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

**Measure Number** (*if previously endorsed*)**:** Click here to enter NQF number

**Measure Title**: Intervention for Prediabetes

**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**: 4/9/2020

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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: Intervention for prediabetes: referral to a diabetes prevention program, medical nutritional therapy, or prescription for Metformin.

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.

**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.)

Individuals with prediabetes can mitigate their clinical and economic risks by participating in a structured, evidenced-based lifestyle change program (LCP), such as the one offered through the Centers for Disease Control and Prevention (CDC)–led National Diabetes Prevention Program (National DPP). CDC-recognized lifestyle change programs are included in the health benefit plans, including the Medicare Diabetes Prevention Program for Medicare beneficiaries.

Implementing this measure to increase treatment for patients with prediabetes can improve health outcomes for patients by preventing the progression to type 2 diabetes. Cost savings associated with preventing diabetes are significant. In the Medicare Diabetes Prevention Program (Medicare DPP) model test conducted through Center for Medicare and Medicaid Innovation, implementation of the MDPP preventive service resulted in an estimated cost savings of $ 2,650.00 per participating Medicare beneficiary over 15 months. Individuals with diabetes typically have medical expenses 2.3 times higher than those without it.

**\*\*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)**

x Clinical Practice Guideline recommendation (with evidence review)

x 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

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Siu L on behalf of the U. S. Preventive Services Taskforce. Screening for abnormal blood glucose and type 2 diabetes mellitus: U. S. Preventive Services Task Force recommendation. Ann Intern Med. 2015;163:861-868.  American Diabetes Association. Standards of medical care in diabetes—2018. Diabetes Care. 2018. (41) Supplement 1. Available at: <http://care.diabetesjournals.org>. |
| 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. | The following evidence statements are quoted **verbatim** from the referenced clinical guidelines and other sources, where applicable:  The USPSTF recommends screening for abnormal blood glucose as part of cardiovascular risk assessment in adults aged 40 to 70 years of age who are overweight or obese. Clinicians should offer or refer patients with abnormal blood glucose to intensive behavioral counseling interventions to promote a healthful diet and physical activity. (USPSTF, 20151) (B recommendation)  Patients with prediabetes should be referred to an intensive behavioral lifestyle intervention program modeled on the Diabetes Prevention Program to achieve and maintain 7% loss of initial body weight and increase moderate-intensity physical activity (such as brisk walking) to at least 150 min/week. (ADA, 20182) (A).  Metformin therapy for prevention of type 2 diabetes should be considered in those with prediabetes, especially for those with BMI ≥35 kg/m2, those aged <60 years, women with prior gestational diabetes mellitus (ADA, 20182) (A)  “As is the case for those with diabetes, individualized medical nutrition therapy (see Section 4 “Lifestyle Management” for more detailed information) is effective in lowering A1C in individuals diagnosed with prediabetes.”  Recommendation from Section 4: Lifestyle Management: An individualized MNT program, preferably provided by a registered dietitian, is recommended for all people with type 1 or type 2 diabetes or gestational diabetes mellitus. (ADA, 20182) (A) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | See above evidence statements with grades |
| Provide all other grades and definitions from the evidence grading system | USPSTF Grading:  A The USPSTF recommends the service. There is high certainty that the net benefit is substantial.  B The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.  C The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.  D The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.  I The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.  ADA Grading:  Grade 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 Centre 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   Grade 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   Grade 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   Grade E   * Expert consensus or clinical experience |
| Grade assigned to the **recommendation** with definition of the grade | B Recommendation-USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.  A Recommendation- ADA Guidelines   * 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 Centre for Evidence-Based Medicine at the University of Oxford * Supportive evidence from well-conducted randomized controlled trials that are adequately powered, including |
| Provide all other grades and definitions from the recommendation grading system | See above |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | In addition to the USPSTF and ADA guidelines, we reviewed and utilized over seven evidence-based peer reviewed journal articles that confirmed the gap in care around treatment for patients with diagnosed prediabetes. |
| Estimates of benefit and consistency across studies | This measure is based on evidence-based guidelines from the United States Preventive Services Task Force (USPSTF) and from the American Diabetes Association (ADA). Numerous other peer reviewed evidence-based publications exist on the treatment and management of patients with prediabetes. One of the largest publications to date comes from the January 2019 ADA Journal, Diabetes Care: Standards of Medical Care in Diabetes—2019[[1]](#endnote-1). This the largest compilation of evidence and recommendations for the diagnosis and treatment of patients with prediabetes and diabetes. Patients with prediabetes should be referred to an intensive behavioral lifestyle intervention program modeled on the Diabetes Prevention Program to achieve and maintain 7% loss of initial body weight and increase moderate-intensity physical activity (such as brisk walking) to at least 150 min/week. Metformin therapy for prevention of type 2 diabetes should be considered in those with prediabetes, especially for those with BMI ≥35 kg/m2, those aged <60 years, women with prior gestational diabetes mellitus. As is the case for those with diabetes, individualized medical nutrition therapy is effective in lowering A1C in individuals diagnosed with prediabetes. Lifestyle Management: An individualized MNT program, preferably provided by a registered dietitian, is recommended for all people with type 1 or type 2 diabetes or gestational diabetes mellitus. |
| What harms were identified? | None |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | None |

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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.

