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

**Measure Number** (*if previously endorsed*)**:** 0057

**Measure Title**: Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Testing

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Comprehensive Diabetes Care

**Date of Submission**: 4/9/2018

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *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.*   * 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. * 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 Standing 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:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * 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. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **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 Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **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

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.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

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

Process: Receiving a HbA1c test during the measurement year

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Adults with diabetes (type 1 or 2) >>> 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** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

N/A

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

Table 1. American Diabetes Association Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018  Diabetes Care (American Diabetes Association)  Standards of Medical Care in Diabetes-2018. Diabetes Care January 2018. 41 (Supp 1): S55-64. https://doi.org/10.2337/dc18-S006  URL: <http://diabetesed.net/wp-content/uploads/2017/12/2018-ADA-Standards-of-Care.pdf>  2013  Diabetes Care (American Diabetes Association)  Standards of Medical Care in Diabetes-2013. Diabetes Care January 2013 36:S1-e4; doi: 10.2337/dc13-S001  URL: <http://mcintranet.musc.edu/agingq3/calculationswesbite/ADA%20Guidelines/ADA%20Binder.pdf> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Recommendations (2018)   * Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control). E * Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals. E * Point-of-care testing for A1C provides the opportunity for more timely treatment changes. E   Recommendations (2013)  Same as above |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018  Level of Evidence & Description:  E Expert consensus or clinical experience  2013  Same as above |
| Provide all other grades and definitions from the evidence grading system | 2018  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., the “all or none” rule developed by the Centre for Evidence-Based Medicine at 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, including:   * 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, including:   * 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 to historical controls) * Evidence from case series or case reports   Conflicting evidence with the weight of evidence supporting the recommendation  2013  Same as above |
| Grade assigned to the **recommendation** with definition of the grade | 2018  No additional grading was provided, grades assigned to evidence is the same with grades assigned to recommendations.  2013  Same as above |
| Provide all other grades and definitions from the recommendation grading system | 2018  No additional grading was provided, grades assigned to evidence is the same with grades assigned to recommendations.  2013  Same as above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The ADA does not provide information on the systematic review conducted to support its guideline and the recommendations mentioned above. In lieu of the ADA systematic review, we provide information on two other systematic reviews that support the ADA’s recommendations in Table 3. |
| Estimates of benefit and consistency across studies | See Table 3. |
| What harms were identified? | See Table 3. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | There have been no new studies that contradict the current body of evidence. |
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| Table 2. American Geriatric Society Guidelines | |
| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018  American Geriatrics Society (AGS).  Guidelines Abstracted from the American Geriatrics Society Guidelines for Improving the Care of Older Adults with Diabetes Mellitus: 2013 Update. American Geriatrics Society Panel on the Care for Older Adults with Diabetes Mellitus. Journal of American Geriatric Society. 2013 November; 61 (11): 2020-2026. Doi:10.1111/jgs.12514 URL:  https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064258/pdf/nihms583558.pdf  2013  American Geriatric Society (AGS)  Guidelines for Improving Care of the Older Adults with Diabetes Mellitus.  California Healthcare Foundation/American Geriatric Society Panel on Improving Care for Elders with  Diabetes. American Geriatric Society. May 2003 – 51 (5) Supplement, JAGS. URL:  <http://www.medicine.emory.edu/ger/bibliographies/geriatrics/bibliography87_files/Guidelines_for_>  Improving\_the\_Care\_of\_the\_Older\_Person\_with\_Diabetes\_Mellitus.pdf |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Recommendations (2018)  Pg. 4  “Glycemic Control”  General Recommendations   1. 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. (IIA) 2. Older adults with DM whose individual targets are not being met should have their HbA1c levels measured at least every 6 months and more frequently as needed or indicated. For older adults with stable HbA1c over several years, measurement every 12 months may be appropriate. (IIIB)   Recommendations (2013)  Pg. S270  “Glycemic Control”  General Recommendations  1. For older persons, target hemoglobin A1c (A1C) should be individualized. A reasonable goal for A1C in relatively healthy adults with good functional status is 7% or lower. For frail older adults, persons with life expectancy of less than 5 years, and others in whom the risks of intensive glycemic control appear to outweigh the benefits, a less stringent target such as 8% is appropriate. (IIIB)” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018  Quality of Evidence   * Level II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, or 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 committee   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   2013  Same as above |
| Provide all other grades and definitions from the evidence grading system | 2018  Quality of Evidence   * Level I: Evidence from at least one properly designed randomized, controlled trial * Level II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, or from multiple time-series studies, or from dramatic results in uncontrolled experiments   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 * C: Poor evidence to support or to reject the use of a recommendation; clinicians may or may not follow the recommendation * D: Moderate evidence against the use of a recommendation; clinicians should not do this * E: Good evidence against the use of a recommendation; clinicians should not do this   2013  Same as above |
| Grade assigned to the **recommendation** with definition of the grade | 2018  No additional grading was provided, grades assigned to evidence is the same with grades assigned to recommendations.  2013  Same as above |
| Provide all other grades and definitions from the recommendation grading system | 2018  No additional grading was provided, grades assigned to evidence is the same with grades assigned to recommendations.  2013  Same as above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The AGS does not provide information on the systematic review conducted to support its guideline and the recommendations mentioned above. In lieu of the AGS systematic review, we provide information on two other systematic reviews that support the AGS’s recommendations in Table 3. |
| Estimates of benefit and consistency across studies | See Table 3. |
| What harms were identified? | See Table 3. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | There have been no new studies that contradict the current body of evidence. |

