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# Improving the Assessment and Care Management of Patients with Diabetes at Risk for Foot Ulcers and Amputations

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Running Head: DECREASING RISKS FOR FOOT ULCERS AND AMPUTATIONS

IMPROVING THE ASSESSMENT AND CARE MANAGEMENT OF PATIENTS WITH  
DIABETES AT RISK FOR FOOT ULCERS AND AMPUTATIONS

by

KAREN ARCHITECT

A CAPSTONE PROJECT

Presented to the Faculty of the University of the Incarnate Word  
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Karen Architect

### Dedication

This capstone project reflects the San Antonio community that I have been a part of since 1995. I want to dedicate the completed project to all the nurses and doctors whom I have worked with over the years who inspired me to further my education. Medical professionals set an example for the community in which we live. They are leaders and mentors to the next generation and I am thankful to have the opportunity to be a part of the future and upcoming changes in our community.

IMPROVING THE ASSESSMENT AND CARE MANAGEMENT OF PATIENTS  
WITH DIABETES AT RISK FOR FOOT ULCERS AND AMPUTATIONS

Karen Architect, DNP

University of the Incarnate Word, 2016

**Purpose:** To implement guidelines set in 2016, by the American Diabetes Association, which recommend annual and periodic foot exams for patients with diabetes.

**Background:** Uncontrolled diabetes and foot complications can lead to permanent disability, loss of employment often leading to depression and increased morbidities (Szpunar, Minnick, Dako, & Saravolatz, 2014).

**Significance of Problem:** Individuals who are diagnosed with diabetes are at risk for foot ulcers and amputations if not properly managed. Implementation of a foot screening program has been shown to reduce foot ulcers and amputations (Peterson & Virden, 2013).

**Methods:** Annual and periodic foot exams occurred from June 6th through August 12, 2016 at the home of 48 diabetic patients. Early education on how to assess the diabetic foot and document findings was provided to primary healthcare providers and medical assistants with a focus on adherence to American Diabetes Association recommendations. The outcome of increased ability to assess the feet and document was measured by a chart audit of 48 patient charts. A chart review was conducted for verification of delivery of educational material to the patient along with the completion of foot screening criteria for podiatry referral.

**Results:** Implementation of the American Diabetes Association guidelines by healthcare providers improved foot care management and documentation by 83% when 40 patients out of 48 received a correct assessment.

**Conclusions:** The Doctor of Nursing Practice project increased adherence to the American Diabetes Association guidelines improving the diabetic foot screenings and documentation with sustained change and better care to diabetic patients.

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## IMPROVING THE ASSESSMENT AND CARE MANAGEMENT OF PATIENTS WITH DIABETES AT RISK FOR FOOT ULCERS AND AMPUTATIONS

Type II diabetes mellitus (T2DM) affects close to 24 million individuals in the United States with 57 million Americans at risk of developing diabetes over the next few years (Peterson & Virden, 2013). It is estimated by the Centers for Disease Control and Prevention (CDC, 2014) that 1.8 million (13%) people have been diagnosed with diabetes mellitus in Texas, and 137,009 (11%) of who live in San Antonio, Texas. The increasing global prevalence of T2DM predicts an increase in diabetic foot disease by 3% to 10% worldwide, and a lifetime risk of diabetic foot ulcers (DFUs) by 15% (Chiwanga & Njelekela, 2015). According to the CDC, primary care services are required to care for socioeconomically and culturally diverse individuals who are at risk for comorbidities and mortality related to T2DM (as cited in Peterson & Virden, 2013).

Nationally, 70% of leg amputations are due to diabetes, which clearly signifies a need for an improved assessment of diabetic feet and a change in the way patients are educated. A multidisciplinary approach that involves preventive strategies, education, and aggressive treatment of foot disorders that lead to ulceration will decrease risk and improve outcomes in the diabetic population (Kumar & Valame, 2014). The lack of foot and nail care is recognized as the most neglected area of healthcare in every setting (Burdette-Taylor, 2015). The Agency for Healthcare Research and Quality (AHRQ) and the Institute of Medicine (IOM) has challenged healthcare providers to lead change, improve the care of diabetic complications related to DFU, and reduce costs (as cited in Burdette-Taylor, 2015).

Patients with diabetes are at increased risk of complications if they have a previous amputation, history of foot ulcers, peripheral neuropathy, foot deformities, peripheral vascular disease, visual impairment, diabetic nephropathy (especially diabetic individuals on dialysis),

poor glycemic control, or use tobacco products (American Diabetic Association, 2016). The study by Chiwanga and Njelekela, (2015) found that most lower limb amputations were preceded by a DFU. Aside from peripheral vascular disease, and peripheral neuropathy, other risks are walking without shoes (barefoot), inappropriate footwear, poor hygiene, and delay in medical care once a DFU is present.

Lower extremity arterial disease is often the result of T2DM and may remain unnoticed until an individual is diagnosed in their later years of life, which can be potentiated with smoking and sedentary life style (Burdette-Taylor, 2015). Therefore, inability of patients to obtain medical care and a timely diagnosis of diabetes increases the risk of DFUs and amputations. A literature review identified the importance of diabetic foot ulcer screening and management indicating a need for improved care for the diabetic population seen in Clinic A.

Guidelines set by the National Institute for Health and Care Excellence in the United Kingdom (2015) and the American Diabetic Association (2016) both recommend an annual foot exam. The American Diabetic Association (ADA) recommends a periodic foot exam during every visit once a patient has been diagnosed with insensate feet, foot deformities or previous ulcers. The National Institute for Health and Care Excellence recommends a foot exam when an individual is diagnosed with diabetes, classified as moderate or high risk for foot ulcers and if any foot problems arise. The guidelines from the ADA and National Institute for Health and Care Excellence were both reviewed and considered, however for the purpose of the quality improvement (QI) project, only the ADA guidelines were utilized by healthcare providers in Clinic A.

**Clinic Information**

The Dartmouth Institute 5P Framework was utilized during the assessment of Clinic A (see Appendix A). The tool was developed to examine systems by obtaining detailed information about the anatomy and physiology of the organization (Nelson, Batalden, & Godfrey, 2007). Once the clinic was examined and stakeholders identified, a closer analysis was required to identify areas of concern regarding the proposed project.

The microsystem assessed, to be known as Clinic A, is a local, privately owned, home-based clinic located in San Antonio, Texas. The city of San Antonio has a multitude of individuals who are not receiving the healthcare they require due lack of transportation, physical or mental disabilities. Clinic A offers a service in which patients can be seen in the privacy of their own home, a group care home or an assisted living facility. Patients can be seen by a healthcare provider monthly for management of chronic morbidities, receive preventive care, education and/or be referred to a specialty provider. Greater than 50% of patients seen by Clinic A suffer from T2DM and will benefit from a comprehensive foot examination with education on how to reduce the risk of ulcers and amputation.

Patients in Clinic A are seen by a physician, family nurse practitioner or physicians assistant and medical assistant Monday through Friday between 8:00 a.m. to 4:00 p.m. Scheduled and walk-in patients are also welcome in the clinic from 2:00 p.m. to 5:00 p.m. on Wednesdays. The four healthcare providers and a MA each travel 40-60 miles daily to patients' residence located throughout the city and the surrounding areas of town. During the visits the providers have approximately 15 to 20 minutes to assess and document activities and findings on each patient. A laptop computer is utilized for documentation during the visit by the healthcare provider. Minimal supplies are carried by the MA who obtain vital signs and perform routine

procedures such as collection of blood sugars, cleaning of ears, trimming toenails, and administering injections.

The principle investigator, is a Doctor of Nursing Practice student, and is also employed in the clinic. The clinic employs 14 team members who strive to work together and optimize care for patients. There are seven medical assistants (MAs), a biller, a receptionist who also fills in as a MA when needed, an office manager, administrator, a physician who is partially retired and serves as director of the practice, two nurse practitioners and a physician assistant. The office is surrounded by a number of hospitals in a busy medical center.

There are approximately 414 patients with diabetes, which is (50%) of the total 823 patients seen by Clinic A on a regular basis. The majority of patients seen in the clinic are on a fixed income and receive financial assistance from the government. Patients who have Medicare account for 539 (63%) of the population in Clinic A, Medicaid is 187 (23%), commercial insurance is 93 (11%), and self-pay is 4 (less than 1%).

The needs assessment in the clinic indicated a gap of care in patients with diabetes. The assessment identified the need to improve foot assessments, documentation, and diabetic self-care education in patients with T2DM. Medicare no longer provides financial compensation for diabetic education and there was not any documentation demonstrating the patient was taught self-care.

### **Problem**

Patients with diabetes are at risk for peripheral artery disease, which may lead to peripheral neuropathy, a decrease in blood flow to the feet limiting the oxygen, nutrients, and antibodies resulting in decreased sensation and autonomic dysfunction lowering the ability for the foot to heal (ADA, 2015; Kumar & Valame, 2014). Diabetes and peripheral artery disease

lead to insensate feet and foot deformities, which together with poor foot care, increases the risk for skin breakdown, ulcers, and amputations (ADA, 2016). The loss of protective sensation (LOPS) can lead to complications, such as foot ulceration, infection, and amputation (ADA, 2016; Kumar & Valame, 2014).

According to the microsystem assessment that was previously done at Clinic A, 22 randomly selected patient charts (100%,  $N = 22$ ) demonstrated poor screening and documentation of diabetic foot assessments necessitating a change in practice. Although foot assessments may be done occasionally on diabetic patients in Clinic A, it was difficult to determine, since the electronic medical record documentation was not available. Fourteen percent of the total 22 charts did show documentation of a referral to podiatry. In those referred, no documentation of a foot assessment was shown in the electronic medical record by a healthcare provider; nor was there a reason for referral listed.

