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UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

EFFECTIVENESS OF THE DEVELOPMENT AND IMPLEMENTATION OF A NURSE-LED DIABETIC FOOT SCREENING CLINIC

A Capstone Research Project Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing Practice

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July 2016

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 $\label{lem:entitled$

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EXECUTIVE SUMMARY

Garcia, Alexandra. Effectiveness of the Development and Implementation of a Nurse-Led Diabetic Foot Screening Clinic. Unpublished Doctor of Nursing Practice Capstone Project, University of Northern Colorado, 2016.

Diabetic foot ulcers are a common health complication in patients with Type 2 diabetes mellitus. Evidence demonstrates the most effective method of reducing the development of such complication is early screening and detection of the disease.

Nevertheless, regular foot screenings are not a common occurrence among patients with Type 2 diabetes mellitus in outpatient settings in Puerto Rico.

A nurse-led diabetic foot screening clinic was developed in a local outpatient clinic. The project objective was to implement a foot screening protocol for all Type 2 diabetes mellitus patients age 18 years or older as a method of preventing the development of a diabetic foot ulcer. In addition, this project helped detect a patient's risk level of developing diabetic foot ulcers and provided patients with foot care management education as part of their yearly checkup. The implementation of the nurse-led diabetic foot screening was piloted amongst a small group of patients. The project was evaluated by utilizing Donabedian's (2003) framework.

Donabedian's (2003) framework assisted in identifying advantages and disadvantages of implementing new healthcare activities in patient care. In this capstone project, various outcomes were evaluated before, during, and after the implementation of this project. The results demonstrated the need for a nurse-led diabetic foot screening

clinic. The results of this project are not final since the project was not fully implemented and is considered a pilot study. Further work is needed to evaluate the viability of this protocol in other outpatient clinic settings to determine the most effective type of approach.

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CHAPTER I

PROBLEM STATEMENT

Introduction

Type 2 diabetes mellitus is considered to be one of the most prevalent public health problems of the 21st century. The Centers for Disease Control and Prevention (CDC; 2011) estimated that approximately 25.8 million people in the United States have been diagnosed with the disease. Some say Type 2 diabetes mellitus should be considered a pandemic, affecting not only the U.S. population but also millions of people around the world (CDC, 2011; Ginter & Simko, 2012). In Puerto Rico, Type 2 diabetes mellitus affects thousands of people. In 2001, 9.8 % of the Puerto Rican population was identified as having diabetes; by 2007, the rate increased to 12.5% (Department of Health of Puerto Rico, 2010).

Studies have demonstrated that the rise of Type 2 diabetes mellitus in today's society is due to lifestyle. Habits such as poor food choices, overeating, and a sedentary lifestyle have been known to increase a patient's ability to develop the disease (CDC, 2011). Patients who have poor control of the disease increase their risk of developing complications. One such health problem is the development of diabetic foot ulcers. The development of diabetic foot ulcer increases a patient's incidence of developing foot infections, prolonged healing time, poor quality of life, gangrene, and lower limb non-traumatic amputations (Aalaa, Malazy, Sanjari, Peimani, & Mohjeri-Tehrani, 2012; Alavi

et al., 2014; American Diabetes Association, 2013; Dorresteijn & Valk, 2012; Driver, Fabbi, Lovery, & Gibbons, 2010; Dunn, 2007; Jaska & Mahoney, 2010; Monteiro-Soares, Boyko, Ribeiro, Ribeiro, & Dinis-Ribeiro, 2011). Evidence has demonstrated that the key to reducing the risk of a patient developing diabetic foot ulcer is prevention and early detection of the disease. For this reason, the aim of this project was the development and implementation of a nurse-led screening protocol for diabetic foot ulcers established in an outpatient clinic in Puerto Rico.

Definitions

In this capstone, there was use of various terms seen in the literature. It was necessary to provide the reader with the definition for each of these terms when discussing diabetic foot ulcer. The following definitions were used in this project.

Diabetic foot. A common foot problem seen in diabetic patients "with neurologic disorders with some degree of vascular involvement with or without metabolic complications of diabetes in lower extremity and prone to infection, scarring, with or without deep tissue damage" (Aalaa et al., 2012, p. 1).

Diabetic foot ulcer. Foot lesions that develop in patients with Type 2 diabetes mellitus due to uncontrolled diabetes and the development of risk factors such as foot trauma (Boulton, 2008).

Foot infection. Wounds with "the presence of inflammation or purulence" (Lipsky et al., 2012, p. e133).

Foot ulcer. "Lesions that involve a skin break with loss of epithelium, and that may extend into the dermis and deeper layers, sometimes involving bone and muscle" (Boulton, 2004, p. 1344).

Background and Significance

A diabetic foot ulcer is a common complication in Type 2 diabetes mellitus patients. Approximately 25% of all patients who have diabetes mellitus will develop diabetic foot ulcer in their lifetime (McCall, 2014). Such lesions are more commonly seen in Type 2 diabetes mellitus patients who have developed peripheral neuropathy and other predisposing risk factors such as ischemia due to peripheral vascular disease, unattended foot traumas, and foot deformities such as claw toe (Boulton, 2008; Clayton & Elasy, 2009; Crawford, Inkster, Kleijnen, & Fahey, 2007; Jaska & Mahoney, 2010). Disease such as peripheral neuropathy contributes to a patient's loss of foot sensation. Absence of foot sensation limits the patient's ability to perceive the development of foot lesions. Therefore, trauma such as punctures and the formation of foot blisters might occur without a patient's knowledge (Dunn, 2007). Sibbald et al. (2012) indicated:

If a person has diabetes and no other complication, he/she has a 2% risk of developing a foot ulcer. Annually this incidence increases to 4.5% with neuropathy and to 13.8% with peripheral vascular disease. When any 2 of 4 criteria are present; previous ulcer, previous amputation, peripheral vascular disease, and neuropathy, the incidence of developing a foot ulcer increases to 32.3%. (p. 467)

Patients who acquire diabetes foot ulcers are at risk of developing complications including infection of the lesions, reoccurrence of foot ulcers, gangrene, and lower limb amputation (Aalaa et al., 2012; Alavi et al., 2014; Dorresteijn & Valk, 2012; Driver et al., 2010; Dunn, 2007; Jaska & Mahoney, 2010; Monteiro- Soares et al., 2011). Foot infections in patients with diabetic foot ulcers are extremely common. It is estimated that 40-80% of patients who develop diabetic foot ulcer have foot infections. These infections are one of the primary causes for a patient's admittance to a hospital and lower limb amputations. Patients who are detected early with diabetic foot ulcer have an

advantage of lowering the risk of foot infection. Moreover, those who receive early attention to diabetic foot ulcers and develop a foot infection are more likely to receive treatment early, reducing their risk of hospitalization and amputation (Richard, Sotto, & Lavigne, 2011).

Recent studies demonstrated that those who developed diabetic foot ulcers had a 60% chance of reoccurrence of the disease in one year's time compared to those who never developed such lesions (Nhan, Strauss, & Miller, 2013). Driver et al. (2010) mentioned in their study that "more than 60% of non-traumatic lower limb amputations occur in diabetic individuals, and at least 80% of amputations are preceded by an ulcer" (p. 17S). Studies demonstrated that amputations occur often in patients who have developed peripheral vascular disease and peripheral neuropathy, which in turn leads to patients developing foot ulcers and infections (Dorsey, Eberhardt, Gress, & Geiss, 2009).

Another important fact is diabetic foot ulcer also have a negative effect on a patient's quality of life. Evidence demonstrated a patient's quality of life is considerably lower in patients with diabetic foot ulcer than those who have diabetes mellitus without foot ulcers (Jaska & Mahoney, 2010). Jaska and Mahoney (2010) stated that the development of such foot ulcers causes patients to have

a substantial negative effect on emotional, physical and economic functioning for diabetic patients. ...patients with diabetic foot ulcers report more depression, less satisfaction with life and poorer psychosocial adjustment to illness than diabetics who do not suffer from foot ulcers. (p. 503)

It is believed that a patient's quality of life is affected due to inexperience of managing the disease, an inability to move easily due to diabetic foot ulcer, and an increased dependability on others (Jaska & Mahoney, 2010). Therefore, diabetic foot ulcers not only affect the patient physically but also affect a patient's mental wellbeing.

The cost of treating diabetic foot ulcer is an economic burden to both the individual and the U.S. government; evidence suggests the total cost of treatment for one ulcer episode might range from \$1,892 to \$27,721 (McCall, 2014). Cost depends on the severity, longevity of the disease, and complications of the disease (Driver et al., 2010; McCall, 2014; Stockl, Tafesse, Vanderplas & Chang, 2004). McCall (2014) conducted a study in which she evaluated the cost of diabetic foot ulcers in the United States. In her study, McCall indicates those who were "employed, privately insured patients with a diabetic foot ulcer incurred over \$3200 in annual work-loss costs due to disability and medically related absenteeism" (para 9). In addition, she stated that diabetic foot ulcers had a crucial impact on the U.S. healthcare budget. McCall estimated that the direct and indirect costs of diabetic foot ulcer to the U.S. government are approximately \$9 billion to \$13 billion. An enormous amount of government money is used for this disease, which could be reduced with prevention and early detection.

The most essential method to reduce patient time of healing and risk of amputation is health prevention and early detection of the disease. Studies have demonstrated that screening patients for developing risk factors such as peripheral neuropathy reduces this risk. Furthermore, regular foot inspections provide the healthcare provider with the ability to educate and reinforce self-care foot behaviors, which help prevent the development of foot ulcers (Boulton, Vileikyte, Ragnarson-Tennvall, & Apelquist, 2005; Bryant, & Beinlich, 2003; Sibbald et al., 2012). Therefore, it is imperative that regular foot screenings be carried out on a regular basis in patients with Type 2 diabetes mellitus.

Purpose Statement and Patient Population, Intervention, Comparison/Intervention, and Outcome Question

Purpose Statement

Diabetic screening should be considered part of the annual physical examination in general practice. However, this is not always the case. The Office of Disease Prevention and Health Promotion (2014) estimated that in 2008 approximately 68% of adults with diabetes mellitus ages 18 years and older received a foot screening that year in the United States and Puerto Rico. One of the major causes contributing to a lack of healthcare providers to practice regular foot screening was limited time (Alavi et al., 2014). The U.S. government has set a goal of raising diabetic foot ulcer screening to 78% in the population by 2020; this objective can be seen in Healthy People 2020 (Office of Disease Prevention and Health Promotion, 2014). However, rural community health centers lack human resources needed for the development and implementation of a diabetic foot screening protocol including those in Puerto Rico. One simple method of improving the shortage of healthcare providers available to screen is the implementation of a nurse-led diabetic foot-screening protocol initiative for early detection of foot problems and a risk of developing foot ulcers.

