**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**: 2603 (New Measure)**

**Measure Title**: **Comprehensive Diabetes Care for People with Serious Mental Illness (SMI) and diabetes: Hemoglobin A1c (HbA1c) testing**

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**:  **7/25/2014**

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| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: **Patients with serious mental illness receiving an HbA1c test during the measurement year**

Structure: Click here to name the structure

Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

**Not applicable.**

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

**Not applicable.**

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

**The rate in this measure relates to the desired outcome in the following way: Patients with serious mental illness (i.e., schizophrenia, bipolar disorder, or depression) and diabetes 🡪 HbA1c test is performed 🡪 Test results are evaluated 🡪 HbA1c health provider determines treatment to keep HbA1c at desirable level 🡪 Maintenance or improvement in HbA1c level and/or quality of life (desired outcome).**

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

**American Diabetes Association. (2014) Standards of Medical Care in Diabetes. Updated January 2014. Guideline URL: http://care.diabetesjournals.org/content/37/Supplement\_1/S14.full.pdf+html, accessed June 11, 2014.**

**American Geriatrics Society (2013 Update)**

**American Geriatrics Society (AGS). 2013. Guidelines Abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 Update. Journal of the American Geriatrics Society. 61(11): 2020-2026. DOI: 10.1111/jgs.12514**

**Department of Veteran Affairs, Department of Defense. (2010) VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Department of Veteran Affairs, Department of Defense. 2010 Aug: 146.**

**Guideline URL:** [**http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010\_FUL-v4e.pdf**](http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010_FUL-v4e.pdf)

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

**American Diabetes Association (ADA) – 2014:**

**Pg. S22-S23**

* **Page S22, Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). (Grade E)**
* **Page S22-S23, Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. (Grade E)**
* **Page S23, Use of point-of-care testing for A1C provides the opportunity for more timely treatment changes. (Grade E)**

**American Geriatrics Society (2013)**

**Pg 2021**

**“Glycemic Control” General Recommendations**

**Target goal for glycosylated hemoglobin (HbA1c) in older adults generally should be 7.5% to 8%. HbA1c between 7% and 7.5% may be appropriate if it can be safely achieved in healthy older adults with few comorbidities and good functional status. Higher HbA1c targets (8–9%) are appropriate for older adults with multiple comorbidities, poor health, and limited life expectancy. (1A evidence for HbA1c 7–8%, and IIA for 8–9%) There is potential harm in lowering HbA1c to less than 6.5% in older adults with type 2 DM. (Recommendation Grade: 11A)**

**Department of Veterans Affairs/Department of Defense (VA/DoD) – 2010:**

**Pg. 42 & 46**

* **Page 42: HbA1c should be measured in patients with diabetes at least annually, and more frequently (up to 4 times per year) if clinically indicated, to assess glycemic control over time. (no grade)**
* **Page 46: The target range for glycemic control should be individualized, based on the provider's appraisal of the risk-benefit ratio and discussion of the target with the individual patient. (Recommendation Grade: C)**

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

**American Diabetes Association – 2014:**

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| **Level of Evidence** | **Description** |
| **E** | **Expert consensus or clinical experience** |

**American Geriatrics Society**

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| **Level of Evidence** | **Description** | |
| **Strength of Evidence** | | |
| **A** | | **Good evidence to support the use of a recommendation; clinicians should do this all the time** |
| **B** | | **Moderate evidence to support the use of a recommendation; clinicians should do this most of the time** |
| **Quality of Evidence** | | |
| **Level II** | | **Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series studies, or from**  **dramatic results in uncontrolled experiments** |
| **Level III** | | **Evidence from respected authorities based on clinical experience, descriptive studies, or**  **reports of expert committees** |

**Department of Veterans Affairs/Department of Defense – 2010:**

|  |  |
| --- | --- |
| **Final Grade** | **Description** |
| **C** | **A recommendation that the intervention may be considered** |

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

**American Diabetes Association – 2014:**

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| **Level of Evidence** | **Description** |
| **A** | **Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted multicenter trial,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Center for Evidence-Based Medicine at the University of Oxford** |
| **Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted trial at one or more institutions,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **B** | **Supportive evidence from well-conducted cohort studies:**   * **Evidence from a well-conducted prospective cohort study or registry,** * **Evidence from a well-conducted meta-analysis of cohort studies** |
| **Supportive evidence from a well-conducted case-control study** |
| **C** | **Supportive evidence from poorly controlled or uncontrolled studies:**   * **Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results** * **Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)**   **Evidence from case series or case reports** |
| **Conflicting evidence with the weight of evidence supporting the recommendation** |