The ADA recommends a comprehensive foot exam and a risk assessment each time a patient is seen by the healthcare provider or at least an annual assessment. The standard of care for a comprehensive exam involves performing 1) a complete history, 2) a general inspection (including footwear), 3) a dermatological assessment, 4) a musculoskeletal assessment, 5) a neurological assessment, 6) a vascular assessment, 7) a risk classification, 8) referral and follow-up, and 9) patient education (ADA, 2016; Peterson & Virden, 2013).

Individuals who are diagnosed with diabetes are at risk for foot ulcers and amputations if the disease is ignored and not properly managed, which ultimately can lead to poor patient outcomes. Early detection of risk factors that lead to DFUs and preventive care decrease the extent of treatment required. Currently foot exams have not been done consistently, because guidelines have not been made available or reinforced. Evaluation forms with the tool in

question were presented to the healthcare providers for their feedback. Two different assessment tools were evaluated and the shortest, more concise tool was chosen due to time constraints of 15-20 minutes for each patient visit (see Appendix B).

### **Aim**

The aim of the quality improvement project was to implement guidelines using a diabetic tool developed by the ADA to improve screening practices in primary care. The tool guided the healthcare provider during a comprehensive or focused assessment of a diabetic foot exam. The project included an educational intervention on foot care for the healthcare providers in the clinic and prepared them to share educational information with patients and/or caregivers via handouts on foot care available in English and Spanish (see Appendices C and D). The patient and/or caregivers were given educational material in daily foot care management that encourages self-care and awareness of risk factors that may lead to foot ulcers and amputations in patients with type II diabetes. Appendices E, F, and G are examples of educational material provided on managing the overall diabetic disease.

### **Objectives**

1. By July 17, 2016, healthcare providers will provide 80% of diabetic patients with a comprehensive foot assessment according to ADA guidelines.
2. By July 17, 2016, healthcare providers will document a complete comprehensive assessment in 80% of the diabetic patient charts using the assessment tool.
3. By August 12, 2016, 80% of diabetic patients who meet ADA criteria will receive a podiatry referral.
4. By August 12, 2016, 80% of patients having T2DM will receive foot care educational materials with documentation in the patient's permanent chart.

### **Guiding Question**

In patients with type II diabetes mellitus, will implementation of the ADA guidelines by healthcare providers improve foot care management and documentation over a 60-day period compared to current practice in a primary care setting?

### **Review of Literature**

The literature review provided insight into a gap of care for patients who suffer from diabetes and who are at risk for serious and costly complications due to foot ulcers or amputation if undiagnosed or untreated (Kumar & Valame, 2014). The articles reviewed provide a foundation for the quality improvement (QI) project at hand and demonstrates pertinent information on how to improve assessment techniques and documentation of healthcare providers. There are different models, interventions, and methods of delivering the foot care information to healthcare providers and the selected population (Kumar & Valame, 2014).

The articles reviewed for this QI project were located using the databases of CINAHL, Cochrane Library, Directory of Open Access Journals and PubMed. Diabetes, foot care, risk of amputations, barriers, and interventions were used as search terms. Inclusion criteria were as follows: published between January 2012 and January 2016, written in English, evidence-based, and provided in full text. The first search by CINAHL delivered 6,713 results after specifying parameters as January 2012 through January 2016, evidence-based, English language, and full text. Cochrane Library delivered 39 results, Directory of Open Access Journal found 115 articles and PubMed found 11 with the same parameters. Some of the articles located in CINAHL were duplicated in the other databases. Many articles were eliminated by the title if it did not mention T2DM and/or management of care. Articles reviewed and included were grouped into several topics: measurement tools, models of care, clinical guidelines, self-care implications and

management, methods of assessment, contributing factors, health perceptions, and accountability. Each topic is described below.

**Guidelines.** The guideline for preventive foot care provided by the ADA correlates with the findings in the research studies (see Appendix H). The study by Chin et al., 2012 found that foot management recommendations were the biggest predictor of daily foot-exam practice. Furthermore, patients who were encouraged by family, friends or healthcare professionals were 527 times more likely to exam their feet on a daily basis. Chin, Huang, and Hsu (2012) utilized an ordinal level of data to measure an APGAR quick assessment tool. The 5-point Likert-style scale assessed perceived threats, benefits and barriers related to diabetes foot care and development of peripheral neuropathy, which can be manipulated to improve the motivation and self-care management of daily foot-exam practice of patients who have been diagnosed with diabetes and peripheral neuropathy (Chin et al., 2012).

The diagnostic ankle-brachial index test compares the blood pressure in the ankles to the blood pressure in your arms and is used to predict the severity of peripheral artery disease. Screening is recommended in patients over 50 years of age and should be considered in patients under the age of 50 if preexisting risks are reported, such as smoking, hypertension, hyperlipidemia, or duration of diabetes greater than 10 years (ADA, 2016). The patient should be referred to a vascular specialist for significant symptoms of peripheral artery disease and ankle-brachial index testing (ADA, 2015; Baba, Foley, Davis, & Davis, 2014).

The criterion for a podiatry referral is classified by using four risk categories ranging zero to three. Category zero indicated no loss of protective sensation (LOPS) in the foot, and patients without any foot deformity, but those who had LOPS were in category one. Patients with LOPS and foot deformities or absence of pulses (dorsalis pedis or posterior tibial) were risk level two.

Individuals with LOPS, absence of pulses, a history of foot ulceration or amputation were in risk category three and required life-long monitoring and a referral to a vascular specialist (Smanioto, Haddad, & Rossaneis, 2014).

Infectious Diseases Society of America, 2012 Guidelines for Diagnosis and Treatment of Diabetic Foot Infections summarize 44 guideline recommendations to manage diabetic foot infections that are often due to neuropathic ulceration. The clinician can help to avoid the majority of foot infections by early diagnosis and therapeutic intervention. Two studies reviewed indicate improved outcome measures when increased awareness of self-management of foot care is encouraged in patients with diabetes (Baba et al., 2015; Sharma et al., 2014).

**Methods of assessment and measurement tool.** There were three articles reviewed which focused on methods for assessing neuropathy, a critical precursor of foot issues experienced by patients with diabetes (Sharma, Kerry, Atkins, Rayman, 2014; Smanioto et al., 2014; Szpunar et al., 2014). Authors utilized the monofilament 10-g touch test to assess foot sensitivity of patients with diabetes. The monofilament touch test improved awareness, education, and empowered the patient making them accountable for their healthcare. Authors of the studies found that the healthcare provider who educates patients will increase their awareness of risk, which may lead to increased adherence to foot care and daily monitoring reducing the occurrence of foot ulcers and amputations (Smanioto et al., 2014). The implication of a comprehensive assessment or monthly screening by the healthcare provider accompanied by patient education decreases risk factors related to development of foot ulcers (Baba et al., 2014; Kumar & Valame, 2014; Smanioto, Haddad, & Rossaneis, 2014; Szpunar et al., 2014).

A research article by Peterson and Virden, (2013) utilized an assessment tool developed to guide parameters identified in the Task Force Foot Care Interest Group of the American

Diabetes Association report, “Comprehensive Foot Examination and Risk Assessment.” The measurement tool tested by Peterson and Virden (2013) in a 3-step process developed to assess improvement in education and training. The quasi-experimental research design demonstrated positive outcomes, while testing tools that were developed to improve the care of type II diabetic patients. When the tool was implemented during patient care, a reduction in foot ulcers and amputations ranged from 45% to 85% (Peterson and Virden, 2013).

The QI tool, a comprehensive foot exam form, was tested by a healthcare provider and is recommended by the ADA annually and during each visit once risk has been identified (Peterson & Virden, 2013). The standard of care is an annual comprehensive foot exam with a general exam performed during each visit. The QI tool is very thorough and the general focus is on visual inspection and sensory testing with the monofilament. The study findings validate how foot exams are under-practiced and it is the most important foot-care behavior, which should be promoted in the diabetic population during each visit (Chin, Huang, & Hsu, 2012; Peterson & Virden, 2013; Szpunar et al., 2014). A descriptive study by Szpunar et al., (2014) provided a foot examination checklist for patients with diabetes that reminds healthcare providers to inspect the feet, assess pedal pulses and test for LOPS. A checklist is utilized to track the last foot examination, timing of exam and to clarify the need for a podiatry referral (Szpunar et al., 2014).

**Patient contributing factors.** While all patients with diabetes are at risk for DFUs related to neuropathy, the risk increases significantly with age. Kumar and Valame, (2014) reported a high-risk increase of diabetic foot complications in the percentage of individuals older than 60 years of age. Healthcare providers have the opportunity to identify patients at high risk of foot ulcers and amputation by assessing their motivation, effort and life circumstances during periodic visits (Bruun, Guassora, Nielsen, Siersma, Holstein, & Olivares, 2014). Smanioto et al.,

(2014) defined the diabetic foot as neuropathic, ischemic or neuro ischemic, which affects 30% to 70% of patients with diabetes and may lead to a DFU. The risk of developing a foot ulcer or having an amputation becomes even greater when a person has peripheral arterial disease, orthopedic deformity or a dermatology disorder (Kumar & Valame, 2014; Smanioto et al., 2014).

The study by Smanioto et al., (2014) observed 66% of patients who had a partner capable of influencing the adoption of a healthier lifestyle and self-care actions, which can sometimes limit adherence to self-care and treatment due to physical disabilities. The findings by Bruun et al., (2014) validated the evaluation of patient motivation made by the healthcare provider, which indicated a higher incidence of DFUs and amputations when life circumstances are poor versus good. The research studies reviewed did not compare diabetic interventions for management and strategies to decrease T2DM and the related comorbidities. The descriptive study by Smanioto et al., (2014) was limited due to the incomplete notes on subjects, outdated and incorrect records related to address and phone numbers decreasing the validity of the findings.

