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

**Measure Number** (*if previously endorsed*)**: 2608 (New Measure)**

**Measure Title**:  **Diabetes Care for People with Serious Mental Illness: Hemoglobin A1c (HbA1c) Control <8.0%**

**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*): **Hemoglobin A1c (HbA1c) <8.0% for patients with serious mental illness and diabetes**

Process: Click here to name the process

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: Patient with a serious mental illness (schizophrenia, bipolar I disorder, or major depression) and diabetes → HbA1c test performed → HbA1c results are less than 8.0% → HbA1c health provider determines treatment plan to maintain or lower HbA1c to desirable level → Improvement in HbA1c level and/or quality of life improved (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 Association of Clinical Endocrinologists. (2011) Diabetes Care Plan Guidelines. Endocrine Practice. 17: 1-53. URL: https://www.aace.com/files/dm-guidelines-ccp.pdf**

**American Diabetes Association. (2014) Standards of Medical Care in Diabetes. Guideline available from:** [**http://care.diabetesjournals.org/content/37/Supplement\_1/S14.full.pdf+html**](http://care.diabetesjournals.org/content/37/Supplement_1/S14.full.pdf+html)**, accessed June 23, 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 Veterans Affairs/Department of Defense. (2010) Department of Defense clinical practice guideline for the management of diabetes mellitus. Department of Veteran Affairs, Department of Defense. Washington (DC): Department of Veteran Affairs, Department of Defense; 2010 Aug. 146 p 42, 46.**

**URL: 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 Association of Clinical Endocrinologists (Guidelines) – 2011**

**Page 8:**

* **Glucose targets should be individualized and take into account residual life expectancy, duration of disease, presence or absence of microvascular complications, cardiovascular risk factors, comorbid conditions, and risk for severe hypoglycemia. Glucose targets should also be formulated in the context of the patient’s psychological, social, and economic status (Grade A; BEL 1). In general, therapy should target an HbA1c level of 6.5% or less for most nonpregnant adults, if it can be achieved safely. (Recommendation Grade: D, BEL 4)**
* **In adults with recent onset of Type 2 diabetes and no clinically significant cardiovascular disease, HbA1c control aimed at normal (or near-normal) HbA1c may be considered, with the aim of preventing the development of microvascular (Recommendation Grade: A, BEL 1) and macrovascular complications over a lifetime, if it can be achieved without substantial hypoglycemia or other unacceptable adverse consequences. Although it is uncertain that the clinical course of established cardiovascular disease is improved by strict HbA1c control, the progression of microvascular complications clearly is benefitted. (Recommendation Grade: A, BEL 1) In certain patients, a less stringent goal may be considered (HbA1c 7%-8%). (Recommendation Grade A, BEL 1) Such individuals those with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, extensive comorbid conditions, or long-standing diabetes in which the general goal has been difficult to attain, despite intensive efforts. (Recommendation Grade: A; BEL 1)**

**American Diabetes Association (Standards of Care) – 2014**

**Pages S22-S23:**

* **Lowering HbA1c to below or around 7% has been shown to reduce microvascular complications of diabetes, and if implemented soon after the diagnosis of diabetes, is associated with long-term reduction in macrovascular disease. (Recommendation Grade: B)**
* **Providers might reasonably suggest a more stringent HbA1c goal (such as <6.5%) for selected individual patients; if this can be achieved without significant hypoglycemia or other adverse effects of treatment. Appropriate patients might include those with a short duration of diabetes, long life expectancy, and no significant cardiovascular disease. (Recommendation Grade: C)**
* **Less stringent HbA1c goals (such as <8%) may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, and extensive comorbid conditions and in those with long-standing diabetes in whom the general goal is difficult to attain despite DSME, appropriate glucose monitoring, and effective doses of multiple glucose-lowering agents including insulin. (Recommendation Grade: B)**

**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. (IA 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: IIA)**

