Evidence-Based Foot Care for Persons With Type 2 Diabetes

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EVIDENCE-BASED FOOT CARE FOR PERSONS WITH TYPE 2 DIABETES

by

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for the degree of

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This journey would have not been possible without the support of my faith, family, and friends. To my brothers and sister, Joe, Thomas, Ruben, and Leticia Gutierrez. Thank you for encouraging me in all my pursuits and providing the inspiration to follow my dreams. To my father Luis Gutierrez, thank you for your emotional and financial support. I knew you believed in me and always had great intentions to see me overcome my fears. I am especially grateful to the love and guidance of my beloved mother, Irene B. Gutierrez who is my rock and the foundation to all my successes. I also would like to recognize the Galaviz family for offering support and being part of this accomplishment. Last but not least, I am gracious to the Lord God, Jesus my savior, and the Virgin Mary for interceding during my difficult times, providing me strength and protection and fulfilling my life with Faith, Hope, and Charity.

Nicole A. Gutierrez
Abstract

Unmanaged Type 2 diabetes leads to macrovascular changes that affect the lower extremities, thereby damaging the sensory nerve fibers and leading to diabetic peripheral neuropathy. These patients may not be able to feel pain, heat, or cold in their lower extremities and often describe feelings of numbness and tingling. This sensory deficit may lead to the development of diabetic foot ulcers which often result in amputation. These preventable foot complications may be identified promptly with adequate diabetic foot exams. Comprehensive diabetic foot examinations reduce the occurrences of foot complications associated with uncontrolled glucose management and improves health outcomes for patients with Type 2 diabetes. The purpose of this quality improvement project is to implement a standardized system for comprehensive diabetic foot examinations as recommended by evidence-based guidelines into clinical practice at a primary care clinic, which will enhance diabetic foot health care performed by providers. Through the intervention period of March-May 2019, 100% of 141 patients received a comprehensive diabetic foot exam. This was facilitated by medical assistants who instructed patients to remove their shoes and socks before the physician entered the exam room. All patients also received an educational handout from the American Diabetic Association. These outcomes were documented in the Diabetic Foot Exam flowsheet and scanned to the electronic medical record.

*Keywords:* type 2 diabetes mellitus, monofilament, diabetic foot care
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Evidence-based Foot Care for Persons with Type 2 Diabetes

An estimated 12.7 million individuals 45 years to 64 years of age and 20.8 million individuals 65 years of age and older are living with diabetes, and the majority of these cases are Type 2 Diabetes Mellitus (T2DM) (Center for Disease Control [CDC], 2017). One of the leading causes of hospitalizations among persons with T2DM is lower extremity amputations due to diabetic foot ulcers, and the incidence of these non-traumatic amputations is increasing (CDC, 2017; Geiss et al., 2019). Diabetic foot ulcers and other foot complications may be prevented or detected early through annual foot examinations (American Diabetes Association [ADA], 2018).

The American Diabetes Association recommends that all patients with T2DM receive annual foot examinations to detect loss of protective sensation (LOPS), which is often associated with diabetic peripheral neuropathy (ADA, 2018a, p. S111). Diabetic peripheral neuropathy consists of nerve damage due to ongoing hyperglycemia and is first manifested in the feet or legs (Rakel & Rakel, 2016). Diabetic peripheral neuropathy (DPN), one of the common consequences of uncontrolled diabetes, often presents as a decrease in sensation to the lower extremities. This sensory damage often begins subtly as 50% of patients with DPN experience no symptoms and fall victim to increased infections, skin breakdowns, and the development of foot ulcers (Miller et al., 2014). Infection is a serious complication, as more than 50% of diabetic foot ulcers (DFUs) become infected, and account for 85% of amputations (Armstrong, Boulton, & Bus, 2017).

Approximately half of people with T2DM are unaware that they lack sensation in their feet, placing them at risk for foot complications such as foot ulceration, ischemia and infection (Boulton et al., 2018; Stino & Smith, 2017). These complications, if left undetected or untreated,
may lead to limb loss (Boulton et al., 2018). Diabetic peripheral neuropathy is associated with 45% to 60% of all foot ulcers (Amin & Doupis, 2016).

Diabetic foot complications are a significant contributor to the increasing rate of hospitalizations for these patients; approximately 84% of patients with T2DM who have had a lower-extremity amputation performed had a history of prior foot ulcerations which may be, in part, due to inadequate foot assessment in primary care (Gallman, Conner, & Johnson, 2017). While many chronic diseases are managed exclusively by specialists (e.g., arrhythmias by cardiologists), primary care providers manage upwards of 90% of all diabetes care (Rakel & Rakel, 2016). Diabetes care should include providing effective foot examinations to detect any potential foot complications, including diabetic peripheral neuropathy.

This document outlines the background, problem, needs assessment, methodology, objectives and results to inform a clinical intervention for enhancing preventative diabetic foot care in primary clinics.