**Models of care and health perception.** In a descriptive study by Baba et al., (2014) 1668 patients received a comprehensive biennial face-to-face assessment and given questionnaires to assess their perceptions of foot health and clinical problems. Ninety-one percent of patients with pre-diabetes or diabetes had never been told by a healthcare provider that they had peripheral sensory neuropathy and 20% of patients in an inpatient setting never received a neurological examination by monofilament or measurement of ankle-brachial index. The majority of patients, 67.9% regarded their feet as normal in a study by Baba et al., 2014, however they were diagnosed with peripheral sensory neuropathy putting them a risk for DFU and amputations. Several limitations were described in the quasi-experimental study by Baba et al.,

(2014) indicating a bias toward an individual idea or feeling of normality reflecting a difference in the social, psychological and situational context as well as personal thoughts or beliefs.

The ADA recommends that the first step in optimizing management in foot care for all patients with diabetes should start by asking about self-perceived foot health (Baba et al., 2014). Common foot problems, such as deformity, dry skin, callus, fissures and infections were perceived as normal foot problems and 90% of patients had at least one of the problems that put them at risk for foot ulcers. Baba et al., (2014) recommends an ankle-brachial index test defined as an index less than .90 on either extremity or history of diabetic-related amputation to diagnose peripheral arterial disease. Researchers found that 46% of patients diagnosed with peripheral neuropathy did not report numbness, tingling or pain and they are still at risk for foot ulceration, hence indicating a need to screen using the of ankle-brachial index testing.

**Self-care management and implications.** In the article by Chin et al., 2012, the Health Belief Model was utilized to evaluate factors related to daily foot-exam practice that is recommended by the ADA among patients who have T2DM and peripheral neuropathy. Manipulation of modifiable risk factors utilized in the Health Belief Model was found to encourage individuals to perform daily foot exams. Self-care behaviors were affected by the perceived benefits, barriers, and threats of the severity of a disease, which are significant in motivating patients in diabetes self-management. Peterson and Virden, (2013) utilize the Chronic Care Model and ADA guidelines for the implementation of a Comprehensive Diabetic Foot Care Program and assessment tool, which proved to decrease hospitalization of patients with foot-related complications.

A descriptive cross-sectional study by Smanioto et al., (2014) analyzed implications of self-care, socioeconomic factors, and lifestyles related to risk of diabetic ulceration. The

assessment of dermatological conditions, LOPS, compromised blood flow, and deformities that lead to pressure points, or falls were recommended during a comprehensive foot examination. To prevent complications, self-inspection of feet and footwear were encouraged during each visit with education given to the patient and caregivers. Patients who wear shoes too small or poorly made are at increased risk of complications. The correct shoe will protect the feet from pressure ulcers and provide increased stability while ambulating. Choosing the correct shoes is an indication of self-care and is the responsibility of the patient or caregivers to protect their feet by wearing shoes that fit.

Healthcare is changing day to day, which requires patients to become accountable for their own health. The healthcare provider is expected to teach and motivate individuals who suffer from this life altering disease. In the study by Bruun et al., (2014) self-care management was affected either positively or negatively by life circumstances, family support, work or overall environment. Health outcomes were improved with interventional measures that involved social support from family and friends increasing motivation to improve self-care management of T2DM. The patients became empowered once taught how to assess the feet for decreased sensation.

Bruun et al., (2014) found that healthcare providers who use a patient-centered, holistic approach is in a position to motivate and empower the patient to become proactive in their care by monitoring blood glucose, daily exercise, healthy eating, and adherence to prescribed medications. The study indicated that prevention of DFUs and amputations is the lifelong goal of diabetic patients and with a timely referral to a multidisciplinary foot care team complications can be avoided. Many of the studies provide strategies that improve self-managed care, which will serve the current diabetic population assessed and caregivers by decreasing foot ulcers,

neuropathy and amputation, thereby improving quality of life (Baba et al., 2014; Bruun et al., 2014; Chin et al., 2012; Peterson & Virden, 2013; & Smanioto et al., 2014).

**Healthcare accountability.** Several studies discussed the importance of how timely assessment and education of T2DM can decrease complications and improve quality of life. A study by Szpunar et al., (2014) identified the effects of amputation related to diabetes, which result in permanent disability, loss of employment often leading to depression and increased morbidities. Chiwango and Njelek, (2015) identified and managed barriers in the diabetic population who are at risk for amputation by assessing 414 randomly selected patients from a clinic and providing self-care education. This study solidified the importance and possibility of decreased complication in T2DM patients simply by instituting early management of foot care and providing education to the patients, caregivers and healthcare providers.

Physical limitations of lower extremity amputations are the most feared complication of diabetes and the lifetime risk of an individual developing a foot ulcer is 25% with an 85% chance of amputation years to follow (Bruun et al., 2014). The correlational study assessed motivation and effort in diabetes self-management during a 6-year follow-up evaluation. The prevalence of foot ulcers during a six-year follow up was found to be 2.93% (95% CI 1.86 - 4.00). Patients with poor motivation in diabetes control and treatment demonstrated a higher risk of DFU and amputations (Bruun et al., 2014). The study indicated that the healthcare providers' view on patient motivation was associated with the presence of foot ulcers indicating poor diabetes control.

### **Outcome Measures and Benchmark**

The QI project was conceptualized as patients in Clinic A were assessed and poor outcomes were noted in patients with T2DM who suffered from foot ulcers or amputation. The

2016 ADA guidelines clearly state that all individuals who are diagnosed with diabetes should obtain a comprehensive foot examination at least once annually to identify any high-risk conditions (see Appendix H). The QI project was designed to improve practice to meet the standard of care. The ADA guidelines recommend healthcare providers to provide the patient and caregivers education in self-care foot management. The benchmark set in the QI project was to see 100 patients with T2DM between June 6th and August 12, 2016. Compliance with ADA guidelines was measured by a post-intervention review of charts via the electronic medical record.

### **Methodology/Project Plan**

This quality improvement project used a descriptive design to improve the care given to patients with T2DM. The review of charts identified a gap in care in Clinic A making it clear that improvement interventions were necessary in the primary care setting. The new knowledge gained during the review of literature emphasized the need to implement 2016 ADA guidelines for patients who have been diagnosed with diabetes. Improving the assessment skills of healthcare providers, and implementing an assessment tool to guide care, and documenting the comprehensive assessment criteria secures positive change for patients with diabetes.

### **Agency/Stakeholder Involvement**

The QI project has drawn the interest of the stakeholders, which include the employees at Clinic A, who seek change and improvement within the organization. Patient care has been of utmost importance to the key stakeholders and implementation of foot care according to the 2016 ADA guidelines is one of the first improvements attempted. Feasibility of the project was assessed and the healthcare providers agreed to participate in the project, which included the use of new assessment tools and procedures. The physician, manager and administrator were asked

to brainstorm ideas regarding the strengths, weaknesses, opportunities and threats (SWOT) within the microsystem that may affect the success of the project (see Appendix I). The SWOT analysis indicated readiness for this QI project.

The family nurse practitioner and physician's assistant participated in a questionnaire regarding healthcare perceptions of diabetic foot care in primary care (see Appendix J). The healthcare providers were asked to evaluate the foot assessment tools and answer eight questions regarding ADA guidelines of diabetic foot care, which increase the likelihood of each participating in the QI project. The nurse practitioner and physician assistant were given the tools, questionnaire, and articles in which, the assessment tool was discussed. Both providers were interested in the short version diabetic screening tool because of its brevity and ease of use. Therefore, this was the tool selected for the project implementation (see Appendix B).

Prior to utilization of the assessment tool developed by the United States Department of Health and Human Services, (n.d.) it was evaluated over a 2-day period to determine the feasibility. The feet of all patients seen in one facility, Seasons Memory Unit were assessed. The healthcare providers stated, "The tool is very easy to use and can be started by a medical assistant and completed by the healthcare provider." The assessment took 10 to 15 minutes depending on the cooperation of the patient.

### **Intervention Strategy**

The intervention of implementing ADA 2016 guidelines involved educating all of the stakeholders who worked together to care for individuals at Clinic A. The ADA guidelines recommend a presentation on foot care screening and management with expected documentation (see Appendix K). Thus, healthcare providers and medical assistants received one educational session lasting 45 minutes which emphasized the following: 1) examining skin integrity and

musculoskeletal deformities, 2) screening for peripheral arterial disease by assessing the pedal pulses, 3) using a 10-g monofilament to assess LOPS, and 4) pinprick, temperature or vibration sensation using a 128-Hz tuning fork, or ankle reflexes to rule out LOPS. While absent monofilament sensation indicate LOPS, two normal tests without an abnormal test rule out LOPS. Additionally, the ADA specifically encourages healthcare providers to refer patients who smoke, have LOPS, a significant claudication, a positive ankle-brachial index (ABI), structural abnormalities, or prior lower-extremity complications to podiatry or a vascular surgeon for lifelong preventive care and management. The foot screening tool and educational materials were given to the healthcare providers and medical assistants using appendices B, C, D, E, F, and G.

The medical assistants have already been trained to scan and link referrals to the permanent medical record. The new healthcare providers will be trained application of the ADA guidelines. The investigator will be training any new healthcare providers and medical assistants as needed. The education materials are in a file and the MA's are responsible for having them available each day as they travel with the providers.