**Department of Veterans Affairs/Department of Defense (Guidelines) – 2010**

**Pages 42, 46:**

* **Page 46: The target range for HbA1c 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)**
* **Page 46: Any patient with diabetes should have an HbA1c target of <9 percent to reduce symptoms of hyperglycemia. (Recommendation Grade: C)**
* **Page 46: The patient with longer duration diabetes (more than 10 years) or with comorbid conditions, and who require combination medication regimen including insulin, should have an HbA1c target of <8 percent. (Recommendation Grade: A)**
* **Page 46: The patient with advanced microvascular complications and/or major comorbid illness, and/or a life expectancy of less than 5 years is unlikely to benefit from aggressive glucose lowering management and should have an HbA1c target of 8 to 9 percent. (Recommendation Grade: A)**

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

**American Association of Clinical Endocrinologists - 2011**

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| --- | --- | --- | --- | --- |
| **Best Evidence Level (BEL)** | **Subjective Factor Impact** | **Two-thirds Consensus** | **Mapping** | **Recommendation Grade** |
| **1** | **None** | **Yes** | **Direct** | **A** |
|  |  |  |  |  |
| **4** | **None** | **Yes** | **Direct** | **D** |

**American Diabetes Association Grading System:**

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| --- | --- |
| **Level of Evidence** | **Description** |
| **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** |

**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 Association of Clinical Endocrinologists - 2011**

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| --- | --- | --- | --- | --- |
| **Best Evidence Level (BEL)** | **Subjective Factor Impact** | **Two-thirds Consensus** | **Mapping** | **Recommendation Grade** |
| **2** | **Positive** | **Yes** | **Adjust Up** | **A** |
|  |  |  |  |  |
| **2** | **None** | **Yes** | **Direct** | **B** |
| **1** | **Negative** | **Yes** | **Adjust Down** | **B** |
| **3** | **Positive** | **Yes** | **Adjust Up** | **B** |
|  |  |  |  |  |
| **3** | **None** | **Yes** | **Direct** | **C** |
| **2** | **Negative** | **Yes** | **Adjust Down** | **C** |
| **4** | **Positive** | **Yes** | **Adjust Up** | **C** |
|  |  |  |  |  |
| **3** | **Negative** | **Yes** | **Adjust Down** | **D** |
|  |  |  |  |  |
| **1,2,3,4** | **Not Applicable** | **No** | **Adjust Down** | **D** |

**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 non-experimental 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** |
| **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 Veteran’s Affairs/Department of Defense – 2010**

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| --- | --- |
| **Final Grade** | **Description** |
| **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 American Association for Clinical Endocrinologists, American Diabetes Association and Department of Veterans Affairs/Department of Defense recommend monitoring HbA1c levels and use the guideline to assist providers and patients with maintaining or improving HbA1c control, thus reducing complications from diabetes.**

**American Association for Clinical Endocrinologists:**

**While individuals should strive for an HbA1c level of 6.5% or less, glucose targets should ultimately be individualized and take into account age, life expectancy, complications, and hypoglycemia risk.**

**American Diabetes Association:**

**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:**

**The evidence points to monitoring of HbA1c levels as key in assisting providers and patients with maintaining or improving HbA1c control, and reducing complications from diabetes.**

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

**American Association of Clinical Endocrinologists Grading System:**

|  |  |
| --- | --- |
| **Level** | **Description** |
| **A** | * **best evidence level – 1; no subjective factor impact; two-thirds consensus; direct mapping) OR** * **best evidence level-2; positive subjective factor impact; two thirds consensus; adjust up mapping** |
| **D** | * **best evidence level – 4; no subjective factor impact, two-thirds consensus, direct mapping,** * **best evidence level – 3; negative subjective factor impact; two-thirds consensus; adjust down mapping, OR** * **best evidence level – 1,2,3,4; N/A subjective factor impact, adjust down mapping** |

**American Diabetes Association:**

|  |  |
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| **Overall Quality** | |
| **Level** | **Description** |
| **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:**

|  |  |
| --- | --- |
| **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)** |
| **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 Association of Clinical Endocrinologists Grading System:**

|  |  |
| --- | --- |
| **Level** | **Description** |
| **B** | * **best evidence level – 2; no subjective factor impact; two-thirds consensus; direct mapping** * **best evidence level – 1; negative subjective factor impact; two-thirds consensus, adjust down mapping, OR** * **best evidence level – 3; positive subjective factor impact; two-thirds consensus; adjust up mapping** |
| **C** | * **best evidence level – 3; no subjective factor impact; two-thirds consensus; direct mapping,** * **best evidence level – 2; negative subjective factor impact; two-thirds consensus; adjust down mapping, OR** * **best evidence level – 4; positive subjective factor impact; two-thirds consensus; adjust up mapping** |

