National Quality Forum

Comments on Draft Report: National Voluntary Consensus Standards for Patient Outcomes (Phases I and II)

Diabetes Measures: OT1-009-09 and OT1-029-09

Comments discussed by the Steering Committee on September 17, 2010.

Cmnt ID#	Member Council/ Public	Organization Contact	Comment	Response	Topic
15	M, Provider	Tammy Czarnecki, Department of Veterans Affairs	<8% measure: 1.There are no exclusion criteria for decreased life expectancy, serious hypoglycemia, or conditions that would increase the risk of serious hypoglycemia, especially for patients on insulin. This would include dementia or cognitive impairment. 2.This is of special importance in the Medicare population 65-75 years of age given a higher prevalence of severe conditions. In the VADT there was no significant benefit in any outcome-other than progression of proteinuria, over 5.6 years in the intensive group (6.9% A1c) vs the treatment group 8.4%. 3.Measurement: Seniors without diabetes have higher A1c levels for any degree of glycemia than younger individuals; the absolute difference is about 0.4% (Pani et alDiabetes Care 2008;31:1991–6). The clinical significance is not known. We are concerned about the failure to include any exclusion criteria in the Medicare population for chronic complex illness, especially for patients on insulin. There are similar issues regarding the A1c measurement issue.	Measure developer response: Thank you for your comment. In general, the trial data from the ACCORD, ADVANCE, and VADT studies showed that the safest control level across the population of nearly all patients with diabetes is <8% (noting that for a substantial portion of the younger population of persons with diabetes, a level below is beneficial). Given the gap in care, it was the decision by NCQA that the most net benefit can be gained by focusing on reducing HbA1c levels below 8% (the gain under 7 may be small compared with reductions at higher levels). Hence, the reason NCQA did not add exclusion criteria to the <8% measure for any segment of the population.	OT1-009: Optimal Diabetes Care

43	M, Provider	Rae Williams, HealthPartners	HealthPartners medical group strongly supports this diabetes composite measure and patient level composite measures in general because they represent the best care and outcomes for the patient. Diabetic patients are less likely to suffer long term complications of renal failure, cardiovascular and peripheral vascular disease if all of their modifiable risk factors are in control. This all-or-none intermediate outcome measure supports these goals. This measure, originally developed by HealthPartners, is now collected state-wide and current scores represent over 135,000 diabetic patients. We believe that focused efforts, which include transparency of results, has led to significantly improved care and outcomes for diabetics. Rates of control have improved at the state and individual clinic level. Rates within our own medical group of 28 clinics have steadily increased from 19%(2007) to 36% (2010)patients achieving all targets.	Thank you for your comment.	OT1-009: Optimal Diabetes Care
44	M, Provider	Rae Williams, HealthPartners	It is our hope that NQF reconsiders this measure for endorsement. MN Community Measurement (MNCM) annually reviews ICSI and ADA guidelines to insure that the targets of the composite are in alignment with current guideline recommendations. When evidence and guidelines have changed MNCM convenes an expert workgroup to review the evidence and make recommendations for changes to the measure. The measure was criticized for its current blood pressure target of < 130/80, which is consistent with current ICSI and ADA guidelines, but incongruent with the 3/14/2010 ACCORD study results recommending a systolic blood pressure no lower than 135 to 140 for higher risk patients. ICSI diabetes guidelines are currently in revision and the measure developers plan to adjust the blood pressure target to align with ICSI when this guideline is released in early August 2010.	This measure has not been given a final recommendation pending the anticipated review of the ICSI guidelines in August 2010. After the guidelines and measure specifications are revised, the Steering Committee will make a final recommendation.	OT1-009: Optimal Diabetes Care