### **Setting**

The intervention took place in San Antonio, Texas in the privacy of the patient's residence. Patients are visited in either a private residence, assisted living or in a group home. A majority of the patients have family, friends or caregivers that help manage the chronic illness of T2DM.

### **Sampling Strategy**

There are 414 diagnosed diabetic type 2 patients enrolled in Clinic A. For purposes of this QI project patients with diabetes seen during June 6th through August

12, 2016 were evaluated. Inclusion criteria: 1) T2DM seen by Clinic A, 2) between the ages of 18 to 90. Exclusion criteria: 1) patients assigned to the principle investigator, and 2) patients who refused the foot exam. Documentation of the assessment was done using the interventional tool provided (see Appendix B), then scanned into the electronic medical records utilized in the clinic, which ultimately became part of the permanent patient record.

### **Timeline**

The timeline for the entire QI project was June 1, 2016 through October 15, 2016 (see Appendix L). The educational sessions that were offered to the healthcare providers and medical assistants began June 1st through June 17, 2016. A second presentation educational education was provided to any new employees, as needed, through July 15, 2016. Data collection began June 6, 2016 once the providers began performing the comprehensive foot assessments and continued through August 12, 2016. Analysis of data was conducted from June 13, 2016 and continued through October 15, 2016.

### **Financial Implications**

The benefit of implementing the project outweighs the cost. An annual or periodic foot assessment is part of the required service healthcare providers should be completing for all diabetic patients. This comprehensive foot exam carries an additional charge and can be performed during the periodic monthly or quarterly exam. To implement the intervention an educational packet cost the company \$0.75. A total of 100 packets were made equaling \$75.00.

The medical assistants are paid \$11.00 per hour and the nurse practitioner and physician assistant are each paid \$100,000.00 annually, without benefits. The healthcare providers use their own car and gas. However, the provider does get 40 cents per mile for mileage. It requires

approximately 10 to 15 minutes to perform the foot exam and complete the assessment tool that is part of the permanent medical record. The average time necessary to assess the feet of a person with diabetes and deliver educational material takes approximately 20 to 30 minutes. This time varies if there are language differences requiring translation and/or mental disability.

The project lasted from June 6th through August 12, 2016. There were three healthcare providers and three medical assistants involved in assessing 48 diabetic patients and delivering the educational materials. The lead medical assistant assisted the investigator in scanning and linking the assessment tool to the patients' medical records. Her time equals approximately 20 hours at \$14.00 per hour for the length of the project. The healthcare providers and medical assistant receive 15 minutes for each of the 48 visits totaling 11 hours for the length of the project. There is a financial incentive for coding the foot exam and education of approximately \$170.00, which can offset the project costs.

Table 1 below describes the variable and fixed cost of the QI project over the time spent to implement the project. The planned intervention costs the company \$1,733.92.00 per 100 patients; however, this cost would have been acquired during scheduled follow-up visits except for the \$36.00 in educational materials. Two additional expenses acquired were the costs of the educational materials, which is an expense most clinics attain by developing and providing diabetic education along with the cost of a lead medical assistant. The estimated cost to reach the planned situation is approximately \$12,116.00 annually, which includes personnel time and supplies.

Table 1

*Variable and Fix Cost of the QI Project*

Fixed	Variable
Healthcare provider cost = \$1,153.92 (48.08/hr ÷ 2 = \$24.04 x 48 visits)	Education materials = \$0.75 each (48 patients x \$0.75 each)
Medical assistant cost = \$264.00 (11.00/hr ÷ 2 = \$5.50 x 48 visits)	--
Lead MA cost = \$280.00 (14.00/hr x 20 hrs)	--
Total fixed cost = \$1,697.92	Total variable cost = \$36.00

**Reimbursement**

The QI project will improve patient care, which will ultimately improve quality of life while decreasing long-term cost of ulcers and amputations. These outcomes are difficult to quantifiably measure; however, there are some financial incentives to following the ADA guidelines. The existing situation in Clinic A includes a visit charge of \$173.62 per patient. The comprehensive foot assessment adds an additional charge of \$64.00 and if education is addressed there is a maximum charge of \$106.00 per visit. This adds an additional \$170.00 of reimbursement per annual visit for each patient with diabetes. The planned situation increases the revenue by \$68,000 annually if the comprehensive foot assessment is completed and education is discussed and documented with all 400 diabetic patients. The total annual projected revenue for Clinic A if 400 diabetic patients receive a comprehensive assessment with education is \$137,448.00 (see Table 2).

Table 2

*Projected Revenue/Profit for Clinic A*

Variable	Plan revenues		Cost of plans		Profits	
	Existing plan	Proposed plan	Existing plan	Proposed plan	Existing plan	Proposed plan
Clinical Time	15 min	30 min	15 min	30 min	15 min	30 min
	Follow up: \$173.62	Follow up: \$173.62	NP/PA hours=	NP/PA hours =		
		Foot Assess: \$64.00	\$100,000/yr (48.08/hr)	\$100,000/yr (48.08/hr)		
		Education: \$106.00	MA hours = \$11.00/hr	MA hours = \$11.00/hr		
				Material = \$0.75/packet		
Total	\$173.62	\$343.62	-\$14.77	-\$30.29	\$158.85	\$313.33
Per 100 visits annually	\$17,362.00	\$34,362.00	\$1,477.00	\$3,029.00	\$15,885.00	\$31,330.00
Per 400 visits annually	\$69,448.00	\$137,448.00	\$5,808.00	\$12,116.00	\$63,540.00	\$125,332.00
Actual patients seen as of today is 48	\$8,333.76	\$16,493.76	\$708.96	\$1,453.92	\$7,624.80	\$15,039.84

**Funding**

The funding in the quality improvement project is provided by the company and is sustained as long as the providers are performing the comprehensive or periodic foot exams on diabetic patients. Sustainability has been discussed and the physician, owner of the clinic, would like to see patients receive an annual comprehensive foot exam. All the providers are currently completing the exams and the MAs are making sure the assessment tool is available on paper until it is uploaded in the electronic medical record, Aprima.

The biller was provided the appropriate billing codes for each charge. The financial reimbursement for the foot assessment and education is covered by Medicare, Medicaid, and other private insurance companies; so additional patient costs were not anticipated. Total expected profit after considering the estimated costs equals approximately \$125,332.00, which offsets the cost of initial implementation and anticipated maintenance of the program. Savings from decreased emergency room visits, hospitalizations and other treatments are expected, which will lead to improvement in patient care, patient satisfaction and sustainment of the project.

**Personnel**

The impact of the business plan has the potential to increase the revenue for the company and provide a potential opportunity for personnel to have an increase in pay. The anticipated change in personnel included committed healthcare providers who value improved patient care and follow recommended diabetic guidelines. To date the nurse practitioner and physician assistant who were involved in the project have left the company and two new nurse practitioners have joined the team. They were also interested in improving patient outcomes for diabetic patients, and have started performing comprehensive foot assessments. The medical assistants will continue scanning and

linking the assessment tool into the medical record or the assessment tool will be added to the permanent electronic medical record under the assessments tab for direct documentation. The physician (practice owner) and administrator will continue to increase their annual profit if the guidelines are implemented, documented, and maintained.

### **Measures and Method of Evaluation**

The project activities were organized according to the Plan-Do-Study-Act Model discussed by Gillam and Siriwardena, (2013) and Kirkpatrick's Evaluation Model by Kirkpatrick Partners (2015). The models provided insight on a higher level of learning that improved communication skills leading to quality improvement and care delivery in the T2DM population. The systematic process used in Plan-Do-Study-Act cycles was designed to improve the development of the quality improvement project, and test the changes during implementation of the intervention (Nelson, Batalden, & Godfrey, 2007).

Kirkpatrick's Foundational Principles are the key to a successful evaluation and measures the effectiveness of the training provided to the healthcare providers and medical assistants (Kirkpatrick Partners, 2015). The Kirkpatrick model was selected because it works well for the proposed intervention by guiding the healthcare provider in education at four different steps, (reaction, learning, behavior, and results) (Kirkpatrick Partners, 2015). The final result in the current project focused on improved care of the diabetic patient. Overall, the benefit of the program not only improved quality of care for diabetic patients, it may also cut cost of medical care related to foot ulcers and amputations over time and increase revenue for Clinic A.

The checklist discussed by Szpunar et al., (2014) is similar to the checklist in the assessment tool utilized by Clinic A and benefits the current QI project by prompting providers

to examine and refer in a timely manner according to ADA guidelines (see Appendix B). Table 3 outlines the goals set during the implementation phase of the quality improvement project, how they are met, assessed and analyzed.

The evaluation tool helped to objectively place patients in one of four risk categories. The four risk categories are developed to guide the healthcare provider on when to perform follow-up evaluations and referral to podiatry or vascular. The variables were defined by identification of LOPS and risk of ulceration during the assessment using the monofilament tool on the feet. Category 0 and 1 predict a low risk, and category 2 and 3 depict a high risk of ulceration (Smanioto et al., 2014). A podiatry referral is recommended for patients who have a category 1 or 2 risk and those who are in category 3 should be referred to a vascular specialist for life-long monitoring.

### **Data Collection Plan**

Demographic data was collected by reviewing 48 patient charts via the electronic medical record (EMR), Aprima along with other information pertaining to the post-intervention assessment of patients with T2DM. The data was collected and kept in a secure lock box at the end of each day. Retrieval of data throughout the QI project was collected and entered on a Microsoft Excel spreadsheet then transferred to a statistical analysis software package, known as SPSS. A checklist (see Appendix B), which is part of the assessment tool was used by the Doctor of Nursing Practice student to evaluate if patients and/or caregivers received education material and an appropriate referral.