**American Diabetes Association Grading System:**

|  |  |
| --- | --- |
| **Level** | **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 non-experimental 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** |
| **E** | **Expert consensus or clinical experience** |

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

|  |  |
| --- | --- |
| **Strength of Evidence** | |
| **Level** | **Description** |
| **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** |

|  |  |
| --- | --- |
| **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** |

|  |  |
| --- | --- |
| **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 Association of Clinical Endocrinologists: 1993-2008**
* **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 Association of Clinical Endocrinologists:**

**Evidence evaluation HbA1c recommendations:**

* **1 meta-analysis of nonrandomized prospective or case-controlled trials**
* **5 meta-analyses of randomized controlled trials**
* **18 randomized controlled trials**
* **6 surveillance studies**
* **2 prospective cohort 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:**

* **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 self blood glucose monitoring: 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 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*)

**The overall quality of evidence for the measure focus is high and the evidence documented below includes several meta-analyses and systematic reviews containing RCTs with large sample sizes.**

**American Association of Clinical Endocrinologists:**

**Overall, the quality of evidence supporting this recommendation is strong built upon at least 1 meta-analysis of nonrandomized prospective or case-controlled trials, 5 meta-analyses of randomized controlled trials, 18 randomized controlled trials, 6 surveillance studies, and 2 prospective cohort study. However, it is important to note that clinical guidelines may vary on the optimal HbA1c level (giving allowance to patient difference and physician discretion).**

**American Diabetes Association:**

**The American Diabetes Association gave the recommendation a grade of [A], meaning that the recommendation is supported from clear evidence from well-conducted, generalizable randomized controlled trials that are adequately powered including evidence from a well-conducted multicenter trial and evidence from a meta-analysis that incorporated quality ratings in the analysis.**

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

**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 HbA1c control. The evidence for periodic HbA1c measurements is strong. The Department of Veterans Affairs/Department of Defense 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 Association of Clinical Endocrinologists:**

**Elevated HbA1c levels are strongly associated with both microvascular and macrovascular complications of diabetes. Accordingly, numerous studies have demonstrated that even minor reductions in glucose concentrations can lower the risk of microvascular complications. Although no randomized controlled trials establish a universal, optimal HbA1c target. Instead, HbA1c targets should generally be less than 7%.**

**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:**

**Randomized clinical trials have demonstrated that improved HbA1c control 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, 10% reduction in HbA1c level was contributed to a 40% to 50% reduction in both the incidence and progression of microalbuminuria and retinopathy. Additional studies have demonstrated that a 1% reduction in HbA1c levels contributed to a 37% decline in microvascular complications (such as retinopathy, nephropathy, and neuropathy) (UKPDS).**

**Citation:**

**Diabetes Control and Complications Trial Research Group (DCCT). (1993) The effect of intensive treatment of diabetes and progression of long-term complications in insulin-dependent mellitus. N Engl J Med 329:977-86.**

**Ohkubo T, 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 Res Clin Pract 28(2):103-17.**

**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 Association of Clinical Epidemiologists:**

**While patients should aim for ‘normal’ HbA1c levels, these target levels should be adjusted, as appropriate, to reduce the risk of hypoglycemia in patients with special circumstances (i.e. age, life expectancy, hypoglycemia unawareness).**

**American Diabetes Association:**

**When there exists a substantially increased risk of hypoglycemia due to strict reduction of HbA1c targets, the risks may outweigh the potential benefits of desirable HbA1c control.**

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

**No harms were associated with HbA1c testing and monitoring. However, in the evidence reviewed literature, there are some potential harms that may result from a regimen of HbA1c testing following by a period of tight control. Strict HbA1c control may, in some cases, result in episodes of hypoglycemia. One study concluded that intensive HbA1c 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 retinopathy at a magnitude of 10%. Intensive HbA1c control increases the relative risk of severe hypoglycemia by 30% (Hemmingsen, 2011).**

**Citation:**

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

**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**