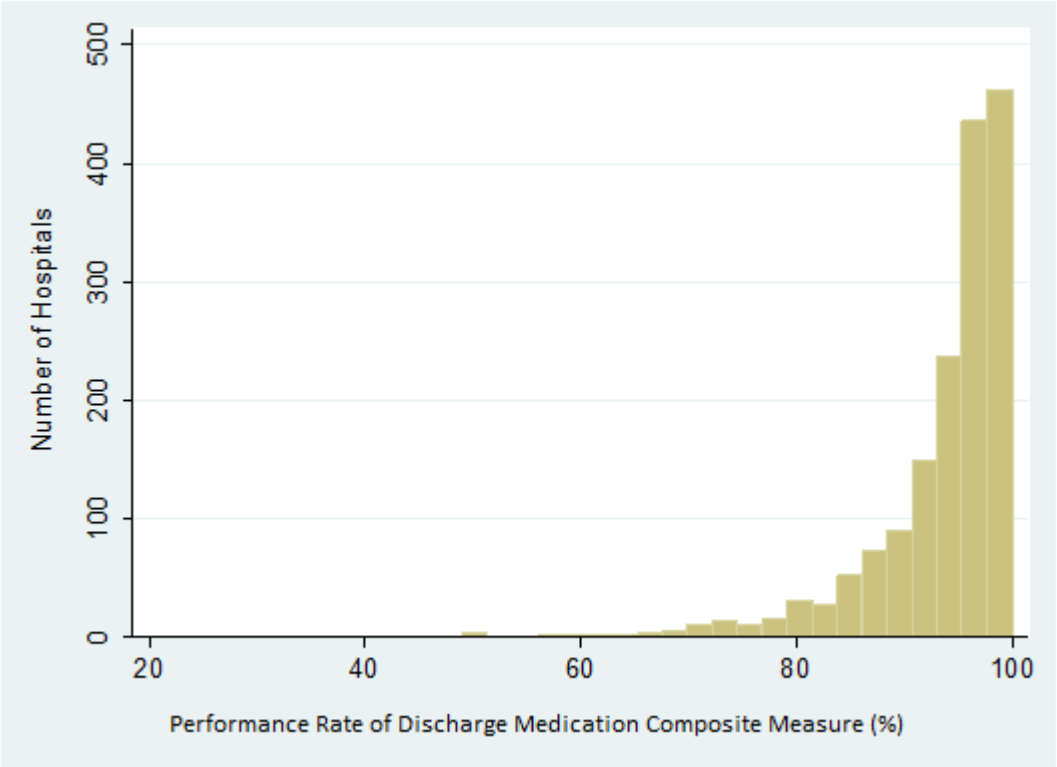
The median rate of performance of the discharge medications composite across all hospitals was 95.8%. There was variation in providing defect free care, ranging from 91.9% to 98.0% for the first and third quartiles of hospitals, respectively (Table 8), and the distribution was right-skewed such that the majority of hospitals scored between 90% to 100% on the discharged medications composite measure (Figure 2).

Table 8: Distribution of Performance of the Discharge Medications Composite (N=1633)

Description	Discharge Medications Composite (%)
Mean	93.58
Std Deviation	7.16
100% Max	100.00
99%	100.00
95%	99.72
90%	99.16
75% Q3	98.02
50% Median	95.83
25% Q1	91.87
10%	85.24

Description	Discharge Medications Composite (%)
5%	79.89
1%	67.57
0% Min	25.93

Figure 2: Histogram of Performance of the Discharge Medications Composite



Subgroups

Across stratified analyses based on sex, age, race, and proportion of patients who are insured through Medicaid, we found significant overlap in the distribution of hospital performance, as detailed below.

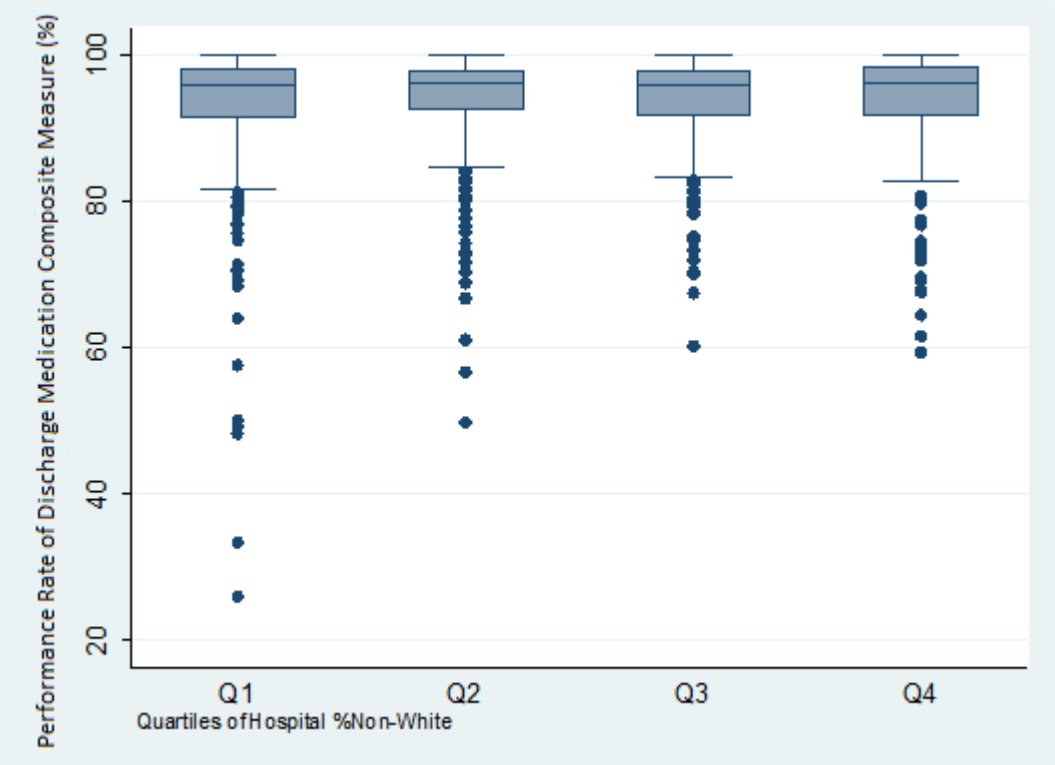
Proportion of Non-White

Hospitals (n=1,633) were stratified into quartiles by the proportion of non-White patients (median: 9.1%, IQR: 3.9% to 19.1%). Hospital performance across quartiles was similar regardless of the proportion of non-White patients treated, with median performance ranging from 95.7% (Q1) to 96.1 (Q4)%, with those hospitals serving a higher proportion of Non-White patients performing slightly better (Table 9, Figure 3).

