NATIONAL QUALITY FORUM

Memo

TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: NQF-Endorsed Measures for Cardiovascular

DA: October 17, 2016

Background

In Phase 4 of this project, the 24-member Cardiovascular Standing Committee met during a 1-day in-person meeting to evaluate a total of six measures against NQF's standard evaluation criteria. The Committee evaluated two newly-submitted measures and four measures undergoing maintenance review against NQF's standard evaluation criteria. Four measures were recommended for endorsement, consensus was not reached on one measure, and one measure evaluation discussion was deferred until the post-comment call on October 7, 2016. During the post-comment call, the measure where consensus was not reached and the measure that was deferred were not recommended for endorsement.

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full committee and once a report of the proceedings has been drafted.

Pre-evaluation comments

The pre-evaluation comment period was open from May 23, 2016 to June 5, 2016 for all six measures under review. Three pre-evaluation comments were received, all of which did not support the new statin measure or the composite with the new statin component. All pre-evaluation comments were provided to the Committee prior to their deliberations during the in-person meeting.

Post-evaluation comments

The Draft Report went out for Public and Member comment August 18, 2016 to September 19, 2016. During this commenting period, NQF received 4 comments all from members of the public:

Consumers – 0	Professional – 0
Purchasers – 0	Health Plans – 0
Providers – 0	QMRI – 0
Supplier and Industry – 0	Public & Community Health - 4

NQF MEMBER votes are due October 31, 2016 by 6:00 PM ET

A complete table of comments submitted pre- and post-evaluation, along with the responses to each comment and the actions taken by the Standing Committee, is posted to the project page on the NQF website, along with the measure submission forms.

The Committee reviewed all comments received and considered the pre-meeting comments prior to making an endorsement recommendation. The Committee also responded to all post-evaluation comments. Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

Two major themes were identified in the post-evaluation comments, as follows:

1. Statin Component
2. Support for the Measure

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%)*

Committee Action: The Committee reviewed the comments during the post-comment before re-voting on the criteria where consensus was not reached on #2939 (see Consensus Not Reached Measures below).

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 recommended the two measures. The measures recommended for endorsement have been placed on the NQF Member voting ballot.

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

Consensus Not Reached Measures

2939: Statin Therapy in Patients with Clinical Atherosclerotic Disease

During the in-person meeting the Committee expressed several concerns with the validity of the measure. 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). The 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 Committee also questioned whether the performance gap (~16.0 – 20.0%) 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.

Ultimately, the Standing Committee did not reach consensus on the validity of 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.

> **Action Item:** The Committee re-voted on the Validity (M-9, L-6, I-4) and Feasibility (H-1, M-10, L-7, I-2) subcriteria. The measure did not pass Validity, a must-pass criterion, therefore is not recommended for endorsement.

Measures with Endorsement Decision Deferred

0288: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival

During the in-person meeting the Committee had multiple concerns with the measure specifications and asked the developer to clarify the numerator, denominator, exclusions and exclusions analysis. The Committee also 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. Some of the Committee's concerns included:

- 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?

NQF did not receive any public or member comments for this measure.

Additional Information provided by the Developer: Based on the discussion that took place at the NQF Standing Committee in-person meeting, the developer provided an algorithm to demonstrate how the measure is calculated. See Appendix A.

Committee Action: The Committee voted on 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) and Overall Recommendation: Yes-9, No-11. The measure did not pass overall recommendation, therefore is not recommended for endorsement.

