NATIONAL QUALITY FORUM

Memo

TO: Consensus Standards Approval Committee (CSAC)

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RE: Cardiovascular 2016-2017

DA: November 9-10, 2016

The CSAC will review recommendations from the Cardiovascular Project at its November 9-10, 2016 meeting.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Member voting on these recommended measures ended on October 31, 2016.

Accompanying this memo are the following documents:

1. **Cardiovascular Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment Table.** Staff has identified themes within the comments received. This table lists four comments received during the post meeting comment period and the NQF/Standing Committee responses.

BACKGROUND

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

NQF's cardiovascular portfolio of measures is one of the largest, with measures for primary prevention and screening, coronary artery disease (CAD), ischemic vascular disease (IVD), acute myocardial infarction (AMI), cardiac catheterization, percutaneous catheterization intervention (PCI), heart failure (HF), rhythm disorders, implantable cardioverter-defibrillators (ICDs), cardiac imaging, cardiac rehabilitation, and high blood pressure. Despite the large number of endorsed measures, gaps remain in patient-reported outcomes and patient-centric composite measures.

For this project, the 24-member Cardiovascular Standing Committee evaluated two-newly submitted measures and four measures undergoing maintenance of endorsement review against NQF's standard evaluation criteria. The Committee recommended four measures

for endorsement and two measures were not recommended. Evaluated measures are listed by topic in the draft report.

DRAFT REPORT

The Cardiovascular Draft Report presents the results of the evaluation of six measures considered under the Consensus Development Process (CDP). Four measures are recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement and two are not recommended for endorsement. The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	4	2	6
Measures recommended for endorsement	3	1	4
Measures not recommended for endorsement	1	1	2
Measures withdrawn from consideration	0	1	1
Reasons for not recommending	Importance – 0 Scientific Acceptability – 0 Overall – 1 Competing Measure – 0	Importance – 0 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	

Pursuant to the CDP, the CSAC may consider approval of four candidate consensus measures.

Cardiovascular Measures Recommended for Endorsement:

- 0066: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (American Heart Association)
  Overall Suitability for Endorsement: Y-17; N-1
- 0076: Optimal Vascular Care (MN Community Measurement)
  Overall Suitability for Endorsement: Y-19; N-3
- 0290: Median Time to Transfer to Another Facility for Acute Coronary Intervention (Centers for Medicare & Medicaid Services)
  Overall Suitability for Endorsement: Y-19; N-2
- 2906: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%) – Legacy eMeasure (AMA-PCPI)
  Overall Suitability for Endorsement: Y-18; N-1

Cardiovascular Measures Not Recommended (See Appendix A for the Committee's votes and rationale)

- 0288: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (Centers for Medicare & Medicaid Services
- 2939: Statin Therapy in Patients with Clinical Atherosclerotic Disease (American College of Cardiology)

COMMENTS AND THEIR DISPOSITION

NQF received four comments from four individuals pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Cardiovascular project page under the Public and Member Comment section.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationale were forwarded to the developers, who were invited to respond.

The Standing Committee reviewed all of the submitted comments and developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Theme 1 – Statin Component

Measure *#0076 Optimal Vascular Care* received one comment noting that substitution of 'statin use' as the component in this composite to address dyslipidemia, to replace LDL < 100 mg/dL is not consistent with 'optimal care' as defined by clinical guidelines which at a minimum require moderate to high intensity statins adjusted to achieve desired therapeutic response as reflected in reduction of LDL-c level. Prescribing is misleading if it does not achieve the desired clinical outcome. Whether the LDL-c is described as a 'target of therapy', 'treatment target', 'goal', or 'threshold', clinically, it is impossible to ensure risk reduction without using the LDL-c to assess the adequacy of a patient's response to treatment.

Developer Response: Thank you for your comment and suggestion for the inclusion of the dose of statin (moderate or high) in the calculation of the cholesterol component of this patient level all-or-none composite measure. While ACC/ AHA guidelines do indicate that most patients with ischemic vascular disease would benefit from high dose intensity statins, there are provisions for moderate intensity statins for patients who cannot tolerate high intensity doses. The measure development work group thoroughly discussed the pros and cons of specifying a certain dose of the statin medication for numerator component compliance and determined that requiring the submission of the dose of statin would cause undue data collection burden for the practices. Additionally, the cardiologists on the workgroup strongly believe that there is some benefit for patients who can only tolerate a low dose of statin.

We do not discount the role of ongoing LDL monitoring to determine effectiveness of statin therapy, but having a physiological target (e.g. LDL < 100) is no longer supported by evidence.

The American College of Cardiology/ American Heart Associate guidelines for the treatment of blood cholesterol indicate the following:

> "Treat to target — this strategy has been the most widely used the past 15 years but there are 3 problems with this approach. First, current clinical trial data do not indicate what the target should be. Second, we do not know the magnitude of additional ASCVD risk reduction that would be achieved with one target lower than another. Third, it does not take into account potential adverse effects from multidrug therapy that might be needed to achieve a specific goal. Thus, in the absence of these data, this approach is less useful than it appears (Section 3). It is possible that future clinical trials may provide information warranting reconsideration of this strategy" (pg. 17)

Yes, our component rates for prescribing statins are high in MN, which is a little bit unexpected for the newly re-designed component, however we would like to clarify the cholesterol component of statin use is not reported as a stand-alone measure. The Optimal Vascular Care measure is reported as an all-or-none composite, patients achieving multiple components of modifiable risk factors to reduce or delay long term complications. Statin use is one component, the other three are blood pressure control, tobacco-free and daily aspirin or antiplatelet medication.

Committee Response: Thank you for your comment. The Committee agrees that monitoring LDL levels remains an important part of providing care for patients with IVD. However, the statin component in this measure aligns with the 2013 ACC/AHA Guideline for the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.

Theme 2 – Support for the Measure

Three commenters expressed their support for two measures, *2939: Statin Therapy in Patients with Clinical Atherosclerotic Disease* and *0066: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%).*

On October 7, 2016, the Committee considered comments received and developer responses in further evaluation of one measure where the Committee did not reach consensus on must-pass criterion and evaluation was deferred on one measure during the July 12, 2016 in-person meeting. On re-revote the Committee did not recommend the two measures. The measures recommended for endorsement proceeded to NQF Member vote.

Details of the comments received and the Committee's discussion are red-lined in the draft report.

NQF MEMBER VOTING RESULTS

The four recommended measures were approved with 88% approval or higher. Representatives of 8 member organizations voted; no votes were received from Consumer, Public/Community Health Agency or Supplier/Industry Councils. Results for each measure are provided in Appendix B.

REMOVE ENDORSEMENT OF MEASURES

Three measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement.

Measure	Description	Reason for removal of endorsement
0092: Emergency Medicine: Aspirin at Arrival for Acute Myocardial Infarction (AMI)	Percentage of patients, regardless of age, with an emergency department discharge diagnosis of acute myocardial infarction (AMI) who had documentation of receiving aspirin within 24 hours before emergency department arrival or during emergency department stay.	Measure was not submitted for maintenance review. Measure is considered "topped out, meaning it no longer addresses a performance gap area.
0163: Primary PCI received within 90 minutes of hospital arrival	Percentage of acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving primary percutaneous coronary intervention (PCI) during the hospital stay with a time from hospital arrival to PCI of 90 minutes or less.	Measure was not submitted for maintenance review. Measure is considered "topped out, meaning it no longer addresses a performance gap area.
0164: Fibrinolytic Therapy received within 30 minutes of hospital arrival	Percentage of acute myocardial infarction (AMI) patients with ST-segment elevation or LBBB on the ECG closest to arrival time receiving fibrinolytic therapy during the hospital stay and having a time from hospital arrival to fibrinolysis of 30 minutes or less.	Measure was not submitted for maintenance review. Measure is considered "topped out, meaning it no longer addresses a performance gap area.

Appendix A – Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for measures not recommended for endorsement.

Measure	Voting Results	Rationale:
0288: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival	**Initial Vote:** **Evidence** H-12; M-6; L-3; I-1 **Gap** H-18; M-3; L-1; I-0 **Post Comment Call Vote:** **Reliability** H-3; M-10; L-7; I-0; **Validity** M-12; L-8; I-0 **Feasibility** H-1; M-17; L-1; I-0 **Usability and Use** H-1; M-14; L-5; I-0 **Standing Committee Recommendation for Endorsement** Y-9; N-11	During the in-person meeting, the Standing Committee voiced several concerns with the validity of the measure including: - The small numbers of patients remaining in the population after a total of 94.1% of patients were removed after the denominator exclusions and numerator exceptions were applied. - The large number of overall exclusions due to the data element "Initial ECG Interpretation" (59.5%). - Do the facilities with the greatest number of excluded cases also have higher performance rates indicating potential data misclassification of the measure? The Standing Committee requested that the developer clarify the numerator, denominator, exclusions, and exclusions analysis. Additionally, the Committee requested that the developer provide an analysis of the facilities with the highest number of exclusions and the highest performing facilities to determine if there is potential misclassification of the measure. At the time of the post-comment call, the developer provided an algorithm to clarify the measure specifications including the initial population, numerator, denominator, and exclusions. The developer was unable to provide the analysis of facilities the Committee requested in time for the post-comment call. The Standing Committee discussed the same concerns raised at the in-person meeting and ultimately did not recommend the measure for endorsement.