Nurse-led screening protocols have become increasing popular around the world (Carey & Courtenay, 2007; Wong & Chung, 2006). Such protocols can be seen as a strategic method to improve a patient's health care by increasing the quantity of patients who are screened without overwhelming the primary care clinic. In addition, these screening protocols provide patients with continuous and supportive health care at an affordable cost compared to clinics run by medical doctors (Carey & Courtenay, 2006; Wong & Chung, 2006). Wong and Chung published an article in 2006 in which they

described different services available in nurse-led protocols in clinics: "health assessments to monitor a patient's health condition and symptoms, health education to facilitate compliance and a healthy lifestyle, and coordination of care" (p. 359). Carey and Courtenay (2006) published a systematic review to examine the effectiveness of nurse-led diabetes clinics; in their article, they concluded that various benefits can be seen in the implementation of such initiatives: improvement in self-management of glucose control, improvement in a patient's quality of life, reduction in the cost of treatment, and reduction in hospital stays (Bryant & Beinlich, 2003; Carey & Courtenay, 2006). For this reason, nurse-led screening protocols in clinics are considered to play a key role in providing patients with optimal health promotion, prevention practices, and managed patient care.

Patient Population, Intervention, Comparison/Intervention, and Outcome Question

The patient population, intervention, comparison/intervention, and outcome (PICO) question format was utilized for the development of the clinical question used in this evidence-based practice project (Melnyk & Fineout-Overholt, 2010). This question provided the clinician with guidance in finding and assessing the evidence needed to improve practice. The following PICO question guided this evidence-based practice project:

Will the implementation of a nurse-led diabetic foot-screening protocol, guided by the structure-process-outcome framework, improve the quality of care, screen, and educate patients on proper foot care for Type 2 diabetes mellitus' patients of a rural area clinic in Puerto Rico?

Theoretical Framework

The theoretical framework used in this capstone project was Donabedian's (2003) structure-process-outcomes framework. This framework provided a structured viewpoint on the importance of quality improvement in health care as a means of enhancing patient health outcomes. In Donabedian's framework, three key aspects must be viewed when improving quality health care: structure, process, and outcomes (see Figure 1).

The theory describes structure as the setting in which medical care is provided to a patient (Hall & Rousel, 2014) including "material resources, human resources and organizational characteristics" (p. 187). By examining the quality of the structure of a healthcare setting, one might identify both opportunities and limitations in the healthcare systems that restrain or enhance the standard of care. Donabedian (2003) suggested that structure be the key factor to the quality of health care a person might receive.

Donabedian's (2003) framework described process as the integration and completion of healthcare activities such as health promotion and prevention, diagnosis, treatment, and rehabilitation. Such tasks might be completed by a healthcare provider, patient, or patient's primary caregiver. Yet, Donabedian's framework did not focus on the quality of the process structure per se but rather on the outcomes this process would provide (Hall & Rousel, 2014).

The concept of outcomes is described as the "desirable and undesirable changes that occur in individual or population that are the result of healthcare" (Hall & Rousel, 2014, p. 188). These changes include empowering patients and family members by improving health promotion and prevention practices, knowledge, application of self-management of the disease, and healthcare satisfaction. Donabedian's (2003) framework

views the evaluation of outcomes as the method of evaluating both the healthcare action and its effective delivery.

Donabedian's (2003) structure-process-outcome framework served as a guide for this capstone project by directing the process for implementing and evaluating a nurse-led diabetic foot clinic screening protocol. This framework guided the project leader in determining the progress by which the implementation of the nurse-led clinic occurred.

The organization and function of the diabetic screening clinic was evaluated retrospectively by tallying the number of patients who were screened in the past year. The process component was evaluated by assessing the nurse's process and ability to perform the screening including supervising the patient—nurse interaction. The outcome component was evaluated by gathering baseline data that were used for elevating true outcomes in a two-year timeframe. Information that was part of the baseline data included calculation of the number of patients evaluated, referrals made, diabetic foot ulcers developed, the nurse's perspective of the implementation, and the patient's perspective of the implementation.

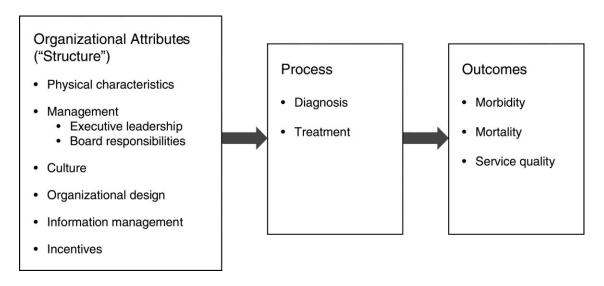


Figure 1. An illustration of Donabedian's structure-process-outcomes framework (Glickman, Baggett, Krubert, Peterson, & Schulman, 2007, p. 342).

Summary

Diabetic foot ulcers are an actual and costly healthcare problem that affects millions of people around the world. The development and implementation of screening protocols in clinics based on evidence-based guidelines are a proven and essential way to reduce the development of diabetic foot ulcers in patients. The goal for this practice change project was to establish an effective screening protocol to help reduce the development of diabetic foot ulcers in diabetic patients by having early detection of the problem through effective screening. The implementation of a nurse-led screening protocol in a clinic would provide the diabetic patient the assessment needed for prevention and early detection.

CHAPTER II

PROJECT DESCRIPTION

Literature Review

The following literature review is a critical appraisal of the evidence, which evaluated the strengths, and value of a nurse-led diabetic foot ulcer screening protocol in a clinic, thereby reducing the risk of developing diabetic foot ulcer and amputations. A sensitive search of evidence was conducted using the following databases: PubMed, CINHAL, EBSCOHOST, and Google scholar. Keywords and phrases utilized in searching for evidence included diabetic foot ulcer and the benefits for screening for diabetic foot ulcer, nurse-led screening protocol in clinics, screening tools for diabetic foot ulcer, and diabetic foot care education. This search for evidence retrieved a total of 1,025 articles and their abstracts. The following criteria were used to identify relevant research: (a) articles published from January 1, 2000 to May 30, 2014; (b) all articles published in the English or Spanish language; (c) systematic reviews, randomized control trials, cohort studies, cross-sectional studies, and exploratory studies; and (d) all studies that took place in an outpatient setting. A total of 21 studies were selected for this literature review.

Diabetic Foot Ulcers and the Benefits of a Screening Protocol

Diabetic foot ulcers are recognized as a severe, worldwide, public health concern. Healthcare providers believe there will be an increase in prevalence in the next decade if this issue is not managed immediately (Boulton et al., 2005; McCall, 2014). Patients with Type 2 diabetes mellitus are considered at high-risk for developing diabetic foot ulcers at least once in their lifetime. (2005) stated this is due to "contributory factors to foot disease, such as peripheral neuropathy and vascular disease are present in more than 10% of people at the time of diagnosis of type 2 diabetes, and the first year after diagnosis of diabetes" (p. 1719). When discussing diabetic foot ulcers, one must not forget contributing risk factors that increase a patient's probability for developing the disease: development of ischemia from peripheral vascular disease, peripheral neuropathy, foot traumas, and foot deformities such as claw toe (Boulton et al., 2005; Crawford et al., 2007). Studies have demonstrated the leading cause of diabetic foot ulcers is diabetic neuropathy. Diabetic neuropathy can be described as nerve damage due to diabetes mellitus. This disease contributes to a patient's loss of sensitivity in his/her feet, thus decreasing a patient's ability to feel trauma or the development of ulcerations (Boulton et al., 2005; Crawford et al., 2007, 2011).

Patients who develop diabetic foot ulcers are at increased risk of developing complications including infections, delay in healing of lesion, gangrene, and foot amputations. In extreme cases where patients do not receive treatment, death might even occur (Aalaa et al., 2012; Boulton et al., 2005; Crawford et al., 2007). Furthermore, patients who develop diabetic foot ulcers have an increased risk of developing depression and have a poor quality of life compared to patients who have not developed the disease.

Over the past two decades, prevention against the development of diabetic foot ulcers has become a primary focus of health care for patients with diabetes. Studies have established the implementation of screening programs that assess a patient's risk factors for diabetic foot ulcer and provide patients with knowledge of self-management practices reduces the risk of hospitalizations, the development of infections, and reducing the risk of amputations by 25% (Boulton et al., 2005; Lavery, Wunderlich, & Tredwee, 2005).

Nurse-Led Screening

To understand what a nurse-led screening protocol in a clinic setting is, it is important to define the concept. There are various definitions of this concept.

Nevertheless, the definition that best suited this project was the following:

Nurse screening protocol in clinics is a formalized and structured healthcare delivery mode involving a nurse and a client. The client is an individual and their family with healthcare needs that can be addressed by a nurse. The nurse demonstrates advanced competence to practice in a specific healthcare area, and functions either independently and/or interdependently with other members of a healthcare team in at least 80% of their work. They are supported by a multidisciplinary team. The key interventions are nursing therapeutics, which encompass assessment and evaluation; health teaching/counseling, treatment and procedures, and case management. A nurse screening protocol in clinics differs from a physician's led protocol in clinics in that it relies less on the use of medications; rather it employs a holistic approach to address the needs of clients and their families. (Wong & Chung, 2006, p. 366)

In recent years, nurse-led prevention initiatives in clinics have become an important part of patient care. The increasing need for such initiatives have occurred due to a growing, aging population with chronic diseases, the reduction of available general medical practitioners, and the need to reduce healthcare cost (Keleher, Parker, Abdulwadud & Francis, 2009). Previous studies have reported a nurse-led protocol's goal is to help prevent illness by providing patients with the knowledge and ability to engage in appropriate health promotion and prevention practices. In addition, they are

known to provide quality screening, primary care, chronic disease management, and are affordable (Carey & Courtenay, 2007; Keleher et al., 2009; Wong & Chung, 2006).

Various studies have examined the quality of care provided by nurses. Horrocks, Anderson, and Salisbury (2002) published a systematic review in which they compared patient care provided by both nurses and medical doctor. In their study, the authors evaluated a total of 34 investigations. Their findings demonstrated that nurses who provided the initial history, assessment, and care attended patients adequately. In addition, patients seemed to be more satisfied with their care. Patient gratification is a result of nurses who were more communicative, pinpointed physical abnormalities quicker, provided patients more time during consults, and provided information in managing their disease (Horrocks et al., 2002).

In 2009, Keleher et al. published a systematic review that evaluated the effectiveness of nursing clinics in a primary care setting. In their review, they evaluated 31 articles relevant to their topic of discussion. The authors concluded the nurses provided patients with excellent care and favorable health outcomes such as improvement in quality of life, compliance to treatment, and knowledge of their illness. A study by Carey and Courtenay (2007) examined the activities and effectiveness of nurse-led screening protocols in clinics for patients with diabetes. In this systematic review, 22 articles were reviewed. Carey and Courtenay found patients who received care from nurse-led protocols received more education on the disease, improved self-management activities, and acquired individualized care. In addition, patients "improved glycemic control, reduced diabetic systems, cost effectiveness and decreased length of hospital stay" (Carey & Courtenay, 2007, p. 302). The literature demonstrated nurse-led

screening protocols are an excellent option in providing patients with quality health care while reducing the cost in primary care settings.

Screening Tools

Patients with Type 2 diabetes mellitus have a higher probability of developing diabetic foot ulcers due to diabetic neuropathies, peripheral vascular disease, trauma, foot deformities, and infections. Studies have demonstrated that patients who develop diabetic foot ulcers acquire peripheral neuropathy prior to formation of lesions (Arad, Peters, Fonseca, & Vinik, 2011; Crawford et al., 2011; Dros, Wewerinke, Bindels, & vanWeert, 2009; Dunn et al., 2011; Singh, Armstrong, & Lipsky, 2005). Therefore, peripheral neuropathy is considered the number one risk factor for developing diabetic foot ulcers. Early detection of risk factors would help reduce the disease risk. Therefore, there is an increasing need for foot screening to occur in primary care settings (Crawford et al., 2007; Singh et al., 2005). Various screening tools are available for the early detection of diabetic neuropathy: the monofilament test, Ipswich touch test, tuning fork screening, and the 60-Second Tool[©].