**Statement of the problem**

Diabetic peripheral neuropathy (DPN), a frequent consequence of uncontrolled diabetes, presents as a decrease in sensation to the lower extremities. This sensory damage usually begins subtly as 50% of patients with DPN experience no symptoms and fall victim to increased infections, skin breakdowns, and the development of foot ulcers (Miller et al., 2014). Infection is a serious complication, as more than 50% of diabetic foot ulcers (DFUs) become infected, and account for 85% of amputations (Armstrong et al., 2017). Notably, Bexar County, Texas, has one of the highest hospital admission rates for lower extremity amputations (Sunil, Limon, & Ochoa, 2019). Rigorous foot care using evidence-based guidelines is essential given the severe consequences of unrecognized or untreated foot ulcers.
Background and Significance

Community context and epidemiology. According to Texas state officials, the incidence of diabetes-related lower extremity amputations is on the rise. Primary care providers remain at the forefront of preventing and managing this challenging disease. Diabetic foot complications are a growing health risk that affects many adults in the workforce. There are as many as 2000 amputations of lower extremities occurring annually in San Antonio. The city of San Antonio ranks high for having the most adults diagnosed with Type 2 Diabetes (59.5% Hispanic and 28.2% non-Hispanic/white). Given these disease rates, it is crucial that diabetic foot care becomes a standard practice in all primary care clinics to prevent severe foot complications. The destructive and debilitating potential when neglected further reinforces this point.

Hispanics with Type 2 Diabetes are predominantly seen at this clinic. This population tends to have the highest occurrences of foot complications related to uncontrolled blood sugars; this may reflect both patient self-care as well as provider practices. This particular clinic places a high emphasis on quality and prevention, which partly explains the success of this particular study intervention.

While community-level education and prevention policies have an important role, there is a significant opportunity to address this issue in the thousands of primary care visits that occur for diabetics across Texas. By applying the ADA clinical practice recommendations for a comprehensive foot exam on all patients, patients at highest risk for complications can be identified early.

Diabetic peripheral neuropathy. The ADA Standards of Care (2018a) outline the proper management of DPN, required foot examinations to prevent complications and treatment
to slow the progression of DPN. The diabetic patients’ sensations to their feet are impaired and they may be incapable of feeling changes or worsening of foot ulcers. DPN first affects the small sensory fibers causing pain, burning and a tingling sensation, then advances to the large sensory fibers causing numbness and the loss of protective sensation (LOPS), a primary factor for the development of diabetic foot ulcers (ADA, 2018a, p. S111). DPN appears alongside reduction of microvascular blood flow (Sadosky, Hopper, & Parsons, 2014).

While DPN was once thought to occur only in late stages of uncontrolled hyperglycemia, recent evidence suggests that, of the 50% of diabetics who develop DPN, 20% of these patients have experienced symptoms prior to initial presentation of T2DM (Stino & Smith, 2017). DPN may be developing in the prediabetic stages associated with obesity and metabolic syndrome (Stino & Smith, 2017). Metabolic syndrome is the aggregation of dyslipidemia, hypertension, obesity, inflammatory cytokine, pro-oxidative and hyperglycemia caused by an insulin resistant state of the body (Rakel & Rakel, 2016, p. 525).

**Foot ulcers.** The treatment management for diabetic foot ulcers (DFU) is a long-lasting commitment to allow the appropriate time for wound healing. This can be compromised by infection due to the slow healing process which then becomes more expensive to treat (Rice et al., 2014, p. 652). DFUs lead to approximately 100,000 amputations annually, resulting in costs of $43.5 billion per year (Boulton et al., 2018).

**Hospitalization rates.** Hospitalization rates for patients with diabetic foot complications continue to increase, highlighting the importance of foot exams to be performed by primary care provider. In 2014, of the 108,000 hospitals for lower extremity amputations (LEA) nationally, 60% were related to complications of diabetes (CDC, 2017). Lower extremity amputations such as a toe amputation are often followed by additional such procedures. In fact, between 9%-17%
of patients undergoing their first amputation will require a second amputation within one year; furthermore, within 5 years of the first amputation, approximately 25% to 68% of patients with diabetes need an amputation to the contralateral extremity (CDC, 2016, p. 49). Mortality rates related to amputations are high as 50% in T2DM patients who receive an amputation caused by infection die within 5 years (Weledji & Fokam, 2014).

**Inadequate foot exams.** Adequate foot care is imperative to implement in primary care practices to prevent life-threatening health complications for T2DM patients and to avoid the expensive continuous treatment required for foot care practices neglected (Jeffcoate, Vileikyte, Boyko, Armstrong, & Boulton, 2018). According to a patient survey, 46% of diabetic patients did not receive a foot exam or screening by their primary care provider (Gallman et al., 2017). Nonetheless, 64% of healthcare providers do not review a DPN assessment questionnaire with patients for proper care, and while patients often report DPN symptoms, only 41% of providers followed up with the specific diagnostic tests that were required (Sadosky et al., 2014).