Measure	Voting Results	Rationale:
2939: Statin Therapy in Patients with Clinical Atherosclerotic Disease	**Evidence** H-19; M-2; L-0; I-0 **Gap** H-16; M-5; L-0; I-0 **Reliability** H-4; M-13; L-3; I-1 ***Initial* Validity** M-11; L-6; I-3 ***Initial* Feasibility** H-1; M-10; L-6; I-3 **Usability and Use** H-1; M-12; L-4; I-3 **Post Comment Call Vote:** **Validity** M-9; L-6; I-4 **Feasibility** H-1; M-10; L-7; I-2;	During the in-person meeting, the Committee did not reach consensus on Validity and Feasibility. During the post-comment call, the Standing Committee reiterated their concerns about the validity of the measure from the in-person meeting because there were no patients with documentation of a patient reason for not prescribing a statin, such as patient refusal, or patients who could not tolerate high or moderate intensity statin therapy. The measure did not pass the Validity subcriterion. The Standing Committee also expressed concern with the feasibility of the measure as outlined in the validation process used to obtain the final dataset, and therefore, did not pass the feasibility criterion of the measure.

Appendix B – NQF Member Voting Results

NQF MEMBER VOTING RESULTS
The four recommended measures were approved with 88% approval or higher. Representatives of 8 member organizations voted; no votes were received from Consumer, Public/Community Health Agency or Supplier/Industry Councils. Results for each measure are provided below.

NQF Member Council	Voting Organizations	Eligible to Vote	Rate
Consumer	0	40	0%
Health Plan	1	18	6%
Health Professional	2	103	2%
Provider Organizations	2	108	2%
Public/Community Health Agency	0	17	0%
Purchaser	2	21	10%
QMRI	1	77	1%
Supplier/Industry	0	36	0%
All Councils	**8**	**420**	**3%**

0066: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (American Heart Association)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	2	0	0	2	100%
Provider Organizations	2	0	0	2	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	0	1	100%
Supplier/Industry	0	0	0	0	
All Councils	**8**	**0**	**0**	**8**	**100%**
Percentage of councils approving					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Voting Comments: No voting comments were received for this measure.

0076: Optimal Vascular Care (MN Community Measurement)

Member Council	Yes	No	Abstain	Total	%Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	1	0	1	2	100%
Provider Organizations	2	0	0	2	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	0	1	100%
Supplier/Industry	0	0	0	0	
All Councils	**7**	**0**	**1**	**8**	**100%**
Percentage of councils approving					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Voting Comments: American Heart Association: We support endorsement of measure 2939 (Statin Therapy in Patients with Clinical Atherosclerotic Disease). Although we acknowledge that there are currently some challenges with feasibility (especially capturing statin dose), it's also possible that wider implementation could help drive improvements in EHRs that would make the measure more feasible to collect. 2939 is fully aligned with the ACC/AHA Cholesterol guidelines and takes into consideration both the recommended statin intensity and patient preferences and is preferred to a measure that addresses prescription of statin alone.

0290: Median Time to Transfer to Another Facility for Acute Coronary Intervention (Centers for Medicare & Medicaid Services)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	1	0	2	50%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	0	1	100%
Supplier/Industry	0	0	0	0	
All Councils	**7**	**1**	**0**	**8**	**88%**
Percentage of councils approving (>60%)					80%
Average council percentage approval					90%

*equation: Yes/ (Total - Abstain)

Voting Comments: Federation of American Hospitals: The Committee Report raised questions about the 0290: Median Time to Transfer. The Committee did not know whether the reliability score was overall reliability or questionable reliability just for the facilities that met the minimum case count. The Committee also questioned the high exclusion rate (almost 60%) since it appears to be a threat to validity but continued to recommend the measure. Therefore, the FAH is concerned with the committee's evaluation of the scientific acceptability criterion given high exclusion rate, which could be viewed as a significant threat to validity and the committee's lack of understanding on whether the reliability score was overall reliability or for the facilities that met the minimum case count. Given these unresolved questions, we do not support continued endorsement of the measure at this time. Consequently, given that the validity and reliability appear to be in question, the FAH votes NO for this measure.

2906: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%) – Legacy eMeasure (AMA-PCPI)

Member Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	2	0	0	2	100%
Provider Organizations	2	0	0	2	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	0	1	100%
Supplier/Industry	0	0	0	0	
All Councils	**8**	**0**	**0**	**8**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Voting Comments: No voting comments were received on this measure.

Appendix C – Measure Evaluation Summary Tables

0066 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Submission

Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy

Numerator Statement: Patients who were prescribed ACE inhibitor or ARB therapy

Denominator Statement: All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR current or prior LVEF <40%

Exclusions: Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, allergy, intolerance, pregnancy, renal failure due to ACE inhibitor, diseases of the aortic or mitral valve, other medical reasons)

Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, lack of drug availability, other reasons attributable to the health care system)

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Behavioral Health/Psychiatric : Outpatient, Ambulatory Care : Urgent Care

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American Heart Association

STANDING COMMITTEE MEETING 07/12/2016

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

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

1a. Evidence: **H-17**; **M-0**; **L-1**; **I-0**; 1b. Performance Gap: **H-12**; **M-6**; **L-0**; **I-1**

Rationale:

- For the 2012 endorsement evaluation, the developer provided one clinical practice guideline with two recommendations from the 2007 chronic angina focused update of the ACC/AHA 2002 Guidelines for the Management of Patients with Chronic Stable Angina as evidence to support ACE inhibitor or ARB therapy for patients with coronary artery disease (CAD) and diabetes or reduced left ventricular systolic function (LVEF).
- For the current evaluation, the developer provided one additional guideline with two recommendations for renin-angiotensin-aldosterone blocker therapy from the 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS Guideline for the Diagnosis and Management of Patients with Stable Ischemic Heart Disease (SIHD) to support ACE inhibitor or ARB therapy for patients with SIHD and diabetes or reduced LVEF. The developer also provided a systematic review of the body of evidence supporting the benefits of ACE inhibitor/ARB therapy for patients with ischemic heart disease that included six randomized controlled trials (RCTs) and two meta-analyses. The Standing Committee agreed that the evidence is strong and the updates support the measure focus; however, one of the Committee members questioned why evidence on minority populations and diabetes was not presented.

0066 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

- The developer provided average performance rates from the Physician Quality Reporting System (PQRS) Experience report from 2011 – 2014. The average performance rate was 63.5% in 2011, 64.0% in 2012, 70.0% in 2013, and 81.2% in 2014. The developer also cited 2008-2012 ACE/ARB prescription rates from the National Cardiovascular Data Registry (NCDR) PINNACLE Registry that ranged from 69.6% to 77.6%.
- The developer did not provide data on disparities, which is encouraged for endorsement maintenance. The developer explained that although the measure is included in federal reporting programs, those programs have not yet made disparities data available to analyze and report. The developer provided evidence from the literature that demonstrated a slight difference between men and women (72.1% vs.71.7%) with LVSD or diabetes that were prescribed ACEI/ARBs (Chan et al. 2010). A separate analysis by Smolderen (2013) evaluated the impact of CAD patients' insurance status and ACEI/ARB prescription rates: privately-insured: 75.5%; publicly-insured: 69.1%; uninsured: 66.7%.
- The Standing Committee recognized the number of CAD patients with diabetes or heart failure who are receiving ACE/ARB therapy has improved since 2011 but approximately 20.0% of patients are not receiving the appropriate therapy. In addition, according to the data provided from the literature, disparities in care based on insurance status exist. The Standing Committee also stated their interest in receiving data on gender-based disparities.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-3**; **M-11**; **L-2**; **I-1;** 2b. Validity: **M-12**; **L-5**; **I-1**

<u>Rationale</u>:

- For the 2012 maintenance of endorsement evaluation, inter-rater reliability was conducted on 100 randomly selected paper medical charts from four physician practices submitted to the Physician Quality Reporting Initiative (PQRI) in 2007. The developer provided Kappa statistics for seven data elements; however, only one data element was relevant to this measure – Diagnosis of CAD. The Kappa statistic for 'Diagnosis of CAD' was 1.00.
- For the current evaluation, the developer provided updated reliability testing. The developer clarified that the data source used for testing was registry data rather than EHR data as indicated on the measure submission form. The developer used patient records from 2,296 providers participating in PQRS and reporting on this measure via the registry option from January 2014 through December 2014. There were 55,272 patients associated with 1,128 (49.1%) providers who had all the required data elements and 10 or more patients eligible for this measure. Reliability testing was conducted at the measure score level, using a beta-binomial model to assess the signal-to-noise ratio. A reliability score of 0.00 implies that all the variability in a measure is attributable to measurement error. A reliability score of 1.00 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one provider from another. This is an appropriate test for measure score reliability. A reliability score of 0.70 is generally considered a minimum threshold for reliability. Reliability at the minimum level of quality reporting events (10) was 0.58 and 0.87 at the average number of quality events (49.0).
- The Committee discussed the potential for misclassification of the measure's population due to one of the exclusions included in the list of the medical reasons for not prescribing ACEI or ARB therapy: diseases of the aortic or mitral valve. One of the Committee members explained that ACE inhibitors are beneficial in patients with mitral regurgitation and aortic insufficiency; therefore, the exclusion should be more specific than "diseases of the aortic or mitral valve". Overall, the Standing Committee agreed that the reliability scores were sufficient.
- For the 2012 maintenance of endorsement evaluation, the developer stated that all PCPI

0066 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

measures were assessed for content validity by expert work group members during the development process. Additional input on content validity was obtained through public comment and a panel of consumer, purchaser, and patient representatives convened by PCPI.

- For the current evaluation, the developer conducted face validity testing. A panel comprised of 18 experts from the American Hospital Association (AHA) Council on Clinical Cardiology systematically assessed whether the performance scores from the measure as specified could be used to distinguish good from poor quality. Of the 18 experts, 94.4% (17) of the respondents either agreed or strongly agreed that this measure can accurately distinguish good from poor quality.
- Overall, the Standing Committee agreed the face validity testing results were sufficient. However, in the pre-evaluation comments it was noted that the developer has not conducted empirical validity testing even though this measure has been in use for six years. The Committee encouraged the developer to conduct empirical validity testing of the measure. Another Committee member suggested that it would be beneficial to evaluate outcomes stratified by patients who did and did not receive appropriate ACEI/ARB therapy to determine if the measure has had the intended effect on the measure population.