Monofilament. The monofilament test is one of the most frequently used screening tools for identifying diabetic peripheral neuropathy. Its simplicity and effectiveness have contributed to its worldwide use. Screening with the monofilament test takes approximately two minutes to complete (Al-Geffari, 2012). Feng, Schlosser, and Sumplio (2009) published a systematic review evaluating the Semmes Weinstein monofilament test. They described the screening tool as easy to use in clinical settings due to its low cost and ease in performance because of its noninvasive nature.

One limitation of the screening tool was the need for standardization of the method by which it was applied. The lack of replication of the test might cause a misdiagnosis in patients (Al-Geffari, 2012; Crawford et al., 2011; Dros et al., 2009; Feng et al., 2009; Singh et al., 2005). The systematic review by Feng et al. (2009) indicated the monofilament test sensitivity fluctuated between "57% (95% confidence interval (CI), 44% to 68%) to 93% (95% CI, 77% to 99%), and specificity ranging from 75% (95% CI, 64% to 84%) to 100%" (p. 676). The authors indicated this might occur due to the wide range in which the test was applied. Many healthcare practitioners did not follow a standardized pattern of applying the monofilament test. Singh et al. (2005) identified another possible reason for the variation in specificity and sensitivity: "certain brands of monofilaments are more accurate than others and they should not be used on more than 10 patients without a recovery period of 24 hours" (p. 218). This might have also contributed to the variations in specificity and sensitivity.

Ipswich touch test. Two studies (Bowling et al., 2012; Dunn et al., 2011) described the Ipswich Touch Test as a new, simple, and standardized screening test that allows healthcare professionals to assess patients more quickly. These studies demonstrated that nurses, nurse practitioners, doctors, and other healthcare professionals might conduct this test and the screening tool needed no instrument. For the health professional to conduct the Ipswich Touch Test, all she or he needs to do is "lightly touching/resting the tip of the index finger for 1-2 s on the tips of the first, third and fifth toes and the dorsum of the hallux" (Dunn et al., 2011, p. 1). The Ipswich Touch Test has been described as a simple test that is easy to teach, low in cost, reliable, and quick to apply (Bowling et al., 2012; Ramon et al, 2011).

Tuning fork screening test. Three studies (Al-Geffari, 2012; Crawford et al., 2011; Singh et al., 2005) discussed the proficiency of the tuning fork test as a screening tool for diabetic foot ulcers. It is a simple test wherein the patient feels a vibratory sensation from the tuning fork. An abnormal response to this testing would be easy to diagnose since a patient's lack of sensation to the vibration gives a positive result to the diagnosis of peripheral vascular disease. However, Singh et al. (2005) stated, "Tuning fork results are less predictive of ulceration than results from using the monofilament" (p. 219). This can be seen when evaluating the sensitivity and specificity of the screening test: the tuning fork vibration test scores a 55% to 61% in sensitivity and a 59% to 72% in specificity. Nevertheless, the tuning fork screening test and the monofilament test should be partnered to make one screening (Al-Geffari, 2012). By combining the tools, the sensitivity and accuracy of the testing would be 90%, which would provide the healthcare provider with a more effective evaluation of patients developing peripheral neuropathy.

The 60-Second Tool--a diabetic foot screening tool. The 60-Second Tool for diabetic foot screening was developed by Sibbald et al. (2012). This simple tool provides the healthcare practitioner with the ability to identify a patient's risk in 60 seconds (see Appendix A). This assessment tool guides the practitioner in identifying previous history of diabetic foot ulcers and an assessment of various foot lesions that increase a patient's risk of developing diabetic foot ulcers and peripheral neuropathy. In addition, it provides the practitioner with the knowledge if the patient is in need of further assessment or scheduling for the next examination without the need of calculating. This tool is considered reliable and valid (Adejumo, Adeniyi, & Fasanmade, 2013; Kuhnke et al., 2013; Sibbald et al., 2012).

Education of Foot Care

Education has become key in reducing a patient's prevalence of developing foot ulcers. Many patients are unaware of their increased propensity of developing foot ulcers due to their diabetes. Studies have demonstrated that patients with poor knowledge of foot care and practices have an increased risk of developing foot ulcers (Dorresteijn & Valk, 2012; Khattak, Marwart, Usman, & Ali, 2014; Schmidts, Mayer, & Panfil, 2008; Vatankhah et al., 2009).

Khattak et al. (2014) conducted a cross-sectional study evaluating diabetic patient foot care knowledge and practices. In their study, they found many patients had poor foot care due to their lack of knowledge of self-management. Patients' poor practices included walking barefoot indoors and outside surroundings of their home, wearing inappropriate shoes, and poor foot hygiene (Khattak et al., 2014). Furthermore, Khattak et al. provided findings that demonstrated a positive correlation between a patient's increased knowledge of foot care and appropriate foot practices and a decreased risk of developing diabetic foot ulcers.

Vatankhah et al. (2009) conducted a study in which they examined the impact a short face-to-face diabetic foot education had on patients with Type 2 diabetes mellitus. Their findings demonstrated that face-to-face diabetic foot education not only improved the patient's knowledge but also improved the patient's foot care management and increased patient motivation to continue to do so. In a study conducted by Schmidts et al. (2008), the findings demonstrated that patients who received both education and a yearly foot screening significantly decreased their risk.

Project Objectives

The principal objective of this capstone project was to implement a foot screening protocol for all Type 2 diabetes mellitus patients age 18 years or older as a method to prevent the development of a diabetic foot ulcer. In addition, this project helped detect patients' level of risk of developing diabetic foot ulcers and provided patients with foot care management education as part of their yearly checkup.

Summary of the Evidence

Regular foot screening for Type 2 diabetes mellitus patients is an essential method of reducing the risk of developing foot ulcers. Various methods of screening patients are available but none have seemed to be as effective as the 60-Second Tool developed by Sibbald et al. (2012). This tool provides the healthcare provider with a way to evaluate a patient's history, assess physical risk factors such as traumas, and carry out the monofilament test quickly to assess the risk of developing a diabetic foot ulcer. In addition, patients receive a brief education on diabetic foot care as a method of improving a patient's knowledge and his/her diabetic feet care practices. Therefore, implementation of a nurse-led screening protocol in a clinic using Sibbald et al.'s 60-Second Tool and a brief diabetic foot care education was the best alternative in reducing diabetic foot ulcers in patients with Type 2 diabetes mellitus.

CHAPTER III

METHOD

Diabetic foot ulcers are a common foot problem among patients with Type 2 diabetes mellitus. In recent years, there has been a growing demand for prevention and early detection of foot complications in order to diminish foot ulcers and the risk of future amputations. For this reason, the aim of this capstone was to establish and implement a diabetic foot screening protocol using as its foundation the Donabedian (2003) framework. This clinical project was implemented in a rural clinic in Puerto Rico to improve patients' quality of care by diminishing patient risk of developing diabetic foot ulcers and its complications. This chapter provides a description of the project design including structure, participants, process, outcomes, risks and benefits, and financial budgeting.

Structure

This project was implemented in a community outpatient clinic. This clinic is considered to be the primary healthcare location for a small rural town in Puerto Rico.

The name of this clinic remained anonymous so the provider and patients would accept participation in this capstone project. Therefore, this clinic shall be called Clinic X.

Clinic X's culture could be best described as a kindred connection between administration and medical faculty. Those working at this clinic strive to provide the best care for their patients. Clinic X has an excellent administrative department that provides

support to the medical personnel and patients who visit the center. There is an exceptional relationship and communication between the administrative board and the medical personnel. In addition, there is support in improving patient care and quality of health when needed. The administrative department is responsible for overseeing the financial budget and agenda as well as supervising medical faculty.

The medical faculty includes primary care doctors (Family Medicine), nurses, an optometrist, a surgeon, and a pediatrician. For this reason, Clinic X provides outpatient care for both pediatric and adult patients. In addition, it has a small urgent care room and a center for vaccination. Age ranges of patients who attend this clinic are from one month to 90-years-old. This outpatient clinic serves mostly a Puerto Rican population but from time to time, people from other countries might need to visit when on vacation or if they have decided to live in Puerto Rico.

Each primary care physician sees from 20 to 30 patients on a daily basis. The exact number of patients has yet to be identified since only recently has the center implemented an electronical health record system (Anonymous, personal communication, 2014). This setting provides treatment to acute and chronic diseases, e.g., hypertension and diabetes mellitus, and the common cold. Each primary care physician treats approximately 5 to 10 diabetes mellitus patients per day. For this reason, this location was an excellent place for the implementation of the capstone project.

The physical structure of Clinic X is a building consisting of one floor with three public bathrooms for both men and women. There are three waiting rooms--one located near the urgent care room for those awaiting care and two for patients who are visiting the outpatient clinic. Six healthcare provider offices are located in the outpatient clinic.

Inside each office are a desk, two chairs, a sink, and an examination table. In addition, each office has a computer with access to the electronic medical record and Internet.

There are three nurses station in the building--one is located in the urgent care department and two are located in the outpatient clinic. Each nurse's station has access to a blood pressure cuff, weight scale, desk, and others tools used in nursing. The building also has an administrative section and an area for patient files, paper records, and billing. The screening clinic is located in one of the available offices in the outpatient clinic area.

This location facilitated accessibility to patients who visited the outpatient clinic as well as provided the project leader and the nurse who screened patients easy access to collaborating with other healthcare personnel during the implementation and maintenance of the new screening protocol.

The organizational structure of this capstone corresponded with state laws that establish nurse practitioner practice, which stipulates that nurse practitioners may practice under supervision of a licensed medical doctor (see Figure 2). Thus, the executive administrative director of Clinic X, who is a medical doctor, was the overseeing physician of this capstone project and gave support to the project (see Appendix B). This director lent support to the project leader and provided assistance in implementing the diabetic foot screening protocol. The project leader of this capstone project is a family nurse practitioner who organized the screening clinic, selected and supervised the nurse who did the screening, and managed any situation that occurred during the project operation in addition to collecting data for evaluating the screening protocol. The nurse's functions included performing the screening test and determining which patients needed a

referral or a follow-up visit. The secretary at the clinic provided patients with a follow-up appointment if needed (see Table 1 for the responsibilities of project members).

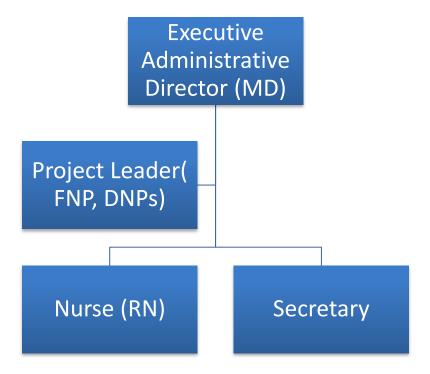


Figure 2. Project organizational heriarchy.