When T2DM patients receive inadequate foot care, it may lead to health-related complications contributing to the loss of sensation, increased infection rate due to improper wound healing, and amputation. The occurrences of DPN and foot ulcers often coexist and are most prevalent in the older adult population (age 55 and up). Diabetic foot complications (which may be avoidable or caught early by provider examination or self-exam) are often severe, costly and debilitating (Matricciani & Jones, 2015, p. 107). Lack of foot exams may increase health care expenditures related to expensive procedures and treatments. The accumulative payer strain for DFUs averages between $9.1 billion to $13.2 billion annually (Rice et al., 2014). In a random sample of patient with diabetes, the annual costs to Medicare and private insurers per Type-2
Diabetes patient, without a DFU, were approximately $7,900. In comparison, the costs per diabetic patient with a DFU averaged between $11,710 to $16,883 (Rice et al., 2014, p. 656).

**Comprehensive foot exams.** According to the ADA (2018) evidence-based guidelines, a comprehensive foot exam assesses bilateral lower extremities at the same time to compare differences. The provider begins with a visual inspection of the skin, noticing any deformities, skin breakdown, developing ulcers, or callouses on the plantar surface of the feet, heels, toes, or between the toes (ADA, 2018). The temperature of the feet is an important part of the foot exam since changes in skin temperature may be a sign of infection or reduced blood flow. The exam should include checking capillary refill to assess circulation and palpating pedal pulses simultaneously to detect any irregularities in pulsation (ADA, 2018). The foot exam should include the entire lower extremities, assessing for any changes in the dermatologic, neurologic, musculoskeletal and vascular structures representing progression of T2DM or DPN foot complications (Miller et al., 2014, p. 647).

The recommendations for practice include an annual clinical test that will assess the large-fiber function and protective sensation using the 10-g monofilament test which identifies if a patient is at risk for developing an ulcer or an amputation (ADA, 2018, p. S111). The 10-g monofilament exam detects changes in foot sensory fibers and utilizes a nylon material that is applied to the plantar surface of the patient foot in distinct locations (ADA, 2018, p. S111). The monofilament exam is 66% to 91% sensitive in determining LOPS; it also provides a 90% confirmation of LOPS or DPN which is evident by a sensory deficit of four sites on the plantar surface during the examination (Amin & Doupis, 2016). When implemented correctly on an annual basis, the foot exam may detect early manifestation of diabetes-related foot complications, which may, in turn, decrease the need for LEAs (Amin & Doupis, 2016).
Patient education. In addition to clinic-based foot exams, it is recommended that patients with T2DM be provided educational information related to foot complications, proper care of the foot, and the need for a daily foot inspection (ADA, 2018, p. S114). Self-examinations should be performed daily while washing and inspecting the feet and any blisters, sores, or cuts which should be immediately reported to the provider (National Institute of Diabetes and Digestive and Kidney Diseases, 2017).

Assessment

The Doctor of Nursing Practice (DNP) student conducted a needs assessment with a focus on adherence to diabetes related evidence-based practice guidelines at a small southwestern private general practice clinic. Specifically, the student was interested in the clinic’s procedure and documentation of foot care for patients with T2DM. Several approaches were taken by the DNP student to provide a comprehensive review of the situation.

The clinic’s employment structure, processes and purpose were analyzed. The clinic is independently owned by the physician. The clinic team is a highly trained group of wellness specialists who provide excellent professional services. Their goal is to ensure that patients feel their very best and remain healthy. The clinic team combined has over 30 years of medical experience, which consists of an internal medicine specialist, three medical assistants (MAs), one of whom is the office manager, and a medical billing coder, all of whom work full time. This wellness team takes pride in providing quality medical care to the community. The physician primarily speaks English but understands Spanish medical terminology. All the MAs are fluent in Spanish and are available to interpret for the physician as needed. The services provided include: wellness and preventative care, management of chronic diseases, and prescription assistance. Specimens or blood work collected are sent to clinical laboratories, and any required
referrals are sent to the local hospital. This clinic accepts Medicaid, Medicare, and most major insurance providers.

The clinic averages 35 to 45 patients per day, including patients with appointments and walk-ins. The patient population primarily consists of Hispanic, Caucasian, and African American adults who are between the ages of 46 years to 64 years old. The population that is most often seen are Mexican Americans. Eighty percent of all patients are bilingual, and most have received both a college and high school education. The highest payer sources are private insurances second to Medicare beneficiaries.

**Reimbursement.** Reimbursement for services provided is an ongoing concern for all health care providers. At the time of the needs assessment, the student met with the clinic’s medical biller and determined that further data and a review of the current medical codes was needed in order to demonstrate the reimbursement value of a comprehensive foot exam, which would provide additional revenue for the clinic. The DNP student researched and identified the standardized Healthcare Common Procedure Coding System, accepted by Medicare and most insurance systems, related to comprehensive diabetic foot exams. The student obtained the following information from the biller and the Centers for Medicare and Medicaid Services manual.

- G0245 - The initial foot evaluation and management (E/M) of the diabetic patient with loss of protective sensation (LOPS). This code can only be reimbursed once. The reimbursement for the exam is $65.21.