3. Feasibility: H-11; M-6; L-0; I-1

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

Rationale:

- This measure is based on clinical registry data and the developer stated that all data elements are available in electronic sources. Some of the Standing Committee members noted that a defined field for LVEF may not be available in all EHRs. Ultimately, the Standing Committee concluded that implementation of the measure is feasible.

4. Usability and Use: H-11; M-4; L-0; I-1

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

Rationale:

- The measure is currently used in PQRS for provider incentive payments and the NCDR PINNACLE Registry for quality improvement with benchmarking.
- A member of the Standing Committee noted that in the Medicare program, an African-American patient with CAD and diabetes has a 90.0% hospitalization rate; due to the lack of disparities data this measure would not capture these patients.

5. Related and Competing Measures

- This measure is related to:
  - #0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy (ACC)
  - #0070: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF>40%) (AMA-PCPI)
  - #0074: Chronic Stable Coronary Artery Disease: Lipid Control (ACC)
  - #0081: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (AMA-PCPI)
  - #1522: ACE/ARB Therapy at Discharge for ICD implant patients with Left Ventricular Systolic Dysfunction (ACC)
  - #1662: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (RPA)

0066 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)
○ #2467: Adherence to ACEIs/ARBs for Individuals with Diabetes Mellitus (CMS) • The developer stated that this measure's specifications are harmonized with existing measures where possible but there are several key differences: ○ #1662, #1522, #0081, and #2467: focus on the prescription of ACEI/ARBS but have different target populations. ○ #0067, #0074, and #0070: focus on antiplatelet therapy, LDL control, and beta blocker therapy for CAD patients.
Standing Committee Recommendation for Endorsement: **Y-17**; **N-1**
6. Public and Member Comment • One commenter stated they supported this measure for endorsement because it is currently included in the Core Quality Measures Collaborative's Cardiovascular core measure set.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0076 Optimal Vascular Care

Submission

Description: The percentage of patients 18-75 years of age who had a diagnosis of ischemic vascular disease (IVD) and whose IVD was optimally managed during the measurement period as defined by achieving ALL of the following: Blood pressure less than 140/90 mmHg, On a statin medication, unless allowed contraindications or exceptions are present, Non-tobacco user, On daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.

Numerator Statement: The number of patients in the denominator whose IVD was optimally managed during the measurement period as defined by achieving ALL of the following: The most recent blood pressure in the measurement period has a systolic value of less than 140 mmHg AND a diastolic value of less than 90 mmHg, On a statin medication, unless allowed contraindications or exceptions are present, Patient is not a tobacco user, On daily aspirin or anti-platelet medication, unless allowed contraindications or exceptions are present.

Denominator Statement: Patients ages 18 to 75 with ischemic vascular disease who have at least two visits for this diagnosis in the last two years (established patient) with at least one visit in the last 12 months.

Exclusions: The following exclusions are allowed to be applied to the eligible population: permanent nursing home residents, receiving hospice or palliative care services, died or diagnosis coded in error.

Adjustment/Stratification: Statistical risk model. No risk stratification.

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Composite

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: MN Community Measurement

STANDING COMMITTEE MEETING 07/12/2016

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

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

1a. Evidence: **H-14**; **M-6**; **L-1**; **I-1**; 1b. Performance Gap: **H-14**; **M-7**; **L-1**; **I-0 ;** Composite: **H-12; M-8; L-1; I-1**

Rationale:

- For the 2012 maintenance of endorsement evaluation, the developer provided the following clinical practice guidelines to support the blood pressure, statin medication, tobacco free (outcome measure), and daily aspirin or anti-platelet medication components:
    - Blood pressure, statin medication, tobacco free, and daily aspirin or anti-platelet medication components: The ICSI Stable Coronary Artery Disease (April 2011), Address Modifiable Risk Factors guideline recommended modifiable risk factors for coronary artery disease such as smoking, inadequate physical activity, stress, hyperlipidemia, obesity, hypertension and diabetes mellitus be evaluated.
    - Blood pressure: The Comorbid Conditions Guideline and the ICSI Hypertension Diagnosis and Treatment Guideline (November 2010) recommended a target blood pressure of 140/90 mmHg or less.
    - Statin medication: The ICSI Lipid Management in Adults (October 2009) guideline recommended target goals for hyperlipidemic patients with coronary artery disease: LDL – less than 100 mg/dL; HDL – 40 mg/dL or greater; Triglycerides – less than 150 mg/dL.
    - Daily aspirin or anti-platelet medication: The ICSI Stable Coronary Artery Disease (April 2011), Address Modifiable Risk Factors guideline recommended the use of one aspirin tablet daily (81-162 mg) unless there are medical contraindications.
- For the current maintenance of endorsement evaluation, the developer provided the following

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updated evidence for all four components:

- Blood pressure: The 2015 AHA/ACC/ASH Scientific Statement on the Treatment of Hypertension in Patients with Coronary Artery Disease included 3 recommendations for blood pressure targets, including a blood pressure goal of <140/90 mm Hg for patients with coronary artery disease (CAD).
- Statin medication: The ICSI Lipid Management in Adults (updated Nov 2013/completed prior to ACC/AHA release) recommends that clinicians initiate statin therapy regardless of LDL in patients with established atherosclerotic cardiovascular disease (ASVCD). The 2013 ACC/AHA Guideline for the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults recommends high-intensity statin therapy be initiated or continued as first-line therapy in women and men <75 years of age who have clinical ASCVD, unless contraindicated. Moderate-intensity therapy should be used as the second option when high-intensity statins are contraindicated or adverse effects are present.
- Tobacco free outcome measure: The developer provided evidence from the United States Preventive Services Task Force (USPSTF) stating that despite considerable progress in tobacco control over the past 50 years, in 2013, an estimated 17.8% of U.S. adults and 15.9% of pregnant women aged 15 to 44 years were current cigarette smokers.
- Daily aspirin or anti-platelet medication: The developer provided three recommendations for antiplatelet agents/anticoagulants for patients with ischemic vascular disease from the AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients with Coronary and Other Atherosclerotic Vascular Disease: 2011 Update.

- The Standing Committee discussed the potential changes to blood pressure parameters based on the results of the Systolic Blood Pressure Intervention Trial (SPRINT), which compared the benefit of treatment of systolic blood pressure to a target of less than 120 mm Hg with treatment to a target of less than 140 mm Hg. The Committee also discussed the anticipated blood pressure guidelines to be released by AHA/ACC sometime in the future. NQF staff asked the Committee to consider the quantity, quality, and consistency of the body of evidence that was presented in the measure submission form. NQF staff reassured the Committee that the NQF process allows for a measure to be reviewed when new evidence becomes available. One of the Committee members noted that the USPSTF recommendations for daily aspirin include patients aged 50 to 70 years old, while the measure includes patients up to 75 years old. Other Committee members noted that the USPSTF recommendations are for primary prevention rather than patients with a diagnosis of ischemic vascular disease (IVD).
- Overall, the Standing Committee agreed that the updated evidence supports blood pressure control, statin use, daily aspirin or anti-platelet medication, and tobacco use assessment and intervention(s) in patients to avoid or postpone long-term complications associated with a diagnosis with IVD.
- The developer provided composite performance rates from clinics in Minnesota for Report Year 2007-2016 (Dates of Service 2006-2015).
  - In 2007, the rate was 38.9% for 4,662 patients and 33.8% in 2010 for 63,241 patients. In 2011, the blood pressure component target changed from <130/80 to <140/90 and the performance rate increase to 39.7% for 66,910 patients.
  - In 2015, the cholesterol management component was suppressed during redesign of the measure and the performance rate increased to 69.3% for 102,654 patients.
  - In 2016, the cholesterol management component was changed from LDL <100 to appropriate statin use and the performance rate was 66.1% for 104,395 patients.
- The developer also provided performance rates for the individual components.
  - The blood pressure component increased from 84.0% in 2012 to 85.0% in 2016.

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  - Daily aspirin use or anti-platelet medication use increased from 92.5% in 2009 to 96.7% in 2016.
  - The number of tobacco free patients increased from 82.4% in 2009 to 83.0 in 2016.
  - Statin use was 95.2% in 2016 (this was the first year the new component was reported).
- The developer provided 2014 disparities data from the measure as specified demonstrating a performance rate of 67.2% for White patients, 47.6% for Black/African-American patients, 51.8% for American Indian/Alaska Native patients, and 53.4% for multi-racial patients. The data also showed a higher performance gap for female patients and younger patients. The Committee asked the developer if there were trend data on disparities that demonstrated a change in performance over time and by individual clinic. The developer did not have additional, specific disparities data. However, according to the developer, some clinics that care for a greater proportion of minority patients have lower performance rates but there are a couple of clinics that are excelling in minimizing disparities.
- The Standing Committee agreed that the data provided demonstrated a performance gap and opportunity for improvement in optimal vascular care for patients with IVD.
- This is an all-or-none composite measure that requires patients to meet all four component targets in the composite measure to be considered 'optimally managed'; all four components are weighted equally. The developer noted that measuring providers on individual targets is not as patient-centric as this composite measure that seeks to reduce multiple risk factors in patients with IVD and maximize health outcomes. One of the members of the Standing Committee noted that the tobacco free component would be more appropriate as a process measure. The Committee member noted that smoking rates are often influenced by geographic location. Providers in areas with high rates of tobacco use will not appear as effective in increasing the number of tobacco free patients as those in areas where tobacco use is less prevalent. In the pre-evaluation comments, another Committee member noted that the absolute benefit of each component is not equal; achieving blood pressure control or smoking cessation is much more difficult than prescribing a statin or aspirin/anti-platelet medication.
- The Standing Committee agreed, that overall, the quality construct and rational for the composite was clearly stated and logical.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity; 2d. Composite Construct)