Table 1

Responsibilities of Project Members

Faculty	Main Responsabilities
Executive Director of Clinic X	Oversaw the administrative and medical responsabilities of the clinic and provided infrastructure and human resources needed for the fulfilment of the project.
Project Leader	Oversaw the administrative and clinical responsabilities of the clinic, clinical outcomes, development and implementation of the project, and attended to any matter concerning protection of patients' rights, training of staff, and care of patients.
Nurse #1	Administered questionaire and education, cared for patients, answered pertinent questions, protected patient confidentiality, and stored and tallied information received.
Secretary	Identified patients for the clinic, handled medical records. In charge of office supplies and other human resources involved in the proper maintanence of the clinic.

Population

The population impacted by this capstone was patients 18 years or older who had been diagnosed with Type 2 diabetes mellitus and were patients of Clinic X. These patients were selected to participate in this nurse-led screening clinic since studies (Alavi et al., 2014; Boulton, 2008; Clayton & Elasy, 2009) demonstrated all patients diagnosed with Type 2 diabetes mellitus should be screened annually as a way of reducing the risk of developing diabetic foot ulcers. Furthermore, these studies indicated Type 2 diabetes mellitus patients are at higher risk of developing foot ulcers because they were diagnosed much later compared to Type 1 diabetes mellitus patients. This delay in diagnosis

increased their chance of having micro- and macrovascular complications, which in turn increased the risk of developing diabetic foot ulcers. All Type 2 diabetic patients who were seen for their annual exam were offered the screening as part of their care.

Process

Process in Donabedian's (2003) structure-process-outcome framework focused on quality care improvement once the implementation of healthcare activities started. No routine screening process was in place at Clinic X dealing with a diabetic patient's feet. Many times patient's feet were assessed only when patients had a symptom or a lesion that worried them. This was due to the high volume each healthcare provider saw each day, which contributed to a lack of regularity in screening for diabetic foot ulcers or the lack of an initiative that implemented these guidelines. Yet, studies demonstrated this should be done at least once a year to identify risks rather than when symptoms became evident (Al-Geffari, 2012; Feng et al., 2009).

The implementation of a nurse-led screening clinic was needed to significantly improve the quality of care in diabetic patients. A diabetic foot screening clinic protocol was implemented upon the approval of Institutional Review Board approval (see Appendix C). Once this was received, a qualified Registered Nurse (bachelor's degree) was selected. This nurse was responsible for implementing the screening protocol of patients at the clinic. The project leader taught the nurse how to implement the 60-Second Tool. In addition, the project leader instructed the nurse on how to provide patients with a brief education on proper foot care practices.

Once the training was completed, the project leader supervised the nurse during the first two days of the screening process at the clinic. The project director continued to supervise the nurse until she was confident the nurse was applying the screening adequately. Thereafter, the nurse continued the screening unassisted. All steps for implementing the screening and education were outlined in a protocol for the nurse to refer to during implementation (see Appendix D).

All Type 2 diabetic mellitus patients who were scheduled to be seen by their primary care provider were identified by the clinic receptionist at the beginning of the day and flagged for the nurse. The nurse then conducted the screening and education to all who had given written consent to participate in the clinic (see Appendix E). If the patient scored one or more on the 60-Second Tool, a note was added to the patient's record for the provider to review as he/she conducted the physical exam. The primary care provider then determined whether the patient needed to be referred to a podiatrist and a referral was made if necessary.

Examination of the patient's feet was carefully done by the nurse following

Sibbald et al.'s (2012) 60-Second Tool (see Appendix A). This foot examination tool

was free for clinical practice use once the clinic was registered where it would be

implemented. This tool provided a simple strategy to complete the foot exam in four

simple steps: a brief history, observation of foot deformities, traumas or the development

of ulcers, and the application of a monofilament test. The tool provided a simple method

for calculating a patient's risk of developing diabetic foot ulcers. High risk was

determined by a scoring on one or more on Sibbald et al.'s 60-Second Tool. It was

estimated that 50 patients were screened and educated in the first month of implementing
this project.

Additionally, all participants were provided with diabetic foot care education based on a National Diabetes Information Clearinghouse diabetic foot care brochure published in 2014. The National Diabetes Information Clearinghouse brochure was developed in both English and Spanish (see Appendix F). In addition, they made this information public domain, allowing for distribution to patients. This education provided patients with a complete overview of proper foot care practices they should know and implement on a daily basis. The nurse conducting the screening went through the brochure with the patient and answered any questions he/she might have had. The brochure took approximately five to seven minutes to discuss. This education provided patients with important information on common foot problems that cause infection, signs and symptoms of Charcot foot, and the importance of examining their feet on a daily basis. The brochure also provided various recommendations on appropriate foot care all diabetes patients should practice on a daily basis. Evidence demonstrated this education helps patients improve their daily foot care and reduces the risk of developing foot ulcers (Dorresteijn & Valk, 2012; Khattak et al., 2014; Schmidts et al., 2008; Vatankhah et al., 2009).

All patients had the right to refuse any aspect of medical care and were notified they had the same right of refusal for receiving the screening and education provided by the nurse. Any patient who did not wish to participate in the screening and education could refuse this routine aspect of care. Consent forms were needed and taken (see Appendix E). No individual health records or personal identifying information were recorded or used for evaluating the screening implementation.

Screening Evaluation

Outcomes are an essential part of Donabedian's (2003) framework. In his framework, outcomes are valuable in identifying advantages and disadvantages of implementing new healthcare activities in patient care. Various outcomes were evaluated before, during, and after implementation of this project (see Table 2). The integration of the screening into the routine care provided at the clinic was evaluated by examining the number of patients screened after implementation of the protocol compared to whether they were screened in the prior two years. As the nurse screened patients, she looked through the medical records of the patient and determined whether they had had a foot screening in the past year or past two years. This was accomplished in such a manner due to the nature of the paper records at the clinic. At the moment of implementation, there was no accurate method for determining the number of overall patients screened for foot ulcers in the clinic over the past year or two years so data were only collected on patients who entered the screening protocol for this project.

Table 2

Evaluating Screening Outcomes Utilizing Donabedian's Framework

Structure	Process	Outcomes
Organization and function of the diabetic screening clinic was evaluated by retrospectively tallying the number of patients who had been screened in the past year.	The process of integration and effectiveness of the diabetic foot screening clinic was evaluated by assessing the nurse's process and ability to do the screening.	The outcome was evaluated by gathering data as a baseline for the true outcomes that would be seen in two-year's time. Information part of this baseline data included: 1. Number of patients evaluated, referrals made, and diabetic foot ulcers developed. 2. Nurse's perspective of the implementation clinic. 3. Patients' perspectives of implementation of clinic.

The process of integration and effectiveness of the diabetic foot screening clinic was evaluated by assessing the nurse's screening technique and ability to educate the patient. The project director, who is an FNP and well-trained in diabetic foot screenings, educated the nurse on how to screen and educate each patient. The project director worked directly with the nurse for the first two days of the project and evaluated her performance at the end of that time period. If additional training was needed, he/she was provided with additional information. Once the nurse felt confident, she began implementing the screening on her own. The project director re-evaluated the nurse's technique after two months of implementing the screening. The project director provided additional training at that time if needed. Additionally, the project director interviewed the nurse after two months to examine the ease of implementation. The project director asked questions related to aspects of the screening that went well and about any challenges/barriers she encountered during the process (see Appendix G). The interview was recorded in written format and a list of positive and challenging aspects to the screening was generated. These data were then examined for changes needed in the screening protocol to ensure its longevity and success in the clinic.

The project director also examined a number of patient outcomes including the number of patients with a score of one or more on the 60-Second Tool (Sibbald et al., 2012), the number of referrals made to primary care providers, and the number of referrals to podiatry. This base line data could provide for a full evaluation of patient outcomes in future studies.

Finally, patients' perspectives of the screening were evaluated by interviewing five patients. All patients were given an appointment date for a follow-up visit after the

initial visit. The project director approached the patients and asked if he/she was willing to answer a couple questions about the screening. If the patient said yes, the project director asked some general questions on how they felt about taking part in the screening and education program (see Appendix H). Their answers were recorded in written format, thus providing the project director with information on the patient's view of the quality of the screening and assisting in developing strategies for making any improvements to the protocol.

Data Collection and Handling

Data collected for this project was done by the project director and nurse implementing the screening and education protocol. A form for data collection was used by the nurse to record information gathered during the screening (see Appendix I). All data were completely devoid of patient identifiers. All data acquired from patients were kept in a locked drawer in the administrative director's office under lock and key only and were only accessible to the project director. Custodian of this key was the nurse who screened the patients, thus providing safety of documents.

Two months after the implementation of the screening, the project director took the data sheets and placed the data in an Excel® file for analysis. The Excel file was kept on a secure, password protected-drive accessible only to the project director and capstone chair. Written recorded data from the interviews with patients and the nurse implementing the protocol were also kept in a secure filing cabinet accessible only to the project director. These interview sheets will be destroyed no later than three years after completion of the project.

Data Analysis

Data collected by the nurse during the implementation of this protocol were summarized and presented in numerical form to provide baseline data for the analysis of future outcomes and to determine the efficacy of the screening program after implementation. Descriptive statistics were used to describe the data from the screening tool (Sim & Wright, 2000). For each item outlined in Appendix I, frequencies and percentages of central tendency were computed using MS Excel software.

Interview data from the patients were summarized and a content analysis was done to determine any overarching themes regarding the foot screening clinic. The data gathered by the RN implementing the screening assisted in evaluating any limitations and changes needed to the protocol as a method of ensuring its success and longevity within the health care center.

Risks and Benefits

Patients who participated in the diabetic foot screening were at minimal risk.

Possible risks included discomfort, which might have occurred upon the removal of shoes, and use of their time in the screening. The screening and education took approximately seven minutes for each patient. Benefits included early detection of risk factors and signs and symptoms of developing a diabetic foot ulcer. Identification of these factors contributed to the implementation of early preventive measures and treatment. It is likely a patient's quality of life was improved due to a diminished risk of developing diabetic foot ulcers and future amputations. Another benefit for patients participating in the screening was an increased awareness of their risk for developing foot ulcers and measures to prevent it. As mentioned above, all patients had the right to refuse

medical care and that right was ensured during the screening clinic as well. All patients were advised of their right to refuse care and if so expressed, they were allowed to leave. This was ensured with the use of a consent form (see Appendix E).

Resources and Budget Support

Facilities needed were provided by the center where this screening clinic took place. The project director and the nurses who work at the clinic provided human resources, thus no need for outsourcing. As for supplies needed, such supplies included paper and ink to print the tool; these were provided by the project director.

Monofilaments used were already found at the clinic. Patients diagnosed at high risk according to the tool used in the screening were referred to one of the physicians who in turn referred them to a podiatrist. No stipend was given to patients who took part in this project. As a result, no monetary budget was needed for this project since all direct costs were absorbed by Clinic X.

Summary

Diabetic foot ulcers affect millions of people worldwide; yet one of the simplest ways of reducing this risk is through screening and prevention. For this reason, the implementation of a diabetic foot ulcer prevention protocol provided nurses with the ability to participate in health promotion and prevention practices t beneficial to the patient's physical and mental health. A simple tool such as the 60-Second Tool (Sibbald et al., 2012) is necessary in all outpatient clinics due to its simple implementation and the enormous benefits it brings the diabetic patient.