Table 9: Distribution of Performance Rate for Discharge Medication Composite Measure at Discharge Stratified by Hospital Quartile Non-White at the Hospital-Level (N=1633)

Description	% Non-White			
	Q1	Q2	Q3	Q4
Mean	93.0%	93.9%	93.7%	93.7%
Std Deviation	8.7%	6.7%	6.0%	7.0%
100% Max	100.0%	100.0%	100.0%	100.0%
99%	100.0%	100.0%	100.0%	100.0%
95%	99.7%	99.5%	99.5%	100.0%
90%	99.2%	99.1%	98.9%	99.6%
75% Q3	98.1%	97.8%	97.7%	98.2%
50% Median	95.7%	96.0%	95.8%	96.1%
25% Q1	91.3%	92.4%	91.8%	91.6%
10%	83.9%	86.1%	85.7%	85.6%
5%	79.0%	80.4%	81.0%	77.3%
1%	50.0%	68.8%	71.9%	67.7%
0% Min	25.9%	49.7%	60.1%	59.2%

Figure 3: Distribution of the Performance for Discharge Medication Composite Measure Stratified by Quartiles of Non-White Patients at the Hospital-Level



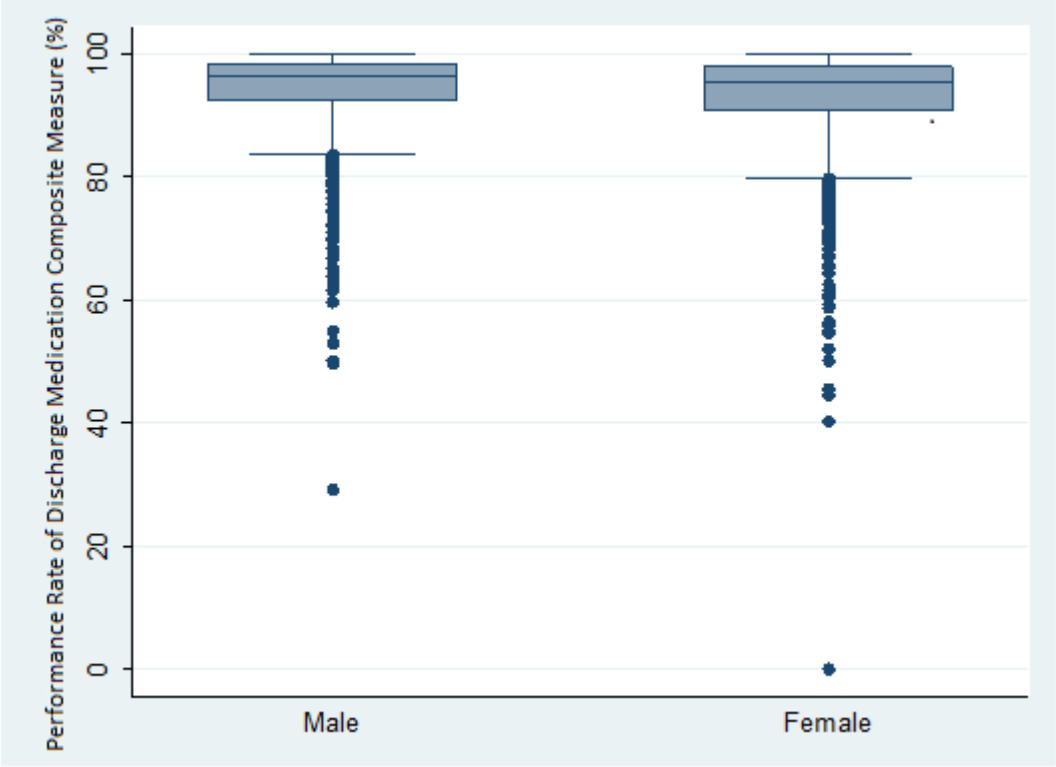
Gender

The median hospital performance among female patients was 95.4% while among male patients it was slightly higher at 96.2% (Table 10, Figure 4).

Table 10: Distribution of Performance rates for Discharge Medication Composite Measure Stratified by Gender at the Hospital-Level (N=1,633)

Description	Gender	
	Female	Male
Mean	92.7%	94.0%
Std Deviation	8.6%	6.7%
100% Max	100.0%	100.0%
99%	100.0%	100.0%
95%	100.0%	99.9%
90%	99.4%	99.3%
75% Q3	97.9%	98.2%
50% Median	95.4%	96.2%
25% Q1	90.6%	92.3%
10%	82.7%	86.3%
5%	77.2%	80.4%
1%	58.6%	68.4%
0% Min	0.0%	29.2%

Figure 4: Distribution of the Performance of the Discharge Medication Composite Measure Stratified by Sex at the Hospital-Level