2a. Reliability: **H-6**; **M-16**; **L-0**; **I-0;** 2b. Validity: **H-3**; **M-17**; **L-1**; **I-1; 2d. Composite Construct: H-7; M-15; L-0; I-0**

<u>Rationale</u>:

- For the 2012 maintenance of endorsement evaluation, patient-level data element validity testing was conducted on 63,241 patients with IVD from 128 medical groups representing 573 clinics that submitted data to Minnesota Community Measurement for 2009 dates of service reported in 2010. After data submission, in-person validation audits requiring a 90% accuracy rate were conducted to compare the submission to the patient's medical record. Of the 128 medical groups that submitted data in 2010, 17 groups initially failed the audit and remedy plans were developed. All 17 groups resubmitted and passed subsequent audit.
- For the current maintenance of endorsement evaluation, the measure was tested at the measure score level using a dataset that included 104,395 patients with IVD in Minnesota and neighboring communities from 111 medical groups representing 671 clinics for dates of service from January 1, 2015 to December 31, 2015.
- To test the reliability of the measure score, the developer used a beta-binomial model to assess the signal-to-noise ratio. A reliability score of 0.00 implies that all the variability in a measure is attributable to measurement error. A reliability score of 1.00 implies that all the variability is

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attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one facility from another. This is an appropriate test for measure score reliability. A reliability score of 0.70 is generally considered a minimum threshold for reliability. The overall reliability for the composite measure was 0.90 and 0.61 at the minimum number of patients per reportable clinic (≥30). The distribution of reliability scores by number of eligible patients per reportable clinic (≥30) ranged from 0.61 for 30 patients per clinic to 0.99 for 4,441 patients per clinic.

- In the pre-evaluation comments, a member of the Standing Committee mentioned that assessing prescribing behavior of statin therapy (as noted in the specifications) is not consistent with the evidence provided to support the statin component. The Committee member noted that prescribing the lowest dose of the weakest statin would meet the intent of the measure but not generate clinically significant outcomes in the IVD population. Other Committee members questioned why 'permanent nursing home residents' are excluded from the denominator. The Committee discussed the fall risks associated with administering blood pressure medication to nursing home patients, excessive treatment in patients with advanced illness, and the lack of clinical trials for these types of medications in the nursing home population.
- The Standing Committee did not express additional concerns with the reliability of the measure, but ultimately decided the testing results were sufficient.
- For the 2012 maintenance of endorsement evaluation, content and face validity were assessed through the Measurement and Reporting Committee and a panel of experts. There was consensus among the expert workgroup that the target components reflected a quality of care that will reduce patients heart attack and stroke risk.
- For the current maintenance of endorsement evaluation, empirical validity testing of the composite measure score was conducted by testing the correlation of a medical group's performance with their performance on the Optimal Diabetes Care measure (#0729). It is expected that the quality of care provided by a medical group to a patient with ischemic vascular disease would be of similar quality as the care provided to a patient with diabetes, therefore the respective performance measure scores should be similar. This is an appropriate method for assessing conceptually and theoretically sound hypothesized relationships. The Optimal Diabetes Care measure (#0729) includes the same four components as #0074 plus a component for hemoglobin A1C; it also measures a different population. The linear regression analysis demonstrated an R^2 value of 0.635, which means that 64.0% of the total variation in performance on the Optimal Vascular Care measure can be explained by variation in performance on the Optimal Diabetes Care measure. The remaining 36.0% of total variation on the Optimal Vascular Care measure remains unexplained.
- This measure is risk-adjusted. The final risk factors selected for the risk model were age and insurance product (Medicare, Medicaid, MSHO, Special Needs, Self-pay, Uninsured). The developer analyzed gender and depression as well, but gender did not show sufficient variation between clinics and 'depression' was not selected due to the high cost of collection. The developer stated that race, ethnicity, language, and country of origin (RELO) were not considered for risk adjustment because these variables did not have a high completion rate across all clinics. The developer is continuing to work with the medical community to achieve the goal of evaluating RELO at the clinic level. The developer conducted an Analysis of Maximum Likelihood Estimates on the 2014 Dates of Service to compare the optimal rate of patients by insurance product (Commercial, MHCP, and Uninsured) to patients with Medicare and patient age (18-25; 26-50; 51-65) to patients aged 66-75. The Analysis of Maximum Likelihood Estimates demonstrated that all of the results for both variables, age and insurance product, were significant, except for ages less than 26 due to the small sample size (n = 44). The developer also found that the only two variables that were correlated were age >65 and Medicare.
- The Standing Committee did not express any concerns on the threats to validity and agreed that

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the testing results satisfied the validity criterion.

- The developer conducted a Pearson Correlation Analysis of the individual components rates and the composite rates. The Pearson correlation coefficient value, r, ranges from +1.00 to -1.00. A value of 0.00 indicates that there is no association between the two variables. A value greater than 0.00 indicates a positive association; that is, as the value of one variable increases, so does the value of the other variable. A value less than 0.00 indicates a negative association; that is, as the value of one variable increases, the value of the other variable decreases. The developer conducted the following Pearson Correlation Analysis for each component:

Variable	Mean	Pearson r coefficient
Blood pressure	0.85048	0.69813
Tobacco Free	0.80901	0.71336
Daily ASA Use	0.96271	0.59223
Statin Use	0.93973	0.62327
Optimal Vascular Care Rate = 0.63919		

- The developer concluded that practices in Minnesota demonstrate relatively high compliance for all of the components; however, there is still an opportunity for improvement at the clinic level. The blood pressure control and tobacco free components demonstrated the most variability, opportunity for improvement, and impact the ability to achieve all four components. Another Committee member suggested that if the two variables with the most variability were more heavily weighted than the other components, the measure would be more impactful. Another Committee member pointed out that three of the components were under the direct control of the provider, yet it was not clear how the tobacco free component captured the quality of care provided by the clinician. A member of the Standing Committee questioned whether there was evidence showing that meeting all four component targets would not generate the same patient outcomes as meeting two or three of the components. The developer pointed out that various combinations of the components and the proportion of patients meeting the different combinations were provided.
- The Standing Committee did not express additional concerns with the construct of the composite measure and agreed the information provided was sufficient to satisfy the criterion for composite construct.

3. Feasibility: H-12; M-10; L-0; I-0

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

Rationale:

- All of the data elements are in defined fields in electronic sources and there are no fees, licensure, or other requirements necessary to use this measure. The Standing Committee agreed this measure met the feasibility criterion.

4. Usability and Use: H-13; M-8; L-1; I-0

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

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Rationale:

- The measure is widely used in Minnesota for public reporting, payment, regulatory and accreditation programs, and quality improvement with external benchmarking to multiple organizations.

5. Related and Competing Measures

- This measure is related to:
  - #0067 : Chronic Stable Coronary Artery Disease: Antiplatelet Therapy (ACC)
  - #0068 : Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet (NCQA)
  - #0073 : Ischemic Vascular Disease (IVD): Blood Pressure Control (NCQA)
- The developer stated that #0068 and #0073 focus on the inpatient setting and patients discharged with AMI, CABG, or PCI. #0067 focuses on patients with CAD.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-3**

6. Public and Member Comment

- One commenter did not agree with statin use as a component to address dyslipidemia and believed it would be misleading to include this as a component of "optimal care." The commenter believed including this component would lead to the lowest level of acceptable care being considered optimal care and would do little to move the quality of care forward.
- Developer Response: Thank you for your comment and suggestion for the inclusion of the dose of statin (moderate or high) in the calculation of the cholesterol component of this patient level all-or-none composite measure. While ACC/ AHA guidelines do indicate that most patients with ischemic vascular disease would benefit from high dose intensity statins, there are provisions for moderate intensity statins for patients who cannot tolerate high intensity doses. The measure development work group thoroughly discussed the pros and cons of specifying a certain dose of the statin medication for numerator component compliance and determined that requiring the submission of the dose of statin would cause undue data collection burden for the practices. Additionally, the cardiologists on the workgroup strongly believe that there is some benefit for patients who can only tolerate a low dose of statin.
  We do not discount the role of ongoing LDL monitoring to determine effectiveness of statin therapy, but having a physiological target (e.g. LDL < 100) is no longer supported by evidence. The American College of Cardiology/ American Heart Associate guidelines for the treatment of blood cholesterol indicate the following:

  "Treat to target — this strategy has been the most widely used the past 15 years but there are 3 problems with this approach. First, current clinical trial data do not indicate what the target should be. Second, we do not know the magnitude of additional ASCVD risk reduction that would be achieved with one target lower than another. Third, it does not take into account potential adverse effects from multidrug therapy that might be needed to achieve a specific goal. Thus, in the absence of these data, this approach is less useful than it appears (Section 3). It is possible that future clinical trials may provide information warranting reconsideration of this strategy" (pg. 17)

  Yes, our component rates for prescribing statins are high in MN, which is a little bit unexpected for the newly re-designed component, however we would like to clarify the cholesterol component of statin use is not reported as a stand-alone measure. The Optimal Vascular Care measure is reported as an all-or-none composite, patients achieving multiple components of modifiable risk factors to reduce or delay long term complications. Statin use is one component, the other three are blood pressure control, tobacco-free and daily aspirin or antiplatelet medication.
- Committee Response: Thank you for your comment. The Committee agrees that monitoring

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LDL levels remains an important part of providing care for patients with IVD. However, the statin component in this measure aligns with the 2013 ACC/AHA Guideline for the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

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

Submission

Description: This measure calculates the median time from emergency department (ED) arrival to time of transfer to another facility for acute coronary intervention (ACI) for ST-segment myocardial infarction (STEMI) patients that require a percutaneous coronary intervention (PCI). The measure is calculated using chart-abstracted data, on a rolling quarterly basis, and is publically reported, in aggregate, for one calendar year. The measure has been publically reported, annually by CMS as a component of its Hospital Outpatient Quality Reporting (HOQR) Program since 2008.

