NATIONAL QUALITY FORUM

Memo

TO: Endocrine Standing Committee

FR: NQF Staff

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

DA: September 15, 2014

Purpose of the Call

The Endocrine Standing Committee will meet via conference call on Tuesday, September 16, 2014, from 10am -noon 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 responses to the post-evaluation comments.
- Determine whether reconsideration of any measures or other courses of action is warranted.

Standing Committee Actions

1. Review this briefing memo.
2. Review and consider the full text of all comments received and the proposed Committee responses to the post-evaluation comments (see Excel and PDF files included with the call materials).
3. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Conference Call Information

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

Speaker dial-in #: 1 (877) 564-4723 (*NO CONFERENCE CODE REQUIRED)*
Web Link: http://nqf.commpartners.com/se/Rd/Mt.aspx?907403

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 soliciting 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 June 16-30, 2014. No pre-evaluation comments were received for the measures under review in this cycle of the project.

Post-evaluation comments

The 30-day post-evaluation comment was open from August 8-September 8, 2014. During this commenting period, NQF received 13 comments from two member organizations:

Consumers – 0	Professional – 0
Purchasers –0	Health Plans – 2
Providers – 0	QMRI – 0
Supplier and Industry – 0	Public & Community Health - 0

In order to facilitate discussion, 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 in the Excel spreadsheet that is included with the call materials. This comment table contains the commenter's name, as well as the comment, associated measure, topic/theme (if applicable), and 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.***

Committee Discussion of Comments

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

1. Osteoporosis: Upper age limit
2. Osteoporosis: Harmonization
3. Osteoporosis: Other
4. Competing foot care measures
5. Foot care measures: Other

Theme 1 - Osteoporosis: Upper age limit

NQF received two comments on measures #0037 (Osteoporosis Testing in Older Women) and #0046 (Screening for Osteoporosis for Women 65-85 Years of Age). These comments noted support for the measures but expressed concern that the upper age limit for the measures would result in under-diagnosis for those older than 85 years of age, given the frequency of occurrence of osteoporosis in this age group. In the Committee's earlier deliberations, there was some discussion of the lower age thresholds for the measures but not on the upper threshold. The developer's response is provided below:

Developer Response:

Thank you for your comment. We continue to recommend limiting this measure to assess osteoporosis screening in women under age 85. Continued screening beyond the age of 85 may be appropriate for some individuals and including the upper age cap does not penalize health plans who do this; however, women over the age of 85 may have limited life expectancy and may not live long enough to realize the benefits of osteoporosis treatment if they are screened positive. The USPSTF recommends providers take into account the patient's

remaining life expectancy compared to the benefits of treatment when deciding whether to screen. There is a concern that without an upper age cap this measure may incentivize plans and providers to pursue too aggressive management in women with limited life expectancy and competing comorbidity. We encourage providers and patients to engage in shared-decision making to determine the best course of action for the patient.

Committee Action Item:

- After review and discussion of the comments on this measure, does the Committee wish to make a recommendation concerning the upper age limit for these measures?

Theme 2 - Osteoporosis: Harmonization

NQF received two comments regarding harmonization of measures #0037 (Osteoporosis Testing in Older Women) and #0046 (Screening for Osteoporosis for Women 65-85 Years of Age). Specifically, the commenters questioned the need for the use of the Health Outcomes Survey in measure #0046.

Committee Action Item:

- Review the proposed Committee responses (below) and provide any additional feedback to incorporate into the responses.

Proposed Committee Response #1:

The issue of different data sources for these two measures was addressed during the Committee's discussion about harmonizing these two measures. In that discussion, the developer explained their reasoning behind using the Health Outcomes Survey for measure #0046 (i.e., that health plans may not have access to claims or medical records needed to compute the measure), and acknowledged that the results from the two sources may be different. The Committee accepted this rationale and did not make any harmonization recommendations nor recommend re-specifying this measure.

Proposed Committee Response #2:

The two measures assess performance for different entities: measure #0037 is specified for measurement at the health plan level; in contrast, measure #0046 is specified for measurement at the individual clinician or group level.