**American Geriatrics Society**

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| **Level of Evidence** | **Description** |
| **Strength of Evidence** | |
| **A** | **Good evidence to support the use of a recommendation; clinicians should do this all the time** |
| **B** | **Moderate evidence to support the use of a recommendation; clinicians should do this most of the time** |
| **Quality of Evidence** | |
| **Level II** | **Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series studies, or from**  **dramatic results in uncontrolled experiments** |
| **Level III** | **Evidence from respected authorities based on clinical experience, descriptive studies, or**  **reports of expert committees** |

**Department of Veterans Affairs/Department of Defense – 2010:**

|  |  |
| --- | --- |
| **Final Grade** | **Description** |
| **A** | **A strong recommendation that the intervention is always indicated and acceptable** |
| **B** | **A recommendation that the intervention may be useful/effective** |
| **D** | **A recommendation that a procedure may be considered not useful/effective, or may be**  **harmful** |
| **I** | **Insufficient evidence to recommend for or against – the clinician will use clinical judgment** |

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

**Not applicable.**

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

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**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

**Not applicable.**

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

**Not applicable.**

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

**Not applicable.**

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

**Not applicable.**

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

**Not applicable.**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

**Not applicable.**

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

**Not applicable.**

***Complete section*** [***1a.7***](#Section1a7)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

**The evidence review focused on the treatment of diabetes.**

**American Diabetes Association, 2014:**

**The American Diabetes Association recommends that HbA1c testing should be performed in all patients with a diagnosis of diabetes mellitus, both at initial assessment and during continuing care. Measurement should be completed approximately every 3 months to determine whether a patient’s individualized targets have been met. HbA1c monitoring may be more or less frequent dependent on the physician’s judgment and the patient’s specific needs.**

**Department of Veterans Affairs/Department of Defense, 2010:**

**This evidence is structured on measuring blood glucose or HbA1c for glycemic control in adults with diabetes. Monitoring of blood glucose can be conducted by patients through self-monitoring (SBGM) or by the provider through point of care treatment (PoCT). Self-monitoring includes using at home blood glucose tests for continuous measuring of glucose levels. HbA1c tests are conducted or ordered by a provider to measure the average blood glucose over a three month period. Results from monitoring assist providers and patients with maintaining or improving glycemic control and reducing complications from diabetes.**

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

**American Diabetes Association:**

|  |  |
| --- | --- |
| **Overall Quality** | |
| **Level** | **Description** |
| **E** | **Expert consensus or clinical experience** |

**American Geriatrics Society**

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| **Level of Evidence** | **Description** | |
| **Strength of Evidence** | | |
| **A** | | **Good evidence to support the use of a recommendation; clinicians should do this all the time** |
| **B** | | **Moderate evidence to support the use of a recommendation; clinicians should do this most of the time** |
| **Quality of Evidence** | | |
| **Level II** | | **Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series studies, or from**  **dramatic results in uncontrolled experiments** |
| **Level III** | | **Evidence from respected authorities based on clinical experience, descriptive studies, or**  **reports of expert committees** |

**Department of Veterans Affairs/Department of Defense Grading System:**

|  |  |
| --- | --- |
| **Strength of Evidence** | |
| **Level** | **Description** |
| **C** | **No recommendation for or against the routine provision of the intervention is made (at least fair evidence was found that the intervention can improve health outcomes, but concludes that the balance of benefits and harms is too close to justify a general recommendation)** |

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

**American Diabetes Association Grading System:**

|  |  |
| --- | --- |
| **Level of Evidence** | **Description** |
| **A** | **Clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted multicenter trial,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **Compelling nonexperimental evidence, i.e., “all or none” rule developed by the Center for Evidence-Based Medicine at the University of Oxford** |
| **Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including:**   * **Evidence from a well-conducted trial at one or more institutions,** * **Evidence from a meta-analysis that incorporated quality ratings in the analysis** |
| **B** | **Supportive evidence from well-conducted cohort studies:**   * **Evidence from a well-conducted prospective cohort study or registry,** * **Evidence from a well-conducted meta-analysis of cohort studies** |
| **Supportive evidence from a well-conducted case-control study** |
| **C** | **Supportive evidence from poorly controlled or uncontrolled studies:**   * **Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results** * **Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)**   **Evidence from case series or case reports** |
| **Conflicting evidence with the weight of evidence supporting the recommendation** |