Numerator Statement: This measure is reported as a continuous variable statement: time (in minutes) from ED arrival to transfer to another facility for ACI.

The numerator includes patients with AMI and ST-segment elevation on the ECG performed closest to ED arrival who are transferred from the ED to a short-term general hospital for inpatient care, or to a Federal healthcare facility specifically for ACI.

Denominator Statement: Time (in minutes) from ED arrival to transfer to another facility for ACI.

Exclusions: Patients are excluded from this measure if they are under 18 years of age, did not have an initial ECG interpretation, received fibrinolytic therapy while in the ED, or were transferred for reasons other than ACI.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 07/12/2016

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-12**; **M-9**; **L-0**; **I-0**

Rationale:

- For the 2012 maintenance of endorsement evaluation, the developer provided one clinical practice guideline from the 2004 ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction stating the delay from patient contact with the healthcare system to balloon inflation, if percutaneous coronary intervention (PCI) is chosen, should be less than 90 minutes.
- For the current maintenance of endorsement evaluation, the developer provided an update to the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction with two recommendations for the transfer of patients who require primary PCI (pPCI), from a non-PCI-capable hospital to a PCI-capable hospital, in cases where pPCI can be performed within 120 minutes of first medical contact. The developer also provided a systematic review of the body of the evidence supporting the timely transfer of ST-elevation myocardial infarction (STEMI) patients requiring a PCI. Lastly, the developer identified five new studies that were published since the systematic review of the body of evidence (2002-2012) that support the measure's focus. The Standing Committee agreed that the updated guideline supports the measure focus and accepted the prior evaluation of this criterion without further discussion.
- The developer provided facility-level performance rates from Hospital Compare from the April 2010 – March 2015 data collection period:

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	2010-11	2011-12	2012-13	2013-14	2014-15
Facilities	421	400	405	409	425
# of patients	8,008	7,621	7,822	7,678	8,166
Minimum time (in minutes)	26	20	14	21	20
Median time (in minutes)	56	54	54	54	54
Maximum time (in minutes)	245	542	307	288	474

- The developer analyzed the relationship of patient and facility characteristics on time to transfer from the emergency department (ED) to another facility for acute coronary intervention (ACI) using 2014 data submitted to the Clinical Data Warehouse (CDW). The results indicated that age, race, sex, and facility characteristics were variables related to timely transfer for ACI.
- The Standing Committee noted that the data presented demonstrate the ongoing quality problem and variation with STEMI patients that arrive at the ED and require transfer to another facility for acute coronary intervention. As a result, the Committee agreed an opportunity for improvement and a gap in care remains.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-2**; **M-18**; **L-0**; **I-0;** 2b. Validity: **H-2**; **M-18**; **L-2**; **I-0**

<u>Rationale</u>:

- For the 2012 maintenance of endorsement evaluation, reliability and validity testing were not provided because the measure was undergoing validation through the CMS Clinical Abstraction Center.
- For the current evaluation, the measure was tested at the measure score level using a dataset that included 1,902 facilities that submitted 64,827 cases to Hospital Compare from April 1, 2014-December 31, 2014. Of those, a total of 13,195 cases remained in the denominator after the exclusions were applied. Facilities with fewer than 11 cases were omitted in accordance with Hospital Compare's minimum case count criteria.
- To test the reliability of the measure score, the developer used a beta-binomial model to assess the signal-to-noise ratio. A reliability score of 0.00 implies that all the variability in a measure is attributable to measurement error. A reliability score of 1.00 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one facility from another. This is an appropriate test for measure score reliability. A reliability score of 0.70 is generally considered a minimum threshold for reliability. The developer stated that the reliability score was 0.78, although it is not clear if this was the reliability score for the facilities meeting the minimum case count (11) or overall reliability.
- The Standing Committee did not express any concerns with the reliability of the measure and agreed that testing results were sufficient.
- For the current evaluation, the dataset used for patient-level data element testing included a sample of 462 cases submitted to the Clinical Data Warehouse (CDW) from 65 facilities from April 1, 2014-March 31, 2015. After exclusions, 86 cases remained in the denominator sample. Data element validity was conducted by assessing the level of agreement between facility abstraction and auditor (CMS Clinical Data Abstraction Center or CDAC) abstraction (gold standard) and calculating a Kappa statistic for categorical data elements or Pearson correlation coefficient for continuous data elements. Kappa/Pearson's correlation values range between 0.00 and 1.00 and are interpreted as degree of agreement beyond chance. By convention, a Kappa/Pearson's correlation > 0.70 is considered acceptable. P-values estimate the statistical significance associated with the test statistics. P-values of less than 0.001 suggest high levels of statistical significance and that the degree of agreement was not due to chance. The kappa score and

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Pearson's correlation coefficient for 5 data elements (E/M Code, Discharge Code, ICD-9 Principal DX Code, Dx Date, Dx Time) was 1.00 (<0.001). The Pearson's correlation for "Arrival Time" was 0.99 (<0.001). The Kappa score for "Fibrinolytic Administration" was 0.93 (<0.001). The Standing Committee noted there were three data elements with scores < 0.70. The Kappa scores for "Initial ECG Interpretation" was 0.63 (<0.001), 0.47 (<0.001) for "Transfer for Acute Coronary Intervention", and 0.39 (<0.001) for "Reason for Not Administering Fibrinolytic Therapy". • The Standing Committee highlighted the threats to validity due to the large number of exclusions for the data element "Initial ECG Interpretation". For this data element, 38,573 cases out of 64,827 (59.5%) from 1,902 facilities were excluded in 2014. This was due to no ST-elevation on the interpretation of the 12-lead ECG performed closest to ED arrival, no interpretation or report available, or unable to determine (UTD) from documentation. The Committee agreed the overall frequency of the other exclusions and exceptions was reasonable and concluded that the measure met the validity criterion.
3. Feasibility: H-1; M-18; L-3; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The developer noted that challenges in interpreting and operationalizing the current measure's algorithm make it difficult to re-specify this measure for an EHR reporting program since some data elements currently rely on logic and inferences that abstractors have been trained to interpret. • The developer stated that the majority of a five-member expert panel agreed that practical aspects of reporting this chart-abstracted measure do not place undue burden on facilities that collect the data, although the costs of data collection and reporting this measure were not provided. • Some data elements are in defined fields in electronic sources and there are no fees, licensure, or other requirements necessary to use this measure. The Standing Committee agreed this measure met the feasibility criterion.
4. Usability and Use: H-2; M-15; L-4; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is in use in the CMS Hospital Outpatient Quality Reporting program (HOQR) and publicly reported on the Hospital Compare website. • Overall, the Standing Committee agreed the measure met this criterion since it is currently publicly reported and used in an accountability program. However, the Committee requested data on the impact of the measure to demonstrate that this process has improved patient care.
5. Related and Competing Measures • This measure is related to: o #0288: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (CMS) • The developer stated that #0288 focuses on the timely administration of fibrinolytic therapy. Additionally, the electronically specified version of #0163 (Primary PCI Received Within 90 Minutes of Hospital Arrival), which is no longer NQF-endorsed, is included in the Hospital Inpatient Quality Reporting (HIQR) Program and focuses on the timely initiation of PCI for a patient who arrives at a PCI-capable hospital.
Standing Committee Recommendation for Endorsement: **Y-19**; **N-2**

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6. Public and Member Comment • No comments received.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2906 Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

Submission

Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI or a current or prior LVEF <40% who were prescribed beta-blocker therapy

Numerator Statement: Patients who were prescribed beta-blocker therapy

Denominator Statement: All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI (within the past 3 years) or a current or prior LVEF <40%

Exclusions: Documentation of medical reason(s) for not prescribing beta-blocker therapy (eg, allergy, intolerance, other medical reasons)

Documentation of patient reason(s) for not prescribing beta-blocker therapy (eg, patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing beta-blocker therapy (eg, other reasons attributable to the health care system)

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: PCPI Foundation

STANDING COMMITTEE MEETING 07/12/2016

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

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

1a. Evidence: **Measure #0070 Evidence Criteria Evaluation Accepted (2015 votes: H-16; M-0; L-0; IE-0);**

1b. Performance Gap: **Measure #0070 Performance Gap Criteria Evaluation Accepted (2015 votes: H-4; M-12; L-0; I-0)**

Rationale:

- This "legacy" eMeasure is the eCQM version of the claims-based/registry measure #0070, currently used in federal programs. The Standing Committee reviewed #2906 and #0070 in 2015,[1] and because the information provided for evidence and opportunity for improvement is identical for both measures, the Standing Committee agreed to assign the *Importance to Measure and Report* ratings for #0070 to #2906.
    - For the 2015 review of this eMeasure and the endorsement evaluation of #0070, the developer provided one clinical practice guideline with two recommendations and a systematic review of the body of evidence associated with the guideline, to support beta-blocker therapy in patients with coronary artery disease (CAD), prior myocardial infarction (MI), or current or previous heart failure.
    - In 2015, during the previous review of this eMeasure and the claims-based/registry version of the measure, the Standing Committee agreed that the evidence provided demonstrates that beta-blocker therapy in patients with CAD leads to a reduced risk of death, reduced angina onset, improved ischemic threshold during exercise and reduced

[1] Measure #2906 was reviewed in 2015 and did not pass the validity criterion; the developer resubmitted the measure with additional testing for review in 2016.