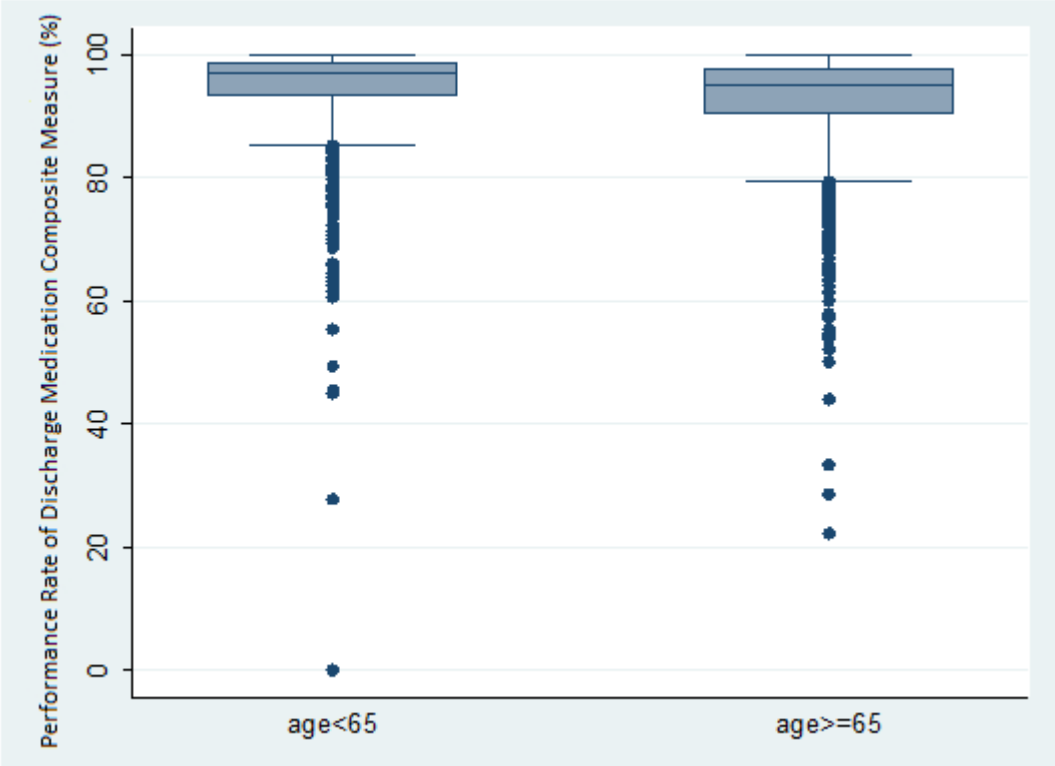
Age

The median hospital performance among patients aged < 65 was 96.8% while that among patients ≥ 65 years of age was 95.1% (Table 11, Figure 5).

Table 11: Distribution of the Performance of the Discharge Medication Composite Measure Stratified by Age at the Hospital-Level (N=1,633)

Description	Age Group	
	Age ≥ 65	Age < 65
Mean	92.6%	94.7%
Std Deviation	8.0%	6.8%
100% Max	100.0%	100.0%
99%	100.0%	100.0%
95%	100.0%	100.0%
90%	99.3%	99.5%
75% Q3	97.6%	98.6%
50% Median	95.1%	96.8%
25% Q1	90.3%	93.2%
10%	83.1%	87.5%
5%	77.8%	82.6%
1%	63.3%	66.0%
0% Min	22.2%	0.0%

Figure 5: Distribution of the Performance for the Discharge Medication Composite Measure Stratified by Age Group at the Hospital-Level



Race/Ethnicity

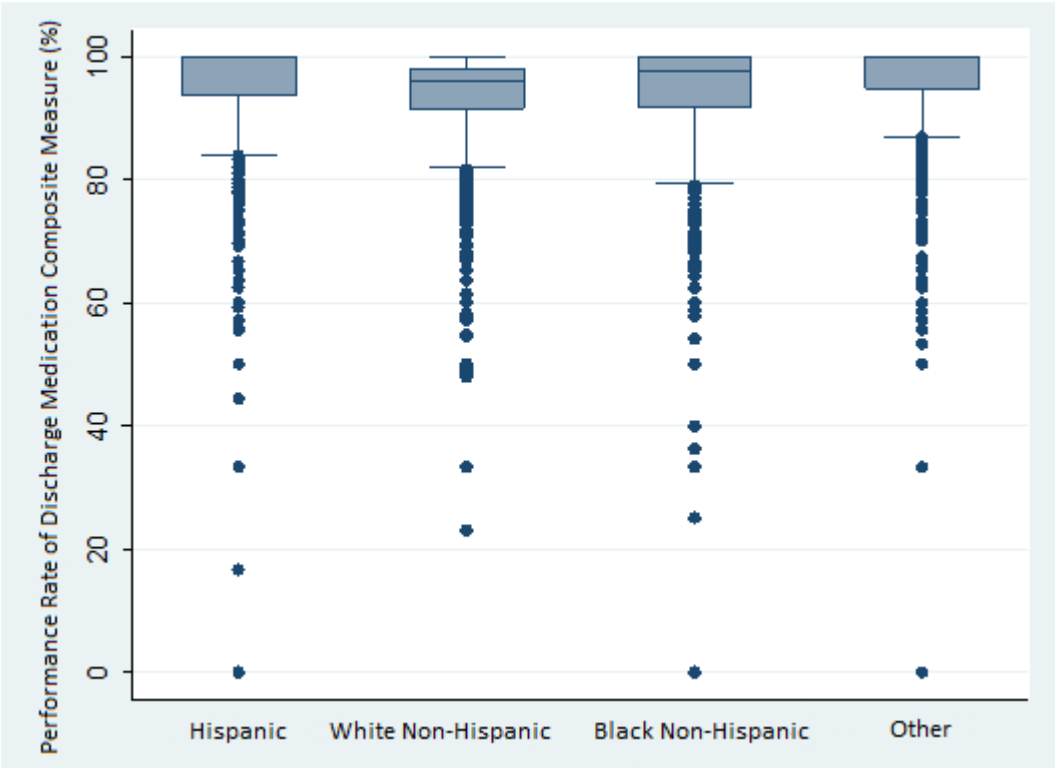
The distribution of hospital performance was examined among White (non-Hispanic), Hispanic, Black (non-Hispanic), and Other race patients. Hospitals more frequently delivered discharge medications to those of Hispanic ethnicity and Other race (median: 100%) than those of White Non-Hispanic (95.9%) and Black Non-

Hispanic (97.5%) race/ethnicity (Table 12, Figure 6).

Table 12: Distribution of Performance for the Discharge Medication Composite Measure Stratified by Race at the Hospital-Level (N=1,633)

Description	Hispanic	White non-Hispanic	Black non-Hispanic	Other
Mean	94.6%	93.4%	93.8%	95.3%
Std Deviation	11.2%	7.4%	10.4%	9.7%
100% Max	100.0%	100.0%	100.0%	100.0%
99%	100.0%	100.0%	100.0%	100.0%
95%	100.0%	99.9%	100.0%	100.0%
90%	100.0%	99.2%	100.0%	100.0%
75% Q3	100.0%	98.0%	100.0%	100.0%
50% Median	100.0%	95.9%	97.5%	100.0%
25% Q1	93.6%	91.5%	91.7%	94.7%
10%	84.6%	85.0%	83.3%	84.6%
5%	75.0%	79.1%	75.0%	75.0%
1%	50.0%	65.2%	50.0%	53.3%
0% Min	0.0%	23.1%	0.0%	0.0%

Figure 6: Distribution of the Discharge Medication Composite Measure Stratified by Race at the Hospital-Level