NQF Member Voting

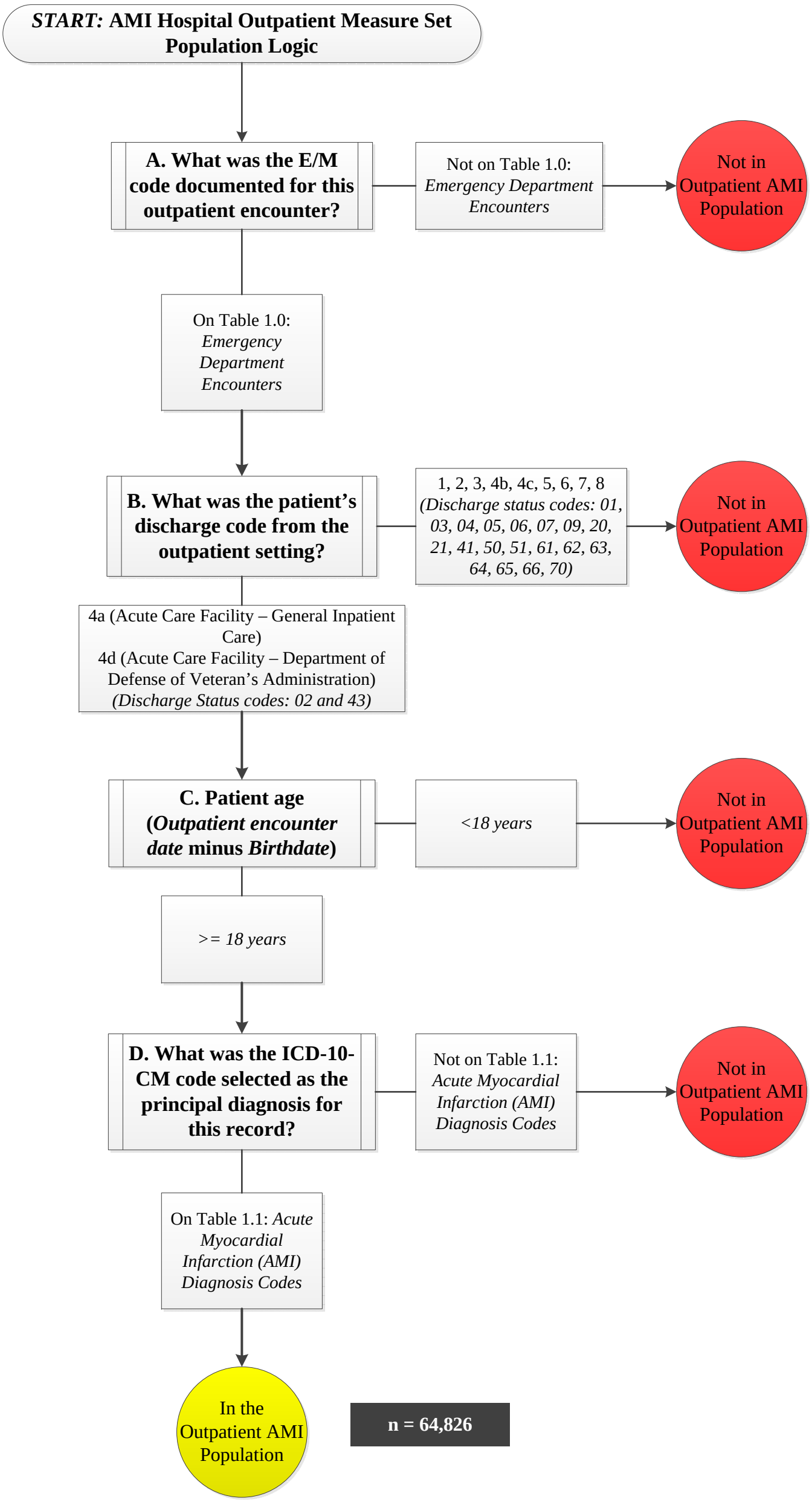
Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on October 31, 2016 at 6:00 pm ET – no exceptions.

Appendix A: Measure #0288 Algorithm

Based on the discussion that took place at the NQF Standing Committee in-person meeting, the developer provided an algorithm to demonstrate how the measure is calculated. This algorithm begins on the following page.

ACUTE MYOCARDIAL INFARCTION (AMI) HOSPITAL OUTPATIENT
POPULATION ALGORITHM



#0288: Fibrinolytic Therapy Received within 30 Minutes of ED Arrival

Measure Algorithm

START: Run cases included in AMI hospital outpatient population (64,826 cases)

1. Is there documentation of ST-segment elevation on the electrocardiogram (ECG) performed closest to emergency department arrival?