- G0246 – A 6 month follow-up foot evaluation of the diabetic patient with LOPS. This code can only be billed and reimbursed if the initial foot examination (G0245) was performed. The reimbursement for this exam is $38.38.
G0247 – Routine foot care for diabetic patients with LOPS. This code can only be billed on the same date of service with either G0245 or G0246 to receive full reimbursement (Department of Health and Human Services Centers for Medicare and Medicaid Services [DHHS & CMS], 2005). The reimbursement for this exam is $74.32.

When Medicare Part B deductible is met the actual charged amount for patient services is $71.24; Medicare will reimburse $61.95, and the beneficiary will be responsible for the remaining balance of $12.29. When the part B deductible is not met the actual charged amount for patient services is $71.24. Medicare will reimburse $61.95 and the beneficiary is responsible to pay $71.24 (Department of Health and Human Services Centers for Medicare and Medicaid Services [DHHS & CMS], 2005).

Findings of the needs assessment indicated that T2DM was the most common chronic disease managed at this clinic. The DNP student identified an inconsistency in diabetic foot care exams, incomplete or lack of documentation concerning the exams, and that limited preventive foot self-care education was being provided. Patients verbalized limited understanding of potential foot complications and most were unaware of need for daily foot self-care.

**Readiness to Change and Stakeholders**

Based on the needs assessment the DNP student met with the physician to discuss the implementation of a quality improvement initiative related to comprehensive diabetic foot exams. The student presented the needs assessment findings to the physician and gained support to develop this initiative in order to benefit his patients. After meeting with the physician, the DNP student spoke with the clinical staff explaining that the primary purpose of a DNP Project was to implement a quality improvement initiative and discussed the staffs’ roles in this project.
The clinical staff conveyed to the student that the clinic was committed to excellence and clinical practice improvements that could benefit patient outcomes and agreed to incorporate the project into their work assignments. The stakeholders related to this project include the physician, MAs, medical code biller, patients, caregivers and their families.

**Project identification**

**Project Purpose**

The purpose of this quality improvement initiative was to implement ADA evidence-based guidelines (2018) to improve provider and staff practices related to comprehensive diabetic foot exams (CDFE) for patients with T2DM and to provide patient educational materials on self foot care.

**Project Objectives and Anticipated Outcomes**

Following is a list of objectives intended to achieve the project purpose along with related outcome measures.

1. Develop and implement a documentation format to record findings from patient foot exams that is congruent with provider practices and insurance requirements.

   **Outcome:** The physician will document complete foot exam results on the new form and the staff will scan this form into the patient EMR.

2. Patients with T2DM will be prepared for foot exams.

   Providers are compensated for only 15 minutes per clinic visit regardless of clothing circumstances.

   **Outcome:** The staff will demonstrate understanding of the practice change by having all patients with T2DM remove their footwear and socks prior to the physician’s exam and prepare the exam room with foot exam supplies.
3. Patients with T2DM will receive educational information regarding foot complications and foot care at the time of their foot exam.

*Outcome:* The physician will provide the educational materials to all patients with T2DM as evidenced by patient record.

**Summary and Strength of Evidence**

Healthy People 2020 is a leading authority on national health goals and has established numerous objectives related to improvement of diabetes outcomes, including a goal to increase the proportion of adults with diabetes who receive at minimum an annual provider foot exam (U.S. Department of Health and Human Services, 2019). This objective is supported by evidence indicating that the current rate of provider foot exams is insufficient to achieve optimal outcomes. In 2015, Texas providers performed 62.9% annual foot exams and ranked below the total national average of 67.3%. Additionally, Healthy People 2020 has set an objective to decrease the rate of LEAs but has not yet established a specific rate for annual foot examinations to be performed by health professionals (U.S. Department of Health and Human Services, 2019).

Expert members of the American Diabetes Association established the current *Standards of Medical Care in Diabetes*, including recommendations for foot care (ADA, 2018a, p. S105). The American Diabetes Association has also established a process to promote evidence-based practices for providers to follow for patients with diabetes. This association has been actively involved in the publications of the Standards of Medical Care in Diabetes for over 25 years. This Professional Practice Committee is an integrated group of medical professionals who perform extensive clinical diabetes research and develop current treatment goals, assessment tools, and risk reduction strategies that prevent acute and long-term diabetic foot complications.
The ADA evidence-grading system for *Standards of Medical Care in Diabetes* was developed in 2002. It represents a classification system which categorizes the quality of scientific evidence supporting the recommendations provided by the ADA. These recommendations are assigned rating using the letters A, B, C, and E. The recommendations given the letter “A” supplied and supported evidence from a well-designed clinical trials and meta-analysis A recommendation that is graded an “A” is substantiated by the highest quality of evidence. Recommendations classified with a “B” rating are supported with evidence from well-conducted cohort and case-control studies. The “C” rating recommendations indicate that there is conflicting evidence from controlled and uncontrolled clinical trials, and suggestions should be interpreted with caution. The recommendations classified with an “E” rating are based on expert consensus. Refer to Table 1 for specific ADA recommendations for patients with T2DM related to foot care and the respective rating.

