NATIONAL QUALITY FORUM

Memo

TO: Endocrine Standing Committee

FR: NQF Staff

RE: Voting Draft Report

DA: April 23, 2015

Background

Endocrine conditions result from disorders of the endocrine system, most often when either too much or too little of a particular hormone is produced.[1] In the United States, two of the most common endocrine disorders are diabetes and osteoporosis.[2] Diabetes, a group of diseases characterized by high blood glucose levels, affects many as 25.8 million Americans and ranks as the 7th leading cause of death in the United States.[3] Many of the diabetes measures in NQF's Endocrine portfolio are among NQF's longest-standing measures.

NQF selected the Endocrine measure evaluation project to pilot more frequent submission and evaluation of measures than what is possible in our current 3-year measure maintenance process. This 22-month project includes three full endorsement "cycles," allowing for the submission and review of both new and previously-endorsed measures every six months. The background and description of the project, review of NQF's Endocrine portfolio, and the results of the cycle 1 and cycle 2 evaluations are available on NQF's project web page. In cycle 3 of this project, the Standing Committee evaluated two measures undergoing maintenance review against NQF's standard measure evaluation criteria. The two measures recommended for endorsement by the Standing Committee include:

- 0061: Comprehensive Diabetes Care: Blood Pressure Control
- 0729: Optimal Diabetes Care

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 Committee and once a report of the proceedings has been drafted.

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[1] WebMD. Endocrine Disorders. 2014;March 14 A.D.

[2] Golden SH, Robinson KA, Saldanha I, et al. Clinical review: Prevalence and incidence of endocrine and metabolic disorders in the United States: a comprehensive review. The Journal Of Clinical Endocrinology And Metabolism, 2009;94(6):1853-1878.

[3] Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National estimates and general information on diabetes and prediabetes in the United Staes, 2011. 2014;Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention

Pre-evaluation comments

The pre-evaluation comment period was open from December 25, 2014 to January 12, 2015. No pre-evaluation comments were received for the measures under review in this cycle of the project.

Post-evaluation comments

The Draft Report was open for Public and Member comment from March 5, 2015 to April 3, 2015. During this commenting period, NQF received six comments from five member organizations:

Consumers – 0	Professional – 0
Purchasers – 0	Health Plans – 2
Providers – 1	QMRI – 0
Supplier and Industry – 1	Public & Community Health - 1

A complete table of comments submitted, 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 and responded to all comments received. 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

The following comments were received in the post-evaluation comment period:

0061: Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)

NQF received one comment (#4719) in support of the Committee's recommendation for endorsement of this measure.

0729: Optimal Diabetes Care

NQF received five comments regarding this measure, each of which was critical of the measure, for various reasons. After discussion of these comments, the Committee declined to revote on the measure.

NQF received two comments (#4687 and #4794) ***specifically related to the glucose control component*** of the composite. Commenters referenced the National Action Plan for Adverse Event Prevention (www.health.gov/hai/pdfs/ADE-Action-Plan-508c.pdf, p 117), which was released in August, 2014. This National Action Plan, developed by representatives of 13 Federal agencies as well as non-Federal subject matter expert consultants, states that the blood glucose threshold of <8% for patients <75 years of age does not conform to glycemic control guidelines from the American Diabetes Association, Department of Veterans Affairs, Department of Defense, and American Geriatrics Society (i.e., by excluding certain patients such as those with limited life expectancy or with certain co-morbid conditions, or by stratifying according to medication type).

> **Developer Response #1:** Thank you for your comments. According to the Institute for Clinical Systems Improvement (ICSI) 2014 Guidelines for Diabetes there is high quality evidence and a strong recommendation in support of an A1c target of less than 8.0.

Excerpt from the guideline is as follows: Algorithm Annotation #4- 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. Benefits: Achieving near-normal glycemic control lowers risk of diabetes microvascular complications such as retinopathy, nephropathy and amputations. Achieving A1c of 6.9 to 7.9% may also significantly reduce macrovascular complications based on Steno-2 and UKPDS data. Quality of Evidence: High Strength of Recommendation: Strong. www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_endocrine_guidelines/diabetes/ Measurement does not and should not preclude good clinical judgement; however the measure development work group believes that a target of < 8.0 is reasonable and supported by guidelines. Our measure does have an upper age limit cut-off of 75 years and we allow exclusions for death, permanent nursing home resident or patients who are receiving hospice or palliative care services.