Table 3

*Methods of Evaluation*

Objective	Outcome indicator	How it is assessed	How it is analyzed
1) By July 17, 2016, healthcare providers will provide 80% of patients with diabetes a comprehensive foot assessment according to ADA guidelines.	Providers will complete a comprehensive foot exam.	Chart review	Change in percentage
2) By July 17, 2016 healthcare providers will document a complete comprehensive assessment on 80% of the patients with diabetes using the assessment tool.	Providers will successfully and correctly document diabetic foot assessment.	Chart review	Change in percentage
3) By August 12, 2016, 80% of patients with diabetes who meet ADA criteria will receive a podiatry referral.	Provider will appropriately refer patient to a podiatrist.	Chart review	Change in percentage
4. By August 12, 2016, 80% of patients having T2DM will receive foot care educational materials with documentation in the patient's permanent chart.	Medical assistants give educational materials to patient or caregivers.	Chart Review	Change in percentage

**Data Analysis Plan**

Descriptive statistics were used to summarize the patients' demographic characteristics and describe their clinical profile along with the findings during each assessment. All the data was collected from the electronic medical record and analyzed. Outcomes were percentages of change with pre and post intervention calculations documented. The QI project was evaluated

during the intervention process to determine what went well, what could have been improved and what were lessons learned (Batalden et al., 2006). In the formative evaluation, the data obtained by the medical assistants served as guidance and allowed for improvement in a second plan-do-study-act cycle. However, due to the time limitation of the study only one full plan-do-study-act cycle was completed.

### **IRB Process**

There is no foreseen risk in this QI project. All healthcare providers, staff and medical assistants were aware of the QI project and willingly participated. A consent form was not necessary since the intervention was a part of their job responsibilities as a standard of care. All information gathered from patients remained confidential. A monetary gift card of \$10.00 was given to the healthcare providers and medical assistants in gratitude of participation in the project.

### **Results**

Implementation of the ADA guidelines by healthcare providers improved foot care management and documentation over a 60-day period compared to previous practice in the primary care setting. However, the goal set to provide 80% of patients who have diabetes with a complete comprehensive foot assessment was not met. There were 162 patients with diabetes scheduled to be seen during the QI project, and 30 % ( $n = 48$ ) were actually provided a comprehensive foot assessment by the healthcare providers (see Table 4). The majority of the patients were seen by the PA. The NP was scheduled for the majority of the 162 patients with diabetes, however many were seen for other reasons instead of a foot assessment.

Since only 48 patients were assessed the focus will be on the data reported on them. Out of the 48 patients evaluated 83 % ( $n = 40$ ) actually indicated a correct assessment and documentation by the healthcare providers. Therefore, the goal set for healthcare providers to

document a complete comprehensive assessment in 80% of the diabetic patients was met.

Referral to podiatry was evaluated by making sure the assessment tool was completed correctly and by chart audit in the referral section of the electronic medical record, Aprima. The charts reviewed demonstrated 11 of the 48 had a prior podiatry referral for unknown reasons. Once the study began it became obvious that many patients would require a vascular referral as well. Objective three was met because of the 37 patients remaining there were 40 % ( $n = 19$ ) of patients who appropriately received a referral based on their categorization and 29 of the patients had a referral made despite their low categorization, which did not warrant a referral.

Finally, objective four was met and 95 % ( $n = 46$ ) showed documentation of receipt of educational material during the foot assessment. The providers and medical assistants documented having taught the patients and/or caregivers how to examine their feet daily and the associated different risk factors of developing ulcers that may lead to infection and amputation. The diabetic educational material distributed was a great resource for the patient and caregivers. The providers reported good feedback from patients and families after delivering the educational materials.

Objectives one, two, three, and four were carried out by the Doctor of Nursing Practice student and a chart review was used to calculate the percentages of change that occurred. The goal was to provide a comprehensive assessment on 100 patients with diabetes and even though 162 were scheduled only 48 were actually assessed.

Table 4

*Pre and Post Intervention Results of Outcome Measures*

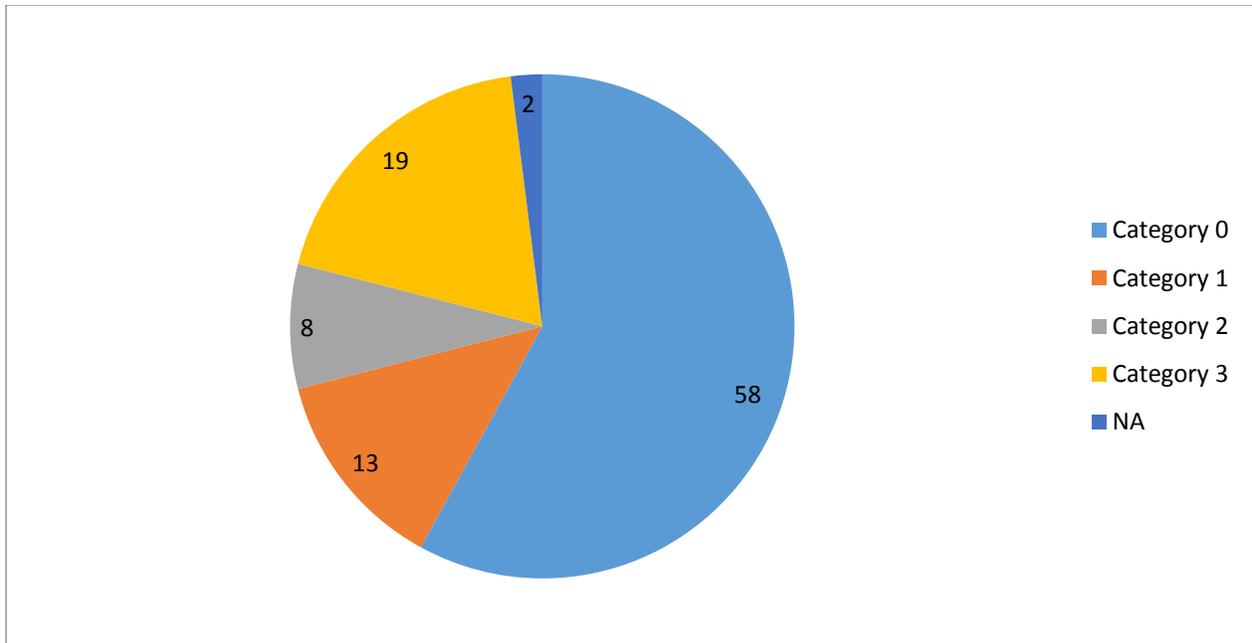
<u>Variable</u>	<u>Pre-intervention</u>	<u>Post-intervention</u>	<u>Goal</u>	<u>%</u>
Complete foot assessment	0	48	80	30.0
Completed assessment tool	0	40	80	83.3
Podiatry Referral	11	10	80	100
Vascular referral	0	9	80	100
Education Material	0	46	80	95.8

Demographic variables of the sample population were analyzed to determine the mean and mode method (see Table 5). Of the 48 patients, 57% were female. Patients' age ranged from 32 - 94 years of age with a mean of 66 years. More than half of the patients (52%,  $n = 25$ ) were Hispanic.

Table 5

*Means and Percentages for Patients on Demographic Variables*

<u>Characteristics</u>	<u><math>N = 48</math></u>	<u>%</u>
Gender		
Male	12	25.0
Female	36	75.0
Age (Years)		
30 - 49	9	18.0
50 - 69	20	42.0
Older than 70	19	40.0
Ethnicity		
Non-Hispanic white	20	41.6
Hispanic	25	52.1
Black	2	4.2
Asian	1	2.1



*Figure 1.* Categories of Referral Recommendation Percentages ( $N = 48$ ). Patients were evaluated for loss of protective sensation and placed in categories 0 through 3 depicting risk level for foot ulcer or amputation. Category 0 and 1 predict a low risk, and categories 2 and 3 depict a high risk of ulceration (Smanioto et al., 2014). A podiatry referral is recommended for patients who have a category 1 or 2 risk and those who are in category 3 should be referred to a vascular specialist for life-long monitoring.

### Summary of Findings

The healthcare providers demonstrated complete assessment skills and documentation of the comprehensive foot assessment of 40 patients. Eight more patients received an assessment, but the assessment tool was not completed correctly. This equals 83% and goal two was met for the 48 patients. There were 28 patients who fell in category 0 indicating no LOPS, 6 were in category 1 indicating minor LOPS, 4 were in category 2 indicating LOPS with a foot deformity or an absent pulse. Finally, there were 9 patients in category 3 indicating a severe risk due to present or past ulceration and/or amputation. One patient was not categorized due to an incomplete chart. Based on these patient categorizations, appropriate referrals were made for 100 % ( $n = 19$ ) of patients.

### **Discussion and Conclusion**

The city of San Antonio has a multitude of individuals who are not receiving annual comprehensive or periodic foot assessments recommended by 2016 ADA guidelines. Kumar and Valame, (2014) reported methods to improve care for patients who suffer from diabetes and are at risk of complications related to foot ulcers or amputation. Identification of LOPS is the start of identifying a problem and seeking collaboration with a specialist. It is the responsibility of healthcare providers to assess, educate and refer patients with T2DM, thereby limiting the disease process.

Clinic A is small local company striving to make a difference in individuals who live with T2DM and suffer from related comorbidities that can be avoided by improved management and education. Diabetes and foot complications have become an economical healthcare burden costing the nation thousands of dollars annually (Baba et al., 2014; Peterson & Virden, 2013; Szpunar et al., 2014). A correct and timely comprehensive assessment, education and referral as demonstrated in this project will decrease complications and improve quality of life for individuals who suffer from diabetes. Individuals who are diagnosed with diabetes are at risk for foot ulcers and amputations if the disease is ignored and not properly managed (Szpunar et al., 2014).