Theme 3 - Osteoporosis: Other

NQF received two comments on measures #0045 (Communication with the physician or other clinician managing on-going care post fracture for men and women aged 50 years and older) and #0053 (Osteoporosis Management in Women Who Had a Fracture). Regarding measure #0045, the commenter noted the importance of communication, expressed concern that the measure is a "low-bar" measure, and suggested that a measure to assess testing and treatment would be more valuable. Regarding measure #0053, the commenter expressed support for the measure but also encouraged development of a drug- or treatment-adherence measure for people with osteoporosis who have had a fracture.

Committee Action Item:

- Review the proposed Committee responses (below) and provide any additional feedback to incorporate into the responses.

Proposed Committee Response #1 (for measure #0045):

Thank you for your comment. The Committee agreed that this measure meets NQF's current criteria for endorsement. During the measure harmonization discussion, Committee members noted the need for testing/treatment post-fracture for both men and women and questioned why men are not included in the testing/treatment measure (#0053), which is specified at the both the health plan and individual/group clinician levels. Although the developer explained their rationale for developing a separate testing/treatment measure for men (which is still under development), some Committee members pointed to a TJC measure is specified to distinguish guideline/treatment differences between men and women without having to split into two measures.

Proposed Committee Response #2 (for measure #0053):

Thank you for your comment. The Committee agrees with these suggestions for future measure development and the report was updated to include this suggestion.

Theme 4 - Competing foot care measures

During the second web meeting of the Committee for Cycle 2 of the Endocrine project, the Committee evaluated measure #0417 (Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation) against NQF's standard evaluation criteria and voted to recommend the measure for endorsement.

However, because this measure is a competing measure to #0056 (Diabetes: Foot Exam), the Committee was asked to identify which of the two measures they considered the superior measure or to provide a rationale for the recommendation of both measures for endorsement. Results from a preliminary vote by the Committee indicated that a majority of members agreed that measure #0056 is superior and that measure #0417 should not be put forward for continued endorsement. However, a sizeable minority indicated that neither measure is superior and recommended endorsement of both measures. This vote was considered preliminary because we did not reach quorum. NQF specifically requested comments about this issue during the public comment period.

NQF received three comments regarding the competing foot care measures. One commenter indicated support for selecting #0417 as the superior measure because it requires a test of motor function. This commenter suggested that a pulse check and visual inspection (elements of measure #0056) be added to #0417 so that all important elements are included in one measure. The second commenter indicated support for continued endorsement of both measures. The third commenter was the developer of measure #0417 (the American Podiatric Medical Association (APMA)); his comment is included below:

Developer Response:

In comparing measures 0056 and 0417 as competing measures, APMA would disagree with the preliminary vote of the committee that measure 0056 was superior to measure 0417 and therefore measure 0056 should be retained and

measure 0417 should not be advanced for endorsement. The neurological status of the feet of a person with diabetes is documented as the primary factor as a precursor to ulcerations and eventually amputations (about 85% of diabetic amputations are preceded by foot ulcerations). Vascular status while a contributing factor is not a primary factor and further simply taking pedal pulses as required in measure 0056 gives little information about the vascular status of the person with diabetes. Further, measure 0056 does not give any guidelines with regards to pedal pulses--grading of pulses, pulses to be considered--dorsalis pedis and posterior tibial or just one per foot or both, etc. Visual inspection is not really relevant as a visual inspection will be done in the process of doing the neurological examination. So the comparison really comes down to the neurological exam described in each of the measures. Measure 0056 only requires a monofilament exam while measure 0417 references the ADA Task Force recommendations--a monofilament exam and at list one other neurological test. Measure 0417 also instructs that the clinician should perform the necessary neurological tests to ascertain the person's neurological status at the discretion of the clinician. Finally, although there have been assurances that the age range for measure 0056 will be changed, it currently still has an age range of 18-75 years of age and thus misses all of those over the age of 75 that are at risk. Therefore, we would assert that measure 0417 is superior to measure 0056 and that at a minimum both measures should be retained (in agreement with the minority of the committee).

Committee Action Item:

- After review and discussion of the attributes of the measures and the submitted comments, is one measure superior or should both measures be recommended for endorsement?

Theme 5 - Foot care measures: Other

NQF received four additional comments regarding the two APMA foot care measures (#0416 and #0417). One commenter suggested combining the two measures and also encouraged the developer to specify the measure so that other clinicians (such as physical therapists) are included in the measure. The developer's response is provided below:

Developer Response:

This quality measure is designed to be reported by any eligible provider and is not designed to be specific to any specialty.