In additional to the above-referenced guidelines that support this measure, there are additional

studies in the literature that also support this measure:

**Mainous A G, Tanner R J, & Baker R. Prediabetes Diagnosis and Treatment in Primary Care. The**

**Journal of the American Board of Family Medicine. 2016. 29(2), 283–285.**

* Significant gaps exist in the treatment of patients that have prediabetes. Patients who are diagnosed with prediabetes benefit from referral to intervention programs, however research shows that most patients with prediabetes are not referred for intervention.
* Data support that there is room for improvement in providing patients with prediabetes an intervention.18% of patients had their blood glucose levels retested; 13% received a physician diagnosis of prediabetes/hyperglycemia; 31.0% had prediabetes, diabetes, or lifestyle documented in the clinical notes; and <0.1% initiated metformin, demonstrating a significant gap in treatment and management.
* Moreover, data from the 2012 National Ambulatory Medical Care Survey demonstrates that only 23% of visits that were associated with prediabetes showed that any type of referral or intervention was made.
* Another study in the American Journal of Preventive Medicine showed that only 23% of physicians report referring any patients to the DPP. 90% reported close follow up (within 6 months) of patients with preDM and11% selected referral to a behavioral weight loss program as the recommended initial management approach to preDM.

**Tseng E, Greer R C, O’Rourke P, Yeh, H-C, McGuire M M, Clark J M, & Maruthur N M. Survey of primary care providers’ knowledge of screening for, diagnosing and managing prediabetes.**

**Journal of General Internal Medicine 2017. 32(11), 1172–1178.**

* Specifically related to opportunities to improve referrals to DPPs, a study of primary care physicians. (PCPs) reported they provide referrals to DPPs on average to 45% of their newly diagnosed patients with pre-diabetes.

**Rehm C D, Marquez, M E, Spurrell-Hus, E, Hollingsworth N, & Parsons A S. Lessons from Launching the**

**Diabetes Prevention Program in a Large Integrated Health Care Delivery System: A Case Study.**

**Population Health Management. 2017. 20(4), 262–270.**

* This study identified data availability and the lack of a feedback loop between community-based DPPs and the health system as a major challenge. The placement rate for the YMCA’s DPP was 20.6%.
* Placement to the DPP increased to 22.1% when the DPP was brought within the health care system. 65%-76% of participants were still participating in the program by Week 9. 32%-37% were still participating in the program by Week 16.

**Chambers, E C, Rehm C D, Correra J, Garcia L E, Marquez M E, Wylie-Rosett, J, & Parsons A. Factors in**

**Placement and Enrollment of Primary Care Patients in YMCA’s Diabetes Prevention Program, Bronx,**

**New York, 2010–2015. Preventing Chronic Disease 2017. 14.**

* This study illustrated that 66% of those referred to a DPP were never placed in a DPP program, meaning they were referred but never enrolled in a session and 53% of those who were placed (meaning they were referred and attended at least one session) only attended fewer than 3 sessions.

**Ali M K, Echouffo-Tcheugui J B, & Williamson D F. How effective were lifestyle interventions in realworld settings that were modeled on the Diabetes Prevention Program? Health Affairs. 2012. 31(1); 67–75.**

* This meta-analysis examined 28 studies applying the findings of the DPP found significant variability in study attrition. Attrition rates ranged from 0% to 49%. There is strong evidence that individualized Medical Nutrition Therapy (MNT) provided by a registered dietitian nutritionist (RDN) is successful in deterring the progression of prediabetes to type 2 diabetes.
* Dietitians who provide individualized MNT demonstrate the use of the extended care team in partnering with patients to prevent type 2 diabetes.

**Ely EK, Gruss SM, Luman ET, Gregg EW, Ali MK, Nhim K, Rolka DB, Albright AL. A national effort to**

**prevent type 2 diabetes: participant-level evaluation of CDC’s National Diabetes Prevention Program.**

**Diabetes Care. 2017. Available at: https://doi.org/10.2337/dc16-2099.**

* Descriptive analysis on data from 14,747 adults enrolled in DPPs from February 2012 through January 2016.
* Participants attended a median of 14 sessions over an average 172 days in the program, 35.5% achieved the 5% weight loss goal. Weekly average of 152 minutes of physical activity with 41.8% meeting the physical activity goal of 150 minutes per week.

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

A thorough literature review was conducted to identify evidence-based guidelines and other evidence, gaps in care with supportive evidence, and gaps in measurement to support the identification of measure concepts.

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

Citations for the evidence are provide in 1a.4.1

1. Diabetes Care Jan 2019, 42 (Supplement 1) S184-S186; **DOI:** 10.2337/dc19-Sdis01 [↑](#endnote-ref-1)