### **Main Findings**

Decreasing the risk of ulcers and amputations is highly recommended by the ADA (Peterson & Virden, 2013). Although too early to determine the implementation of an assessment tool for staff and healthcare providers to utilize while performing diabetic foot screenings and management in primary care is expected to increase observation methods. The use of appropriate referrals to podiatry or vascular specialty will limit complications. The project was successful in

increasing comprehensive foot examinations and documentation in the medical record, but did not reach the anticipated goal of 80% for all patients with diabetes seen during this period. This could be related to unexpected changes in provider staffing and scheduling issues.

### **Implications for Practice**

Similar to the QI project in Clinic A, Kumar and Valame (2014) report a high-risk increase of diabetic foot complications in the percentage of individuals who are greater than 60 years of age. Many of the diabetic patients seen by Clinic A were greater than 70 years of age (40%,  $n = 19$ ). This finding is another reason a comprehensive foot exam should be completed as soon as an individual is diagnosed with T2DM and annually thereafter.

The CDC (2014) identified a 20% drop in foot care preventative practices in the Hispanic population when compared with different ethnic groups. Since the majority of the clinic population is of Hispanic ethnicity it is especially relevant to Clinic A to perform an annual comprehensive assessment. In Clinic A there are 414 patients with diabetes; even though more than half of the patients are Hispanic all are in need of education of self-care management to lower the risk of ulcers and/or amputation. Future plans are to address the need to educate the population in Clinic A on self-management of foot care which will decrease risk of complications while improving quality of life as individuals live longer.

This project was similar to Chiwango and Njelek, (2015) who identified and managed barriers in the diabetic population who are at risk for amputation by assessing patients from a clinic and providing self-care education. The 48 patients seen in Clinic A were not aware of their disease process, which could potentially lead to DFUs and/or amputation. Patients' who are unaware of the need to have an annual foot assessment or are unable to identify early signs of

risks should be educated at the time they are diagnosed with T2DM (Bruun et al., 2014; Peterson & Virden, 2013; Sharma et al., 2014).

### **Lessons Learned**

The QI project made it possible to build relationships between the patient and healthcare providers. To improve the planning and implementation of the QI project a non-working professional relationship prior to start may have made a difference with participation involving key stakeholders. The Doctor of Nursing Practice student was the investigator and healthcare provider employed within the clinic. Future QI projects may have a higher buy in and success rate if the investigator is not an employee of the organization. As time passes, the company may see the benefits of the improved knowledge; cares provided to patients and appreciate the work done in the project.

The most important lesson learned from this QI project is that quality healthcare services can be developed and implemented in any size clinic despite the financial and staffing limitations. The development of a QI project, which encouraged a diabetic foot assessment using an American Diabetic Association recommended assessment tool resulted in positive outcomes for the patients and the clinic. The literature review supports the need to implement ADA guidelines, provide education and refer to specialist early in the stages of preventive care as the need presents.

### **Limitations**

During the QI project only 48 patients of the set goal of 100 were assessed even though 162 were actually scheduled to be seen by providers other than the Doctor of Nursing Practice student. Unavailability of patients with diabetes due to scheduling conflicts impacted the

outcome of the project. There was a limited time for the number of providers available to actually see each patient with the additional time required for the foot assessment.

To improve the adherence to ADA guidelines healthcare providers should be scheduled for no more than three comprehensive foot assessments daily thereby allowing plenty of time for the monthly follow-up visits scheduled for medication refills or sick calls. One recommendation made to the person scheduling the appointments is to list the reason for the visit on the daily schedule. This would limit confusion to why the patient is being seen, help remind providers that the foot assessment is necessary for this patient, and thus continue to increase revenue for the clinic.

A limitation encountered was due to time constraint as many patients are disabled and require assistance with taking off their socks or shoes. The healthcare provider did not feel that there was time to take the shoes or socks off and they did not ask the MA for their assistance. Many patients do not like going to the trouble to take off their shoes since it can be difficult and requires help taking them off and putting them back on. This is where education is important and teaching the importance of foot exams with a rationale can decrease ulcers and/or amputation and increase adherence to guidelines.

### **Relevance to the Role for Doctor of Nursing Practice Graduate and Implications for Practice**

The advanced practice registered nurse implemented evidence based nursing practice by developing and utilizing guidelines according to the ADA while meeting the needs of the diabetic population in the present microsystem assessed. Leadership skills in the QI process and systems thinking allowed the Doctor of Nursing Practice student to improve patient and healthcare outcomes by implementing DM foot assessment, documentation, education, and timely referrals

to specialist for patients, and caregivers (AACN, 2006). *The Doctoral Essentials of Nursing Practice* gave direction to the Doctor of Nursing Practice student in leadership and interdisciplinary collaboration to ameliorate quality of care and provide the healthcare providers, medical assistants and patients the guidance and education needed to be successful with self-management of patients with type II diabetes.

To provide the patient with resources and opportunity for quality care it was relevant for the Doctor of Nursing Practice student to seek guidance with multidisciplinary teams, such as podiatry and vascular cardiology. A multidisciplinary approach to diabetic foot care will reduce the probability of ulceration and amputations. Once referred to podiatry and/or a vascular specialist early preventive care, monitoring and education decreases the risk of hospitalization and limited mobility.

The goal of the project was to implement ADA guidelines using a diabetic tool developed by the United States Department of Health and Human Services, (n.d.) to improve screening practices in a primary care setting while teaching healthcare providers, patients, and caregivers techniques on self-care and assessment of feet of patients with diabetes. The Doctor of Nursing Practice student has the knowledge and ability to promote healthy lifestyle and illness prevention by reducing risk in the community through education. This was demonstrated by implementing 2016 guidelines in Clinic A. The Doctor of Nursing Practice student is prepared to communicate and employ collaborative skills to improve standards of care for aggregates, such as patients with diabetes. The Doctor of Nursing Practice student provided care and education to individuals in Clinic A, closing the gap between research and practice while helping the individual adapt to changes, which ultimately improved healthcare.

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## Appendices

Appendix A Microsystem Assessment Data

<b>Element</b>	<b>What information would help focus your assessment?</b>	<b>How could you get this information?</b>
Purpose	-Provide exceptional medical care and develop a positive provider/patient relationship that will improve satisfaction for both parties. -Full fill the medical needs of homebound patients or those who choose to be cared for in the privacy of their own home to promote health, independence and quality of life. -Utilize the latest evidence-based information to provide diagnosis, treatments, and laboratory services.	Located information from company website, "DoctorAtYourService"
Patients	Patients between 19-45 Patients between 65-79 Patients 80+ <hr/> High Risk Chronic Healthy Hospice	Paper charts or via computer
Professionals	1 Physician 2 Nurse practitioners 1 Physicians assistant 1 Administrator 1 Office Manager 5 Medical assistants 1 Scheduler	Observation of Office
Process	Admission- lab tests, medication reconciliation, Referrals -cardiology -neurology -psychology -endocrinology -HH referral for physical therapy  Follow up visit –review labs, education	Experience in field
Patterns	Monthly meeting Home Health Services Rotation of call schedule	Experience in field and collaboration of team members.

Appendix B Assessment Tool

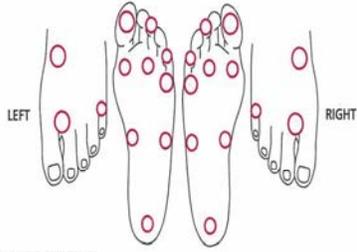
**COMPREHENSIVE FOOT ASSESSMENT**

**Diabetes Foot Screen** **Checklist for Diabetic Education**

Fill in the following blanks with a "Y" or "N" to indicate findings in the right or left foot.	R	L
Is there a history of a foot ulcer?		
Is there a foot ulcer now?		
Is there a claw toe deformity?		
Is there swelling or an abnormal foot shape?		
Is there elevated skin temperature?		
Is there limited ankle dorsiflexion?		
Are the toenails long, thick, or ingrown?		
Is there a heavy callus build-up?		
Is there foot or ankle muscle weakness?		
Is there an absent pedal pulse?		
Can the patient see the bottom of their feet?		
Are the shoes appropriate in style and fit?		

- Annual and periodic foot exams
- Daily foot inspections (abrasions)
- Daily exercise (walking)
- Clean, dry feet with nail and skin care
- Application of moisturizers to feet daily except between the toes
- Proper fitting shoes with clean socks
- Those with LOPS should assess feet with hands and visual inspection
- Does the patient need a Podiatry Referral?
- Does the patient need an Ankle-Brachial Index (ABI)?
- Did the patient receive diabetic educational materials during the comprehensive assessment?

Note the level of sensation in the circles:  
 "+" = Can feel the 5.07 filament      "-" = Can't feel the 5.07 filament



**RISK CATEGORY:**

- 0 No loss of protective sensation
- 1 Loss of protective sensation
- 2 Loss of protective sensation with either high pressure (callus/deformity) or circulation
- 3 History of plantar ulceration, neuropathic fracture (Charcot foot), or amputation

## Appendix C Handout on Foot Care - English

## Foot care for people with diabetes

Cornerstones4Care®

People with diabetes have to take special care of their feet. You should have a comprehensive foot exam by your doctor every year. Have your feet examined during every visit if you have problems with your feet, like loss of feeling, changes in the shape of your feet, or foot ulcers. This page shows some more things you can do on your own every day to keep your feet healthy.