**Methods**

**Barriers and Facilitators**

The student did note an informative communication related to foot care and diabetic teaching between the provider and patients with T2DM. Potential barriers impacting this project were evaluated and included the cost of the monofilament needed to conduct the exam, reimbursement for services, insufficient resources in the EMR to allow documentation of the foot exam and adding additional time to the clinical encounter.

The student identified several facilitators related to readiness for project implementation. First, it was clear that the physician demonstrated leadership abilities with the staff and patients and that respectful communication was taking place at all levels. Second, the organizational Table 1
**Summary of ADA Recommendations for Foot Care**

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<tr>
<th>Recommendation</th>
<th>Rating</th>
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<tr>
<td>All patients should be assessed for diabetic peripheral neuropathy starting at diagnosis of T2DM.</td>
<td>B</td>
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<tr>
<td>All patients should have an annual 10-g monofilament test to identify risk for developing an ulcer and amputation.</td>
<td>B</td>
</tr>
<tr>
<td>Inspect the feet of all patients with T2DM at every clinic visit.</td>
<td>C</td>
</tr>
<tr>
<td>Document history of foot ulcers or amputations and assess for current symptoms of DPN.</td>
<td>B</td>
</tr>
<tr>
<td>CDFE should include inspection of the skin, assessment of foot deformities, neurological assessment using the 10-g monofilament, and a vascular assessment.</td>
<td>B</td>
</tr>
<tr>
<td>Provide general preventive foot self-care education.</td>
<td>B</td>
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*Note.* T2DM = Type 2 Diabetes Mellitus, DPN = diabetic peripheral neuropathy; CDFE = comprehensive diabetic foot exam. Adapted from “Standards of Medical Care in Diabetes-2018.” *Diabetes Care, 41*, p. S111-S113.

Climate established by the physician encouraged all staff to offer input on quality of patient care and workflow processes. Finally, the physician dedicated time to the student to develop and evaluate the practice changes, including documentation changes, and entrusted the student to work with staff to proceed with this quality improvement initiative. The staff were encouraged to voice concerns and ask the student any questions regarding the project. All clinical staff and the physician agreed to the proposed changes and committed to implementing the project on standard guidelines for diabetic foot care for T2DM patients.

**Project Intervention**

The following steps were required to implement this quality improvement initiative.
**Develop documentation record.** Because the EMR did not contain a template to document a comprehensive diabetic foot examination consistent with CMS Medicare guidelines (Department of Health and Human Services, Centers for Medicare and Medicaid Services [DHHS & CMS], 2005) the student needed to develop a documentation form acceptable to the physician and appropriate for reimbursement purposes (See Appendix A).

**Educate provider and medical assistants.** The DNP student educated the provider and medical assistants by discussing project goals and reviewed each member’s roles and responsibilities to implement and sustain the project. Initially, the DNP student obtained a daily list of patients scheduled to be seen and highlighted patients with T2DM so that they could receive a foot exam. The MAs followed the process of the DNP student to assure continually of the project.

The DNP student downloaded two language versions (i.e., English and Spanish) of the handout to be given to patients from the ADA website. These are written in simple-to-understand language along with illustrations (see Appendix B).

Medical assistants were instructed on implementing the following changes to their role.

- Review diagnoses in chart to identify patients with T2DM and prepare patients for foot exam.
- Ask the patients with T2DM to remove their socks and shoes after entering the exam room.
- Prepare the examination tools including 10-gm monofilament, gloves, documentation form and patient education information.
- After the physician has examined the patient, the MAs will scan provider documentation of the foot exam into the EMR.
The patient is given the educational handout at the end of their appointment.

The physician initiated the following recommendations for foot examinations.

- Assess patients with T2DM for a history of foot ulceration, LEAs, awareness of physical limitations and need for rehab therapy.
- Explain the purpose of the foot exam including purpose of the 10-g monofilament neurological test to evaluate LOPS
- Assess the width and depth of the patient’s shoes to determine if they are non-constrictive and suitable for wearing. After examination, if the physician felt the shoes were constrictive, potentially causing and worsening current foot complications, a referral to the local diabetic shoe store would be made which is covered by insurance.
- Inspect the lower extremities noticing any skin discolorations, calluses, small fissures or skin breakdowns, carefully assessing the toenails and the skin surrounding the nail beds.
- A vascular assessment would be performed which includes feeling the skin temperature and palpating bilateral pulses in the legs and feet which includes the popliteal, dorsalis pedis and tibialis posterior.
- Perform the neurological portion of the foot exam using a 10-g monofilament test to identify LOPS. The provider will place the monofilament nylon wire on the patient's arm or hand by touching the skin so that the patient knows what to expect when the nylon wire begins to touch the plantar surface and can verbalize when they feel the monofilament on select areas of the plantar surface of the feet.
- Instruct the patient to close their eyes during the foot examination. While examining both feet, the patient is advised to tell the PCP when he or she feels the nylon wire touch their feet.

- Follow recommendations for conducting the 10-g monofilament exam including: holding the monofilament wire perpendicular to the foot being examined using a steady motion to test sensation in 10 specific sites on each foot and with sufficient force.

