NATIONAL QUALITY FORUM

Memo

April 30, 2019

To: Primary Care and Chronic Illness Standing Committee

From: NQF staff

Re: Post-comment web meeting to discuss public comments received and NQF member expressions of support

Purpose of the Call

The Primary Care and Chronic Illness Standing Committee will meet via web meeting on May 6, 2019 from 2:00 pm to 4:00 pm 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;
- Review and discuss NQF members' expressions of support of the measures under consideration;
- Revote on validity and vote on an overall recommendation for 3475e *Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture*
- Determine whether reconsideration of any measures or other courses of action are warranted.

Standing Committee Actions

1. Review this briefing memo and the 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).
3. Review the NQF members' expressions of support of the submitted measures.
4. 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:

Teleconference
NQF staff, Standing Committee members, public participants:

Speaker dial-in: 800-768-2983

Access code: 4249109

Weblink: https://core.callinfo.com/callme/?ap=8007682983&ac=4249109&role=p&mode=ad

Background

Primary care has a central role in improving the health of people and populations. Primary care practitioners manage the uniqueness and complexities of each patient. In this setting, the diagnosis and treatment of the patient is focused on the health of the entire patient and not a single disease. Chronic illnesses are long-lasting or persistent health conditions or diseases that patients and providers must manage on an ongoing basis. The Primary Care and Chronic Illness portfolio includes endocrine conditions; nonsurgical eyes, ears, nose, and throat conditions; infectious disease; musculoskeletal disorders; and pulmonary disease.

The 20-person Primary Care and Chronic Illness Standing Committee reviewed two measures: one was recommended for endorsement (0729), and consensus was not reached for the other (3475e).

- 0729 *Optimal Diabetes Care* (MN Community Measurement)
- 3475e *Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture* (Centers for Medicare & Medicaid Services/NCQA)

Comments Received

NQF solicits comments on measures undergoing review in various ways at multiple 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 during a 16-week comment period via an online tool on the project webpage.

Pre-evaluation Comments

NQF solicits comments prior to the evaluation of the measures via an online tool on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from December 5, 2018 to April 16, 2019 for the measures under review. As of January 25, 2019, one comment was submitted for the Committee's consideration prior to the measure evaluation web meetings.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment for 30 calendar days from March 18 to April 16, 2019. During this commenting period, NQF received five comments from four member organizations.

Member Council	# of Member Organizations Who Commented
Health Professional	2
Provider Organization	1
Purchaser	1

We have included all comments that we received (both pre- and post-evaluation) in the comment table (excel spreadsheet) posted to the Committee SharePoint site. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—responses (including measure steward/developer responses) for the Committee's consideration. Please review this table before the meeting and consider the individual comments received and the proposed responses to each.

In order to facilitate discussion, the majority of the post-evaluation comments have been categorized into major topic areas or themes. Although all comments are subject to discussion, the intent is not to discuss each individual comment on the May 6 post-comment call. Instead, we will spend the majority of the time considering the two themes discussed below, and the set of comments as a whole. Please note that the organization of the comments into major topic areas is not an attempt to limit Committee discussion. Additionally, please note that measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Committee to consider.

Comments and their Disposition

Themed Comments

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

1. Opposition to 0729 *Optimal Diabetes Care*
2. Support for 0729 *Optimal Diabetes Care*

Theme 1 – Opposition to 0729: Optimal Diabetes Care

One of the major themes of the comments received was the conflicting guidelines for hemoglobin A1c targets and blood pressure control. Two members submitted comments indicating opposition to this measure given these concerns. Both were concerned that the composite does not adequately address recommendations from specific guidelines in the specifications and risk model, and that the measure is not focused on patient-centered, individualized HbA1c goals and/or blood pressure control. One commenter also noted opposition to "all-or-none" composite measures, stating that they are inappropriate for use in value-based payment systems as they penalize providers who meet 0/5 or 4/5 components equally. Additionally, this commenter noted that some of the components are process measures, while others measure outcomes that are highly impacted by social determinants of health, which individual practices cannot control.