- *Missing value* → Case will be Rejected
- ***Yes**: ST-segment elevation on the interpretation of the 12-lead ECG performed closest to emergency department arrival* → Y = 26,253 (40.5%)
- ***No**: No ST-elevation on the interpretation of the 12-lead ECG performed closest to emergency department arrival, no interpretation or report available for the ECG performed closest to emergency department arrival, or unable to determine from medical record documentation* → Not in Measure Population — N = 38,573 (59.5%)

2. Did the patient receive fibrinolytic therapy at this emergency department?

- *Missing value* → Case will be Rejected
- ***Yes:** Fibrinolytic therapy was initiated at this emergency department* → Y = 4,599 (7.1%)
- ***No:** There is no documentation fibrinolytic therapy was initiated at this emergency department, or unable to determine from medical record documentation* → Not in Measure Population — N = 21,654 (33.4%)

3. What was the *date* primary fibrinolytic therapy was initiated during this hospital stay?

- *Missing value* → Case will be Rejected
- The documented non-UTD date that fibrinolytic therapy was initiated is: *DD-YYYY* *Fibrinolytic administration date* → Y = 4,596 (7.1%)
- *Unable to determine* → In Denominator — X_1 = 3 (0%)

4. What was the *time* primary fibrinolytic therapy was initiated during this hospital stay?

- *Missing value* → Case will be Rejected
- The documented non-UTD time that fibrinolytic therapy was initiated is: *HH-MM* *Fibrinolytic administration time* → Y = 4,578 (7.1%)
- *Unable to determine* → In Denominator — X_2 = 18 (0%)

5. What was the *earliest* documented time the patient arrived at the outpatient or emergency department?

- *Missing value* → Case will be Rejected
- *HH-MM* (non-UTD) *Arrival time* → Y = 4,577 (7.1%)
- *Unable to determine* → In Denominator — X_3 = 1 (0%)

Time to fibrinolysis:
Fibrinolytic administration date and *fibrinolytic administration time*
minus
Outpatient encounter date and *arrival time* (in minutes)

- *< 0 minutes* OR *> 360 minutes* → Not in Measure Population — N = 37 (0.1%)
- *> 30 minutes* AND *<= 360 minutes* → Y = 2,249 (3.4%)
- *>= 0 minutes* AND *<= 30 minutes* → In Denominator and Numerator — X_4 = 2,291 (3.5%)

6. Is there a clinical *or* patient-centered reason documented by a physician/APN/PA for a delay in initiating fibrinolytic therapy after hospital arrival?

- *Missing value* → Case will be Rejected
- ***Yes:** Reason documented by a physician/APN/PA for a delay in initiating fibrinolytic therapy after hospital arrival* → Not in Measure Population — N = 718 (1.1%)
- ***No:** No reason documented by a physician/APN/PA for a delay in initiating fibrinolytic therapy after hospital arrival, or unable to determine from medical record documentation* → In Denominator — X_5 = 1,531 (2.4%)

Denominator = $X_1 + X_2 + X_3 + X_4 + X_5$ = 3,844 (5.9%)
Numerator = X_4 = 2,291 (3.5%)

Key

Grey = Rejected case results if abstractor does not populate data element with an allowable value; abstractor **must** select an allowable value before proceeding

Red = Not included in the measure population (denominator)

Yellow = Included in measure denominator (all but the last node are numerator exceptions; last node is final denominator)

Green = Included in measure numerator

N = Number of cases removed from the measure at a particular node

Y = Number of cases with an acceptable value that advance to the next node of the algorithm

X = Number of cases that comprise the measure denominator

(%) = Percentage of AMI population (number of cases / total AMI population of 64,826)

Numerator = Total number of cases that pass the measure criteria

Denominator = Total "effective sample" after denominator exclusions have been applied

Data Source = Clinical Data Warehouse (CDW)

Data Dates
Denominator: April 1, 2014–March 31, 2015

Numerator: April 1, 2014–March 31, 2015

Exclusions: April 1, 2014–March 31, 2015

Exceptions: April 1, 2014–March 31, 2015

Data Elements: **Acute Myocardial Infarction Hospital Outpatient Population**

A. E/M Code
B. Discharge Code
C. Patient Age
D. ICD-10-CM Principal Diagnosis Code

Data Elements: **NQF #0288 Measure**

1. Initial ECG Interpretation
2. Fibrinolytic Therapy
3. Fibrinolytic Therapy Date
4. Fibrinolytic Therapy Time
5. Arrival Time
6. Reason For Delay in Fibrinolytic Therapy