- The provider will document the foot exam assessment on the paper form developed by the student and approved by the provider (see Appendix A).

**Setting and population.** This project implementation took place in a clinic located on the south side of a large metropolitan city in the southwest United States. The target population included any patient over the age of 18 being seen at the clinic who had a new or existing diagnosis of T2DM.

**Ethical considerations.** The DNP project was submitted to the university IRB and was deemed as not meeting the regulatory definition of research with human subjects and will not require further review by the IRB. A signed letter of support (See Appendix C) from the primary care provider was submitted with the IRB application. Patient consent was not required as this project was not research but instead was application of best clinical practices. Educational materials were provided in both English and Spanish.

**Results**

This quality improvement initiative prospectively assessed adoption of ADA practices within a primary care setting.

A total of n=141 Type 2 Diabetic patients were seen during the implementation phase of the quality improvement initiative over 3 months in the Spring of 2019. This excludes two
patients – one had already undergone a bilateral below-knee amputation, and the other presented with acute chest pain and was evaluated for those symptoms. Following each visit, patient charts were reviewed by the DNP candidate to assess for documentation of the CDFE including 10-g monofilament use and patient education. Table 2 summarizes the demographics (Appendix D) of the 141 patients seen during the intervention period of March-May 2019.

Table 2

Demographics of Intervention Population

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Category</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>47</td>
</tr>
<tr>
<td>Race</td>
<td>Hispanic/Latinx</td>
<td>79</td>
</tr>
<tr>
<td></td>
<td>White/Caucasian</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>All other</td>
<td>3</td>
</tr>
<tr>
<td>Payer Mix</td>
<td>Private insurance</td>
<td>61</td>
</tr>
<tr>
<td></td>
<td>Medicare</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>None/private-pay</td>
<td>3</td>
</tr>
</tbody>
</table>

Note. The population (N = 141) examined had an age range of 27-92, with a mean age of 57.6 and a standard deviation of 13.6

Findings

Figure 1 demonstrates the frequency of CDFE and education in clinic visits during the intervention period.
Delivered Project Objectives and Outcomes

The anticipated project outcomes were achieved.

1. Develop and implement documentation format to record findings from patient foot exams that is congruent with provider practices and insurance requirements.

   Outcome: The physician will document complete foot exam results on the new form and the staff will scan this form into the patient EMR.

One hundred percent of 141 patients received the comprehensive exam. This outcome was recorded in the EMR for each patient. The provider utilized the CDFE appropriately by answering all areas on the form demonstrating that preventative foot care was performed.

2. Patients with T2DM will be prepared for foot exams.

   Outcome: The staff will demonstrate understanding of the practice change by having all patients with T2DM remove their footwear and socks prior to the physician’s exam and prepare room with foot exam supplies.

As a matter of implementation, this outcome was achieved to a large extent. While not specifically tracked, most patients had removed their shoes and socks to have the exam. In a
handful of cases, according to the physician, patients had not completely completed the removal prior to the beginning of the exam. This waiting added to the total time of the appointment by at most a few minutes.

3. Patients with T2DM will receive educational information regarding foot complications and foot care at the time of their foot exam.

   Outcome: Staff will provide the educational materials to all patients with T2DM as evidenced by patient record.

One-hundred percent of patients received the educational handout. This was documented in diabetic foot exam flowsheet and scanned to EMR.

**Discussion**

This project demonstrated success in standardization of practice, namely the use of a comprehensive diabetic foot exam (CDFE) and educational material for a clinic population. One-hundred-fourty-one patients were examined between March and May 2019, and every patient received the exam and education. An additional aim was for medical assistants to instruct patients to remove footwear prior to their encounter with the physician, which occurred in most cases. These changes in practice represent a consistent use of an evidence-based approach supported by the American Diabetes Association. The strength of a diabetic foot exam flowsheet “checklist” supported a uniform adoption.

The benefit of this project is to demonstrate that such exams can be included consistently, thereby improving care for patients who are at-risk for severe complications without such early detection. While this study did not follow patients prospectively for multiple years to assess a decrease in the incidence of diabetic foot complications, this improvement in clinic visit activities suggests optimism for early detection. This consistency within the current project
intervention is higher than reported in the literature. In studies cited previously, over 40% of patients have not received a foot exam. An even higher percentage may have signs of early peripheral neuropathy which may go undiagnosed.

**Limitations**

The project limitations include: (a) the time frame allowed to evaluate performance outcomes accurately, as 3 months is insufficient to properly assess a follow-up foot exam which can determine any changes to LOPS, and (b) during the physical exam, socks and shoes remained on patient feet which contributed to longer-than-expected visit times. For the latter, MAs failed to ask the patient if they needed assistance with removing socks and shoes.

