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

**Measure Number** (*if previously endorsed*)**:** 0056

**Measure Title**: Diabetes: Foot Exam

**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**: 4/9/2018

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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: Diabetic Foot Exam

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) >>> foot exam (visual inspection with sensory and pulse exam)>>> Exam results are evaluated >>>Results indicative of improper foot care >>>Health provider determines treatment to prevent further damage to the foot, such as possible infections or amputations>>>improvement in diabetes complications and quality of life.

**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 (ADA) Guidelines

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  American Diabetes Association. (2018). Standards of Medical Care in Diabetes – 2018. Diabetes Care 2018; 41(Suppl. 1): S105-S118; doi: 10.2337/dc18-S010  Guideline available from:  <http://care.diabetesjournals.org/content/41/Supplement_1>  2013 Submission  American Diabetes Association. (2013). Standards of Medical Care in Diabetes – 2013. Diabetes Care 2013; 36:S1-e4; doi: 10.2337/dc13-S001  Guideline available from:  <http://care.diabetesjournals.org/content/36/Supplement_1/S11> |
| 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. | 2018 Submission   * Perform a comprehensive foot evaluation at least annually to identify risk factors for ulcers and amputations. B * All patients with diabetes should have their feet inspected at every visit. C * Obtain a prior history of ulceration, amputation, Charcot foot, angioplasty or vascular surgery, cigarette smoking, retinopathy, and renal disease and assess current symptoms of neuropathy (pain, burning, numbness) and vascular disease (leg fatigue, claudication). B * The examination should include inspection of the skin, assessment of foot deformities, neurological assessment (10-g monofilament testing with at least one other assessment: pinprick, temperature, vibration), and vascular assessment including pulses in the legs and feet. B * Patients with symptoms of claudication or decreased or absent pedal pulses should be referred for anklebrachial index and for further vascular assessment as appropriate. C * A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet (e.g., dialysis patients and those with Charcot foot, prior ulcers, or amputation). B * Refer patients who smoke or who have histories of prior lower-extremity complications, loss of protective sensation, structural abnormalities, or peripheral arterial disease to foot care specialists for ongoing preventive care and life-long surveillance. C * Provide general preventive foot self-care education to all patients with diabetes. B * The use of specialized therapeutic footwear is recommended for highrisk patients with diabetes including those with severe neuropathy, foot deformities, or history of amputation. B   2013 Submission  Pg S8-S9   * “For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and testing for loss of protective sensation (LOPS) (10-g monofilament plus testing any one of the following: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold). (B) * Provide general foot self-care education to all patients with diabetes. (B) * A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (B) * Refer patients who smoke, have LOPS and structural abnormalities, or have a history of prior lower-extremity complications to foot care specialists for ongoing preventive care and lifelong surveillance. (C) * Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with PAD are asymptomatic. (C) * Refer patients with significant claudication or a positive ABI for further vascular assessment and consider exercise, medications, and surgical options. (C)” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  Level of evidence and description:   * 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   * + 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 Submission  Same as above |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  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 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 * E:   Expert consensus or clinical experience  2013 Submission  Same as above |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described 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 2018 or 2013 guideline and the recommendations mentioned above. In lieu of the ADA systematic review, we provide information on one other systematic review that support the ADA’s recommendations in Table 4. |
| Estimates of benefit and consistency across studies | See Table 3 below |
| What harms were identified? | See Table 3 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

Table 2. American Geriatrics Society (AGS)

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | 2018 Submission  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. 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 Submission  American Geriatrics Society (AGS). 2003. Guidelines for Improving the Care of the Older Person with Diabetes Mellitus. California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes. American Geriatrics Society. May 2003; 51, Suppl 5, JAGS  URL |
| 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. | 2018 Submission   * Older adults with DM should have a careful foot examination at least annually to check skin integrity and to determine whether there is loss of sensation or decreased perfusion and more frequently if there is evidence of any of these findings (IIIA)   2013 Submission  Pg S272   * “The older adult who has DM should have a careful foot examination at least annually to check skin integrity and to determine whether there is bony deformity, loss of sensation, or decreased perfusion and more frequently if there is evidence of any of these findings. (IIIA) There are no RCT data to support examination of the feet at regular intervals to prevent lower-extremity ulceration or amputation, but a randomized trial of an intervention consisting of patient and provider foot-care education and a team approach to foot care found an increase in rates of foot examinations at routine office visits and a reduction in serious foot lesions (odds ratio (OR) = 0.41, *P* =.05). In addition, several uncontrolled studies have found a reduction in rates of amputation after implementation of comprehensive foot-care programs. Regular foot examinations permit identification of diabetic neuropathy and foot lesions and may in turn prevent progression to ulcers and amputation, but there are no data to support the optimal interval for evaluation. Most current recommendations specify that the foot examination should be done at all nonurgent outpatient visits. Quality of evidence is level II for more frequent examinations for persons at high risk for foot problems and level III for routine annual screening.” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | 2018 Submission  Quality of Evidence   * Level III: Evidence from respected authorities based on clinical experience, descriptive studies, or reports of expert committees   Strength of Evidence   * A: Good evidence to support the use of a recommendation; clinicians should do this all the time   2013 Submission  Same as above |
| Provide all other grades and definitions from the evidence grading system | 2018 Submission  Quality of Evidence   * Level I: Evidence from at least one properly randomized controlled trial * Level II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytical studies, from multiple time-series, or from dramatic results in uncontrolled experiments   Strength of Evidence   * 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 Submission  Same as above |
| Grade assigned to the **recommendation** with definition of the grade | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described above |
| Provide all other grades and definitions from the recommendation grading system | 2018 Submission  No additional grading was provided for the recommendations aside from what is described above  2013 Submission  No additional grading was provided for the recommendations aside from what is described 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 4. |
| Estimates of benefit and consistency across studies | See Table 3 below |
| What harms were identified? | See Table 3 below |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | N/A |