> **Measure Steward/Developer Response 1:**
> Thank you for your comments. As discussed in more detail below (see Appendix B for additional developer response/rationale), MNCM believes that the HbA1c component of the measure is consistent with current evidence and guidelines while appropriately balancing the benefits and potential harms of managing patients to this target. Additionally, MNCM believes that the all-or-none composite measure construct is a patient-centric measure that is more likely to reduce risk, prevent or reduce complications and maximize health outcomes by simultaneously achieving several intermediate physiological targets and medication adherence components.

Please see Appendix B for the full response from the developer.

Measure Steward/Developer Response 2:
Thank you for your comments. As discussed in more detail below, MNCM believes that both the HbA1c and blood pressure components of the measure are consistent with current evidence and guidelines while appropriately balancing the benefits and potential harms of managing patients to these targets.

Please see Appendix C for the full response from the developer.

Proposed Committee Response:
Thank you for your comments. The Committee took careful consideration of both the issues related to guideline-based targets for blood pressure and A1c, as well as the all-or-none aspect of the measure. The Committee agrees with the measure developer's assessment that a more relaxed requirement for blood pressure and A1c targets gives clinicians some leeway for personalized care, but still establishes a baseline that the majority of patients should minimally fall within. The majority of the Committee also felt no strong conflict with the all-or-none approach to the measure scoring methodology, not only for the reasons that the measure developer cited, but also because the approach overall will improve the quality of care that persons with diabetes receive at the population level, which is the goal of the measure.

Action Item:
On the Post-Comment Call, the Committee will discuss the commenter's concern and the developer's response. The Committee should approve or revise the proposed response above, drafted by staff.

Theme 2 – Supportive Comments for 0729: Optimal Diabetes Care

The other major theme was comments in support of this measure; two commenters submitted comments supporting it. One purchaser group noted that its use of the measure helped drive improvement in optimal diabetes care outcomes in Minnesota from 6 percent to 45 percent over a 12-year period. A second health professional group also noted that its use of the measure has resulted in significant improvement in results and outcomes.

Proposed Committee Response:
Thank you for your comment.

Action Item:
No Committee action required.

Measure-Specific Comments

3475e Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture

One comment was received on measure 3475e, in support of the Committee's concerns regarding the limited exclusions included in the measure specifications and associated impact on the validity of the measure. This commenter stated the Committee should not endorse the measure until the potential unintended consequences have been addressed and minimized.

During the February 5, 2019 Committee measure evaluation web meeting, the Committee discussed threats to validity in the course of deliberations of this measure. The Committee had concerns about the measure. The algorithm for inclusion in the denominator of this measure includes the use of FRAX scoring—an osteoporosis assessment tool—but the thermal bone density from DXA is a part of the FRAX score. The Committee also expressed concern that the EHR might not be capturing risk factors that the patient has, that there aren't enough exclusions, and that providers won't offer DXA scans to many women at risk for osteoporosis.

During the web meeting, the Committee also acknowledged that it is important not to overuse screening tools. With low pretest probability, even with an excellent test with high specificity, there will still be many false positives that create problems for the patient. The Committee expressed concerns that DXA scans are an overused test.

Measure Steward/Developer Response:

Thank you very much for the feedback. CMS developed the list of exclusions by reviewing clinical guidelines regarding osteoporosis screening and evidence identifying risk factors for osteoporosis and fractures. CMS also discussed potential exclusions with a clinical expert work group comprised of 4 experts in the areas of skeletal health, osteoarthritis, rheumatoid arthritis and family medicine. When determining patients to exclude based on conditions and medications, CMS had to balance prevalence of a condition (i.e., how many women would be excluded) with the relative risk of the condition causing osteoporosis. This consideration was essential to develop exclusions that would not overexclude patients with fairly common conditions (e.g., type 2 diabetes). Based on feedback from experts, we selected the most critical clinical exclusions; however, the list of exclusions will be reviewed annually by clinical experts should the measure be implemented in CMS's Quality Payment Program.