109	M, Consumer	Debra Ness, National Partnership for Women & Families	We support this measure, noting of course the concerns regarding the change in evidence base that recently were released. We look forward to seeing the review and evaluation of that measure when it is resubmitted, following the updates that will be made to reflect new evidence that pertains to that measure.	Thank you for your comment.	OT1-009: Optimal Diabetes Care
141	P	Kay Jewell, Center for Consumers of Healthcare	Should stick with <7% with exclusions. BP article that raised concern - was for 120- not 130 which is what the current recommendation is. Good to have ICSI review and recommend.	Measure Developer Response: Thank you for your comments. We understand your viewpoint about leaving the target at < 7.0 because many diabetics are better managed at this level, but applying the appropriate exclusions proved to be very burdensome in terms of data collection. In December 2008, following ACCORD study results and changes to both the ICSI Diabetes Guidelines and the American Diabetes Association Standards of care, we convened an expert workgroup to determine what the A1c component should be, at that time it was < 7.0. Initially the workgroups set out to define using available data to identify patients who were more appropriate for an A1c goal of < 7.0 and those patients who were more appropriately managed at < 8.0 due to co-morbid conditions. Some of the co-morbid conditions could be defined by ICD-9 code very reliably, like cardiovascular disease and heart failure, but other significant co-morbids like history of hypoglycemia or limited life expectancy could not be reliable captured unless resource intensive chart abstraction was undertaken for each patient. Due to the inability to define what the group felt was the most important co-morbid, history of hypoglycemia, that for measurement purposes mindful of patient safety, the A1c target for all patients was set at < 8.0. Systolic blood pressure < 130 versus < 140: Agree that the ACCORD study results were based on intensive hypertension control to a systolic BP of 120 and that our current measurement target of < 130/80 is not promoting a blood pressure target as low as the intensive arm of the ACCORD study. ICSI Diabetes guidelines are currently undergoing revision with a planned release in August 2010 and one of the areas of focus is blood pressure management. Also, recently finalized (7/13/10) Meaningful Use Measures have a measure for diabetes blood pressure control set at less than 140/90. We are most likely to align with the national measure, but need to formalize the measure change with our diabetes technical advisory group to gain consensus over the next weeks.	OT1-009: Optimal Diabetes Care

167	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	BI supports certain elements of the composite but would like to raise some other important issues for your consideration. Therefore, we agree with NQF's decision to withhold a final recommendation pending further evidence and deliberation. The "all-or-none" approach taken by this measure (in which practices achieve credit only if they meet all of its components) has been supported by key stakeholders in the quality measurement community. Purported benefits of this model include reflecting patient interests, fostering a system outlook, and providing a sensitive scale for performance assessment. The Optimal diabetes care measure in particular has had success in Minnesota; the statewide practice average of diabetes patients with diabetes (Type I and Type II) ages 18 to 75 who reached all of the D5 treatment goals has increased from 4 percent in 2004 to nearly 19 percent in 2009. The measure emphasizes each outcome as equally crucial in diabetes care and shows how measures can more holistically quantify best practices with respect to a disease. While "all-or-none" measures are emerging as a valuable route for performance evaluation, this model can also be burdensome to providers and may not adequately recognize whether select outcomes within the measure were achieved. Further, for certain therapeutic areas there may not be consensus as to which measures should comprise an "all-or-none" approach. We encourage NQF to carefully consider these complex issues as it considers endorsing similar measures.	The Diabetes TAP and Steering Committee discussed the pros and cons of "all or none" measures at length including the issues you have raised. The Steering Committee supported the measure concept as identifying "optimal" care and not merely adequate performance. Measure Developer Response: Thank you for your comments. As more practices move towards electronic health records (EHRs) the burden for data collection is reduced. Approximately 67% of the clinics in MN have implemented an EHR system. EHRs also allow for full population reporting, providing powerful outcome results beyond that achieved with sampling. Results for the individual components are available to providers to better understand their patient population and may be used for quality improvement purposes. Individual component results are also available on our public website www.mnhealthscores.org. Many medical groups provide patient educational material geared towards the individual goals within the all or none composite. We have a companion consumer centered website for viewing and understanding diabetes results at www.theD5.org.	OT1-009: Optimal Diabetes Care