Insurance

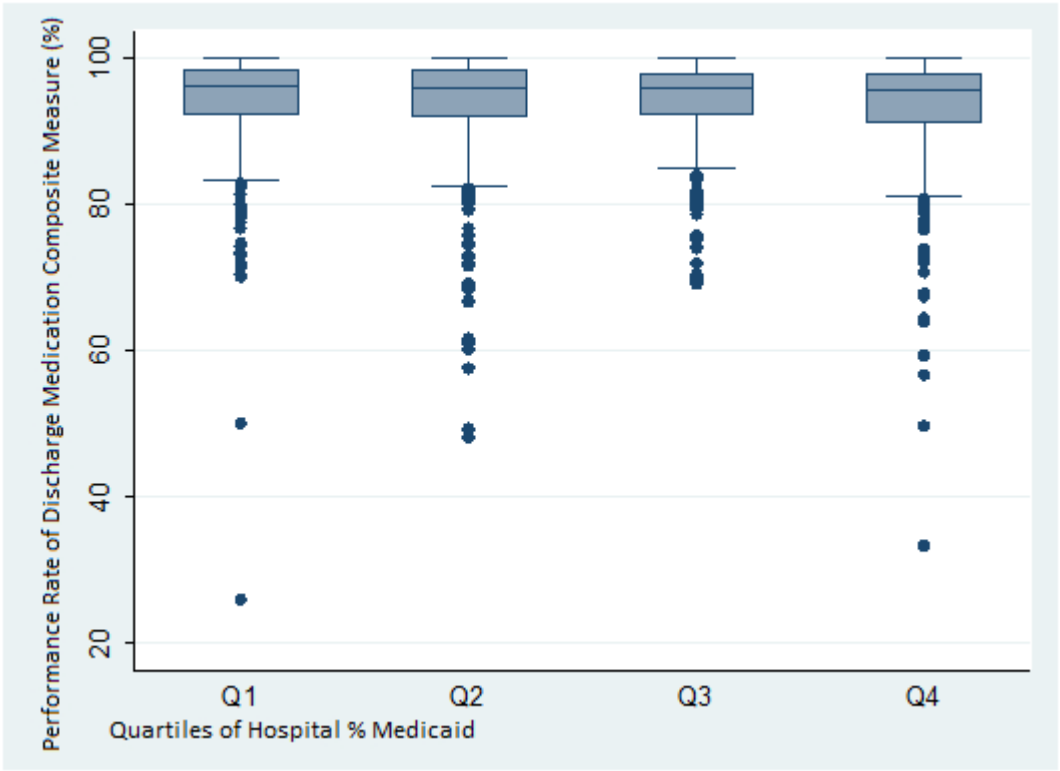
Hospitals (n=1,633) were stratified into quartiles by their proportion of patients with Medicaid as the primary insurance (median: 9.8%, IQR: 5.9% to 15.1%). Hospital performance was similar across hospitals stratified by quartile based the proportion of patients with Medicaid insurance coverage. Median hospital performance

ranged from 95.6% (Quartile 4, highest proportion of Medicaid) to 96.1% (Quartile 1, lowest proportion of Medicaid) (Table 13, Figure 7).

Table 13: Distribution of Performance for the Discharge Medication Composite Measure Stratified by Quartile of Hospital Percent Medicaid (N=1,633)

Description	Medicaid			
	Q1	Q2	Q3	Q4
Mean	93.7%	93.6%	94.1%	93.0%
Std Deviation	7.5%	7.6%	5.5%	7.7%
100% Max	100.0%	100.0%	100.0%	100.0%
99%	100.0%	100.0%	99.9%	100.0%
95%	100.0%	99.8%	99.3%	99.5%
90%	99.6%	99.3%	98.8%	98.9%
75% Q3	98.4%	98.3%	97.7%	97.7%
50% Median	96.1%	95.9%	95.8%	95.6%
25% Q1	92.1%	92.0%	92.3%	91.0%
10%	85.1%	84.4%	87.2%	84.1%
5%	79.0%	79.1%	80.7%	79.4%
1%	70.4%	61.0%	74.0%	63.9%
0% Min	25.9%	48.1%	69.1%	33.3%

Figure 7: Distribution of the Performance for the Discharge Medication Stratified by Quartile of Hospital Percent Medicaid



2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.*e., what do the results mean in terms of statistical and meaningful differences?*)

The wide gap in performance rates, along with broad interquartile ranges, across various stratified populations demonstrates that this measure is necessary to improve the quality gap.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

Note: *Applies to all component measures, unless already endorsed or are being submitted for individual endorsement.*

If only one set of specifications, this section can be skipped.

Note*: This item is directed to measures that are risk-adjusted (with or without social risk factors)* ***OR*** *to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* ***Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.***

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

N/A

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

N/A

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted?*)

N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

Note: *Applies to the overall composite measure.*

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

There were no missing data for this measure. Any hospitals with missing data were excluded from the measure as they would not have passed the NCDR data quality review.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

N/A

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i.*e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

N/A

2c. EMPIRICAL ANALYSIS TO SUPPORT COMPOSITE CONSTRUCTION APPROACH

Note: *If empirical analyses do not provide adequate results—or are not conducted—justification must be provided and accepted in order to meet the must-pass criterion of Scientific Acceptability of Measure Properties. Each of the following questions has instructions if there is no empirical analysis.*

2d1. Empirical analysis demonstrating that the component measures fit the quality construct, add value to the overall composite, and achieve the object of parsimony to the extent possible.

We believe the content and face validity of this measure has been achieved by virtue of the noted expertise of those individuals who developed this measure. The individual components of the composite have already shown to impact clinical outcomes.

The empirical validity analysis demonstrated that the individual component measures fit the overall quality construct by assessing the Pearson correlation of the discharge medications composite measure with its components, including: aspirin, P2Y12 and statins.

2d1.1 Describe the method used (*describe the steps—do not just name a method; what statistical analysis was used; if no empirical analysis, provide justification)*

We computed hospital-level measures for the three measure components individually and then correlated the results with the hospital-level composite results using Pearson correlation.

2d1.2. What were the statistical results obtained from the analysis of the components? (e.g., *correlations, contribution of each component to the composite score, etc.*; *if no empirical analysis, identify the components that were considered and the pros and cons of each*)

The Pearson correlation coefficients between the discharge composite medication measure and its components were: aspirin (r=0.7774), P2Y12 (r=0.5910) and statin (r=0.9508).