**American Geriatrics Society**

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| **Level of Evidence** | **Description** |
| **Strength of Evidence** | |
| **A** | **Good evidence to support the use of a recommendation; clinicians should do this all the time** |
| **B** | **Moderate evidence to support the use of a recommendation; clinicians should do this most of the time** |
| **Quality of Evidence** | |
| **Level II** | **Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series studies, or from**  **dramatic results in uncontrolled experiments** |
| **Level III** | **Evidence from respected authorities based on clinical experience, descriptive studies, or**  **reports of expert committees** |

**Department of Veterans Affairs/Department of Defense Grading System:**

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| --- | --- |
| **Strength of Evidence** | |
| **Level** | **Description** |
| **A** | **A strong recommendation that clinicians provider the intervention to eligible patients (good evidence was found that the intervention improves important health outcomes and concludes that benefits substantially outweigh harm)** |
| **B** | **A recommendation that clinicians provide the service to eligible patients (at least fair evidence was found that the invention improves health outcomes and concludes that benefits outweigh harm)** |
| **D** | **Recommendation is made against routinely providing the intervention to asymptomatic patients (at least fair evidence was found that the intervention is ineffective or that harm outweigh benefits)** |
| **I** | **The conclusion is that the evidence is insufficient to recommend for or against routinely providing the intervention (evidence that the intervention is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined)** |

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| **Quality of Evidence** | |
| **Level** | **Description** |
| **I** | **At least one properly done randomized controlled trial** |
| **II-1** | **Well-designed controlled trial without randomization** |
| **II-2** | **Well-designed cohort or case-control analytic study** |
| **II-3** | **Multiple time series, dramatic results of uncontrolled experiment** |
| **III** | **Opinion of respected authorities, case report, and expert committees** |

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| **Overall Quality** | |
| **Level** | **Description** |
| **Fair Grade Evidence**  **(I or II-1)** | **Linked to intermediate outcome** |
| **Moderate Grade Evidence**  **(II-2 or II-3)** | **Directly linked to health outcome** |
| **Good** | **High grade evidence (I or II-1) directly linked to health outcome** |
| **Poor** | **Level III evidence or no linkage of evidence to health outcome** |

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| **Net Effect of the Intervention** | |
| **Level** | **Description** |
| **Substantial** | **More than a small relative impact on a frequent condition with a substantial burden of suffering OR a large impact on an infrequent condition with a significant impact on the individual patient level** |
| **Moderate** | **A small relative impact on a frequent condition with a substantial burden of suffering; OR a moderate impact on an infrequent condition with a significant impact on the individual patient level** |
| **Small** | **A negligible impact on a frequent condition with a substantial burden of suffering; OR a small impact on an infrequent condition with a significant impact on the individual patient level** |
| **Zero or Negative** | **Negative impact on patients; OR no relative impact on either a frequent condition with a substantial burden of suffering; OR infrequent condition with a significant impact on the individual patient level** |

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**:

**American Diabetes Association: 1985-2008**

**Department of Veterans Affairs/Department of Defense: 1997 - 2008**

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

**American Diabetes Association:**

**Evidence evaluating HbA1c recommendations:**

* **1 randomized controlled trial**
* **1 multicenter clinical trial**
* **1 meta-analysis**

**Department of Veterans Affairs/Department of Defense, 2010:**

* **Periodic HbA1c measurements: over 20 studies including 14 randomized controlled trials, 4 descriptive prospective studies, 1 comparative retrospective study, clinical trials, observational studies, epidemiological data, and literature reviews (amount unspecified for the preceding study designs)**
* **Instruction in interpretation and use of SBGM: over 20 randomized controlled trials, clinical trials, and literature reviews**
* **Self-blood glucose monitoring in non-insulin requiring type 2 diabetics to adjust treatment: over 20 studies including randomized controlled trials**
* **Utilizing remote self-blood glucose monitoring data: over 40 randomized controlled trials**