17	P	Kay Jewell, Center for Consumers of Healthcare	This is a good composite and very valuable however, it is hard to support a composite measure when the individual measure's within are not considered solid enough to stand on their own, e.g. the A1c<7%.	NQF's Composite Measure Evaluation Framework describes the criteria for evaluating composite measures - see http://www.qualityforum.org/Publications/2009/08/Composite_Measure_Evaluation_Framework_and_National_Voluntary_Consensus_Standards_for_Mortality_and_Safety—Composite_Measures.aspx Information on NQF's composite measures evaluation framework will be added to the report. NQF's composite measure evaluation criteria does not require a measure to be endorsed as a stands alone measure to be included in a composite. After further discussion of the Hgb A1c <7 measures, the Committee will be re-evaluating this measure at the same time as the final evaluation and reocmmendation of OT1-009: Optimal Diabetes Care. Measure developer response: Thank you for your comment. Although we recognize your concern regarding the A1c <7% measure, the recommendation to include the measure is closely tied to the most recent clinical trials from ACCORD, ADVANCE, and VADT on diabetes and expert consensus on the implications of these studies on HbA1c measurement. Therefore, it was the decision of NCQA that the evidence suggests that the benefit for control of HbA1c under 7% is for microvascular rather than macrovascular complications and the group with the most benefit and least risk are younger and earlier in the stage of their diabetes. Also, the benefit from avoiding microvascular progression requires 10-20 years to begin to be manifest with respect to important patient outcomes. Therefore, the safest control level across the vast majority of persons with diabetes is somewhere between 7-8%. NCQA has submitted a separate measure of good control for HbA1c <7% (with some exclusionary criteria) for endorsement by NQF.	OT1-029: Comp. Diabetes Care

57	M, Provider	Kenneth Henriksen, Advocate Physician Partners	The descriptive specification for this measure could benefit from clarification on the measures that comprise Comprehensive Care. The narrative statement for this measure (line 270) expresses that this composite measure includes Smoking Status and Cessation Advice or Treatment. However, the Appendix A: Measure Specifications statement for this measure does not include this element. Similarly, medical literature and comments by NQF staff in the past have expressed that segmenting the measurement and reporting of smoking cessation counseling and cessation advice is not optimal when measured by individual disease state; it is more effectively evaluated and used for quality improvement at a population health level. We have an interest in seeing the manner in which the composite measure uses threshold cutoffs and weights to generate a summary score. This detail did not appear to be provided in the report materials.	NQF staff has reviewed and cross walked the various documents - revisions have been made to assure consistency. The component weightings and the summary score calculation are included in the measure submission information posted on the project page at http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx#t=2&s=&p=6%7C Measure Developer Response: Thank you for your comment. The ADA guidelines recommend that patients with diabetes do not smoke and that those who do smoke receive cessation counseling or treatment. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement.	OT1-029: Comp. Diabetes Care
66	M, Health Professionals	G. Timothy Petito, American Optometric Association	The American Optometric Association is pleased with the inclusion of the eye exam in the diabetes composite measure. According to AOA's Clinical Practice Guideline for the Care of the Patient with Diabetes Mellitus, patients diagnosed with DM need regular eye examinations. Examination of the patient with DM should include all aspects of a comprehensive eye examination, with supplementary testing as indicated to detect and thoroughly evaluate ocular complications. The frequency of examination is determined on the basis of several factors, including the type of DM, duration of the disease, age of the patient, level of patient compliance, concurrent medical status, and both nonretinal and retinal ocular findings.	Thank you for your comment.	OT1-029: Comp. Diabetes Care

74	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	Please see "Level of measurement" comments for OT2-22-09: Proportion of patients with a chronic condition that have a PAC.	Unlike measure OT2-22-09, the developer indicates that this measure is used for clinician-level measurement . This measure is used by NCQA for its Physician Recognition program.	OT1-029: Comp. Diabetes Care
75	M, QMRI	Bernard M. Rosof, MD, MACP, Physician Consortium for Performance Improvement®	Clarification: We have noticed that measure OT1-029-09 appears in the report with two different names: Diabetes Composite (as on page 14 of the PDF report) and Comprehensive Diabetes Care (as on page 51 of the PDF report). We suggest that one name be used throughout the document.	We agree - the name has been standardized in the revised draft.	OT1-029: Comp. Diabetes Care
82	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Please see "Level of measurement" comments from OT2-022-09: Proportion of patients with a chronic condition that have a PAC.	Unlike measure OT2-22-09, the developer indicates that this measure is used for clinician-level measurement . This measure is used by NCQA for its Physician Recognition program.	OT1-029: Comp. Diabetes Care
83	M, QMRI	Nancy H. Nielsen, MD, PhD, American Medical Association	Clarification: We have noticed that measure OT1-029-09 appears in the report with two different names: Diabetes Composite (as on page 14 of the PDF report) and Comprehensive Diabetes Care (as on page 51 of the PDF report). We suggest that one name be used throughout the document.	We agree - the name has been standardized in the revised draft.	OT1-029: Comp. Diabetes Care
90	M, Health Plan	Rebecca Zimmerman, AHIP	Support.	Thank you for your comment.	OT1-029: Comp. Diabete