Table 14: Distribution of Performance of the Discharge Medication Composite Measure and its Components (N=1,633)

Description	Composite Value	Aspirin Value	P2Y12 Value	Statin Value
Mean	93.6%	98.1%	99.0%	95.3%
Std Deviation	7.2%	2.9%	2.5%	5.4%
100% Max	100.0%	100.0%	100.0%	100.0%
99%	100.0%	100.0%	100.0%	100.0%
95%	99.7%	100.0%	100.0%	99.9%
90%	99.2%	100.0%	100.0%	99.5%
75% Q3	98.0%	99.7%	99.9%	98.7%
50% Median	95.8%	99.0%	99.6%	97.0%
25% Q1	91.9%	97.8%	98.9%	94.1%
10%	85.2%	95.3%	97.6%	89.0%
5%	79.9%	93.3%	96.2%	85.1%
1%	67.6%	85.1%	91.5%	76.5%
0% Min	25.9%	50.0%	29.2%	33.3%

Pearson Correlation Coefficient between the Composite and its Components

Aspirin	0.7774
P2Y12	0.5910

Aspirin	0.7774
Statin	0.9508

2d1.3. What is your interpretation of the results in terms of demonstrating that the components included in the composite are consistent with the described quality construct and add value to the overall composite? (i.*e., what do the results mean in terms of supporting inclusion of the components; if no empirical analysis, provide rationale for the components that were selected)*

A correlation coefficient of 0.6 or higher is considered a 'strong correlation'. The results of the empirical validity testing demonstrate a strong correlation between the discharge medication composite and all of its components.

Reference:

Mukaka, M. M. (2012). Statistics corner: A guide to appropriate use of correlation coefficient in medical research. *Malawi Medical Journal, 24*(3), 69-71.

2d2. Empirical analysis demonstrating that the aggregations and weighting rules are consistent with the quality construct and achieve the objective of simplicity to the extent possible

2d2.1 Describe the method used (*describe the steps—do not just name a method; what statistical analysis was used; if no empirical analysis, provide justification)*

This is an all-or-none composite, thus no empirical analyses pertinent to aggregations or weighting were conducted. The components mentioned throughout the application are part of the composite measure indicator definition, not the composite of different measures.

2d2.2. What were the statistical results obtained from the analysis of the aggregation and weighting rules? (e.g., *results of sensitivity analysis of effect of different aggregations and/or weighting rules; if no empirical analysis, identify the aggregation and weighting rules that were considered and the pros and cons of each*)

This all-or-none composite method indicates that each of the individual measure components were weighed equally. While the overall performance is higher on the ASA and P2Y12 components than the statin component, there is still clinically meaningful variation across hospitals for each component particularly when one considers the fact that the consequences of failing to prescribe DAPT may in fact be more severe in both the short- and mid-term (i.e., stent thrombosis) than failing to prescribe a statin.

2d2.3. What is your interpretation of the results in terms of demonstrating the aggregation and weighting rules are consistent with the described quality construct? (i.*e., what do the results mean in terms of supporting the selected rules for aggregation and weighting; if no empirical analysis, provide rationale for the selected rules for aggregation and weighting*)

N/A

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information

(e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

There were no difficulties noted with regard to data collection, availability of data, missing data, the frequency of data collection, patient confidentiality, time and cost of data collection, or other feasibility/implementation issues. In addition, the NCDR has a robust data collection process as outlined below"

Availability:

Participating hospitals report patient demographics, medical history, risk factors, hospital presentation, initial cardiac status, procedural details, medications, laboratory values and in-hospital outcomes. The majority of the 5 required data elements are routinely generated and acquired during the delivery of standard cardiac care to this patient population. Electronic extraction of data recorded as part of the procedure expedites data collection. This strategy offers point of care collection and minimizes time and cost. Institutions can manually report using a free web-based tool or automate the reporting by using certified software developed by third-party vendors. The data elements required for this measure are readily available within the patient's medical record or can be attained without undue burden within the hospital. Most data elements exist in a structured format within patient's electronic health record.

Sampling:

There is no sampling of patient data allowed within the contractual terms of participation in the CathPCI Registry in NCDR. The registry is designed to include 100 percent of consecutive adult patients who undergo PCI at participating institutions. Section 2.b of the NCDR Master Agreement with participants includes 'Participant Responsibilities': "b. Use of ACCF Data Set and ACCF-Approved Software. Participant will submit a data record on each patient who receives medical care and who is eligible for inclusion in the Registries in which Participant is participating under this Agreement." Adult patients, ages 18 years and older, who undergo a diagnostic cardiac catheterization and/or PCI. Eligible diagnostic catheterizations are characterized by the passage of a catheter into the aortic root for pressure measurements and/or angiography, and can include Left Ventricle (LV) pressure measurements, LV angiography, coronary angiography, and coronary artery bypass angiography. Eligible PCI procedures include those that involve passage or attempted passage of a coronary device across one or more coronary lesions for purposes of increasing the intraluminal diameter of the vessel and/or restoring or improving circulation. Patients are selected for inclusion by reviewing existing medical records and no direct interaction with the patient will be required outside of the normal course of care. There will be no discrimination or bias with respect to inclusion on the basis of sex, race, or religion.

Patient confidentiality:

Patient confidentiality is preserved as the data are in aggregate form. The CathPCI Registry dataset, comprised of approximately 263, data elements was created by a panel of experts using available ACC-AHA guidelines, data elements and definitions, and other evidentiary sources. Private health information (PHI), such as social security number, is collected. The intent for collection of PHI is to allow for registry interoperability and the potential for future generation of patient-level drill downs in Quality and Outcomes Reports. Registry sites can opt out of transmitting direct identifiers to the NCDR, however, so inclusion of direct identifiers in the registry is at the discretion of the registry participants themselves. When using the NCDR web-based data collection tool, direct identifiers are entered but a partition between the data collection process and the data warehouse maintains the direct identifiers separate from the analysis datasets. The minimum level of PHI transmitted to the ACCF when a participant opts out of submitting direct identifiers meets the definition of a Limited Dataset as such term is defined by the Health Insurance Portability and Accountability Act of 1996.

Data collection within the NCDR conforms to laws regarding protected health information. Patient confidentiality is of utmost concern with all metrics. The proposed measure does not include a patient survey. Physician and/or institutional confidentiality is maintained by de-identified dashboard reports. There is no added procedural risk to patients through involvement in the CathPCI Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed. The primary risk associated with this measure is the potential for a breach of patient confidentiality. The ACCF has established a robust plan for ensuring appropriate and commercially reasonable physical, technical, and administrative safeguards are in place to mitigate such risks.