**Recommendations**

Three recommendations are offered for maintaining and enhancing this intervention. First, improve consistency by investing in a CDFE e-template within the electronic medical record. The paper form for CDFE documentation developed by the student meets all the requirements for Medicare & Medicaid for full reimbursement of services as well as for other insurance providers which require the same criteria. The student explored the expense of creating and implementing an e-template but found it was cost-prohibitive. The advantage of having an electronic template is accessibility for all future hire providers and clinic staff to input data. During project implementation, the CDFE form was scanned to EMR which increases the possibility of being misplaced or lost thereby violating HIPPA regulations and receiving penalties.

Second, confirm the feasibility/success of this intervention by similar intervention in other clinic settings. While this one clinic setting demonstrated successful implementation, external validity is improved by a greater variety of such demonstrations. This approach may
also identify specific opportunities for improvement, such as MAs remaining with the patient until footwear is removed.

Third, continue longer-term research on the benefits of comprehensive foot exams on patient outcomes and care costs. Initially, continue the project for one year to experience its full potential and health benefits for Type 2 Diabetics. Additional time will provide accurate results for the 6-month follow-up exam which can help determine potential changes during the re-evaluation period using the CDFE form to compare results and quality improvement outcomes. This may ultimately help reduce the overall morbidity and mortality rates if project implementation continues indefinitely.

**Implications for Nursing Practice**

The DNP student was able to implement change in clinical practice by combining the clinical skills of a primary care provider with the current clinical practice recommendations of ADA on diabetic foot care. Combining the willingness of introducing change at this clinic in foot care practices for Type 2 Diabetics and the support of the provider ultimately allowed improvement in healthcare for Type 2 Diabetics. Nurses may facilitate such changes in clinic operations and documentation in some settings.

The DNP student developed a CDFE tool following the required guidelines of Medicare and recommendations of the ADA. This screening tool applied to all Type 2 Diabetics that were seen by the provider; the CDFE accurately assessed and identified Type 2 Diabetic patients who have a loss of protective sensation (LOPS). Diagnosing a patient with LOPS brings awareness to the provider and requires immediate intervention in prevention and patient education on foot self-care to delay the progression of DPN and the development of a diabetic foot ulcer and amputation with Type 2 Diabetes.
Implementation of best practices related to diabetic foot care and patient education by the DNP student demonstrates an essential role of DNP-prepared nurse practitioners. The DNP student implemented a quality improvement project, featuring the skills of a DNP-prepared nurse and made a contribution to enhance patient care and safety.
References

http://dx.doi.org/https://doi.org/10.2337/cd17-0119

http://dx.doi.org/10.2337/dc18-S010


http://dx.doi.org/https://dx.doi.org/10.4239%2Fwjd.v7.i7.153


Appendix A: Diabetes Foot Examination Form

Diabetes Foot Examination

Patients Name: 
Medicare #: 
Date: 
DOB: 

Findings regarding the **RIGHT** and **LEFT** foot:

<table>
<thead>
<tr>
<th></th>
<th>RIGHT</th>
<th>LEFT</th>
<th>NO FINDINGS</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Is there a foot ulcer now?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Is there a history of foot ulcer?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Is there any abnormal shape of the foot?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Is there toe deformity?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Are the toenails thick of ingrown (fungal)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Is there a callus buildup?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Is there swelling?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Is there elevated skin temperature?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Is there muscle weakness?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Is there lower extremity pain?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Has there been a previous amputation?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>Is there a blister or laceration?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13.</td>
<td>Can the patient see the bottom of his/her feet?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Does the patient use appropriate footwear</td>
<td>Yes</td>
<td>No</td>
<td>Comment</td>
<td></td>
</tr>
</tbody>
</table>
DOB:

Vascular Findings: Present = P  Not Present = NP

<table>
<thead>
<tr>
<th></th>
<th>RIGHT = P</th>
<th>RIGHT = NP</th>
<th>LEFT = P</th>
<th>LEFT = NP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsalis Pedis Pulse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post Tibial Pulse</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foot Hair</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capillary Refill</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Indicate the level of sensation by the number indicated on the foot diagram:

**POSITIVE:** Can Feel 10g Monofilament  **NEGATIVE:** Cannot Feel 10g Monofilament

![Diabetic Foot Screen Test Sites](image)

<table>
<thead>
<tr>
<th>LEFT FOOT</th>
<th>RIGHT FOOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSITIVE</td>
<td>NEGATIVE</td>
</tr>
<tr>
<td>1.</td>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
<td>4.</td>
</tr>
<tr>
<td>5.</td>
<td>5.</td>
</tr>
<tr>
<td>6.</td>
<td>6.</td>
</tr>
<tr>
<td>7.</td>
<td>7.</td>
</tr>
<tr>
<td>8.</td>
<td>8.</td>
</tr>
<tr>
<td>9.</td>
<td>9.</td>
</tr>
<tr>
<td>10.</td>
<td>10.</td>
</tr>
<tr>
<td>SCHEDULED FOLLOW-UP CARE:</td>
<td>DATE</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------</td>
</tr>
<tr>
<td>☐ <strong>G0245</strong> - Initial foot exam for patient with LOPS</td>
<td>☐ <strong>G0247</strong> – Routine Footcare for patient with LOPS</td>
</tr>
</tbody>
</table>
| ☐ **G0246** – F/U 6 mon. evaluation of foot patient with LOPS | ☐ Patient educated on diabetic foot care  
☐ Diabetic Shoe referral |
Taking Care of Your Feet

There are many things you can do to keep your feet healthy. Take care of your diabetes. Work with your health care team to keep your blood glucose in your target range.