99	M, Health Professionals	Janet Leiker, on behalf of the AAFP Commission on Quality and Practice, American Academy of Family Physicians	The AAFP supports the diabetes composite measure overall. There is a concern regarding the use of the same targets across such a large population (18-75 yrs old, type 1 & 2). These targets may be appropriate for some patients but not others. There are no exclusions to allow for consideration of individualized care and treatment goals.	Measure Developer Response: Thank you for your comment. The components of the submitted composite measure were included based on existing guideline recommendations for diabetes care and expert consensus. We recognize your concern about individualized care. The composite is flexible in that 100% performance is not required for the component measures and the targets included are the most reasonable based on existing evidence. We have included exclusions for the A1c <7% component only.	OT1-029: Comp. Diabetes Care
105	M, Consumer	Debra Ness, National Partnership for Women & Families	We support this measure.	Thank you for your comment.	OT1-029: Comp. Diabetes Care
112	M, Health Plan	Tom James, National Network Operations	Disagree with the inclusion of "smoking status and cessation advice or treatment" as part of the measure. That element is a process measure that does not hold up well in studies, per the Joint Commission article in the NEJM last month. The other elements are measureable and represent outcome measures. Without smoking status notation, this composite could be drawn from administrative or clinical sources. With the measure it requires chart audit.	Measure Developer Response: Thank you for your comment. The ADA guidelines recommend that patients with diabetes do not smoke and that those who do smoke receive cessation counseling or treatment. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement.	OT1-029: Comp. Diabetes Care

127	M, Health Plan	Catherine MacLean, WellPoint, Inc.	WellPoint supports this composite measure and its component measures, except for component measure HbA1c < 7.0. An HbA1c < 7.0 is not indicated for all patients and may lead to poor outcomes in some patients. There is stronger evidence for reducing higher HbA1c levels than driving patients below 7. NCQA has a different denominator population for this measure to address the patients that might be harmed by HbA1c < 7.0. For these reasons, we do not support this component measure. We would also like to note that data collection is still difficult because CPT II codes are not routinely admitted and it is costly to collect lab values. Lastly, WellPoint would like to ask NCQA to be clearer about how it will report the total score. Available component scores should be available in addition to the total composite score for quality improvement purposes.	The Steering Committee will re-evaluated this measure with the Optimal Diabetes Care composite measure again in light of further discussion of the Hgb A1c < 7 measure. As previously discussed, the Committee supported the <7% component within the context of other measures, such as the composite, rather than a stand alone measure. Measure Developer Response: Thank you for your comment. This measure has been collected as part of the Comprehensive Diabetes Care composite measure set for the HEDIS population for two years. the data collected indicates that there is significant variation among organizations and that there is room for improvement in the management of this select population. It has also been introduced as a requirement of the Diabetes Provider Recognition (DRP) program and the provider-level data submitted supports the variability across providers and that there is still much room for improvement. According to the evidence, lowering A1c to below or around 7% has been shown to reduce microvascular and neuropathic complications of type 1 and type 2 diabetes	OT1-029: Comp. Diabetes Care
140	P	Kay Jewell, Center for Consumers of Healthcare	Good measure - much needed but it is hard to support a composite when all the measures within are not considered able to stand alone.	NQF's Composite Measure Evaluation Framework describes the criteria for evaluating composite measures - see http://www.qualityforum.org/Publications/2009/08/Composite_Measure_Evaluation_Framework_and_National_Voluntary_Consensus_Standards_for_Mortality_and_Safety—Composite_Measures.aspx Information on NQF's composite measures evaluation framework will be added to the report. The composite criteria requires that the component measures be evaluated against the criteria but are not required to be sufficiently important as a stand alone measure.	OT1-029: Comp. Diabetes Care