Data are maintained on secure servers with appropriate safeguards in place. The project team periodically reviews all activities involving protected health information to ensure that such safeguards including standard operating procedures are being followed. The procedure for notifying the ACCF of any breach of confidentiality and immediate mitigation standards that need to be followed is communicated to participants. ACCF limits access to Protected Health Information, and to equipment, systems, and networks that contain, transmit, process or store Protected Health Information, to employees who need to access the PHI for purposes of performing ACCF's obligations to participants who are in a contractual relationship with the ACCF. All PHI are stored in a secure facility or secure area within ACCF's facilities which has separate physical controls to limit access, such as locks or physical tokens. The secured areas are monitored 24 hours per day, 7 days per week, either by employees or agents of ACCF by video surveillance, or by intrusion detection systems.

Each participant who has access to the NCDR website must have a unique identifier. The password protected webpages have implement inactivity time-outs. Encryption of wireless network data transmission and authentication of wireless devices containing NCDR Participant's information ACCF's network is required. Protected Health Information may only be transmitted off of ACCF's premises to approved parties, which shall

mean: A subcontractor who has agreed to be bound by the terms of the Business Associate Agreement between the ACCF and the NCDR Participant.

Time of Data collection:

1 Full time employee can enter on average roughly 1200 patient records per year

(citation: ACC Marketing Intelligence Team)

Annual Fee:

See section 3c2

Overall there is no added procedural risk to patients through their hospital's involvement in the CathPCI Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm)*.

This measure was developed and designed to be used across other organizations and by other measure implementers. The fee and licensing information include below is specific to NCDR program requirements:

The ACCF's program the National Cardiovascular Data Registry (NCDR) provides evidence-based solutions for cardiologists and other medical professionals committed to excellence in cardiovascular care. NCDR hospital participants receive confidential benchmark reports that include access to measure macro specifications and micro specifications, the eligible patient population, exclusions, and model variables (when applicable). In addition to hospital sites, NCDR Analytic and Reporting Services provides consenting hospitals' aggregated data reports to interested federal and state regulatory agencies, multi-system provider groups, third-party payers, and other organizations that have an identified quality improvement initiative that supports NCDR-participating facilities. Lastly, the ACCF also allows for licensing of the measure specifications outside of the Registry. For calendar year 2017, the annual pricing for hospitals, NCDR Analytic and Reporting Services, and licensing of measure specifications ranges from $2900-$50,000.

Measures that are aggregated by ACCF and submitted to NQF are intended for public reporting and therefore there is no charge for a standard export package. However, on a case by case basis, requests for modifications to the standard export package will be available for a separate charge.

There is no added procedural risk to patients through their hospital's involvement in the CathPCI Registry. No testing, time, risk, or procedures beyond those required for routine care will be imposed.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
	Public Reporting NCDR Public Reporting https://cvquality.acc.org/ncdr-home/acc-public-reporting Payment Program Quality Hospital Insight program for Anthem https://www.anthem.com/wps/portal/ahpmedprovider?content_path=shared/noapplication/f2/s3/t0/pw_b140403.htm&rootLevel=1&label=Hospital%20Quality%20and%20Safety Blue Distinction Centers for Cardiac Care https://www.bcbs.com/sites/default/files/file-attachments/page/Cardiac.SelectionCriteria_0.pdf Quality Improvement (external benchmarking to organizations) National Cardiovascular Data Registry https://cvquality.acc.org/NCDR-Home/registries/hospital-registries/cathpci-registry

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Payment Programs:

Name of program and sponsor: Blue Distinction Centers for Cardiac Care; Sponsor: Blue Cross Blue Shield Association

Purpose:

The Blue Distinction Centers for Cardiac Care is a national designation program that recognizes hospitals that demonstrate expertise in delivering quality specialty care, safely and effectively. To earn the Blue Distinction Centers+ designation, hospitals must meet the same quality criteria as Blue Distinction Centers, and go an extra step to demonstrate that they do so cost efficiently. Quality is key: only those facilities that first meet Blue Distinction's nationally established, objective quality measures will be considered for designation as a Blue Distinction Center+. Blue Distinction Centers' goal is to help consumers find both quality and value for their specialty care needs, on a consistent basis, while encouraging healthcare professionals to improve the overall quality and delivery of care nationwide. [Retrieved from http://www.bcbs.com/healthcare-partners/blue-distinction-for-providers/cardiacprogramcriteria.pdf on 11/25/13]

Geographic area and number and percentage of accountable entities and patients included

Geographic Area: National program.

Number: Directory of Providers available at http://www.bcbs.com/why-bcbs/blue-distinction/blue-distinction-cardiac/bluedistinctioncardiac.pdf

% of accountable entities: Total of 414 hospitals

Alabama	10
Arizona	4
Arkansas	3
California	46
Colorado	6
Connecticut	5
Delaware	3
Florida	29
Georgia	4
Hawaii	1

Idaho 3
Illinois 29
Indiana 12
Iowa 8
Kansas 5
Kentucky 5
Louisiana 5
Maine 1
Massachusetts 8
Michigan 23
Minnesota 12
Missouri 12
Nebraska 5
New Hampshire 2
New Jersey 3
New York 12
Nevada 2
North Carolina 10
North Dakota 4
Ohio 26
Oklahoma 4
Patients included: information not available .

The measure is also used in the Quality Insight Hospital Program with Anthem, which overlaps with what is included above for Blue Distinction program

NCDR Public Reporting

ACC's National Cardiovascular Data Registry (NCDR) Voluntary Hospital Public Reporting Program: The ACC currently runs a program to give hospitals the opportunity to voluntarily publicly report their measure results based on data from the National Cardiovascular Data Registry (NCDR). Hospitals that choose to participate have their results displayed on ACC's CardioSmart. Currently Hospitals can report on the following NQF-endorsed measures:

NQF #0965: Use of all recommended medications (ACEI or ARB and beta-blocker) to improve heart function and blood pressure after ICD implant.

