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

**Measure Number** (*if previously endorsed*)**:** 0416

**Measure Title**: **Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear**

**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**: 6/6/2014

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

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

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

Outcome

Health outcome: Click here to name the health outcome

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

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

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

Process: Evaluation of footwear in people with diabetes to ensure proper fit

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.**

**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*).**

*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**. People with diabetes are at increased risk for foot ulcerations. Mechanical factors that cause physical irritation to the foot can be a contributing factor towards development of foot ulcerations. People with diabetes and peripheral neuropathy often cannot feel this mechanical irritation and are not aware that their shoes do not fit properly. Periodic evaluation of footwear in people with diabetes can help reduce ulcerations by making sure that the proper size and type of shoe is worn by the person with diabetes to protect the foot. Decreasing ulcerations decreases amputations.

**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*):

**Comprehensive Foot Examination and Risk Assessment**

A report of the Task Force of the Foot Care Interest Group of the American Diabetes Association, with endorsement by the American Association of Clinical Endocrinologists

**ANDREW J.M. BOULTON, MD, FRCP,1,2; DAVID G. ARMSTRONG, DPM, PHD 3; STEPHEN F. ALBERT, DPM, CPED 4; ROBERT G. FRYKBERG, DPM, MPH, 5; RICHARD HELLMAN, MD, FACP, 6,7; M. SUE KIRKMAN, MD, 8; LAWRENCE A. LAVERY, DPM, MPH, 9;**

**JOSEPH W. LEMASTER, MD, MPH, 10; JOSEPH L. MILLS, SR., MD, 11; MICHAEL J. MUELLER, PT, PHD, 12; PETER SHEEHAN, MD, 13; DANE K. WUKICH, MD, 14**

DIABETES CARE, VOLUME 31, NUMBER 8, AUGUST 2008

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

Pages 1679-80

“Because inappropriate footwear and foot deformities are common contributory factors in the development of foot ulceration (1,5), the shoes should be inspected and the question “Are these shoes appropriate for these feet?” should be asked.

Examples of inappropriate shoes include those that are excessively worn or are too small for the person’s feet (too narrow, too short, toe box too low), resulting in rubbing, erythema, blister, or callus.”

1. Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM: Preventive foot care in people with diabetes. *Diabetes Care* 21:2161–2177, 1998

5. Reiber GE, Vileikyte L, Boyko EJ, del Aguila M, Smith DG, Lavery LA, Boulton AJ: Causal pathways for incident lower extremity ulcers in patients with diabetes from two settings. Diabetes Care 22:157– 162, 1999

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

Expert panel recommendation

**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.*)

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

**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*):

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

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

**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.*)

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

***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*):

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

***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.*

There is not a lot of published literature examining if people with diabetes wear the proper sized shoe, however, poor shoe fit is known to be a contributory factor to the development of diabetic foot ulcerations.

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

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

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

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

**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*)

**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*)

**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*)

**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**

**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**.

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

The multifactorial etiology of diabetic foot ulcers is evidenced by the numerous pathophysiologic pathways that can potentially lead to this disorder. Among these are two common mechanisms by which foot deformity and neuropathy may induce skin breakdown in persons with diabetes. The first mechanism of injury refers to prolonged low pressure over a bony prominence (i.e., bunion or hammertoe deformity). This generally causes wounds over the medial, lateral, and dorsal aspects of the forefoot and is associated with tight or ill-fitting shoes. (ACFAS/ACFAOM Clinical Practice Guidelines)

1: Int J Clin Pract. 2007 Nov;61(11):1900-4

Do patients with diabetes wear shoes of the correct size? Harrison SJ, Cochrane L, Abboud RJ, Leese GP.

The Diabetic Clinic, Ninewells Hospital and Medical School, University of Dundee, Dundee, UK.

Background: Fifteen per cent of patients with diabetes will develop a foot ulcer at some point in their life. Ill-fitting footwear frequently contributes to foot ulceration. A good fitting shoe is an essential component in the management of the diabetic foot. The objective of this study was to assess the feet and footwear of patients with diabetes to determine whether they are wearing the correct-sized shoes. Methods: One-hundred patients with diabetes who were attending the general diabetic clinic had their foot length measured using a 'Clarks' shoe shop device and foot width using a pair of callipers. Measurements were taken whilst seated and standing. Shoe dimensions were also assessed by recording the manufactured shoe length and using callipers to assess shoe width. A calibrated measuring stick standardised shoe lengths. Neurovascular status and the presence of deformities in the foot were also recorded. Results: One-third of diabetic patients were wearing the correct shoes on either foot whilst seated or whilst standing. However, only 24% of patients were wearing shoes that were of the correct length and width for both feet whilst seated and 20% upon standing. Seventeen per cent of patients appeared in both groups. No significance was found between any other variables, such as sensory neuropathy. Conclusions: Many patients with diabetes wear shoes that do not fit, particularly, shoes that are too narrow for their foot width. Assessing the appropriateness of footwear maybe an important part of foot examination.

2. J Am Podiatr Med Assoc. 2006 Jul-Aug;96(4):290-2.

Do US veterans wear appropriately sized shoes?: the Veterans Affairs shoe size selection study.

Nixon BP, Armstrong DG, Wendell C, Vazquez JR, Rabinovich Z, Kimbriel HR, Rosales MA, Boulton AJ.

Department of Surgery, Southern Arizona Veterans Affairs Medical Center, Tucson, USA.

Diabetic foot ulcerations are among the most common severe complications of diabetes. Ulcers form in patients with diabetes because of a lack of sensation (neuropathy), coupled with repetitive pressure forces (walking). One of the central tenets in reducing the incidence of ulcers is pressure reduction through the use of appropriate shoes and insoles. Poorly fitting shoes may account for a large proportion of diabetic foot ulcers 5, 8, 9 and may also play a role in creating or exacerbating other complications in people without diabetes.

Poorly fitting footwear has frequently been cited as an etiologic factor in the pathway to diabetic foot ulceration. However, we are unaware of any reports in the medical literature specifically measuring shoe size versus foot size in this high-risk population. We assessed the prevalence of poorly fitting footwear in individuals with and without diabetic foot ulceration. We evaluated the shoe size of 440 consecutive patients (94.1% male; mean +/- SD age, 67.2 +/- 12.5 years) presenting to an interdisciplinary teaching clinic. Of this population, 58.4% were diagnosed as having diabetes, and 6.8% had active diabetic foot ulceration. Only 25.5% of the patients were wearing appropriately sized shoes. Individuals with diabetic foot ulceration were 5.1 times more likely to have poorly fitting shoes than those without a wound (93.3% versus 73.2%; odds ratio [OR], 5.1; 95% confidence interval [CI], 1.2-21.9; P = .02). This association was also evident when assessing only the 32.3% of the total population with diabetes and loss of protective sensation (93.3% versus 75.0%; OR, 4.8; 95% CI, 1.1-20.9; P = .04). Poorly fitting shoes seem to be more prevalent in people with diabetic foot wounds than in those without wounds with or without peripheral neuropathy. This implies that appropriate meticulous screening for shoe-foot mismatches may be useful in reducing the risk of lower-extremity ulceration

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

**Literature review.**

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

1: Int J Clin Pract. 2007 Nov;61(11):1900-4

Do patients with diabetes wear shoes of the correct size? Harrison SJ, Cochrane L, Abboud RJ, Leese GP.

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