CHAPTER IV

RESULTS

In the past three decades the literature has emphasized the importance of increasing efforts to prevent diabetes foot ulcers. Studies demonstrated "foot ulcerations affect 15% to 25% of people with diabetes mellitus at some point during their life" (Dorresteijn & Valk, 2012, p. 101). Several studies have shown the most effective way of diminishing a patient's risk of developing foot ulcers is in early detection through screening (Bakker, Apelquist, & Schaper, 2012; Bonner, Foster, & Spears-Lanoix, 2016; Chamberlain, Rhinehart, Schaefer, & Neuman, 2016; Dorresteijn & Valk, 2012). These studies found it is vital that along with the screening, patients are educated on a daily self-examination and appropriate foot care.

To date, various tools have been developed and implemented in different healthcare settings. Yet, the simplest and quickest validated tool that can be implemented by any health care provider is Sibbald et al.'s (2012) 60-Second Tool. Thus, the objective of this capstone project was the development and implementation of a nurse-led diabetic foot-screening protocol to improve the quality of care, screening, and education of patients on proper foot care for Type 2 diabetes mellitus patients of a rural area clinic in Puerto Rico. This chapter provides a detailed description of the results.

Project Implementation

The implementation stage of this project started on September 16, 2015 in a meeting with the medical director of Clinic X. During this meeting, the project director and medical director of the clinic reviewed the nurse-led diabetic foot screening protocol along with a brief education brochure from The National Diabetes Information

Clearinghouse (2014) and the Sibbald et al. (2012) 60-Second Tool. Both the project director and medical director of the clinic agreed the protocol would offer a practical way of implementing a consistent diabetic foot screening program at the clinic. During the first week of October 2015, the nurse led- diabetic foot protocol was presented to the nursing director during a meeting with the medical director. During this meeting, the nursing director indicated she wanted to be present during the initial orientation of the selected nurse. In addition, she invited other nurses to participate in the initial education. The project director agreed. The medical director and nursing director suggested and the project director agreed that the diabetic foot clinic would be implemented one day a week.

Initial Education

The education date was set for mid-October 2015. A PowerPoint© presentation was given to a group of seven Bachelor of Science in Nursing (BSN) nurses including the nursing director of the clinic. Each nurse received a handout with the information given during the education. The information presented during this education provided the nurses with knowledge on how to implement the Sibbald et al. (2012) 60-Second Tool along with a comprehensive review of the different foot deformities and lesions that commonly occur with diabetic feet. The education session lasted approximately 30

minutes. Afterward, the nurses had an opportunity to test each other using the Sibbald et al. 60-Second Tool along with performing a monofilament test on each other. No pre- or post-test was given during this education. Nevertheless, upon conversing with the nurses and supervising them in applying the monofilament test with each other, the project director assessed they had acquired the knowledge and skill needed. The nurses were told the Sibbald et al. 60-Second Tool would be used at the clinic and that documentation would be placed in the patient's file. After the meeting, the project director asked the group if they had any comments. All agreed the tool seemed user friendly and would only need a short amount of time to master.

Applying the Nurse-Led Protocol

The nurse led protocol was implemented the following week. Implementation of this project was originally developed so the project director would train one BSN nurse for two days. During these two days, the project director trained and evaluated the nurse. If the project director observed the performance of the nurse during the screening and education was appropriate, the nurse would then continue on his/her own. The project director visited the clinic once again after five weeks to reevaluate the nurse's implementation of the protocol along with the patient's satisfaction. Furthermore, the project director carried out a brief interview of the nurse's perspective of the protocol and his/her recommendations. In addition, a minimum of 50 patients were seen in the first four weeks. The data collected from the Sibbald et al. (2012) 60-Second Tool for each patient was kept on a separate data sheet by the project director. All patients were given a number. These data were kept in a safe locked drawer in the administration office for safekeeping.

Adaptation of Project During Implementation

Implementation of this project did not occur exactly as planned. Instead of one nurse to be trained, a new nurse was assigned each week and had to be trained to participate in the nurse-led diabetic foot clinic. On the first day of implementation, the nurse-led diabetic foot clinic was scheduled on Wednesday, which is the clinic day for seeing all diabetic patients. That day, the project director was able to train and supervise two nurses. Ten patients were seen that day. The following week, the nursing director decided to schedule the clinic on Tuesday. That day, only one of the two nurses was supervised and four patients were seen. The project director decided to give the nurse extra support by paying another visit. During this visit, the project director was surprised with having to train another new nurse and only two patients were seen. The following weeks, the nursing director kept changing the nurses. One of those days, the nurse assigned to the clinic arrived three hours late and only one patient was seen. On the fifth week of implementation, the project director decided to terminate the project due to low patient encounters and the inability to implement the protocol.

Outcomes

The method for evaluating the outcomes of implementing the diabetic foot screening clinic was done utilizing Donabedian's (2003) framework. This framework viewed outcomes as the essential component in identifying advantages and disadvantages of implementing change. The first outcome evaluated was the prior structure utilized to screen Type 2 diabetes mellitus at Clinic X. This was done by examining the frequency by which patients' feet were screened. Prior to implementing the Sibbald et al. (2012)

60-Second Tool, the nurse review the patient's medical file to determine if he or she had had a foot screening during the past year.

The results indicated 17 patients had been screened during the past year. Upon further examination, only two patients (12%) had been examined in the past two years. Guidelines on diabetic foot screening clearly stipulate patients who have diabetes mellitus and even those at low risk of developing foot complication should have a yearly foot exam. However, patients who are elderly or have a mild to high risk should be evaluated every three to six months (National Guidelines Clearinghouse, 2013). These results further supported a substantial need for a nurse-led diabetic foot clinic at Clinic X.

The second outcome evaluated using Donabedian's (2003) framework was the process of integration and effectiveness of the diabetic foot-screening clinic, which was evaluated by assessing the nurse's process and ability to do the screening. The project director was able to assess the ability of various nurses who took part in this pilot study. Upon evaluation, the project director noted that using the Sibbald et al. (2012) 60-Second Tool was easily implemented by all three nurses who were trained. All were able to complete the tool on their own without much reinforcement or correction.

The third outcome was to evaluate patient demographics to have baseline data for future investigations. A total of 17 patients were evaluated within a five-week timeframe. This population of patients consisted of 14 (82%) females and 3 (18%) males. The mean age was 62.6 with a standard deviation of 13.13. The mean years of having Type 2 diabetes mellitus was 11.35 with a standard deviation of 11.92. Using the screening protocol, 8 of the 17 (47%) patients were referred by the nurse to their primary care provider for further assessment. Among those referred, six (35%) of the patients in

this small sample had fissures and an additional two (12%) patients had both fissures and neuropathy, which had not been previously identified. In addition, two (5%) of this population had either a callus or absent pedal pulses. Among this small sample of patients, only one (5%) of the 17 patients had prior foot ulcers. Thankfully, none of the patients had any active ulcers and none of these patients had previous foot amputations.

Nurse Perspectives

To evaluate the nurse perspective of the diabetic foot protocol, an informal interview was completed. Two of the three nurses agreed to be interviewed. Each was interviewed individually. They were asked five questions. The first question asked of both nurses during the interview was: Did you feel you had the skills to provide the screening adequately? Both agreed they had most of the skills necessary to apply the protocol. Their only concern was identifying the correct foot lesions since this was new to them. Once they were able to identify the different lesions, they felt more comfortable being on their own and had the following comments:

I have the skills to implement this protocol since it is fairly easy to do so. All I really needed to learn the different foot deformity since I have never really see them before. But, once I reviewed them I found it fairly easy to identify. (Nurse 1)

I understand how to implement this tool. What caused me a bit of stress was knowing if I would be able to identify the different foot deformities. After seeing a couple of patients, I realized that I might not know the names of the foot deformities, but I can definitely identify them. I also had to learn how to apply the monofilament test. I learned to do that quickly. (Nurse 2)

The second question of the interview was: What aspects of the protocol were easy to implement? Both nurses agreed the protocol was fairly easy to implement:

The protocol is fairly easy to implement, once you done it about three times you become extremely familiar with both the tool and education. The easiest aspect of the protocol is providing the patient the diabetic foot education. I like to provide

patients with education. But, I would like to say that the tool is also easy after you go over those deformities. Anyone can ask the first two questions, as well as identifying foot ulcers, ingrown toes nails, and foot callus. Those are extremely basic concepts. (Nurse 1)

The easiest part of the protocol to me is the starting the tool. You have to ask two simple questions which helps open up conversation with the patient. But as a whole, I think the tool is the easiest aspect once you do it a few times. It takes you very little time to complete. (Nurse 2)

The third question asked during the interview was: What were some of the challenges encountered in the implementation of the diabetic screening clinic? During the interview, the nurses indicated the major challenge of the implementation was not the protocol or the Sibbald et al. (2012) 60-Second Tool but the nursing director's opinion and feeling toward the project. The nursing director's attitude toward the project was considered "hostile and resentment." They indicated the director on various occasions had commented the diabetic foot screening was something a doctor did, not nurses. In addition, they stated the one of the major challenges for implementation was it should be conducted on the day diabetes patients were scheduled and not the day most hypertension patients were scheduled. Both agreed the complete adoption of such a clinic protocol would take time and the true results for such a clinic would be seen in a long time rather than a short one:

One of the major challenges of implementing this protocol is by placing this type of clinic on the wrong day. How can we see patients who have to be diabetic when we are implementing on the day in which almost all patients are hypertension. ...I also must admit that the nursing director does not want this protocol implemented. She has said so various times.. ...I also believe the time frame was too short. If given more time, maybe the nursing director would have gotten accustomed to having us do this type of work and would be more open to the idea. (Nurse 1)

One of the biggest challenges is the nursing director's feeling towards the project. The nursing director continuously states that this is not a nursing function. That

this is a job for the medical doctor, that we should not being doing such jobs. (Nurse 2)

The fourth question asked of each nurse was: How would you improve the protocol? Nurse 1 indicated,

There is nothing that needs improvement for the protocol. I would, however, make a sheet in which the nurse could write the patients name record, telephone number, and the next date which he or she should be evaluated in order for the nurse to have more control of when the patient should have the next foot screening.

Nurse 2 said, "The protocol is fine just as it is.".

Patient Perspectives

Part of the evaluation process stipulated that the patient's perspective of the project would be evaluated at the end of the project during a return visit. This did not occur as planned. The project director luckily was able to speak to the patients during their initial visit. The first question asked was: Do you feel the screening has improved your care of your feet? Many of the patients indicated the nurse's screening made them aware of the importance of checking their feet on a daily basis. Various patients said they were unaware of the importance of screening their feet. One of the patients stated, "I didn't know that checking my feet daily was so important. No one ever told me. I will be checking my feet more often now. Maybe I won't check my feet everyday but some days". Another stated, "I was told that I should check my feet daily once but I thought it was not that important since none of the doctors ever check them for me". Therefore, they improved their knowledge on the importance of checking their feet daily.

The second question asked was: How satisfied are you with the screening? All patients seem to concur with being very satisfied with the screening. One patient indicated, "I believe this should be done every time I visit since it's so quick to

complete." Another patient stated, "At first I thought this would take too long and that the instrument would hurt. But this was super quick and that plastic tool you use doesn't hurt at all. So, I am very satisfied with what you are doing". Still another patient commented, "I am very satisfied with this screening since no one else has ever checked my feet and I have been a diabetic for years."