NQF # 0964: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients (composite measure)

NQF: 2377: Overall Defect Free Care Composite (which is identified on the website as the "Complete Heart Attack Care")

NCDR CathPCI Registry:

The CathPCI Registry is sponsored by ACC in conjunction with the Society for Cardiovascular Angiography and Interventions. The registry was designed to create a national surveillance system to assess the characteristics, treatments, and outcomes of patients with coronary heart disease who undergo procedures in cardiac catheterization laboratories. Eligible patients are adults (18 years of age and older) who undergo a diagnostic cardiac catheterization and/or PCI. More than 1,300 hospitals across the U.S submit data to the CathPCI registry. Participation provides risk-adjusted quarterly benchmark reports that compares institutional performance with that of volume-based peer groups and the national experience. The registry includes standardized, evidence-based data elements and definitions, a Dashboard tool that provides a custom query to control for variables (facility size, number of procedures, teaching vs. non-teaching sites, states and regions) to compare the participating facility data, metrics and volumes. ABIM Diplomates can also meet MOC

recertification requirements by using CathPCI Registry data to earn up to 80 points toward evaluation of practice performance through the Clinical Quality Coach mobile app

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)
N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

N/A

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Performance results are distributed to all CathPCI registry participants as part of quarterly benchmark reports, which provide a detailed analysis of an institution´s individual performance in comparison to the entire registry population from participating hospitals across the nation. Reports include an executive summary dashboard, at-a-glance assessments, and patient level drill-downs. Registry participants also have access to an outcome report companion guide which provides common definitions and detailed metric specifications to assist with interpretation of performance rates.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

The majority of the required data elements are routinely generated and acquired during the delivery of standard cardiac care to this patient population. Electronic extraction of data recorded as part of the procedure expedites data collection. This strategy offers point of care collection and minimizes time and cost. Institutions can manually report using a free web-based tool or automate the reporting by using certified software developed by third-party vendors. The data elements required for this measure are readily available within the patient's medical record or can be attained without undue burden within the hospital. Most data elements exist in a structured format within patient's electronic health record.

There are a number of methods used to educate and provide general support to registry participants. This includes the following:

- Registry Site Manager Calls are available for all NCDR participants. RSM calls are provided as a source of communication between NCDR and participants to provide a live chat Q and A session on a continuous basis.
- New User Calls are available for NCDR participants, and are intended for assisting new users with their questions.
- NCDR Annual Conference

The NCDR Annual Conference is a well-attended and energetic two-day program at which participants from across the country come together to hear about new NCDR and registry-specific updates. During informative general sessions, attendees can learn about topics such as transcatheter therapies, the NCDR dashboard, risk models, data quality and validation, and value-based purchasing. Attendees also receive registry updates and participate in advanced case studies covering such topics as Appropriate Use Criteria and outcomes report interpretation.

- Release notes (for outcomes reports)
- Clinical Support

The NCDR Product Support and Clinical Quality Consultant Teams are available to assist participating sites with questions Monday through Friday, 9:00 a.m. - 5:00 p.m. ET.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Feedback is typically obtained through monthly registry site manager monthly calls, ad hoc phone calls tracked with salesforce software, and during registry –specific break-out sessions at the NCDR's annual meeting. Registry Steering Committee members may also provide feedback during regularly scheduled calls.

4a2.2.2. Summarize the feedback obtained from those being measured.

Users have not reported any difficulties with reporting this measure.

4a2.2.3. Summarize the feedback obtained from other users

No feedback was received from other users.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

N/A

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

The trend identified in the EFFECT study [JAMA. 2009; 302(21):2330-2337. doi: 10.1001/jama.2009.1731] with respect to the effectiveness of public report cards for improving the quality of cardiac care, we feel this measure made available for public reporting continues to stimulate local, hospital-specific changes in delivery of care that may contribute to the better outcomes. This composite measure provides the opportunity to develop common strategies across hospitals for addressing needs associated with medication prescribing, medication reconciliation at discharge, guideline driven care and potentially the reduction of morbidity, mortality and hospital readmissions costs by encouraging the proper use of cardiac prescription medication. Performance rates for the composite measure have increased over time, corresponding to a growing denominator (Table 4). These 2011-2016 rates indicate that outcomes are improving, as more patients undergoing PCI are receiving all medications for which they are eligible.

Table 4: Performance Rates for Discharge Medications Composite Measure From 2011-2016

YEAR	DEN	NUM	%
2011	618146	551717	89.25
2012	627181	570435	90.95
2013	633696	586406	92.54
2014	651046	608801	93.51
2015	682385	643508	94.30
2016	703998	669255	95.06

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

Inaccuracies may occur if certified vendors export data incorrectly, in transmission of data from medical record to a paper form and then to the online data collection tool. Some sites may over-code medication exclusions.

A vendor certification process has been established to ensure high quality data collection and submission.

The NCDR Data Quality Program is in place to assess reliability of data abstraction. For additional details about the NCDR Data Quality Program please see testing supplement.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

None

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0067 : Chronic Stable Coronary Artery Disease: Antiplatelet Therapy

0068 : Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet

0074 : Chronic Stable Coronary Artery Disease: Lipid Control

0118 : Anti-Lipid Treatment Discharge

0142 : Aspirin prescribed at discharge for AMI

0543 : Adherence to Statin Therapy for Individuals with Cardiovascular Disease

0569 : ADHERENCE TO STATINS

0631 : Secondary Prevention of Cardiovascular Events - Use of Aspirin or Antiplatelet Therapy

0639 : Statin Prescribed at Discharge

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

Statin measures

0543: Adherence to Statin Therapy for Individuals with Coronary Artery Disease is not specific to patients undergoing a PCI. This measure uses claims data and it is not evaluated at the point of discharge. This is a measure using claims data and determines whether patients are filing their prescription. The measure we propose evaluates if the prescription has been provided to the patients.

0569: Adherence to Statin is similar to measure 0543 listed above and is not specific to patients undergoing PCI. This is a measure using claims data and determines whether patients are filing their prescription. The measure we propose evaluates if the prescription has been provided to the patients.

0118: Anti-Lipid Treatment Discharge includes patients undergoing CABG, not PCI. It also includes non statins as well as statins.

0074: Chronic Stable Coronary Artery Disease: Lipid Control includes all patients with CAD and is not specific to those patients who have had a PCI.

0639: Statin Prescribed at Discharge evaluates patients who have had a myocardial infarction. There may be patient overlap with this measure and the one proposed. The composite measure proposed in this application however contains two other guideline recommended medication. Our measure includes all PCI patients not only those who have had a MI, thus ours is monitoring secondary prevention as well as the tertiary prevention that is measured by CMS.

P2Y12/Aspirin component

0142: Aspirin prescribed at discharge for AMI evaluates patients who have had a myocardial infarction. There may be patient overlap with this measure and the one proposed. The composite measure proposed in this application however contains two other guideline recommended medication. Our measure includes all PCI patients not only those who have had a MI, thus ours is monitoring secondary prevention as well as the tertiary prevention that is measured by CMS.

0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy includes all patients with CAD and is not specific to those patients who have had a PCI.

0068: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic includes a larger patient population of patients who were discharged for acute myocardial infarction, coronary artery bypass graft or percutaneous coronary interventions. The measure 0068 measures patients who had documentation of use of aspirin or another antithrombotic during the measurement year. The critical difference is the use of the term “or” that allows patients to be included into the numerator of this measure. Evidence indicates that Dual Antiplatelet Therapy is the ideal medical therapy of choice for this patient population. The composite measure proposed in this application follows the current medical guidelines for treating patients undergoing PCI with both Aspirin and a specifically anti platelets medications within the P2Y12 inhibitor drug class.

