NATIONAL QUALITY FORUM

Memo

TO: Cardiovascular Standing Committee

FR: NQF Staff

RE: Post-Comment Call to Discuss Public and Member Comments

DA: October 7, 2016

Purpose of the Call

The Cardiovascular Standing Committee will meet via conference call on Friday, October 7, 2016 from 2:00-4:00pm ET. The purpose of this call is to:

- Review and discuss comments received during the post-evaluation public and member comment period.
- Provide input on proposed responses to the post-evaluation comments.
- Re-vote on criteria where consensus was not reached.
- Determine whether reconsideration of any measures or other courses of action is warranted.

Due to time constraints, during this call we will review comments by exception, in the case the Committee disagrees with the proposed responses.

Standing Committee Actions

1. Review this briefing memo and Draft Report.
2. Review and consider the full text of all comments received and the proposed responses to the post-evaluation comments (see Comment Table included with the call materials).
3. Be prepared to provide feedback and input on proposed post-evaluation comment responses.
4. Be prepared to re-vote on the Validity and Feasibility sub-criteria for the selected measure (indicated below).
5. Be prepared to resume voting on Reliability, Validity, Feasibility, Use and Usability, and Overall Suitability for the selected measure (indicated below).

Conference Call Information

Please use the following information to access the conference call line and webinar:

Speaker dial-in #: 1-(877) 563-3590
Web Link: http://nqf.commpartners.com/se/Rd/Mt.aspx?419057
Registration Link: http://nqf.commpartners.com/se/Rd/Mt.aspx?419057

Background

In Phase 4 of this project, the 24-member Cardiovascular Standing Committee met during a 1-dayin-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.

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

In order to facilitate discussion, the majority of the post-evaluation comments have been categorized into major topic areas or themes. Where possible, NQF staff has proposed draft responses for the Committee to consider. Although all comments and proposed responses are subject to discussion, we will not necessarily discuss each comment and response on the post-comment call. Instead, we will spend the majority of the time considering the major topics and/or those measures with the most significant issues that arose from the comments. Note that the organization of the comments into major topic areas is not an attempt to limit Committee discussion.

We have included all of the comments that we received (both pre- and post-evaluation) in the Comment Table. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses for the Committee's consideration. Please refer to this comment table to view and consider the individual comments received and the proposed responses to each.

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.

Proposed 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.

Action Item: Does the Committee agree with the proposed response?

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%))*

Action Item: See Consensus Not Reached below for #2939.

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 must re-vote on the validity and feasibility criteria. Validity is a must-pass criterion. Measure #2939 must receive > 60% of votes (includes high and moderate) for the validity subcriterion for the measure to be recommended for endorsement by the Committee. A measure that does not receive >60% of votes will not move forward to NQF member vote or the Consensus Standard Approval Committee (CSAC).

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.

Action Item: This measure has passed the evidence criterion (Evidence 12-H; 6-M; 3 -L; 1-I; Opportunity for Improvement 18-H; 3 -M; 1-L; 0-I). The Committee will vote on the reliability, validity, feasibility, usability and use, and overall suitability for endorsement. Reliability and alidity are must-pass criteria. Measure #0288 must receive > 60% of votes (includes high and moderate) for the reliability and validity subcriteria for the measure to be recommended for endorsement by the Committee. A measure that does not receive >60% of votes will not move forward to NQF member vote or the Consensus Standard Approval Committee (CSAC).

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.