With regards to combining the measures, we agree that ideally there should be a single measure (really a composite measure) that is a comprehensive diabetic foot examination that encompasses all aspect of evaluating the diabetic foot and could be based on the American Diabetes Association's recommendations from their Task Force of the Foot Care Interest Group. We would further recommend that once this comprehensive diabetic foot examination is performed that the patient be risk categorized based on the findings and a plan of preventive care and evaluations be implemented based on their risk classification. Actually, we have developed a comprehensive diabetic foot examination measure that is part of the US Wound Registry QCDR in an attempt to collect data. The stumbling block is that EHR providers will not implement the measure specifications into their products due to the cost and the fact that it is

not currently among the CQM's in meaningful use. Without implementation into an EHR reporting to a QCDR is not possible. Further in an attempt to get the evidence base from a prospective study we have met with several major insurance providers with a pilot study proposal that implements this process to demonstrate that such a protocol would reduce complications in the foot and ankle particularly ulcerations and would lead to decreased infections, hospitalizations and ultimately amputations. We have also proposed this to PCORI. To date no company has been willing to implement this pilot demonstration project despite the potential to improve patient care and have significant cost savings. We would be more than happy to work with Highmark to implement this as a pilot program to demonstrate the value, provide the evidence base and testing required to get a comprehensive diabetic foot examination through the process of NQF endorsement.

Another commenter questioned the difference between the two APMA measures and and recommended that measures for diabetic foot care be evidence-based. For measure #0417, the commenter requested clarification and expressed concern regarding the specifications of the measure. The developer's response is provided below:

Developer Response:

Measure 0416 is focused on evaluation of the footwear for people with diabetes. This involves examining the feet and measuring the person's feet and making sure that they are wearing the proper size and style of shoes for their feet. Measure 0417 involves the components of performing a neurological exam of the person's feet. I do not see how the difference between evaluating the neurological status of the feet of a person with diabetes is unclear from determining that they are wearing the proper size and style of shoe. Two different actions.

Regarding Measure 0416: Although available evidence to demonstrate that proper size and style of shoes prevents diabetic foot complications, this is probably because this is an accepted fact that has no driving force to perform a study to determine the obvious--how would you set up such a study randomized trial that put some people with diabetes in proper size and style of shoes and others randomized to be in shoes that were too small or too tight? Essentially, there is expert opinion acceptance that wearing the wrong size shoes contributes to diabetic foot complications. There is an evidence base that a percentage of people with diabetes wear the wrong size shoe.

With regards to the specifications, we believe that they are very clear. All persons with a diagnosis of diabetes 18 years or older. Also, we are clear as to how to measure the foot.

Finally, what "evidence base" leads you to make a statement that podiatrists either do not know how or do not use G codes. Podiatrists have been eligible providers under the PQRI(S), e-prescribing and meaningful use programs since their inception. The PQRS data on this measure, measure 0417 and measure 0056 (in 2014) all utilize G codes and podiatrists are the ones that most commonly submit these on claims. Further, podiatrists are probably the one of the most knowledgeable professions with regards to coding. In fact, podiatrists are substantially ahead of their allopathic and osteopathic colleagues in preparation for the conversion of ICD-9 to ICD-10.

Committee Action Item:

- Review the proposed Committee responses (below) and provide any additional feedback to incorporate into the responses.

Proposed Committee Response #1 (for measure #0417):

During their deliberations, the Committee agreed that the evidence presented for measure #0417 is supportive of the measure and therefore meets NQF's evidence subcriterion. Committee members acknowledged that the evidence supporting measure #0416 is indirect, but agreed that promoting proper shoe fit likely would decrease rates of foot ulceration and amputation and that an exception to the evidence subcriterion is appropriate.

Proposed Committee Response #1 (for measure #0416):

During their deliberations, Committee members acknowledged that the evidence supporting measure #0416 is indirect, but agreed that promoting proper shoe fit likely would decrease rates of foot ulceration and amputation and that an exception to the evidence subcriterion is appropriate. Some members did express concern that the specific "standard measuring device" for measuring the foot was not identified, but overall, the Committee agreed that the measure meets NQF's reliability subcriterion.