Proposed Committee Response:

Thank you for your comments. The Committee will review these comments during its deliberations on the Post-Comment Call scheduled on May 6, 2019.

Action Item:

After discussing the comment and the response submitted by the developer, the Committee should revote on the Validity criterion in an attempt to reach consensus. If the measure passes this vote, the Committee will vote on an overall recommendation for endorsement.

NQF Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support ("support" or "do not support") for each measure submitted for endorsement consideration to inform the Committee's recommendations. No NQF members expressed support for the measures. Two members did not support measure 0729, and one member did not support measure 3475e. See Appendix A.

Appendix A: NQF Member Expression of Support Results

Two NQF members provided their expressions of support. Neither of the two measures under consideration received support from NQF members. Results for each measure are provided below.

0729 Optimal Diabetes Care (MN Community Measurement)

Member Council	Support	Do Not Support	Total
Health Professional	0	2	2
All Councils	**0**	**2**	**2**

3475e Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture (NCQA)

Member Council	Support	Do Not Support	Total
Health Professional	0	1	1
All Councils	**0**	**1**	**1**

Appendix B: Developer Response 1 to Comment Received on 0729 Optimal Diabetes Care

Previous Committee Discussion

Prior to measure evaluation, the Primary Care and Chronic Illness (PCCI) committee received a comprehensive measure worksheet completed by NQF staff that included a similar concern about the A1c target of < 8.0 from another organization. As part of the pre-evaluation process, committee members provided written comments on each of the NQF endorsement criteria prior to the discussion of the measure. For the evidence criteria, all 13 comments agreed that the evidence provided supported each individual component. The PCCI committee utilized all of this information as they were discussing, evaluating and voting on each criteria for endorsement.

Appropriateness of HbA1c Target

Over the history of stewardship of this measure, the MNCM measure development workgroup has re- convened to consider re-design of the measure construct when there have been significant changes in guidelines. Prior to the publication of the ACCORD study results, the A1c target was < 7.0. In 2008 ACCORD demonstrated the risks of intensive A1c levels < 6.0.

In early 2009, the MNCM workgroup explored the possibility of having two stratified targets, < 7.0 for the patients who can be safely managed to this target and < 8.0 for high risk patients with multiple co- morbidities. The workgroup had to abandon this effort because the data to capture the most significant co-morbidities, history of severe hypoglycemia and limited life expectancy, were not consistently and reliably capturable. The workgroup recommended a target of < 8.0 for all patients age 18 to 75. This does allow for individualized A1c goals if the patient can safely achieve a level < 7.0. Additional concerns expressed by the commenter are addressed by the measure's upper age cap of 75 and exclusions (death, permanent nursing home resident and hospice or palliative care). The measure is risk adjusted by age, insurance product, type 1 or type 2 diabetes and deprivation index (socio economic status). The MNCM workgroup and the NQF Endocrine standing Committee (PCCI's predecessor) who reviewed the measure in 2014 supported the concept that an A1c of < 8.0 can be achieved by most patients.

The ICSI guideline states: "Glycemic Control and A1c Goals Recommendation: A clinician should personalize goals with patients diagnosed with T2DM to achieve glycemic control with a hemoglobin A1c < 7% to < 8% depending on individual patient factors."

MNCM firmly believes the measure is in accordance with the ICSI guideline. The measure does not preclude establishment of personalized goals that are lower than 8.0 for individual patients. The developer is unaware of any clinical guideline that advocates for or promotes an A1c level of between and 8.9 as being good control or a desired outcome. The measure is constructed with a target of less than 8.0% to acknowledge the balance between benefits and harms and is supported by a number of guidelines.