**Wash your feet** in warm water every day. Test the water with your elbow to make sure that it is not too hot.



**Dry your feet well**, especially between the toes.



**Keep the skin soft** with a moisturizing lotion, but do not apply it between the toes.



**Inspect your feet every day** for cuts, sores, blisters, redness, calluses, or other problems. If you cannot see well, ask someone else to check your feet for you. Report any changes in your feet to your diabetes care team right away.



**Ask your diabetes care team or your podiatrist (foot specialist)** how you should care for your toenails. If you want to have a pedicure, talk with your team about whether it is safe for you.



Appendix D Handout on Foot Care - Spanish

## Cuidado de los pies para personas con diabetes

Cornerstones4Care™

Las personas con diabetes tienen que brindarle un cuidado especial a sus pies. Su médico debe hacerle un examen completo de los pies todos los años. Esta hoja muestra algunas cosas que puede hacer usted mismo para mantener sus pies saludables.

**Lávese los pies** con agua tibia todos los días.



**Séquese bien los pies**, sobre todo entre los dedos.



**Mantenga la piel suave** con una loción humectante, pero no la aplique entre los dedos.



**Inspeccione sus pies todos los días** en busca de cortaduras, llagas, ampollas, enrojecimiento, callosidades u otros problemas. Si no ve bien, pídale a otra persona que le revise los pies.



**Pregunte a su equipo para el cuidado de la diabetes** cómo debe cuidar las uñas de los pies.



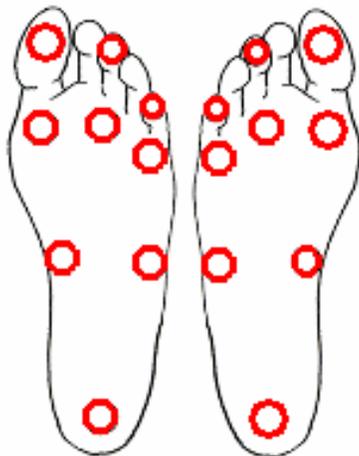
## Appendix E Diabetic Foot Self-Testing Instructions

Self-testing instructions (You may screen your own feet or ask a relative, friend, or neighbor to do it for you)

**Step 1 Step 2**

1. Hold the red filament by the paper handle, as shown in Step1.
2. Use a smooth motion to touch the filament to the skin on your foot. Touch the filament along the side of and NOT directly on □an ulcer, callous, or scar. Touch the filament to your skin for 1-2 seconds. Push hard enough to make the filament bend as shown in step 2.
3. Touch the filament to both of your feet in the sites circled on the drawing below.
4. Place a (+) in the circle if you can feel the filament at that site and a (-) if you cannot feel the filament at that site.
5. The filament is reusable. After use, wipe with an alcohol swab. Diabetic Foot Screen Test Sites

**If you have a (-) in any circle, take this form to your healthcare provider as soon as possible.**



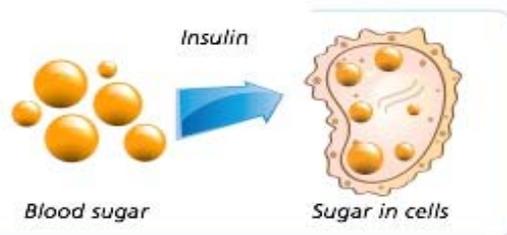
Appendix F Insulin Instructions – English

# Type 2 diabetes and insulin

Cornerstones4Care™

## What is insulin?

Insulin is a hormone that helps sugar move from your blood into your cells. Insulin is made by the beta cells in your pancreas.



Your cells need sugar for energy. Sugar from food makes your blood sugar level go up. Insulin lowers your blood sugar level by helping sugar move from your blood into your cells.

If you have type 2 diabetes, your body prevents the insulin it does make from working right. Your body may make some insulin but not enough.

## How insulin can help with type 2 diabetes

Many people with type 2 diabetes follow meal and physical activity plans to help manage their blood sugar. But following a meal plan and staying active often are not enough to keep blood sugar in check. Medicine is almost always necessary.

In type 2 diabetes, many people find that as their beta cells stop working over time, they need to take insulin. If you have been told that you could benefit from insulin but have delayed starting it, you are not alone. Many people worry about injecting themselves. They wonder if insulin has side effects. They wonder if taking insulin will interfere with their lives.

Today, there are many insulin products and insulin devices available to treat all the stages of type 2 diabetes. You and your diabetes care team can work together to find the diabetes products that are right for you.

Types of Insulin	When It's Usually Taken	How Soon It Starts Working*	When Its Effect Is Strongest	How Long It Lasts
<b>Analog insulin</b>				
Fast-acting insulin	Right before a meal	15 minutes	30 to 90 minutes	3 to 5 hours
Long-acting insulin	30 minutes before the evening meal or at bedtime	1 hour	Steady over time	Up to 24 hours
Premixed (mixture of fast-acting and intermediate-acting insulins)	Before breakfast and/or before the evening meal	5 to 15 minutes	Varies	Up to 16 hours <sup>†</sup>
<b>Human insulin</b>				
Short-acting insulin (also called regular insulin)	30 minutes before a meal	30 to 60 minutes	2 to 4 hours	5 to 8 hours
Intermediate-acting insulin (NPH)	30 minutes before breakfast, the evening meal, or at bedtime	1 to 3 hours	8 hours	Up to 16 hours
Premixed (mixture of short-acting [regular] and intermediate [NPH] insulins)	30 minutes before breakfast and/or before the evening meal	30 to 60 minutes	Varies	Up to 16 hours <sup>†</sup>

\*All times shown are approximate. <sup>†</sup>Check label.

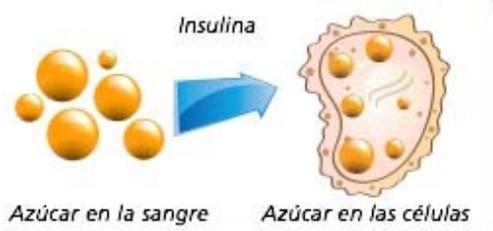
Appendix G Insulin Instructions – Spanish

# Diabetes tipo 2 e insulina

Cornerstones4Care™

## ¿Qué es la insulina?

La insulina es una hormona que ayuda al azúcar a moverse de su sangre a sus células. La insulina es producida por las células beta en su páncreas.



Sus células necesitan azúcar para generar energía. El azúcar de los alimentos hace que su nivel de azúcar en la sangre suba. La insulina baja su nivel de azúcar en la sangre al ayudar a que el azúcar se mueva de su sangre a sus células.

Si usted tiene diabetes tipo 2, su cuerpo evita que la insulina que produce funcione correctamente. Su cuerpo puede producir algo de insulina, pero no lo suficiente.

## Cómo puede ayudar la insulina a la diabetes tipo 2

Muchas personas con diabetes tipo 2 siguen un plan de comida y actividad física para ayudar a controlar su azúcar en la sangre. Pero muchas veces seguir un plan de comida y mantenerse activo no es suficiente para tener controlada el azúcar en la sangre. Casi siempre es necesario tomar medicinas.

En la diabetes tipo 2, muchas personas descubren que según sus células beta dejan de funcionar con el tiempo, necesitan usar insulina. Si le han recomendado que la insulina puede beneficiarle pero lo ha estado posponiendo, no está solo. Muchas personas se preocupan por tener que ponerse inyecciones. Se preguntan si la insulina tiene efectos secundarios. Se preguntan si usar insulina interferirá con sus vidas.

Hoy día existen muchos productos de insulina y dispositivos de insulina para tratar todas las etapas de la diabetes tipo 2. Usted y su equipo para el cuidado de la diabetes pueden trabajar juntos para encontrar los productos para la diabetes adecuados para usted.

Tipos de insulina	Cuándo se usa generalmente	Cuán rápido comienza a funcionar*	Cuándo es más fuerte su efecto	Cuánto dura
<b>Insulina análoga</b>				
Insulina de acción rápida	Justo antes de comer	15 minutos	30 a 90 minutos	3 a 5 horas
Insulina de acción prolongada	30 minutos antes de la cena o a la hora de acostarse	1 hora	Uniforme	Hasta 24 horas
Premezclada (mezcla de insulinas de acción rápida y acción intermedia)	Antes del desayuno y/o antes de la cena	5 a 15 minutos	Varía	Hasta 16 horas <sup>†</sup>
<b>Insulina humana</b>				
Insulina de acción rápida (también llamada insulina regular)	30 minutos antes de comer	30 a 60 minutos	2 a 4 horas	5 a 8 horas
Insulina de acción intermedia (NPH)	30 minutos antes del desayuno, la cena, o a la hora de acostarse	1 a 3 horas	8 horas	Hasta 16 horas
Premezclada (mezcla de insulinas de acción rápida [regular] e intermedia [NPH])	30 minutos antes del desayuno y/o antes de la cena	30 a 60 minutos	Varía	Hasta 16 horas <sup>†</sup>

\*Todos los tiempos son aproximados. <sup>†</sup>Consulte la etiqueta.

## Appendix H Foot Care Recommendations

- Perform a comprehensive foot evaluation each year to identify risk factors for ulcers and amputations.
- 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).
- The examination should include inspection of the skin, assessment of foot deformities, neurological assessment including 10-g monofilament testing and pinprick or vibration testing or assessment of ankle reflexes, and vascular assessment including pulses in the legs and feet.
- Patients with a history of ulcers or amputations, foot deformities, insensate feet, and peripheral arterial disease are at substantially increased risk for ulcers and amputations and should have their feet examined at every visit.
- Patients with symptoms of claudication or decreased or absent pedal pulses should be referred for ankle-brachial index and for further vascular assessment.
- 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).
- 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 lifelong surveillance.
- Provide general foot self-care education to all patients with diabetes.