Check your feet every day
Look at your bare feet for red spots, cuts, swelling, and blisters. If you cannot see the bottoms of your feet, use a mirror or ask someone for help. See your health care provider right away if there are any changes or if you hurt your feet.

Wash your feet every day
Use warm water and a mild soap. Avoid soaking since it can dry out the skin and lead to cracks. Dry them carefully, especially between the toes.

Keep your skin soft and smooth
Rub a thin coat of skin lotion (lotion, cream, or petroleum jelly) over the tops and bottoms of your feet, but not between your toes.

If you can see and reach your toenails, trim them when needed
Trim your toenails straight across and file the edges with an emery board or nail file. Wear shoes and socks at all times. Never walk barefoot. Wear comfortable shoes that fit well and protect your feet. Check inside your shoes before wearing them. Make sure the lining is smooth and there are no objects inside.

Wear comfortable shoes and socks that fit well and protect your feet.

Protect your feet from hot and cold
Wear shoes at the beach or on hot pavement. Don’t put your feet into hot water. Test water before putting your feet in it just as you would before bathing a baby. Never use hot water bottles, heating pads, or electric blankets. You can burn your feet without realizing it.

Keep the blood flowing to your feet
Put your feet up when sitting. Wiggle your toes and move your ankles up and down for 5 minutes, two (2) or three (3) times a day. Don’t cross your legs for long periods of time. Don’t smoke.

Get started now.

Begin taking good care of your feet today.
Set a time every day to check your feet.
SU CONSEJERO DE DIABETES

El cuidado de los pies

Examíñese los pies todos los días
- Revise si tiene cortes, moretones o hinchazón.
- Vaya al médico inmediatamente si nota cambios en sus pies o si se lastimó los pies.

Lávese los pies todos los días
- Utilice agua tibia y jabón suave. Evite remojarlos, ya que esto puede resecar demasiado la piel y causar que se agriete.
- Séquese bien los pies, especialmente entre los dedos.

Mantenga su piel suave y tersa
- Aplique un poco de loción para la piel (crema o vaselina) en la planta y parte de arriba del pie, pero no entre los dedos.

Si puede ver y alcanzar las uñas de los pies, recórtelas cuando sea necesario
- Use una lima de uñas para rebajar los bordes.
- Pida ayuda para recortarse las uñas de los pies si le resulta difícil alcanzarlos o si no va tan bien como para recortárselos sin lastimarse.

Si tiene callos en las plantas de los pies o en los dedos, pídale a su médico que se los rebaje o lime.

Póngase zapatos y calcetines cómodos, que le queden bien y le protejan los pies.

Revise el interior de sus zapatos cada vez que se los ponga para asegurarse de que se encuentre liso. Sacuda bien sus zapatos para sacar cualquier objeto que se haya metido dentro.

Para más información sobre la Asociación Americana de la Diabetes, visite professional.diabetes.org/PatientEd o llame al 1-800-DIABETES (342-2383).

Corresponding English Advisor Taking Care of Your Feet
February 22, 2019

I, Dr. Maher Saloum, am aware of the Doctor of Nursing Practice (DNP) project that will be conducted by Nicole Gutierrez here at Primary Med clinic. I have been informed of the quality improvement project, *Evidence-Based Foot Care for persons with Type 2 Diabetes* recommended by the American Diabetes Association 2018 “Standards of Medical Care in Diabetes”, implementation will begin on March 1st and continue until May 15th with final reports. DNP project will be overseen by Dr. Christina Hernandez. I approve and support this DNP clinical practice project.

SINCERELY,

MAHER SALOUM
Appendix D: CDFE Documentation

Data Collection Worksheet

DOB: __________

1. Provider:
   - Provider 1
   - Provider 2

2. Age: ______

3. Sex:
   - Male
   - Female

4. Race:
   - Hispanic
   - Caucasian
   - African American
   - Other: __________
     - Patient declined to answer

5. Payer Source:
   - Medicare
   - Medicaid
   - Private Insurance
   - Private Pay/No Insurance

6. Was there a Comprehensive Diabetic Foot Exam performed?
   - Yes
   - No
   - Other: ________________

7. Did the primary care provider scan the comprehensive diabetic foot exam documentation form?
   - Yes
   - No
8. Did the primary care provider complete all elements of the comprehensive diabetic foot exam documentation form?
   - Yes
   - No

9. Did the primary care provider document that patient education on diabetic foot care was provided?
   - Yes
   - No

10. Did primary care provider check appropriate billing code located on comprehensive diabetic foot exam form?
    - Yes
    - No

11. Did the patient demonstrate any signs of diabetic peripheral neuropathy?
    - Yes
    - No
    - List findings:___________________

12. Was the patient asked to follow up with provider based on foot exam?
    - Yes
    - No