The commenter cites the National Diabetes Education Program as a reference. This document is not a guideline but does use guidelines as a source of information. Guiding Principle 7 of this education program does promote individualized glycemic goals in the context of shared decision making, however goes on to state additional principles:

- Consider an A1C < 7 or near-normalization of A1C in persons who have sufficiently long-life expectancy to see potential long-term benefits on microvascular risks and who are at low risk of potential harms.
- Moderate A1C goals, such as < 8 percent, are appropriate for persons with a history of or risk factors for severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, multiple or advanced comorbid conditions, or long-standing diabetes.

The concerns for the frail elderly achieving specific targets is understood, however there are several aspects of the measure specification and risk adjustment that take this into consideration. The upper age limit of the measure is 75. The exclusions of death during the measurement period, hospice or palliative care and permanent nursing home could account for some patients age 60 to 75 with complex medical conditions. Individual patient factors are going to influence personalized goals for glycemic control for individual patients, and as such, risk adjustment is applied to the measure results using age, type of diabetes, insurance product and deprivation index as proxies for social determinants of health.

Incidentally, 69% or 212,286 patients with diabetes in MN achieved the target of A1c below 8.0 in the 2018 report year.

Patient Centric All-Or-None Composite Measure

The all-or-none composite measure seeks to reduce modifiable risk factors associated with long term macrovascular and microvascular complications associated with diabetes. Patients with diabetes are more likely to reduce their overall risk, prevent or reduce complications and maximize health outcomes by simultaneously achieving several intermediate physiological targets and medication adherence components. The rates of the individual components are not lost and can be used to identify specific areas for improvement and boost achievement of the composite, but a measure construct where only the component rates are reported singly do not necessarily support patient centric health outcomes by achieving several goals simultaneously. For example, a patient whose blood pressure is well controlled but has A1c levels greater than 9 is at increased risk for developing long term-complications.

Measurement does not and should not preclude good clinical judgement. This is a measure of optimal management of the modifiable risk factors that have the greatest potential impact to reduce long term complications for patients with diabetes.

One of the guiding principles in measure development is to design measures that improve the health outcome of the measured population; moving the quality needle forward. There is not an expectation that every single patient achieves that goal, but the target selected is the goal that all patients should strive for.

In a recent large-scale study of over 270,000 patients with type 2 diabetes in Switzerland found that excess risk of cardiovascular event outcomes decreased in a stepwise fashion for each risk factor variable that was within the target range. Patients who were successful in achieving targets for all five risk factors had little or no excess risk of death, myocardial infarction or stoke as compared to the general population. [Rawshani, A et al Risk Factors, Mortality, and

Cardiovascular Outcomes in Patients with Type 2 Diabetes N Engl J Med 2018; 379:633-644 DOI: 10.1056/ NEJMoa1800256]

HealthPartners, a large integrated health system in MN, has been using this measure for two decades resulting in significant improvement in results and outcomes for their patients and members. In addition to seeing improved intermediate outcomes and medication adherence, HealthPartners has reduced the incidence of long-term complications of diabetes. Rates per 1000 members between 2000 and 2015 fell from 17.8 to 11.3 for acute myocardial infarction, from 4.8 to 4.2 for amputations, and from 68.0 to 37.9 for retinopathy.

Appendix C: Developer Response 2 to Comment Received on 0729 Optimal Diabetes Care

Previous Committee Discussion

Prior to measure evaluation, the Primary Care and Chronic Illness (PCCI) committee received a comprehensive measure worksheet completed by NQF staff that included this comment. As part of the pre-evaluation process, committee members provided written comments on each of the NQF endorsement criteria prior to the discussion of the measure. For the evidence criteria, all 13 comments agreed that the evidence provided supported each individual component. The PCCI committee utilized all of this information as it was discussing, evaluating and voting on each of the criteria for endorsement.

Appropriateness of HbA1c Target

Over the history of stewardship of this measure, the MNCM measure development workgroup has re- convened to consider re-design of the measure construct when there have been significant changes in guidelines. Prior to the publication of the ACCORD study results, the A1c target was < 7.0. In 2008 ACCORD demonstrated the risks of intensive A1c levels < 6.0.