Foot ulcers and amputation, which are consequences of diabetic neuropathy and/or peripheral arterial disease (PAD), are common and represent major causes of morbidity and mortality in

people with diabetes. Early recognition and treatment of patients with diabetes and feet at risk for ulcers and amputations can delay or prevent adverse outcomes.

The risk of ulcers or amputations is increased in people who have the following risk factors:

- History of foot ulcer
- Amputation
- Foot deformities
- Peripheral neuropathy with LOPS
- Preulcerative callus or corn
- PAD
- Poor glycemic control
- Visual impairment
- Diabetic nephropathy (especially patients on dialysis)
- Cigarette smoking

Clinicians are encouraged to review ADA screening recommendations for further details and practical descriptions of how to perform components of the comprehensive foot examination.

Evaluation for Loss of Protective Sensation:

All adults with diabetes should undergo a comprehensive foot evaluation at least annually to identify high-risk conditions. Clinicians should ask about history of foot ulcers or amputation, neuropathic and peripheral vascular symptoms, impaired vision, renal disease, tobacco use, and foot care practices. A general inspection of skin integrity and musculoskeletal deformities should be performed. Vascular assessment should include inspection and assessment of pedal pulses.

The neurological exam performed as part of the foot examination is designed to identify LOPS rather than early neuropathy. The 10-g monofilament is the most useful test to diagnose LOPS.

Ideally, the 10-g monofilament test should be performed with at least one other assessment (pinprick, temperature or vibration sensation using a 128-Hz tuning fork, or ankle reflexes).

Absent monofilament sensation suggests LOPS, while at least two normal tests (and no abnormal test) rule out LOPS.

Evaluation for Peripheral Arterial Disease:

Initial screening for PAD should include a history for decreased walking speed, leg fatigue, claudication, and an assessment of the pedal pulses. Ankle-brachial index testing should be performed in patients with symptoms or signs of PAD. Due to the high estimated prevalence of PAD in patients with diabetes and the fact that many patients with PAD are asymptomatic, an ADA consensus report on PAD (68) suggested that ankle-brachial index screening be performed in patients 50 years of age and older and be considered in patients under 50 years of age who have other PAD risk factors (e.g., smoking, hypertension, dyslipidemia, or duration of diabetes >10 years).

Patient Education:

Patients with diabetes and high-risk foot conditions (history of ulcer or amputation, deformity, LOPS, or PAD) should be educated about their risk factors and appropriate management.

Patients at risk should understand the implications of foot deformities, LOPS, and PAD; the proper care of the foot, including nail and skin care; and the importance of foot monitoring on a daily basis. Patients with LOPS should be educated on ways to substitute other sensory modalities (palpation or visual inspection using a nonbreakable mirror) for surveillance of early foot problems.

The selection of appropriate footwear and footwear behaviors at home should also be discussed.

Patients' understanding of these issues and their physical ability to conduct proper foot

surveillance and care should be assessed. Patients with visual difficulties, physical constraints preventing movement, or cognitive problems that impair their ability to assess the condition of the foot and to institute appropriate responses will need other people, such as family members, to assist in their care.

#### Treatment:

People with neuropathy or evidence of increased plantar pressures (e.g., erythema, warmth, or calluses) may be adequately managed with well-fitted walking shoes or athletic shoes that cushion the feet and redistribute pressure. People with bony deformities (e.g., hammertoes, prominent metatarsal heads, bunions) may need extra-wide or -deep shoes. People with bony deformities, including Charcot foot, who cannot be accommodated with commercial therapeutic footwear will require custom-molded shoes. Special consideration and a thorough workup should be performed when patients with neuropathy present with an acute onset of a red, hot, swollen foot or ankle, and Charcot neuroarthropathy should be excluded. Early diagnosis and treatment of Charcot neuroarthropathy is the best way to prevent deformities that increase the risk of ulceration and amputation.

Most diabetic foot infections are polymicrobial, with aerobic gram-positive cocci. *Staphylococci* are the most common causative organisms. Wounds without evidence of soft-tissue or bone infection do not require antibiotic therapy. Empiric antibiotic therapy can be narrowly targeted at gram-positive cocci in many patients with acute infections, but those at risk for infection with antibiotic-resistant organisms or with chronic, previously treated, or severe infections require broader-spectrum regimens and should be referred to specialized care centers (69). Foot ulcers and wound care may require care by a podiatrist, orthopedic or vascular surgeon, or rehabilitation specialist experienced in the management of individuals with diabetes (69).

American Diabetes Association. (2016). Microvascular complications and foot care. *In Standards of Medical Care in Diabetes. Diabetes Care, 39, S72–S80*

Appendix I SWOT Analysis

<b>Strengths</b>	<b>Weaknesses</b>
<p>Local company</p> <p>Employee diversity -different ideas, perspectives</p> <p>New management</p> <p>Doctor reputation</p> <p>Improved organization structure</p> <p>The drive to strive for more</p> <p>Company established in 2010 -continues to improve</p>	<p>Limited services offered by the company</p> <p>Lack of standard guidelines</p> <p>Only one doctor</p> <p>Communication issues among staff and management</p> <p>Low moral level</p> <p>Work ethics (unreliable employees)</p> <p>Employee retention (high turnover)</p> <p>Lack of employee appreciation</p> <p>Lack of educational material for patients</p>
<b>Opportunities</b>	<b>Threats</b>
<p>New management</p> <p>New ideas</p> <p>Practice is more open minded to ideas</p> <p>Growth in the community</p> <p>“The Niche” –not many companies offer home visits.</p> <p>Huge need for services</p> <p>Marketing. We have not invested to much money or time yet</p>	<p>Competition</p> <p>“Bad seed employees”</p> <p>Keep with the norm of before “start to get comfortable”</p> <p>Unwillingness to change</p> <p>Medical reviews (audits by insurance companies)</p> <p>Payment reimbursement</p> <p>Retirement of physician</p>

## Appendix J Healthcare Perceptions Questionnaire

<b>Healthcare Perceptions of diabetic foot care</b>	<b>Family Nurse Practitioner</b>	<b>Physicians Assistant</b>
1. In your opinion, what needs to be done to improve the care of the diabetic population in our clinic?	Get A1c down Teach self-care Motivate them to eat 3 meals/day.	Teach them diet, exercise, & medication adherence.
2. What do you think about the documentation pertaining to the ADA guidelines? For example, DM and aspirin therapy?	Aspirin therapy is not our problem. Most of the DMs have a specialist who should have them on it.	Not sure
3. How often do you do foot exams on diabetic patients?	Annually and when I think they need it.	Annually
4. Will you list 2 to 3 reasons why diabetic patients should have a foot assessment?	Standard of Care per ADA guidelines & Most DMs are unaware they have neuropathy issues.	Early detection of sores or ulcerations that lead to serious infection. To detect neuropathy or vascular compromise.
5. Is there a reimbursement for foot care?	Yes	I suspect there could be reimbursement once a year for the comprehensive exam.
6. Would you be willing to give the interventional assessment tool a trial run?	Yes, I already implement my own foot exam.	Yes
7. How long would you expect to assess the foot and document findings?	2 minutes	5-10 minutes
8. What is it that you do not like about the assessment tool?	The comprehension exam is difficult to understand.	Not sure, I have not used it.

## Appendix K Comprehensive Foot Exam Lesson Plan

Objective 1) By July 17, 2016, healthcare providers will provide 80% of patients with diabetes a comprehensive foot assessment according to ADA guidelines.

- A presentation regarding guidelines for a diabetic foot exam including recommended times was delivered to the healthcare providers over 45 minutes.
- The healthcare provider demonstrated how and when to perform a diabetic foot exam on a medical assistant. The return demonstration was observed for accuracy and thoroughness.
- Providers will obtain a history of past foot ulcers, amputations, neuropathy, peripheral disease, impaired vision, deformities, tobacco use, and self-management of feet (ADA, 2015).
- Visual inspection of feet, assessment of pulses, and testing for loss of protective sensation (LOPS) by a 10g monofilament (HRSA, n.d.).
- The healthcare provider will explain why and how the feet are assessed during the examination.

Objective 2) By July 17, 2016, healthcare providers will document a complete comprehensive assessment in 80% of the diabetic patient charts using the assessment tool.

- The healthcare provider will complete the assessment tool during the examination.
- The assessment tool will be scanned into the permanent electronic medical record and linked to the permanent chart.

Objective 3) By August 12, 2016, 80% of patients with diabetes who meet ADA criteria will receive a podiatry referral.

- Educational session regarding guidelines for diabetic foot exams and recommendation for referral to podiatry or vascular were conducted.
- Question/answer session after power point presentation were held.
- Diabetic patients who meet ADA criteria will receive a podiatry referral after a foot assessment.
- A mechanism for communication of referral was developed and conducted by MAs

Objective 4) By August 12, 2016, 80% of patients having T2DM will receive foot care educational materials with documentation in the patient's permanent chart.

- A presentation on foot care management will be delivered to MAs. Educational material provided in English and Spanish was made available to MAs for distribution.
- MAs distributed educational material on foot care and diabetes management to the patient and/or caregiver.

Appendix L QI Project Timeline

Week#	June					July				August					September					October					November				
	1	2	3	4	5	1	2	3	4	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
Provide Instructional Section	x	x				x	x																						
Review Charts			x	x	x	x	x	x	x	x			x	x															
Data Analysis			x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x								
Education to new employees		x	x			x	x								x	x													
Manuscript development	x	x						x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x					
Dissemination of findings to stakeholders			x								x	x											x	x	x				
Presentation of project																									x	x			