Table 3. Systematic Review

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| **Citation** | Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. 2010. Washington (DC): Department of Veteran Affairs, Department of Defense. Retrieved from <http://www.healthquality.va.gov/diabetes/DM2010_FUL-v4e.pdf>. |
| **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?** | The evidence for this measure is based on measurement of blood glucose or HbA1c to facilitate 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 to continuously measure 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. |
| **Grade assigned for the quality of the quoted evidence with definition of the grade** | Level of Evidence (LE)  I At least one properly done RCT  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  Quality of Evidence  Fair High grade evidence (I or II-1) linked to intermediate outcome; or Moderate grade evidence (II-2 or II-3) directly linked to health outcome  Strength of Recommendation  B A recommendation that the intervention may be useful/effective  C A recommendation that the intervention may be considered |
| **Provide all other grades and associated definitions of the evidence in the grading system** | Level of Evidence (QE)  III Opinion of respected authorities, case reports, and expert committees  Quality of Evidence  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  Strength of Recommendation  A A strong recommendation that the intervention is always indicated and acceptable  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   |  |  | | --- | --- | | Net Effect of the Intervention | | | 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 relative 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*  An infrequent condition with a significant impact on the individual  patient level. | |
| **What is the time period covered by the body of evidence?** | 1997-2008 |
| **Quantity and Quality of Body of Evidence** | Periodic HbA1c measurements: over 20 studies including 14 RCTs, 4 descriptive prospective studies, 1 comparative retrospective study, clinical trials, observational studies, epidemiological data, and literature reviews.  Instruction in interpretation and use of SBGM: over 20 RCTs, clinical trials, and literature reviews  SBGM in non-insulin requiring type 2 diabetics to adjust treatment: over 20 studies including RCTs  Utilizing remote SBGM data: over 40 RCTs |
| **What is the overall quality of evidence across studies in the body of evidence?** | 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 VA/DoD evidence review gave this recommendation the following grading: LE=II, QE=fair, SR=B. The fair rating for the quality of evidence (see 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 – what are the estimates of benefits?** | 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).  American Diabetes Association. Standards of Medical Care in Diabetes—2013 Diabetes Care January 2013 36:S11-S66; doi:10.2337/dc13-S011  The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes and progression of long-term complications in insulin-dependent mellitus. N Engl J Med 329:977-86, 1993. |
| **What harms were studied and how do they affect the net benefit (benefits over harms)?** | 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. Intensive glycemic control increases the relative risk of severe hypoglycemia by 30% (Hemmingsen et al. 2011).  Hemmingsen, B. et al. 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 |
| **Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?** | Numerous studies have been conducted since the systematic reviews we cite in this table, none of which change the conclusion that routine HbA1c testing for individuals with diabetes are appropriate. Below we list two additional studies that support this measure.  Perrotta PL, Jones R, Souers RJ, et al. Frequency of monitoring hemoglobin A1c, low density lipoprotein and urine protein laboratory testing. Archives of Pathology and Laboratory Medicine 2014; 138:1009-1014. doi: 10.5858/arpa.2013-0349-CP  Driskell OJ, Holland D, Waldron JL, et al. Reducing testing frequency for glycated hemoglobin HbA1c, is associated with deteriorating diabetes control. Diabetes Care 2014; 37(10):2731-2737. <https://doi.org/10.2337/dc14-0297> |

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**1a.4 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.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

N/A

**1a.4.2 What process was used to identify the evidence?**

N/A

**1a.4.3.** **Provide the citation(s) for the evidence.**

N/A