2906 Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

recurrent MIs in patients with prior MIs.

- For the 2015 review of this measure and the endorsement evaluation of #0070, the developer provided average performance rates from the claims-based/registry version of the measure (#0070) from the 2014 Physician Quality Reporting System (PQRS) Experience Report from 2010 to 2014. The average performance rate was 71.4% in 2010, 82.1% in 2011, 69.9% in 2012, 74.2% in 2013, and 79.3% in 2014. The developer provided additional rates of beta-blocker prescriptions among patients with CAD from 2008-2010 from the National Cardiovascular Data Registry (NCDR) PINNACLE Registry®, a national outpatient cardiology practice registry, which demonstrated a median prescription rate of 78.4% at the initial clinic visit and 79.4% within a year of the initial clinic visit. The developer did not provide disparities data from the claims-based, registry, or electronically-specified measure but cited literature showing uninsured patients were less likely to receive beta-blocker therapy after an MI compared to those with private health insurance (73.3% vs. 80.5%).
- In 2015, during the previous review of this eMeasure and the claims-based/registry version of the measure, the Committee agreed that there was an opportunity for improvement based on the data provided from the registry measure but expressed the importance of obtaining performance data to adequately evaluate this eMeasure against this criterion in the future.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-12**; **M-6**; **L-0**; **I-0;** 2b. Validity: **M-12**; **L-3**; **I-2**

<u>Rationale</u>:

- The developer used patient records from 2,762 providers participating in the Physician Quality Reporting System (PQRS) and reporting on this measure via the EHR option from January 2014 through December 2014. There were 25,605 patients associated with 473 providers who had all the required data elements, 10 or more patients eligible for this measure and remained after exceptions were removed. Reliability testing was conducted at the measure score level, using a beta-binomial model to assess the signal-to-noise ratio. A reliability score of 0 implies that all the variability in a measure is attributable to measurement error. A reliability score of 1 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one provider from another. This is an appropriate test for measure score reliability. A reliability of 0.70 is generally considered a minimum threshold for reliability. Reliability was 0.69 when evaluated at the minimum number of eligible patients (10) and 0.92 at the average number of eligible patients (54.1).
- The Standing Committee agreed that the data elements are clearly defined and the reliability scores demonstrate that differences in provider performance can be identified.
- Face validity of the measure score was systematically assessed using an expert panel of 12 members from the AMA-PCPI Measure Advisory Committee. Nearly 92.0% of the respondents (12) either agreed or strongly agreed that this measure can accurately distinguish good from poor quality.
- Patient-level data element validity testing was conducted by comparing the values obtained from electronic extraction using 2004 data from an academic general internal medicine clinic using a commercial EHR (Epic) to values obtained by manual abstraction from the EHR by a trained investigator (Validity against the Gold Standard); this is an appropriate test for data element testing. A sample of 134 patient charts was selected using random sampling via automated EHR review. Of the 134 patients, the automated EHR review detected 111 patients (82.8%) that met

2906 Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

the numerator criteria. An additional 10 patients were detected through comparison of automated and manual EHR review and the percent agreement increased to 90.3%. The developer noted that the discrepancies between the EHR automated review alone and the automated review plus manual review were due to two types of misclassification: failure to correctly identify performance of quality measures among true, eligible patients; and failure to correctly exclude patients. The developer provided percent agreement of one final overall computation for all patients. NQF guidance for eMeasures states that testing at the level of data elements requires that all critical data elements be tested. At a minimum the numerator, denominator, and exclusions/exceptions must be assessed and reported separately. In addition to percent agreement, statistical analyses such as sensitivity and specificity, positive predictive value, and negative predictive value are required.

- NQF currently accepts testing in a simulated dataset (e.g., use of the BONNIE tool) for "legacy" eMeasures used in federal programs. In addition to the patient-level data element testing of the numerator, the developer provided BONNIE testing results for 72 synthetic patient records that demonstrated a 100.0% passing rate and confirmed that all the test cases performed as expected with the following data elements:
  - Age
  - Encounter
  - Diagnosis: Coronary artery disease, No MI
  - Procedure: Cardiac Surgery
  - Population 1: Diagnostic Study, Result: Ejection fraction result <40%
  - Population 1: Diagnosis: LVSD
  - Population 1: Diagnosis: LVSD severity moderate or severe
  - Population 2: Diagnosis Resolved: MI
  - Medication, Order: Beta Blocker Therapy
  - Medication, Active: Beta Blocker Therapy
  - Exceptions
- Some Standing Committee members questioned how exceptions were documented and extracted in the EHR. The developer explained that the exceptions are most likely structured data fields in the majority of EHRs. However, if an EHR uses an organization-specific code or a vendor-specific code those codes can be mapped to the nationally recognized value sets in the measure specifications. One of the Standing Committee members questioned how patients with a MI that occurred over three years ago would be captured in the EHR and/or measure. The developer explained that they have included prior MIs that have occurred ≤ 3 years in the value set and measure logic so only those patients with a prior MI within the past three years will be included in the denominator. Overall, the Standing Committee agreed the measure met the validity criterion.

3. Feasibility: H-7; M-11; L-0; I-1

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

Rationale:

- Feasibility testing was conducted in 2011 as the first phase of the Physicians Advancing Health Information Technology to Improve Cardiovascular Care (Cardio-HIT) project. Five physician offices, using five different EHRs (NextGen, Allscripts, GE Centricity, Epic, and a hybrid EHR) were included in the feasibility assessment. The developer stated that all of the data elements were successfully identified and exported to a warehouse for measure calculation by all five sites. At the time of the feasibility assessment, individual mapping of the data elements was required because each practice had a unique set of data fields. However, since the conclusion of the

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testing project in 2011, value sets have been developed to capture data in a standardized manner. The measure logic also performed as expected in BONNIE, the synthetic testing environment. • The Standing Committee did not note any concerns regarding feasibility.
4. Usability and Use: H-7; M-10; L-1; I-1 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • The Standing Committee noted that this measure is used in Meaning Use Stage 2 (MU-2).
5. Related and Competing Measures • This measure is related to: ○ #0070: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF<40%) (AMA-PCPI) ○ #0071: Persistence of Beta-Blocker Treatment After a Heart Attack (NCQA) ○ #0083: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (AMA-PCPI) ○ #2908: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (AMA-PCPI) • The developer stated that # 0070 is the registry version of this eMeasure and is completely harmonized. #2906 is harmonized with #0071, #0083, and #2908 to the extent possible. As a result, the denominator specifications for the measures differ where needed based on the differing patient populations.
Standing Committee Recommendation for Endorsement: Y-18; N-1
6. Public and Member Comment • No comments received.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

Measures Not Recommended

0288 Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

Submission

Description: This measure calculates the percentage of Emergency Department (ED) acute myocardial infarction (AMI) patients with ST-segment elevation on the electrocardiogram (ECG) closest to arrival time receiving fibrinolytic therapy during the ED stay and having a time from ED arrival to fibrinolysis of 30 minutes or less. The measure is calculated using chart-abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one calendar year. The measure has been publicly reported, annually, by CMS as a component of its Hospital Outpatient Quality Reporting (HOQR) Program since 2012.

Numerator Statement: The number of ED AMI patients whose time from ED arrival to fibrinolysis is 30 minutes or less.

Denominator Statement: The number of ED AMI patients with ST-segment elevation on ECG who received fibrinolytic therapy.

Exclusions: Patients are excluded who are less than 18 years of age. Additionally, patients who are not administered fibrinolytic therapy within 30 minutes AND had a Reason for Delay in Fibrinolytic Therapy, as defined in the Data Dictionary, are also excluded.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 07/12/2016

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

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

1a. Evidence: **H-12**; **M-6**; **L-3**; **I-1**; 1b. Performance Gap: **H-18**; **M-3**; **L-1**; **I-0**

Rationale:

- For the 2012 maintenance of endorsement evaluation, the developer provided one clinical practice guideline from the 2004 ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction stating the medical system goal is to facilitate rapid recognition and treatment of patients with ST-elevation myocardial infarction (STEMI) such that door-to-needle (or medical contact–to-needle) time for initiation of fibrinolytic therapy can be achieved within 30 minutes.
- For the current evaluation, the developer provided an update to the 2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction with three recommendations for fibrinolytic therapy when there is an anticipated delay to performing primary PCI within 120 minutes of first medical contact (FMC). The developer also provided a systematic review of the body of the evidence supporting the management of patients with ST-elevation myocardial infarction, specifically with reperfusion therapy. Lastly, the developer identified three new studies that were published since the systematic review of the body of evidence (1986-2012) that support the measure's focus.
- A member of the Standing Committee noted in the pre-evaluation comments and again at the in-person meeting that a preponderance of evidence suggests that in an era where thrombolytic therapy (TT) was first-line therapy for STEMI, TT administered within 30 minutes was associated with modestly improved survival vs. TT administered within 30-60 minutes. However, this calculus might be substantially different for a patient presenting to an institution where

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percutaneous coronary intervention (PCI) (in-house or via transfer) is sometimes available. If PCI is preferred, then there is a legitimate concern that patients might be better served by a policy which does not promote immediate reflexive action. The Committee member concluded that dichotomizing the outcome as within or not within specified minutes has always been at odds with clinical evidence or statistical theory or practice.