In early 2009, the MNCM workgroup explored the possibility of having two stratified targets, < 7.0 for the patients who can be safely managed to this target and < 8.0 for high risk patients with multiple co- morbidities. The workgroup had to abandon this effort because the data to capture the most significant co-morbidities, history of severe hypoglycemia and limited life expectancy, were not consistently and reliably capturable. The workgroup recommended a target of < 8.0 for all patients age 18 to 75. This does allow for individualized A1c goals if the patient can safely achieve a level < 7.0. Additional concerns expressed by the commenter are addressed by the measure's upper age cap of 75 and exclusions (death, permanent nursing home resident and hospice or palliative care). The measure is risk adjusted by age, insurance product, type 1 or type 2 diabetes and deprivation index (socio economic status). The MNCM workgroup and the NQF Endocrine standing Committee (PCCI's predecessor) who reviewed the measure in 2014 supported the concept that an A1c of < 8.0 can be achieved by most patients.

MNCM firmly believes the measure is consistent with both ICSI and ACP guidelines:

- The ICSI guideline states: "Glycemic Control and A1c Goals Recommendation: A clinician should personalize goals with patients diagnosed with T2DM to achieve glycemic control with a hemoglobin A1c < 7% to < 8% depending on individual patient factors."
- American College of Physicians (ACP) guidelines:
    - Guidance Statement 1: Clinicians should personalize goals for glycemic control in patients with type 2 diabetes on the basis of a discussion of benefits and harms of pharmacotherapy, patients' preferences, patients' general health and life expectancy, treatment burden, and costs of care.
    - Guidance Statement 2: Clinicians should aim to achieve an HbA1c level between 7% and 8% in most patients with type 2 diabetes.

The measure target of 8.0% or below is consistent with both the ICSI and ACP guidelines, while allowing for individual targets that are lower and excluding patient populations for whom the goal of less than 8.0% may not be appropriate.

One of the guiding principles in measure development is to design measures that improve the health outcome of the measured population, moving the quality needle forward. There is not an expectation that every single patient achieves that goal, but the target selected is a goal that all patients should strive for.

Measurement does not and should not preclude good clinical judgement. This is a measure of optimal management of the modifiable risk factors that have the greatest potential impact to reduce long term complications for patients with diabetes. It is understood that individual patient factors are going to influence personalized goals for glycemic control for individual patients, and as such, risk adjustment is applied to the measure results using type of diabetes, insurance product and deprivation index as proxies for social determinants of health. The measure is constructed with a target of less than 8.0% to acknowledge the balance between benefits and harms and is supported by a number of guidelines.

Incidentally, 69% or 212,286 patients with diabetes in MN achieved the target of A1c below 8.0 in the 2018 report year.

Appropriateness of Blood Pressure Component

The commenter expresses concerns about the blood pressure component as well. The current target of < 140/90 is less stringent than the American College of Cardiology (ACC)/ American Heart Association (AHA) recommended target for patients with diabetes of < 130/80. This 2017 guideline is not without controversy. Both the American College of Physicians and the American Academy of Family Practice have declined endorsement of the guideline. All agree that a lower blood pressure is better, but only if it can be achieved safely.

MNCM convened a technical expert panel in 2018 to evaluate recent changes in guideline and evidence for blood pressure targets for patients with diabetes. The workgroup felt that the guidelines, which relied on the SPRINT trial and excluded patients with diabetes, did not address treatment risks of hypotension and kidney function. The workgroup was concerned that in setting a lower target for all patients to strive for, knowing that providers will want to meet that target and may be accountable for hitting that target, may put some patients at risk for serious and costly side effects of intensive treatment. The workgroup supported individualized targets, striving for a lower blood pressure, but only if it can be achieved safely. The workgroup reached consensus for continuing with a blood pressure target of < 140/ 90 for this measure, which allows for lower individual targets as appropriate while avoiding concerns about potential harms for some patients.