Committee Response: Thank you for your comment. During its review of the individual measure assessing HbA1c<8% in the spring of 2014 (#0575), the Committee considered the clinical practice guideline recommendations from American Diabetes Association (2013), American Geriatric Society (2003), VA/DOD (2010), and American Association of Clinical Endocrinologists (AACE) (2011). During their discussion of measure #0575, members specifically noted that for some patients (e.g., frail elderly patients, those with limited life expectancy,) HbAc1 values slightly above 8% might be reasonable and that target HbA1c values for such patients should be individualized. In their more recent evaluation of the composite measure (#0729) in January 2015, the Committee considered the2014 clinical practice guideline recommendations from the Institute for Clinical Systems Improvement, which suggest a target threshold of <7% - <8%, depending on patient factors. The Committee acknowledged that the <8% threshold may not be appropriate for all patients, but agreed that the 8.0% cutoff was a reasonable target for a national healthcare performance measure and that 100% performance on the measure is not expected. The Committee also noted that measure #0729 includes an the upper age limit of 75 and excludes patients who died, are permanent nursing home residents, or are receiving hospice or palliative care services, which addresses at least some of the concerns voiced by the commenters. Finally, the Committee strongly recommended development of performance measures that assess occurrence and severity of hypoglycemia in the outpatient setting.

Two of the comments (ID #4717 and #4720) were critical of the composite measure itself, citing concern that use of the composite measure could mask the individual care processes that most need improvement.

Developer Response #1 (ID# 4717): Thank you for your comment. While it is true that the measure is reported at the composite level, the individual components and the associated rates are available to the medical groups for better understanding their rates and for use in quality improvement to know which areas have opportunity for improvement. MNCM and the measure development work group firmly believe that achieving the intermediate physiological outcome targets related to blood pressure and glycemic control in addition being tobacco free and use of daily aspirin and statins where appropriate are the diabetic patient's best mechanisms of avoiding or postponing long term complications associated with this chronic condition which affects millions of Americans. Measuring providers separately on individual targets is not as patient centric as a measure that seeks to reduce multiple risk factors for each patient. Diabetic patients are more likely to reduce their overall risk and maximize health outcomes by

achieving several intermediate physiological targets. *(remainder of response refers to other issues)*

Developer Response #2 (ID# 4720): Thank you for your comment and support of the components of this patient level all-or-none composite measure. (*remainder of response same as above and/or refers to other issues)*.

Committee Response: Thank you for your comment. Use of an all-or-not scoring approach does not hinder providers from tracking performance of the individual components of the composite and instituting appropriate improvement initiatives. Moreover, use of such composite measures is a patient-centric approach that allows providers to assess their success in reducing multiple patient risk factors across a variety of clinical areas.

These same two comments (ID #4717 and #4720) also noted that documenting HbA1c levels >8% but less than 9% cannot be done using CPT-II coding, necessitating need for medical chart review. In a continuation of the developers' responses noted above, developers noted:

Developer Response #1 (ID# 4717): A point of clarification, these measure do not rely on CPTII codes for numerator compliance, nor are they indicated anywhere in our measure specification. Measure specifications focus on the electronic health record as a source of clinical information for calculating numerator compliance; actual A1c values are utilized in the case of the A1c target. Additionally, 80 to 90% of all the clinics in MN are reporting this information from their electronic health records without the need for additional chart abstraction.

Developer Response #2 (ID# 4720): *Almost identical to above.*

One comment (ID#4720) also suggested a need for including sociodemographic factors in the risk-adjustment approach.

Developer Response: Additionally, our risk adjustment model does include insurance product which is a proxy for socioeconomic status. During the process of measure development, the expert panel discusses potential variables for risk adjustment that are important to consider for the measured population. For this measure, variables that are available for evaluation include gender, age, zip, race/ethnicity, country of origin, primary language, insurance product, diabetes type, depression and ischemic vascular disease. The potential risk adjustment variables are then evaluated for appropriate inclusion in the model based on a t value outside the range of -2.0 and +2.0. Currently, the variables that have demonstrated acceptable properties are insurance product, age bands (18-25, 26-50, 51-65 and 65 to 75) and diabetes type (1 or 2). Race/ethnicity has been collected for this measure in MN for the past few years, but has now reached a level of reliability in which it can be evaluated for its impact. MNCM continues to review variables and their impact on the measure and part of its measure risk adjustment strategy.

Committee Response: Thank you for your comment. The Committee acknowledged NQF's recent policy change that has lifted the prohibition against including sociodemographic factors in risk-adjustment for outcome, resource use, and other quality measures. The Committee agreed that insurance type, which is included in the risk-adjustment model for this measure, can be considered a proxy for sociodemogrpahic status. The Committee also accepted the developer's explanation that other potential sociodemogrpahic were considered for inclusion in the measure's risk-adjustment approach but ultimately were not included because they were not statistically significant.

Finally, one comment (ID #4792) suggested the need for additional detail regarding moderate or high intensity in the description of statin use for the measure. The developer's response is provided below:

> **Developer Response:** Thank you for your comment and suggestion for the inclusion of a dose of statin (moderate or high intensity statin). The measure development work group thoroughly discussed the pros and cons of specifying a certain dose of the statin medication and based on the following factors ultimately decided to not specify a dose of moderate or high intensity for numerator compliance: 1) data burden for practices, 2) controversy and burden surrounding the CV risk calculator, 3) ICSI 2014 Diabetes Guideline recommendations for measurement and 4) cardiology work group member's believe that there is some benefit for some patients who can only tolerate a lower intensity dose.

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 May 07, 2015 at 6:00pm ET – no exceptions