The last question patients were asked was if they would change anything in this protocol. Various patients who spoke with the project director indicated they would like this be done more frequently. Furthermore, they stated they felt comfortable with the nurse completing this job and taking the time to not only screen their feet but to educate them on proper foot care.

Summary

This project sought out to implement a nurse-led diabetic foot protocol in Clinic X as a method of increasing screening, providing quality care, and giving patients education on foot care. The onset of this implementation occurred with educating seven nurses on the application of Sibbald et al.'s (2012) 60-Second Tool. This was followed by applying the protocol wherein various nurses were trained compared to the original method that stipulated only one nurse would be trained. In this study, the data demonstrated the entire sample of patients who engaged in this pilot program had not participated in foot screening in the past year and only 12% of this same population had participated in foot screening in the past two years. Furthermore, 47% of the sample group was referred for further evaluation. This statistic demonstrates Clinic X has an immense need for such a protocol due to a lack of screening Type 2 diabetic mellitus patient's feet in the past two years. With respect to the nurses' ability to provide such

screening, the data demonstrated the BSN nurse is highly capable of implementing such protocols and applying the Sibbald et al. 60-Second Tool. In addition, they themselves verbalized the protocol was simple and easy to implement. Moreover, patients also found the protocol as simple and educational. Many of them indicated they did not know the importance of daily foot care. In conclusion, the data of the present project suggested an immense need for such a protocol as an effective way of screening Type 2 diabetic mellitus patients.

CHAPTER V

RECOMMENDATIONS

Diabetic foot problems are a prevalent complication that occurs in patients with Type 2 diabetes mellitus around the world. Numerous articles have documented the benefits of diabetic foot screening as a method of preventing the development of complications and foot amputations. In addition, this type of screening is also seen as cost effective against the economic burden diabetic foot complications cause in these patients. Nevertheless, large numbers of primary care clinics have yet to implement routine diabetic foot screening protocols in Puerto Rico. The principal objective of this capstone project was the implementation of a foot screening protocol for all Type 2 diabetes mellitus patients age 18 years or older as a method of preventing the development of a diabetic foot ulcer. In addition, this project was focused on detecting a patient's risk level of developing diabetic foot ulcers and providing the patient with foot care management education as part of his/her yearly checkup. This chapter provides details on the challenges and recommendations of implementing a nurse-led diabetic foot-screening protocol in a community clinic in Puerto Rico.

Overview of the Diffusion of Innovation Theory

Rogers' (2003) diffusion of innovation theory is a theoretical framework that provides understanding of the adaptation or non-adaption of innovative practices in clinical settings. This theory describes an innovative diffusion of new ideas and practices

as "a general process, not bound by the type of innovation studied, by who the adopters are, or by the place or culture" (Rogers, 2004, p. 16). The emphasis is on how the individual or organizational group perceives the innovation and the elements that influence the course of action taken to adopt or reject the innovation. The term *diffusion* is best defined as "the process through which an innovation is communicated through certain channels over-time among the members of a social system" (Rogers, 2003, p. 5). The term *innovation* is defined as "an idea, practice, or object that is perceived as new by an individual or other unit of adaptation" (Rogers, 2003, p. 12). The theory states the innovation does not necessarily need to be new but rather the decision to adopt new knowledge and practices.

Rogers's (2003) theory reveals five components in behaviors when innovation is presented: relative advantage, compatibility, complexity, trialability, and observability. These components determine if the innovation will be adopted into clinical practice. Relative advantage is the extent to which the change is seen as more beneficial than the current practice. Such benefits include cost effectiveness and improvement in social status (Rogers, 2002, 2003). Yet, Rogers's (2003) theory indicates preventive practices are seen as difficult to adopt. Studies (Fleuron, Wiefferink, & Paulussen, 2004; Rogers, 2002, 2003) found the implementation of innovative practices in healthcare was traditionally seen as complex, especially such practices that focus on prevention of disease and complications. Innovative prevention practices at times are seen as being ineffective and less likely to be adopted

Compatibility of the innovation is measured by an innovation's ability to conform to the existing culture and its values. One way compatibility of an innovation might be

evaluated is by examining the demand of the innovation. Therefore, adaptation is most likely to occur if the innovation is compatible to the individual or organizational culture (Rogers, 2003). Rogers (2002) indicated there are five different categories in which people of the organization fall during the adoption of the innovation: (a) innovators, (b) early adopters, (c) early majorities, (d) late majorities, and (e) laggards. Rogers (2002) describes innovators as "the first 2.5% of the individuals in a system to adopt an innovation" (p. 991). These tend to be individuals who have a more worldwide view compared to their peers. "Early adopters are the next 13.5% of the individuals in a system to adopt an innovation" (Rogers, 2002, p. 991). Early adopters are part of the local social circle, yet tend to have a leadership position due to their liberal views. Rogers (2002) goes on to describe the last three categories:

Early majority are the next 34% of the individuals in a system to adopt an innovation. Late majority are the next 34% of the individuals in a system to adopt an innovation. Laggards are the last 16% of the individuals in a system to adopt an innovation. These later adopters will only accept a new idea when they are surrounded by peers who have already adopted and who are satisfied with the new idea. (p. 991)

Complexity is best described as the perceived difficulty in using the innovation. Rogers's (2003) theory suggests a negative opinion of the complexity of an innovation can be a barrier for effective implementation. Hence, innovations perceived as simple are more likely to be adapted efficiently. Rogers describes trialability as "the degree to which an innovation may be experimented with on a limited basis" (p. 258). Innovations implemented in steps are more likely to be adopted by individuals and organizations because it provides time for modification during the process. The final element to implementing innovation is observability of positive outcomes easily seen by the

adopters (Roger, 2003). The findings from this project were evaluated using the five elements from Rogers's theory.

Rogers's (2003) theoretical framework views the diffusion of innovation as a difficult process for preventive activities. Rogers found preventive activities in health care are seen by society as preventing unseen, undesirable repercussions that could possibly be seen in the future where rewards might never be seen. Therefore, society is less eager to adopt such measures since outcomes for implementation might not be seen immediately. This was clearly the case in this project. There were various attempts by the clinical administration and medical department in trying to implement a diabetic's foot clinic but none were fruitful. The following paragraphs provide a brief overview of the nurses' viewpoints on implementing the innovation using Rogers's diffusion of innovation model.

Relative Advantages

Relative advantage is the magnitude by which the innovation provides improvement in cost effectiveness and advantages in practice compared to prior practices. Implementation of a diabetic foot screening is a preventive practice. Prior studies have noted that preventive practice innovations are often adopted more reluctantly than innovations where end results can be seen more rapidly (Rogers, 2002). The results of this study were consistent with the theory, demonstrating preventive practices can be much more difficult to adopt, especially in nursing care. Innovations might encounter resistance because changes are difficult to accept, especially when the rewards are not immediate. This was clearly the case at Clinic X. The data findings of this project

demonstrated healthcare providers at this clinic had not screened Type 2 diabetes mellitus patients continuously for the past two years.

An interesting fact was the nurse participants of this protocol viewed the diabetic foot screening as a method of preventive care, which was much needed at Clinic X. In addition, they verbalized during their interviews that the Sibbald et al. (2012) 60-Second Tool was fairly easy to implement along with the education they provided to patients. They indicated they learned to manage the tool quickly. They also commented that patients were happy with their work and how quick and easy it was done. However, surprisingly, the nurses indicated the implementation of such a protocol caused them stress due to their inexperience in screening and they did not believe this protocol would be fully implemented due to the nursing's director animosity toward the protocol. Both nurses complained the hostility they experienced made them feel more intimidated in implementing the screening. They believed the nursing director viewed the protocol as nonessential and should be done by a doctor and not a nurse, perhaps due to a limitation in staff numbers and their utilization. Stress amongst novice nurses when implementing new procedures has been well documented over the years. Studies (McVicar, 2003; Pellico, Brewer, & Kovner, 2009) have demonstrated that novice nurses have pressure and stress at a professional level owing to feeling inadequate due to inexperience with procedures, increased workload, and receiving ill treatment by the management because of their inexperience. McVicar (2003) published a literature review discussing the causes for workplace stress: "workload, leadership/management, professional conflict, and 'emotional labour' have been the main collective sources of distress for nurses" (p. 637).

Contrary to expectations, this study demonstrated the nurse-led diabetic foot protocol had a low relative advantage due to beliefs by nursing management that preventive practices were not imperative. Rogers (2002) stated, "Past research shows that perceived relative advantage is the most important predictor of the rate of adoption of innovations" (p. 991). Therefore, the disturbance in the implementation of the nurse-led diabetic foot protocol could be seen as a challenge, which contributed to a low relative advantage seen by nurse management. For this reason, it is possible that communicating with the nursing director at an earlier date would have allowed her to incorporate her views and expertise in the development of the protocol; an as a result, there is a high probability there would have been an increase in acceptance of the project.

Compatibility

Compatibility of an innovation is identified as the innovation being reliable and needed compared to past experiences and existing needs. Compatibility of the diabetic foot protocol and the culture of Clinic X were oppositional due to the nursing staff's lack of BSN nurses in the outpatient clinic. Nurses indicated they were usually staffed in the emergency care clinic due to Puerto Rico's regulation that stipulates emergency care must be staffed with BSN nurses rather than licensed practical nurses (LPNs) and associate degree nurses (ADNs). Thus, Clinic X staffed its outpatient clinics with LPNs and ADNs. Nurses who participated in the clinic stated they believed staffing might have been one of the reasons the nursing director found the protocol so inconvenient. They believed if the protocol had been run by an ADN, there would be a higher probability that the nursing director would support this type of clinic. Therefore, it would be imperative to integrate the nursing director in the initial process of development; thus, the project

director would have had a better perspective on the nursing culture of the clinic. If the project director would have had the knowledge of the clinic's nursing culture, i.e., the clinic did not have BSN nurses in the outpatient clinic, then the project director could have analyzed if the use of an ADN nurse would have been an alternative for implementing the protocol instead of a BSN nurse.

The nurses who were interviewed also stipulated they believed this protocol was compatible with the outpatient clinic since it was extremely easy to implement. The nurses who were part of this pilot program found the process was fairly quick between educating the patient and screening for foot problems. This was extremely important for the outpatient clinic in Clinic X since they saw numerous diabetic patients on Wednesdays.

Complexity

Complexity of an innovation is the degree of complication by which the innovation is perceived (Rogers, 2002). The nurse-led diabetic foot protocol was implemented by using Sibbald e al.'s (2012) 60-Second Tool and education from the National Diabetes Information Clearinghouse (2014) diabetic foot care brochure. Nurses viewed the diabetic foot protocol as user friendly and simple for implementation. The nurses stated they were able to follow the tool easily and in a timely manner. They indicated they were able to provide the prevention protocol in less than five minutes. However, these nurses were provided supplementary information on diabetic foot lesions and deformities. This information provided the nurses with the additional reassurance needed to identify foot lesions and deformities correctly. Various studies (Kuhnke et al., 2013; Lowe et al., 2015) have found Sibbald et al.'s 60-Second Tool easy to use and can

be implemented by non-foot specialist healthcare providers. As mentioned in the literature, Sibbald et al.'s 60-Second Tool waas demonstrated to be effective in helping identify patients at increased risk of developing foot lesions (Kuhnke et al., 2013; Lowe et al., 2015). A recent study conducted by Lowe et al. (2015) found the implementation of Sibbald's 60-Second Tool as a screening tool helped identify patients at high risk earlier due to its easy implementation and diminished the possibility of major amputations by 68%. Therefore, the complexity of the nurse-led diabetic foot protocol was minimal.