- The Standing Committee agreed that rapid assessment of patients experiencing a STEMI, determining the best reperfusion strategy, and administering fibrinolytic therapy (if indicated/chosen) to STEMI patients as rapidly as possible reduces mortality and morbidity.
- The developer provided facility-level performance rates from Hospital Compare from the April 2010 – March 2015 data collection period:

	2010-11	2011-12	2012-13	2013-14	2014-15
Facilities	121	109	103	79	76
# of patients	1,257	1,691	1,552	1,260	1,221
Minimum	9.0	17.0	9.0	9.0	9.0
Median	65.0	70.0	69.0	73.0	73.0
Maximum	100.0	100.0	100.0	100.0	100.0

- In the pre-evaluation comments, one of the Standing Committee members agreed that the ultimate goal of STEMI process of care is to provide timely reperfusion--whether using PCI or fibrinolytic therapy. The Committee member noted that 94.0% of patients with STEMI in the U.S. are treated with primary PCI; this measure addresses the remaining 6.0% of patients. However, the Standing Committee member expressed concern with the small proportion of patients treated in a combination of hospitals where fibrinolytic therapy is the primary reperfusion strategy because PCI is not available and hospitals where PCI is available and fibrinolytic therapy is the secondary reperfusion strategy. This is a useful measure for the hospitals where fibrinolytic therapy is the primary reperfusion strategy. However, the measure does not accurately reflect performance of a hospital's STEMI system of care for hospitals that use fibrinolytic therapy as a secondary reperfusion strategy; this is particularly important since this measure is publicly reported.
- Other Standing Committee members agreed that it was difficult to determine which patients are included in the performance rates: patients who presented at facilities where PCI was not available and fibrinolytic therapy was the only treatment option; patients transferred to a PCI-capable facility; or patients who presented at facilities where PCI was available and fibrinolytic therapy was the secondary reperfusion strategy. The developer explained that #0290 captures the patients with STEMI that are transferred to another facility for a PCI. The developer further explained that due to the minimum case count of 10 (required for public reporting) and the sampling algorithm, the facilities reporting on this measure are those where fibrinolytic therapy is the primary reperfusion strategy. The Standing Committee stressed that the information provided by the developer did not clearly state that the facilities included in the performance rates were those where fibrinolytic therapy is the primary reperfusion strategy and minimum case count is not clearly defined in the measure information form (MIF).
- Another member of the Standing Committee noted in the pre-evaluation comments that the data for 2015 represent <1.0% of all STEMIs, <7.0% of patients receiving TT for STEMI, and <3.0% of facilities that treat STEMI patients. This could mean there is room for improvement for these 1,211 patients, but it might also suggest that the 30-minute goal is not appropriate. The use of 30 minutes as a dichotomous outcome is particularly problematic in determining whether there is a clinically-relevant difference. The Standing Committee member concluded that the magnitude of the problem cannot be determined from the available information.
- The developer analyzed the effect of patient and facility characteristics on the likelihood of patients receiving fibrinolytic therapy within 30 minutes of emergency department (ED) arrival.

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The analysis included 3,844 cases submitted to the Clinical Data Warehouse (CDW) in 2014 that included a principal diagnosis of acute myocardial infarction (AMI), ST-segment elevation on ECG performed closest to ED arrival, and received fibrinolytic therapy. The results indicated that age, race, sex, and facility size were variables related to the timely delivery of fibrinolytic therapy. The Standing Committee agreed that rapid diagnosis of STEMI is measurably worse for nonwhites, females, age <30, and patients treated in smaller hospitals.

- The Standing Committee noted that the data presented demonstrate that there continues to be a quality problem and variation with STEMI patients receiving timely fibrinolytic therapy upon arriving in the ED; therefore, the Committee agreed an opportunity for improvement and a gap in care remains.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability Criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-3; M-10; L-7; I-0 2b. Validity: M-12; L-8; I-0**

Rationale:

- For the 2012 maintenance of endorsement evaluation, reliability and validity testing were not provided because the measure was undergoing validation through the CMS Clinical Abstraction Center.
- For the current evaluation, the Standing Committee had multiple concerns with the measure specifications including:
  - The specifications do not state that the intended target is facilities that are not PCI-capable; the specifications should be explicit if this is the intent of the measure.
  - The measure only includes patients that received fibrinolytic therapy; it does not capture patients who needed fibrinolytic therapy but did not receive it.
  - It was not clear why presence of ST-elevation on ECG is part of the denominator. If fibrinolytic therapy is given for anything other than stroke symptoms, then it is because the provider interpreted the ECG as showing ST-elevation.
  - The large number cases (59.5%) excluded due no ST-elevation on the interpretation of the 12-lead ECG performed closest to ED arrival, no interpretation or report available, or unable to determine (UTD) from documentation.
    - ST-elevation is frequently not documented.
    - The potential for misclassifying exceptions and exclusions (e.g., do not record ECG interpretation if fibrinolytic therapy is administered late).
  - The measure should be re-specified for receiving fibrinolytic therapy for suspected STEMI, not ECG (note that the same logic does not apply to the #0290).
- For the current evaluation, the measure was tested for reliability at the measure score level using a dataset that included 76 facilities that submitted 1,221 cases (denominator after exclusions) to Hospital Compare from April 1, 2014-March 31, 2015. Of those, a total of 871 cases met the numerator.
- To test the reliability of the measure score, the developer used a beta-binomial model to assess the signal-to-noise ratio. A reliability score of 0.00 implies that all the variability in a measure is attributable to measurement error. A reliability score of 1.00 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one facility from another. This is an appropriate test for measure score reliability. A reliability score of 0.70 is generally considered a minimum threshold for reliability. The developer stated that the distribution of the performance score reliability for the facilities meeting the minimum case count requirements during the April 2014 – March 2015 data collection period ranged from 0.49 to 1.00 with a

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median reliability of 0.67, though a value for minimum case count was not provided.

- Several of the concerns about the reliability of the measure discussed by the Standing Committee included:
  - No statistical method used to account for facilities with smaller sample sizes, which incorrectly depicts large confident intervals around the estimate, and ultimately making it difficult to distinguish low and high performers from the national estimate.
- For the current evaluation, the dataset used for patient-level data element testing included a sample of 462 (denominator) cases submitted to the Clinical Data Warehouse (CDW) from 23 facilities from April 1, 2014-March 31, 2015. After exclusions, 28 cases remained in the denominator sample; 18 of those cases met all of the numerator requirements. Data element validity was conducted by assessing the level of agreement between facility abstraction and auditor (CMS Clinical Data Abstraction Center or CDAC) abstraction (gold standard) and calculating a kappa statistic for categorical data elements or Pearson correlation coefficient for continuous data elements. Kappa/Pearson's correlation values range between 0.00 and 1.00 and are interpreted as degree of agreement beyond chance. By convention, a Kappa/Pearson's correlation > 0.70 is considered acceptable. P-values estimate the statistical significance associated with the test statistics. P-values of less than 0.001 suggest high levels of statistical significance and that the degree of agreement was not due to chance. The Kappa/Pearson's correlation for 7 data elements (E/M Code, Discharge Code, ICD-9 Principal DX Code, Fibrinolytic Administration Date, Fibrinolytic Administration Time, Arrival Time, Reason for Delay in Fibrinolytic Therapy) was 1.00 (<0.001). The kappa score for "Fibrinolytic Administration" was 0.93 (<0.001) and 0.63(<0.001) for" Initial ECG Interpretation".
- The Standing Committee voiced several concerns with the validity of the measure including:
  - The small numbers of patients remaining in the population after a total of 94.1% of patients were removed after the denominator exclusions and numerator exceptions were applied.
  - The large number of overall exclusions due to the data element "Initial ECG Interpretation" (59.5%).
  - Do the facilities with the greatest number of excluded cases also have higher performance rates indicating potential data misclassification of the measure?
- The developer provided the following statement with the statistical results from the exclusions analysis, "*The sampled population included 64,826 cases where a patient (age 18 years or older) presented with an acute myocardial infarction **with** ST-segment elevation on the ECG closest to ED arrival*." The Standing Committee requested that the developer clarify if this statement should instead say "***with and without***" which would best describe the data from the exclusions/exceptions analysis.
- The Standing Committee requested that the developer clarify the numerator, denominator, exclusions, and exclusions analysis. Additionally, the Committee requested that the developer provide an analysis of the facilities with the highest number of exclusions and the highest performing facilities to determine if there is potential misclassification of the measure.
- For the post-comment call, the developer provided an algorithm to clarify the measure specifications including the initial population, numerator, denominator, and exclusions. The Standing Committee expressed the same concerns on the post-comment call as discussed during the in-person meeting. The majority of the Standing Committee agreed the measure met the reliability and validity criteria.

3. Feasibility: H-1; M-17; L-1; I-0

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

Rationale:

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• Although the data are available through medical records, the Committee recognized the data collection burden for manual chart abstraction that could result in various interpretations. • The Standing Committee agreed that electronic collection was a likely possibility in the future, greatly increasing the feasibility of the measure when available. • The Standing Committee agreed this measure meets the feasibility criterion.
4. Usability and Use: H-1; M-14; L-5; I-0 *(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)* Rationale: • This measure is currently publicly reported and in use in the CMS HOQR (Hospital Outpatient Quality Reporting Program) accountability program. • The Standing Committee asked the developer for threshold percentages to determine what percentage of hospitals this measure would apply to, but this information was not readily available during the Standing Committee discussion of this measure during the in-person meeting or the post-comment call. • The Standing Committee agreed this measure meets the Usability and Use criterion.
5. Related and Competing Measures • This measure is related to: ○ #0290: Median Time to Transfer to Another Facility for Acute Coronary Intervention (CMS) • The developer stated that #0290 focuses on the timely transfer of patients who require PCI. Additionally, the electronically specified version of #0163, which is no longer NQF-endorsed, is included in the Hospital Inpatient Quality Reporting (HIQR) Program and focuses on the timely initiation of PCI for a patient who arrives at a PCI-capable hospital.
Standing Committee Recommendation for Endorsement: **Y-9**; **N-11** Rationale • The Standing Committee agreed that the information provided for evidence, scientific acceptability, feasibility and usability and use met the NQF criteria. However, the Committee agreed that overall the measure was not suitable for endorsement.
6. Public and Member Comment • No comments received.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2939 Statin Therapy in Patients with Clinical Atherosclerotic Disease

Submission

Description: Percentage of patients 18-75 year of age with clinical atherosclerotic cardiovascular disease (ASCVD) who were offered moderate-to high-intensity statin.