Table 3. Additional Systematic Reviews

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| **Citations** | Singh, N., Armstrong, D. G., & Lipsky, B. A. (2005). Preventing foot ulcers in patients with diabetes. *JAMA: the journal of the American Medical Association*,*293*(2), 217-228. |
| **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?** | This systematic evidence review focused on the efficacy of methods advocated for preventing diabetic foot ulcers. We will present the evidence for the efficacy of screening to identify patients at risk for diabetic foot ulcers and two specific clinical interventions to prevent foot ulcers (foot examination by a clinician and foot specialist/multidisciplinary care team). Additional information (not presented here) can be found in the review on the effectiveness of optimizing glycemic control, smoking cessation, custom footwear, debridement of calluses, and surgery on reducing the incidence of foot ulcers. |
| **Grade assigned for the quality of the quoted evidence with definition of the grade** | No grading provided. |
| **Provide all other grades and associated definitions of the evidence in the grading system** | N/A |
| **What is the time period covered by the body of evidence?** | 1980-2004 |
| **Quantity and Quality of Body of Evidence** | Studies related to efficacy of screening to identify patients at risk for diabetic foot ulcer: 5 prospective cohort studies; 2 case control studies  Studies related to clinical interventions to prevent food ulceration: 3 RCTs; 1 case-control; 1 cohort study |
| **What is the overall quality of evidence across studies in the body of evidence?** | The authors of the review did not comment on the quality of the evidence related to efficacy of screening to identify patients at risk for foot ulcers. However, authors concluded the evidence from the seven studies of screening test efficacy was strong enough to support the use of screening to identify patients at risk.  The case-control study of the effectiveness of foot examination by a clinician did not show any significant reduction in amputation among 244 diabetic patients (OR 0.55; 95% CI, 0.2-1.7; P=.31). However, the study was limited by high rates of foot examination in both case and control patients, different degree of risk between the groups as well as the unusually high rates of diabetes and amputation among the Pima Indian population included in the study.  The three RCTs of clinician and specialist intervention were of reasonable size (N=91-498) and good quality. |
| **Estimates of benefit and consistency across studies in body of evidence – what are the estimates of benefits?** | Evidence related to efficacy of screening to identify patients at risk for diabetic foot ulcer: The authors summarized the efficacy of different screening methods in the table below. They conclused that the monofilament test is the most validated test, however the number of test sites needed for the test is still unclear. The Biothesiometer test has similar accuracy to the monofilament test, but is not as widely available. The Tuning form and pressure mat tests are not as accurate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Screening Method to Identify Patients at Risk for Diabetic Foot Ulcer | Monofilament (Light Touch Sensation) | Biothesiometer (Vibratory Sensation) | Tuning Fork (Vibratory Sensation) | Pressure Mat or Platform (Plantar Pressure) | | Sensitivity, % | 66-91 | 83-86 | 55-61 | 57-64 | | Specificity, % | 34-86 | 57-63 | 59-72 | 46-70 | | Positive Predictive Value % | 18-39 | 20-32 | 16 | 17-31 | | Negative Predictive Value % | 94-95 | 95-97 | 93 | 82-90 |   Evidence Related to Clinical interventions to prevent food ulceration: One randomized study of diabetic persons (N=91) with a previous foot ulceration found a significantly reduced risk for ulceration recurrence (RR, 0.52; 95% CI, 0.29-0.93; P = .03) at 1 year for those who received routine podiatric care. In another randomized study trial of diabetic persons with neuropathy (N=498), patients randomized to receive podiatric care at least twice a year had no difference in the incidence of foot ulcers compared to usual care, but fewer deep ulcers (6 vs 12), infected ulcers (1 vs 10; P\_.01), and hospital admission days (24 vs 346; P\_.01) compared to usual care patients. A cohort study included diabetic persons (N=341) who were examined to categorize baseline risk, initiate appropriate education and interventions, and schedule follow-up foot examinations and podiatric care with a multidisciplinary team. After 3 years, the incidence of lower-extremity amputation was only 1.1 per 1000 persons per year. Among high-risk persons, those who missed more than 50% of their appointments with the team were 54 times more likely to develop an ulcer and 20 times more likely to require an amputation than those who kept most appointments. |
| **What harms were studied and how do they affect the net benefit (benefits over harms)?** | There were no harms to screening or clinician examination reported in the review. |
| **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 review we cite in this table, none of which change the conclusion that routine foot exams for individuals with diabetes are appropriate. Below we list two additional studies that support this measure.  Sloan FA, Feinglos MN, Grossman DS. Receipt of care and reduction of lower extremity amputations in a nationally representative sample of U.S. Elderly. Health Serv Res. 2010;45(6 pt 1):1740-1762.  Carls GS, Gibson TB, Driver VR, et al. The economic value of specialized lower-extremity medical care by podiatric physicians in the treatment of diabetic foot ulcers. J Am Podiatr Med Assoc. 2011;101:93-115. |

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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.*

N/A

**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?**

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

N/A