Trialability

Trialability was limited in this project due to the time in which this innovation was effectively tested. Innovations tried on a limited basis minimize the risk of rejection from adopters who do not see the importance of the innovation (Rogers, 2002). It was an interesting finding that both nurses believed the trialability of the diabetic foot protocol was extremely short. They believed that for this innovation to be adopted by the clinic and the nursing staff, it would take more than six months. Thus, the trialability for implementation of this protocol should be more extensive than the two month timeframe for the project to be adopted and become permanent in their preventive efforts. In addition, the protocol should be implemented on the day most diabetic patients are seen in Clinic X rather than the day when most patients have hypertension appointments (Wednesday).

Observability

Observability is best described as positive outcomes seen upon implementing innovation by the adopters. Upon interviewing both nurses who participated in the

implementation of the diabetic foot screening protocol, they both agreed that would not see positive outcomes upon implementation for various years since this was a prevention program rather than a treatment program. The short time span for implementation was seen as a major challenge for this capstone project.

Advanced Practice Nurse Role Acceptance in the Nursing World

The practice of advanced practice nursing has become prevalent worldwide. Such practice has become key to providing the general population with better access to health care (Sheer & Wong, 2008). Limitations to the acceptance of the advanced practice nursing role have been seen throughout history in clinical settings (Bryant-Lukosius, Dicenso, Browne, & Pinelli, 2004; Zammuto, 1982). In his writings, Zammuto (1982) stated that in the beginning, advanced practice nurses faced animosity by other nurses and medical staff due to their new role. Bryant-Lukosius et al. (2004) published an article in which they discussed various obstacles that affected the introduction of advanced practice nursing in a work setting. One such aspect was the failure to address environmental factors such as role acknowledgement and support from peers and other medical staff. Consequently, advanced practice nurses who face these circumstances "expend considerable effort overcoming role conflicts and resistance" (Bryant- Lukosius et al., 2004, p. 525). Although there was insufficient direct evidence of the lack of support for the advanced nursing practice role in this capstone project, one can speculate this issue also affected the implementation of this project. These obstacles are present due to the nurse practitioner role being fairly young to the healthcare system of Puerto Rico. For the past two decades, the nurse practitioner role was only implemented in federally funded healthcare institutions such as San Juan Veterans Affairs Hospital. Recently, the

governor of Puerto Rico signed Law #254 (LexJuris of Puerto Rico, 2015) recognizing the nurse practitioner role on the island, which has opened up new possibilities for a nurse practitioner's practice with the general population. Thus, for nurse practitioners in Puerto Rico, role acknowledgement and support from their peers and other medical staff will take time.

Limitations and Recommendations

One major limitation of this capstone project was lack of BSN staffing at Clinic X. Those employed at this clinic are assigned to other areas, not the outpatient clinic. For this reason, there was a constant interchanging of nurses on the days the protocol was implemented. The present study raised the possibility that the use of an LPN or an ADN nurse would have been more readily available compared to a BSN nurse, this in turn would have provided more sustainability and compatibility with Clinic X's nursing culture. Therefore, it is important to keep a clinic's nursing culture in mind for future research.

Another limitation of this project was the lack of sustainability and the short timeframe in which it was completed. This nurse-led diabetic foot protocol was unable to sustain itself due to challenges that occurred during implementation. Further work is needed to evaluate the viability of this protocol in other outpatient clinic settings to determine the types of approaches that might be most effective. In addition, the sample size of the population was extremely small. Therefore, the results might not be indicative of the general population found at Clinic X. However, the data collected demonstrated a need for implementing such a protocol at the clinic since none of those who participated in the project had received screening in the prior year by their healthcare provider.

Therefore, further work is required to evaluate the outcomes of such protocols for a longer period of time.

Conclusion

Diabetic foot ulcers are recognized as a worldwide public health concern. It is estimated that patients with Type 2 diabetes mellitus have a 25% chance of developing foot ulcers in their lifetime (Boulton et al., 2005; Lavery et al., 2005). Studies indicate there will be an increase in prevalence in the next decade due to the rise in diabetes worldwide including Puerto Rico (Boulton et al., 2005; Lavery et al., 2005). For this reason, in recent years there has been an increased interest in the implementation of health promotion and prevention practices against developing diabetic foot ulcers in patients with Type 2 diabetes mellitus. Studies have established the implementation of screening programs that assess a patient's risk factors for diabetic foot ulcer and provides patients with knowledge of self-management practices reduces the risk of hospitalizations and the development of infections (Boulton et al., 2005; Lavery et al., 2005; McCall, 2014).

The main goal of this current capstone project was the development and implementation of a nurse-led diabetic foot screening protocol. This pilot program was a method of addressing the absence of clinic guidelines that recommend yearly foot screenings for Type 2 diabetes mellitus patients (National Diabetes Information Clearinghouse, 2014). Data findings of the sample population this capstone project evaluated demonstrated an immense need for this protocol to be fully implemented at Clinic X. However, further work is needed to evaluate factors that might increase the

viability of this protocol in an outpatient clinic setting and determine the most effective approach to full implementation of this protocol.

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APPENDIX A 60-SECOND TOOL©

Screening for the high risk diabetic foot: A 60-Second Tool (2012) Sibbald

Name:		CHECK BOTH FEET (Circle correct response)			
DOB (dd/mm/yy):					
Gender: M F Years w		"YES	s" on either	foot = HIGH	RISK
	Caucasian Mixed Other				
Date of Exam (dd/mm/yy):		LI	EFT	RI	GHT
HISTORY	1. Previous ulcer				
motoki	2. Previous amputation	NO	YES	NO	YES
PHYSICAL EXAM	3. Deformity	NO	YES	NO	YES
PHISICAL EXAM	Absent pedal pulses (Dorsalis Pedis and/ or Posterior Tibial)	NO NO	YES	NO NO	YES
FOOT LESIONS Remember to check 4 th and 5 th web spaces/nails for fungal infection and check for inappropriate footwear.	5. Active ulcer	NO	YES	NO	YES
	6. Ingrown toenail	NO	YES	NO	YES
	7. Calluses (thick plantar skin)	NO	YES	NO	YES
	8. Blisters	NO	YES	NO	YES
	9. Fissure (linear crack)	NO	YES	NO	YES
NEUROPATHY MORE THAN 4/10 SITES LACKING FEELING = "YES"	10. Monofilament exam (record negative reaction): a) Right/10 negatives (≥ 4 negatives = Yes) b) Left/10 negatives (≥ 4 negatives = Yes)	NO	YES	NO	YES
		Total # of YES:		Total # of YES:	
for prevention, treatment These individuals are at changes to observe and the Referral to: b) NEGATIVE SCREEN	Results when there are one or more "Yes' ent and follow up. (Bony deformity, curr increased risk of a foot ulcer and/or infect report, while waiting for the specialist app Appointmen Results when there are all "No" respons t any new changes to their healthcare pro-	rent ulcer, ab etion. Patient pointment. t time:	sent pulse a s should be ral require	re most urger educated on d.	nt).
	Examination (dd/mm/yy):/_			*	
Completed By:	Date:			-	
Additional Note:	mendations from the International Dia				Vorking
The second secon	ot. y vary depending on expertise and avail	able resourc	ces.		

APPENDIX B LETTER OF SUPPORT FROM CLINIC X

Statement of Mutual Agreement University of Northern Colorado

Doctorate of Nursing Practice Capstone Project

Effectiveness of the development and implementation of a nurse-led diabetic foot screening clinic

The purpose of the "Statement of Mutual Agreement" is to describe the shared view between NeoMed Center and Alexandra Garcia- Rosanda, DNP Candidate from University of Northern Colorado, concerning her proposed capstone project.

Brief Description of Proposed Project: This capstone project will develop and implement a nurse-led diabetic foot clinic screening protocol by applying the 60-Second Tool₀ and providing a brief education to patients using the National Diabetes Information Clearinghouse brochure.

Proposed on-site activities:

On site activities during the development and implementation of this protocol will be limited to educating and supervising the nurse in order to assure appropriate application. When the project is completed patients will be asked simple questions and answer activity in order to receive recommendations.

Dr. Mildred Negron has agreed to participate in the review and approval of the proposal and presentation of the final version of the project. The DNP Capstone project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency, preferences in how it is to be named (or not) in the work.

APPENDIX C INSTITUTIONAL REVIEW BOARD APPROVAL



Institutional Review Board

DATE: August 19, 2015

TO: Alexandra Garcia, MSN, FNP

FROM: University of Northern Colorado (UNCO) IRB

PROJECT TITLE: [756502-4] Effectiveness of the development and implementation of a nurse-

led diabetic foot screening clinic

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED
APPROVAL DATE: August 16, 2015
EXPIRATION DATE: August 16, 2016
REVIEW TYPE: Expedited Review

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB has APPROVED your submission. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on applicable federal regulations.

Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant. Federal regulations require that each participant receives a copy of the consent document.

Please note that any revision to previously approved materials must be approved by this committee prior to initiation. Please use the appropriate revision forms for this procedure.

All UNANTICIPATED PROBLEMS involving risks to subjects or others and SERIOUS and UNEXPECTED adverse events must be reported promptly to this office.

All NON-COMPLIANCE issues or COMPLAINTS regarding this project must be reported promptly to this office.

Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of August 16, 2016.

Please note that all research records must be retained for a minimum of three years after the completion of the project.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

APPENDIX D SCREENING IMPLEMENTATION PROTOCOL

Title: Assessment and Education Protocol for Adult Type 2 Diabetes mellitus Patients

1. Introduction – Core Vision of Protocol

"To prevent the development of diabetic foot ulcers, amputation and early death in all patients with Type 2 Diabetes mellitus".

The focus of this protocol is implementation of a nurse-led diabetic foot screening and education that will provide the following outcomes:

- 1.1 Early detection of risk factors for developing diabetic foot ulcers
- 1.2 Improving patients quality of life
- 1.3 Improving patients foot care practices by increasing patient knowledge
- 1.4 Prevent the need for amputations

2. Purpose

2.1 The purpose of this protocol is to provide a framework for the nursing staff to assess patient for diabetic foot ulcers and educating them and diabetic foot care. The nurse-led clinic is to prevent the development of diabetic foot ulcers and future amputations.

3. Duties

- 3.1 Executive Director of Clinic will oversee the administrative and medical responsabilities of the clinic, and to provide medical, infrastructure and human resources need for the fulfilment of the protocol.
- 3.2 The qualified nurse assigned to screening patients for diabetic foot ulcers shall be responsible for screening patients against diabetic foot ulcers.
- 3.3 Examination of the feet will be carefully done following Sibbald et al.'s (2012) 60-Second Tool $_{\odot}$.
- 3.4 The education provided to patients will be based on the National Diabetes Information Clearinghouse diabetic foot care brochure, which was published in 2014.