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

**American Diabetes Association:**

**The American Diabetes Association gave the recommendation a grade of [E], meaning that the recommendation is supported through expert consensus or clinical experience.**

**Department of Veterans Affairs/Department of Defense, 2010:**

**Overall, the quality of evidence supporting this measure is strong. There are over 100 studies in the evidence review that examine the effectiveness of measuring HbA1c or blood glucose and glycemic control. The evidence for periodic HbA1c measurements is strong. The Department of Veterans Affairs evidence review gave this recommendation the following grading: LE=II, QE=fair, SR=B. The fair rating for the quality of evidence (see 1a7.1 for quality grading) indicates that the evidence can be linked to the health outcome. The B grading for this evidence signifies that HbA1c testing may be useful or effective. Furthermore, the level of evidence indicates that the studies used were well designed controlled trials, cohort or case controlled studies, or included multiple time series.**

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

**American Diabetes Association:**

**One study was conducted on type 1 diabetic patients greater than 25 years of age. Those who used HbA1c testing and intensive insulin therapy experienced a 0.5% reduction in HbA1c level compared with those who strictly self-monitored their blood glucose level. Additionally, a meta-analysis showed that HbA1c test use is associated with a 0.26% reduction in HbA1c level.**

**Department of Veterans Affairs/Department of Defense, 2010:**

**Randomized clinical trials have demonstrated that improved glycemic control, as evidenced by reduced levels of glycohemoglobin, correlates with a reduction in the development of microvascular complications in both Type 1 and Type 2 diabetes (DCCT 1993, Ohkubo 1995). In particular, the Diabetes Control and Complications Trial (DCCT) showed that for patients with Type 1 diabetes mellitus, important clinical outcomes such as retinopathy (an important precursor to blindness), nephropathy (which precedes renal failure), and neuropathy (a significant cause of foot ulcers and amputation in patients with diabetes) are directly related to level of glycemic control (DCCT 1993). Similar reductions in complications were noted in a smaller study of intensive therapy of patients with Type 2 diabetes by Ohkubo and co-workers, which was conducted in the Japanese population (Ohkubo 1995).**

**Based primarily on the strength of the DCCT study and the corroborating evidence, most experts agree that control of glycemia as measured by glycohemoglobin is an important way to minimize the incidence of the microvascular complications of diabetes (ADA 2013). Consequently, based on the findings of the DCCT and UKPDS, many organizations in this country published guidelines for the achievement of good metabolic control in diabetes (ADA 2013).**

**Citation:**

**Ohkubo, Y., Kishikawa, H., Araki, E. et al. (1995) Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. Diabetes Research and Clinical Practice. Volume 28, Issue 2, Pages 103-117.**

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**American Diabetes Association:**

**No harms associated with testing were identified in the evidence reviewed. However, it is recommended that psychological assessment and treatment be included in routine care. One study found that 44.6% of participating patients experienced diabetes-related distress, yet only 23.7% were asked how diabetes impacted their life (Nicolucci et al. 2013).**

**Department of Veterans Affairs/Department of Defense, 2010:**

**No harms associated with testing were identified in the evidence reviewed. However, there are potential harms that may stem from a program of Hba1c testing followed by tight control. This tight glycemic control may result in episodes of hypoglycemia. One study concludes that intensive glycemic control does not seem to reduce all-cause mortality in patients with type 2 diabetes. Data available from randomized clinical trials remain insufficient to prove or refute a relative risk reduction for cardiovascular mortality, non-fatal myocardial infarction, composite microvascular complications, or retinopathy at a magnitude of 10%. Intensive glycemic control increases the relative risk of severe hypoglycaemia by 30% (Hemmingsen et al. 2011).**

**Citation**

**Hemmingsen, B. et al. (2011) Intensive glycemic control for patients with type 2 diabetes: systematic review with meta-analysis and trial sequential analysis of randomized clinical trials. BMJ 2011; 343:d6898. https:// http://dx.doi.org/10.1136/bmj.d6898**

**Nicolucci A, Kovacs Burns K, Holt RI, et al. (2013) DAWN2 Study Group. Diabetes Attitudes, Wishes and Needs second study (DAWN2\_): cross-national benchmarking of diabetes-related psychosocial outcomes for people with diabetes. Diabet Med 2013;30:767–777**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

**There have been no new studies that contradict the current body of evidence.**

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

**Not Applicable.**

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

**Not Applicable.**