159	M, Health Professionals	Ralph Sacco, American Heart Association, American Stroke Association; Ralph W. Brindis, President, American College of Cardiology; Frederick A. Masoudi, Chair, ACCF/AHA Task Force on Performance Measures	It is possible that we are misinterpreting the specifications for this measure due to the difficult tabular format, as noted above, but it appears that this measure doesn't discriminate between good and poor glycemic or blood pressure control. Moreover, even if it did, there is no evidence that glycemic targets are particularly helpful which, we would note, is given as the reason for not recommending endorsement of measure OT1-028-09—HbA1c Control for a Selected Population. Please also note that several of the numerator components listed in Appendix A (LDL-C screening, BP <130/80 mmHg, BP <140/90 mmHg) were not accurately duplicated in the list in the discussion section of the report, which created some confusion for our reviewers.	The measure submission forms have the final specifications. Apparently Appendix A did not include all the late changes. Corrections have been made in the revised report.	OT1-029: Comp. Diabetes Care

166	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	BI supports the endorsement of this composite. These eight measures provide a holistic assessment of the many aspects that are part of diabetes management. Because diabetes is a multi-faceted condition, the care provided to patients must address all aspects of the disease. In light of this fact, we recommend revision of the nephropathy assessment measure specifications. This measure currently does not include estimated glomerular filtration rate (eGFR) testing in the specifications only urine micro and macro-albumin testing. eGFR monitoring in the assessment of nephropathy is included in widely-accepted clinical guidelines. Incorporating this test into the measure specifications would ensure that providers utilize it consistently. As such, BI urges NQF to discuss the potential revision of this specification with the National Committee for Quality Assurance (NCQA), the measure developer.	Measure Developer Response: Thank you for your comment. This measure has been collected as part of the Comprehensive Diabetes Care composite measure set for the HEDIS population for years. We recognize your concern regarding eGFR and will take this into consideration as we work to re-evaluate the nephropathy measure.	OT1-029: Comp. Diabetes Care

168	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	NQF notes that recent ACCORD findings suggest that the blood pressure (BP) threshold in this measure should be less aggressive. While BI acknowledges and supports the importance of considering newly published literature during the measure endorsement process, we urge NQF to also rely on the larger body of evidence on this topic. ACCORD has produced compelling results that prompt reflection in the diabetes community about how this study's finding can be incorporated into the larger body of evidence on management of diabetes. It is for this reason that we recommend that NQF postpone its decision for endorsement of this measure until relevant clinical guidelines are revised and released (e.g., those of the American Society of Hypertension, Institute for Clinical Systems Improvement, and the Eighth Report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 8)). Each of these entities will independently consider the ACCORD findings and will have valuable perspectives on the appropriate BP threshold for diabetes patients.	The Steering Committee reconsidered both measures after revisions to the Optimal Diabetes Care measure were submitted after ICSI guidelines were revised. The harmonization of BP target at <140/90 for both measures as well as other components was important in the Committee's reocmmendation of the measures.	OT1-029: Comp. Diabetes Care

169	P	Hemal Shah, Boehringer Ingelheim Pharmaceuticals, Inc.	Finally, BI agrees with NQF Committee member recommendations that the measure developer (Minnesota Community Measurement) consider adding metrics on eye examinations and renal function to this composite. We would additionally note that Body Mass Index (BMI) is another significant characteristic that has clear implications for diabetes management, as has been noted in national clinical guidelines; as such, this should also be considered for inclusion in this composite. These are all important aspects of diabetes management that should be applied to every patient. Like the proposed NCQA measure, we believe these metrics in tandem would provide a holistic assessment of diabetes management.	Measure Developer Response: Thank you for your comments. We agree that there are many processes that are important for the management of patients with diabetes for the prevention or reduction of complications. Measuring processes tells you that a service was performed, but does not demonstrate achievement of treatment goals. Focusing on Intermediate outcomes gets us closer to the goal of reducing the long term complications of this chronic disease. It is more valuable to know, for example, that 57% of patients had an LDL < 100 than 92% of the patients had an LDL lab test done in the last 12 months. At a recent measurement committee meeting, our members were discussing the value of publicly reporting a separate measure for retinal eye exams for diabetes patients. Currently, our state's HEDIS rates for this measure hover between 60 and 70%, but there are some potential flaws with this claim based measure in that patients who have their exams at Vision World or Wal-Mart are not necessarily captured by claims and included in this rate. One group's analysis of their diabetic patients demonstrated that 35% of patients were receiving their eye exams at one of these alternative locations.	OT1-029: Comp. Diabetes Care