Numerator Statement: Patients in the denominator who have been offered* high-intensity statin† OR have been offered* moderate-intensity statin†.

Definitions:

*A statin is "offered" if it is prescribed or if a patient reason exception for not being prescribed a statin is documented.

†Moderate-intensity and high-intensity statin doses are defined in Table 5 of the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adult http://content.onlinejacc.org/article.aspx?articleid=1879710)

Denominator Statement: All patients 18-75 years of age with clinical ASCVD* who were seen within a 12-month period. This measure is designed to apply to chronic care populations and does not apply to patients in acute care hospitals.

Definition:

*Clinical ASCVD includes acute coronary artery syndromes, a history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, TIA, and peripheral arterial disease presumed to be of atherosclerotic origin.

Exclusions: Exceptions: Documentation of medical reason(s) for not prescribing a statin (e.g., allergy, intolerance to statin[s], other medical reasons).

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING 07/12/2016

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

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

1a. Evidence: **H-19**; **M-2**; **L-0**; **I-0**; 1b. Performance Gap: **H-16**; **M-5**; **L-0**; **I-0**

Rationale:

- The developer provided a clinical practice guideline from the 2013 ACCF/AHA Guideline for the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults with three secondary prevention recommendations to support moderate- or high-intensity statins for individuals with clinical atherosclerotic cardiovascular disease (ASCVD). Clinical ASCVD includes acute coronary syndrome (ACS), a history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), and peripheral arterial disease presumed to be of atherosclerotic origin. The developer also included results of a systematic review of 10 secondary prevention randomized controlled trials (RCTs) and four meta-analyses supporting the recommendations on ASCVD risk reduction in the secondary prevention setting.
- The Committee agreed that the developer presented strong evidence supporting moderate- or high-intensity statin therapy in individuals with clinical ASCVD.
- Since this is a new measure, there are no performance scores on the measure as specified. However, the developer provided differences in provider performance from the 2013 and 2014 PINNACLE Registry that included 1,701 and 1,890 providers and 209,770 and 239,948 patients,

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respectively. The mean performance rate for 2013 was 16.3% and 20.9% for 2014. The 2013 performance rate for the lower quartile was 4.30% and 8.33% for 2014. The 2013 performance rate for the upper quartile was 25.0% and 29.0% for 2014. The developer also provided additional data from the literature that indicated that patients are not receiving optimal statin doses. Additionally, the developer provided evidence indicating potential disparities in care for ASCVD patients receiving statin therapy based on race (African-American), gender (male), and insurance status (uninsured).

- The Committee noted that more than two-thirds of the PINNACLE data could not be analyzed for various reasons (see discussion below on reliability and validity), therefore, the gap in care and disparities may be greater than the performance and disparities data provided by the developer.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability Criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-4**; **M-13**; **L-3**; **I-1;** Initial 2b. Validity: **M-11**; **L-6**; **I-3**

Re-vote on 2. Validity: **M-9; L-6; I-4**

<u>Rationale</u>:

- The final dataset the developer used to calculate the signal-to-noise ratio using a beta-binomial model included PINNACLE Registry data with 1,701 providers and 209,770 patients (121 practices) from 2013 and 1,890 providers and 239,948 patients (136 practices) from 2014. Using 2014 data, the developer described the validation process used to obtain the final datasets (this process was also applied to 2013 data):
  - 2,503,852 patients were treated by 206 practices in 2014. Of those, 68 practices (678,475 patients) were excluded because their EHR did not transmit the data on medication dose.
  - An additional 841,376 patients were excluded due to missing comorbidity data needed to determine the presence of ASCVD as indicated by the measure specifications.
  - Another 205,345 patients were excluded because the developer was unable to define the statin dose or there was a medical exclusion for statins.
  - Lastly, 16,188 patients and two additional practices were excluded because the providers treated <10 eligible patients.
- The reliability score for a minimum of 10 patients was 0.985 for 2013 and 0.986 for 2014. The average number of patients for 2013 was 124 with a reliability score of 0.995; for 2014 it was 127 patients with a reliability score of 0.995. A reliability score of 0.00 implies that all the variability in a measure is attributable to measurement error. A reliability of 1.00 implies that all the variability is attributable to real differences in performance. The higher the reliability score, the greater is the confidence with which one can distinguish the performance of one provider from another. This is an appropriate test for measure score reliability. A reliability score of 0.70 is generally considered a minimum threshold for reliability.
- The Committee agreed that the data elements are clearly defined and the reliability scores demonstrated sufficient reliability. However, some members questioned whether the measure can be consistently implemented inside and outside of the registry due to the large number of patients that were excluded in the final dataset due to several missing data elements needed to calculate the measure including statin medication and/or dosage and comorbidity data to determine the presence of ASCVD. Other Committee members questioned the representativeness of the sample data obtained from the PINNACLE Registry to generalize for widespread implementation. The developer responded that the PINNACLE data were a convenient sample that was available to test the measure specifications and determine the measure gap, but the data were not intended to be representative of national performance.

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- Face validity of the measure score was systematically assessed by members of two existing committees from the ACC and AHA who were not involved in the development of the measure; the developer did not identify the committee members.
- The developer noted that eight committee members completed the survey and 100% of the respondents either agreed or strongly agreed that this measure can accurately distinguish good from poor quality.
- The only exclusion for this measure is documentation of a medical reason(s) for not prescribing a statin (e.g., allergy, intolerance to statin[s], other medical reasons). No patients in either the 2013 or 2014 data had such a contraindication. Although, the developer stated, there were a few patients identified as having patient-centered reasons for not receiving statins, these were not considered exclusions from this performance measure. The Standing Committee questioned the validity of the data because there were no patients with documentation of a medical reason for not prescribing a statin in 2013 or 2014. The developer clarified that documentation of a patient reason for not prescribing a statin, such as patient refusal, would be considered meeting the measure. One of the Committee members noted that many EHRs currently do not have extractable data fields for 'patient refusal' of statin therapy.
- The Standing Committee expressed concern with the significant number of patients (approximately 27.0%) that were excluded because the EHR was not able to transmit the data on statin dose. The measure developer stated that in the future, practices would need to remap their EHRs to the registry to ensure the correct data are transmitted. The Standing Committee also questioned whether the performance gap reported by the measure developer was a true gap in care or due to the inability to capture the critical data elements required to calculate the measure. Another Committee member noted that some patients may be prescribed high-intensity statins but due to economic reasons take half a pill per day or one pill every other day; there is currently no way to distinguish the difference between how medications are *prescribed* and how they are *taken*, potentially impacting the validity of the measure.
- The Standing Committee did not reach consensus on the validity criterion during the in-person meeting and re-voted on the post-comment call. During the call, The Standing Committee reiterated their concerns that the data offered no documentation for medical contraindications for statin therapy, patients who could not tolerate the prescribed dosage, or patient refusal.
- Ultimately, the Standing Committee did not recommend the measure. In addition, the Committee encouraged the developer to improve their data collection efforts and the quality of data presented to the Committee in the future.

3. Feasibility: Initial H-1; M-10; L-6; I-3

Re-vote on 3. Feasibility: H-1; M-10, L-7; I-2 <u>The measure does not meet the Feasibility Criteria</u>

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

<u>Rationale</u>:

- This measure is based on clinical registry data and all data elements are available in electronic sources. The Standing Committee expressed concern with the feasibility as outlined in the validation process used to obtain the final dataset, and therefore, did not pass the feasibility criterion of the measure.
- The Committee noted implementation of the measure was not currently feasible in many EHRs or outside of the PINNACLE Registry and was more 'aspirational'.

4. Usability and Use: H-1; M-12; L-4; I-3

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

<u>Rationale</u>:

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• The Standing Committee noted that this measure is currently used for internal quality improvement in the PINNACLE Registry.

5. Related and Competing Measures
• This measure is related to:
  ○ #0074 : Chronic Stable Coronary Artery Disease: Lipid Control (ACC)
  ○ #0118 : Anti-Lipid Treatment Discharge (STS)
  ○ #0439 : STK-06: Discharged on Statin Medication (TJC)
  ○ #1519 : Statin Therapy at Discharge after Lower Extremity Bypass (LEB)
  ○ #0696: STS CABG Composite Score (STS)
  ○ #0964: Therapy with aspirin, P2Y12 inhibitor, and statin at discharge following PCI in eligible patients (ACC)
  ○ #2452: Percutaneous Coronary Intervention (PCI): Post-procedural Optimal Medical Therapy (ACC)
• The developer stated that this new measure, #2939, focuses on optimal treatment of statins. Most measures on statin therapy that are NQF-endorsed address subsets of the patients included in this broad measure and do not yet reflect the updated recommendations and/or are intended to be used in a different setting, level of analysis or different data source.

Standing Committee Recommendation for Endorsement: **Y-13**; **N-7**
6. Public and Member Comment • One commenter expressed their support for this measure and stated that it would advance the practice of medicine relative to existing statin measures by focusing on a broad population of patience and adherence to guidelines. The commenter also stated that due to the measure already being present in EHR systems, it will likely improve accessibility and interoperability of medication related data. • Another commenter indicated their support of this measure due to the potential to drive change and impact a broader patient population. The commenter also supported the measure as it is the only measure currently adhering to the multi-society cholesterol guideline recommendation.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

[1] 2015 National Healthcare Quality and Disparities Report and 5th Anniversary Update on the National Quality Strategy. Content last reviewed May 2016. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/research/findings/nhqrdr/nhqdr15/index.html.