0631 Secondary Prevention of Cardiovascular Events - Use of Aspirin or Antiplatelet Therapy

The critical difference is the use of the term “or” that allows patients to be included into the numerator of this measure. Evidence indicates that Dual Antiplatelet Therapy is the ideal medical therapy of choice for this patient population. The composite measure proposed in this application follows the current medical guidelines for treating patients undergoing PCI with both Aspirin and a specifically anti platelets medications within the P2Y12 inhibitor drug class.

Measure # 2452 has a clear distinction between absolute “Exclusions” (e.g., death, transfer) and relative “Exceptions”, (e.g., medical reasons, system reasons, and patient reasons). While patients with exclusions are always automatically removed from the denominator and numerator, exceptions allow clinicians the opportunity to identify an intervention/process/medication as not clinically indicated based on the unique patient scenario. When no exception has been documented, then the performance has not been met for the physician level reported Measure #2452.

Measure # 0964 does not provide detail on exceptions that would removed the patients from the numerator or denominator. Each of the three medications incorporated into this composite may be coded as Yes (medication prescribed), No (medication not prescribed), Blinded (pt. involved in a clinical trial, medication type unavailable for data entry), and Contraindicated (used to capture many of the medical exceptions used in measure #2452). The difference between these two measures is that the medical record must describe the contraindication in detail in order for this option to be selected. A list of medical exceptions has not been provided by the ACC for this hospital based level of reporting.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

see below for discussion of harmonization and competition.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Statin measures

0543: Adherence to Statin Therapy for Individuals with Coronary Artery Disease is not specific to patients undergoing a PCI. This measure uses claims data and it is not evaluated at the point of discharge. This is a measure using claims data and determines whether patients are filing their prescription. The measure we propose evaluates if the prescription has been provided to the patients.

0569: Adherence to Statin is similar to measure 0543 listed above and is not specific to patients undergoing PCI. This is a measure using claims data and determines whether patients are filing their prescription. The measure we propose evaluates if the prescription has been provided to the patients.

0118: Anti-Lipid Treatment Discharge includes patients undergoing CABG, not PCI. It also includes non statins as well as statins.

0074: Chronic Stable Coronary Artery Disease: Lipid Control includes all patients with CAD and is not specific to those patients who have had a PCI.

0639: Statin Prescribed at Discharge evaluates patients who have had a myocardial infarction. There may be patient overlap with this measure and the one proposed. The composite measure proposed in this application however contains two other guideline recommended medication. Our measure includes all PCI patients not only those who have had a MI, thus ours is monitoring secondary prevention as well as the tertiary prevention that is measured by CMS.

P2Y12/Aspirin component

0142: Aspirin prescribed at discharge for AMI evaluates patients who have had a myocardial infarction. There may be patient overlap with this measure and the one proposed. The composite measure proposed in this application however contains two other guideline recommended medication. Our measure includes all PCI patients not only those who have had a MI, thus ours is monitoring secondary prevention as well as the tertiary prevention that is measured by CMS.

0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy includes all patients with CAD and is not specific to those patients who have had a PCI.

0068: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic includes a larger patient population of patients who were discharged for acute myocardial infarction, coronary artery bypass graft or

percutaneous coronary interventions. The measure 0068 measures patients who had documentation of use of aspirin or another antithrombotic during the measurement year. The critical difference is the use of the term "or" that allows patients to be included into the numerator of this measure. Evidence indicates that Dual Antiplatelet Therapy is the ideal medical therapy of choice for this patient population. The composite measure proposed in this application follows the current medical guidelines for treating patients undergoing PCI with both Aspirin and a specifically anti platelets medications within the P2Y12 inhibitor drug class.

0631 Secondary Prevention of Cardiovascular Events - Use of Aspirin or Antiplatelet Therapy

The critical difference is the use of the term "or" that allows patients to be included into the numerator of this measure. Evidence indicates that Dual Antiplatelet Therapy is the ideal medical therapy of choice for this patient population. The composite measure proposed in this application follows the current medical guidelines for treating patients undergoing PCI with both Aspirin and a specifically anti platelets medications within the P2Y12 inhibitor drug class.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Available at measure-specific web page URL identified in S.1 **Attachment:**

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): American College of Cardiology

Co.2 Point of Contact: Sana, Gokak, sgokakt@acc.org, 202-375-6596-

Co.3 Measure Developer if different from Measure Steward: American College of Cardiology

Co.4 Point of Contact: Esteban, Perla, eperla@acc.org

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

For this particular topic those individuals who were involved in identifying the key attributes and variables for this process measure were leaders and experts in the field of interventional cardiology. Serial phone calls were held to both define the eligible population and given process. These clinical leaders are noted below.

At the time of initial endorsement, the following groups oversaw the measure:

NCDR Clinical Subworkgroup ensured the measure demonstrated an opportunity for improvement, had strong clinical evidence, and was a reliable and valid measure. These members included Drs. Jeptha Curtis (Chair), Frederick Masoudi, John Rumsfeld, Issam Moussa, and David Malenka.

NCDR Scientific Quality and Oversight Committee—a committee that served as the primary resource for crosscutting scientific and quality of care methodological issues. These members included Drs. Frederick

Masoudi (Chair) , David Malenka, Thomas Tsai, Matthew Reynolds, David Shahian, John Windle, Fred Resnic, John Moore, Deepak Bhatt, James Tcheng, Jeptha Curtis, Paul Chan, Matthew Roe, and John Rumsfeld.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2012

Ad.3 Month and Year of most recent revision: 05, 2012

Ad.4 What is your frequency for review/update of this measure? With dataset revisions and based on new evidence.

Ad.5 When is the next scheduled review/update for this measure?

Ad.6 Copyright statement: American College of Cardiology Foundation All Rights Reserved

Ad.7 Disclaimers: ACC realizes the various NCDR endorsed measures are not readily available on their own main webpage. However, ACCF plans to update their main webpage (cardiosource.org) to include the macro-specifications of the NQF endorsed measures. ACC will collaborate with NQF to create a consistent and standard format would be helpful for various end users. In the interim, the supplemental materials include the details needed to understand this model.

Ad.8 Additional Information/Comments: ACC appreciates the opportunity to submit measures for this NQF endorsement maintenance project.