4. General Patient Management Approach

- 4.1 The purpose of the screening assessment of the patient is the identification of any risk factors that increases patients of developing a foot ulcer.
- 4.2 This assessment shall be completed using Sibbald et al.'s 60-Second Tool_☉.
- 4.3 Patients with one or more positive signs of risk factor shall be referred to primary care doctor, who may then refer to the podiatrist.
- 4.4 Once patient is screened the nurse shall provide an education using the National Diabetes Information Clearinghouse diabetic foot care brochure, which was published in 2014. This will help improve patient knowledge and diabetic foot care practices.
- 4.5 Schmidts et al. (2008) state that patients who received both education and yearly foot screening decreased their risk significantly.
- 4.6 Patients with no risk shall be scheduled for yearly follow-up. Those who develop risk factors should be assessed earlier.

- 4.7 All outcomes of the assessment should be documented and presented to the general practitioner.
- 4.8 All patients must be assessed minimum once a year. It should be conducted earlier if risk factors are developed.

APPENDIX E

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH



CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH

<u>Project Title</u>: *Effectiveness of the development and implementation of a nurse-led diabetic foot screening clinic*

Researcher: Alexandra Garcia, FNP-BC, Doctor of Nursing Practice Student Email:

garc6486@bearsunco.edu

Committee Chair: Melissa Henry, PhD, RN, FNP-C

University of Northern Colorado, School of Nursing, Gunter Hall 3340

Greely, CO 80639

Email: Melissa.Henry@unco.edu

General Purpose of the study: The purpose of this project is to implement of a nurse-led Diabetic Foot-Screening improve the quality of care for patients by screening and educating on proper foot care for those with type 2 Diabetes Mellitus.

<u>Procedure:</u> You will be asked to take off your shoes for a one-minute foot exam. The procedure consists of looking over your feet and touching them with a small plastic wire, called a monofilament, to test your feet's sensation. In addition, you will receive an education pamphlet on proper foot care. You may be asked to visit the clinic again in two months time for reevaluation. You will be assigned a number identifier, rather than your name and record number, for the data collection which will occur during this project. Only the project director and nurse will have a record of the data collected. The data collected will be stored under lock and key by the nurse and will be collected and destroyed once the pilot project is completed.

<u>Disclosure risk:</u> Potential risks to participating in this project are considered to be minimal. Risk includes discomfort, which may occur upon the removing of shoes, and the use of time for the screening and education to take place. Minimal risk of identifying you as a participant can occur since you will receive a numerical number for data collection. In addition, there may be a risk of payment in follow- up visits.

<u>Direct benefits</u>: Direct benefits as a participant include early detection of risk factors and signs and symptoms of the development of diabetic foot ulcer. Identification of these factors contributes to early preventive measures and treatment. It is likely that your quality of life will also improve due to the diminishing risk of developing diabetic foot ulcers and future amputations. Another benefit in participating in the screening is the

increased awareness of the risk for developing foot ulcers and learning measures to prevent it.

<u>Participation</u>: Participation is voluntary. If you do not want to participate in the project you are free to do so. In addition, if at any moment during the project you do not want to participate you may do so. You may verbalize your wish to withdraw by notifying the nurse. Your decision will not affect you or your treatment at the clinic.

Confidentiality: Your confidentiality will be protected. You will be given a number identifier that will be used for the data collection process. Only the nurse and project director will have access to data collected and it will be kept safe.

I have read the above information and had the opportunity to ask questions and any questions have been answered to my satisfaction. By taking part in this project you will give us permission for your participation. You may keep this form for future reference. If you have any future questions or concerns you may email at garc6486@bearsunco.edu.



CONSENTIMIENTO PARA PARTICIPAR EN ESTUDIO DE INVESTIGACIÓN

<u>Título del proyecto</u>: Efectividad en la elaboración y ejecución de una clínica de prevención y detección temprana de enfermedades en el pie diabético.

Investigador: Alexandra Garcia, FNP-BC, Doctor of Nursing Practice Student Email:

garc6486@bearsunco.edu

Committee Chair: Melissa Henry, PhD, RN, FNP-C

University of Northern Colorado, School of Nursing, Gunter Hall 3340

Greely, CO 80639

Email: Melissa.Henry@unco.edu

Objetivo general del estudio: El propósito de este proyecto es implementar una clínica de prevención y detección temprana de enfermedades en el pie diabético dirigida por enfermeras, para mejorar la calidad de atención a los pacientes mediante el examen de los pies y la educación del cuidado adecuado de estos en personas con diabetes mellitus tipo 2.

Procedimiento: Durante el proceso se le pedirá que se quite los zapatos para un examen de los pies que toma aproximadamente un minuto. El procedimiento consiste en mirar sus pies y tocarlos en puntos específicos con un pequeño hilo de plástico, llamado monofilamento, para detectar la sensación en sus pies. Además, recibirá un folleto de educación sobre el cuidado adecuado de sus pies. Se le pedirá visitar la clínica de nuevamente en dos meses para una reevaluación. Se le asignará un número identificador, en lugar de su nombre y su número de expediente, para la recolección de datos que se hara durante este proyecto . Sólo el director del projecto y la enfermera del proyecto tendrán un registro de los datos recogidos. Los datos recogidos serán almacenados bajo llave por la enfermera y serán recogidos y destruidos una vez completado el proyecto piloto.

<u>Divulgación de riesgo</u>: Los riesgos potenciales a participar en este proyecto son mínimos. El único riesgo incluye el malestar que puede ocurrir al pedirle que se quite los zapatos, y el uso de su tiempo en examinar los pies y proveerle una educación. Mínimo riesgo de ser identificado como un participante puede ocurrir ya que usted recibirá un número para la recopilación de datos. Además, puede haber un riesgo de pago en visitas de seguimiento.

Los beneficios directos: Los beneficios directos como participante incluyen:

- La detección temprana de los factores de riesgo y signos y síntomas de la evolución en las úlceras del pie diabético.
- La identificación de estos factores contribuye a las medidas de prevención temprana y el tratamiento.
- Es probable que su calidad de vida mejore debido a la disminución en el riesgo de desarrollar úlceras en el pie diabético y prevenir amputaciones futuras.
- Otro de los beneficios al participar en este estudio es el tener mayor conciencia del riesgo a desarrollar úlceras en los pies y el aprender las medidas para prevenirlas.

<u>Participación</u>: La participación es voluntaria. Si usted no desea participar en el proyecto no tiene que hacerlo. Si en cualquier momento durante el proyecto decide que no quiere participar, puede dejárselo saber a la enfermera. Su decisión no afectará su tratamiento en la clínica.

<u>Confidencialidad</u>: Su confidencialidad será siempre protegida. Se le asignará número para identificarlo en el estudio que se utilizará para el proceso de recolección de datos. Sólo la enfermera y el director del proyecto tendrán acceso a los datos recogidos.

He leído la información anterior y tuve la oportunidad de hacer preguntas y todas las preguntas fueron contestadas a mi satisfacción. Al participar en este proyecto usted nos está dando el consentimiento de su participación.

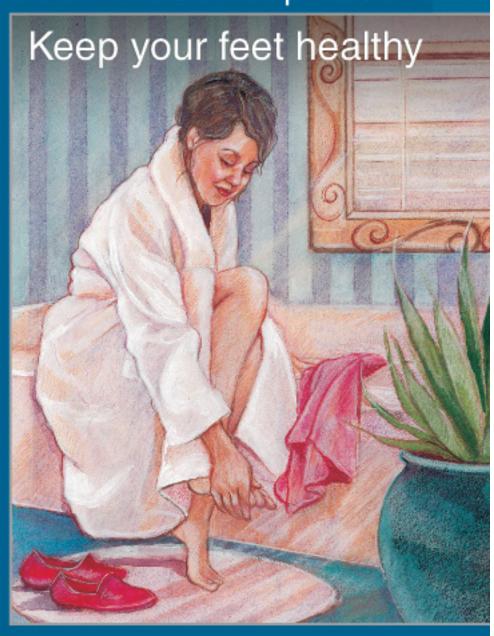
Usted puede mantener este documento para referencia futura. De tener cualquier pregunta o preocupación puede enviar un email a garc6486@bearsunco.edu.

APPENDIX F

PREVENT DIABETES PROBLEMS: KEEP YOUR FEET HEALTHY

Prevent diabetes problems

Number 5 in a Series of 7







How can diabetes affect my feet?

Too much glucose,* also called sugar, in your blood from diabetes can cause nerve damage and poor blood flow, which can lead to serious foot problems.

Nerve Damage

Damaged nerves may stop sending signals, or they may send signals too slowly or at the wrong times. Nerve damage can cause you to lose feeling in your feet. You may not feel pain, heat, or cold in your legs and feet. You may not feel a pebble inside your sock that is causing a sore. You may not feel a blister caused by poorly fitting shoes.

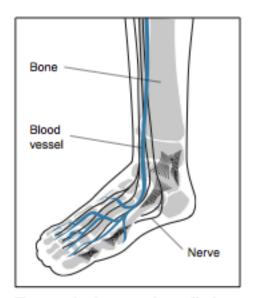
Sores on your feet can become infected. If your blood glucose is high, the extra glucose feeds the infection in those sores and the infection gets worse. Nerve damage can also cause pain and lead to foot **deformities**, or changes in the muscles, bones, and shape of your feet.

^{*}See the Pronunciation Guide for tips on how to say the words in **bold** type.

Poor Blood Flow

Poor blood flow means not enough blood flows to your legs and feet through your blood vessels. Poor blood flow makes it hard for a sore or an infection to heal. This problem is called **peripheral** artery disease, also called PAD.

Sometimes, a bad infection never heals. The infection might cause **gangrene**. If you have gangrene, the skin and tissue around the sore die. The area becomes black and smelly.



Too much glucose, also called sugar, in your blood from diabetes can cause nerve damage and poor blood flow, which can lead to serious foot problems. Prompt attention to any sore or infection on your toe or foot can prevent gangrene. Your doctor may decide to cut away the infected tissue or give you antibiotics. Your doctor also may perform tests to see how well blood is reaching your legs and feet. Sometimes, your doctor may be able to clear blocked blood vessels to improve the blood flow.

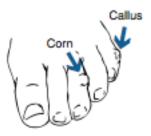
If these treatments don't work, or if you have severe pain or infection, a doctor may have to perform an **amputation**—surgery to cut off a body part—of your toe, foot, or part of your leg. A surgeon performs this operation in a hospital. You will receive **anesthesia** and be asleep during the operation.

What common foot problems can lead to pain or infections?

If you have diabetes, the common foot problems below can lead to pain or infections that make it hard to walk. If you have any of these problems, make sure you get prompt treatment from your doctor.

Corn and callus

Corns and calluses are thick layers of skin.



- Corns and calluses are caused by too much rubbing or pressure on the same spot. They often form where the first and second toes overlap.
- You can gently rub a pumice stone on a corn or callus after you take a bath or shower to wear it down. A pumice stone is a type of rock used to smooth the skin. However, check with your doctor about the best way to care for a corn or callus.
- If an infection occurs in an area of a corn or callus, your doctor may need to remove the unhealthy tissue and give you antibiotics.

Blister

Blisters are areas of skin that are raised and filled with fluid.



- A blister can form if your shoe always rubs the same spot on your foot.
- Wearing shoes that do not fit or wearing shoes without socks also can cause blisters.
- To prevent a blister, use socks or a bandage over the spot being rubbed. Wear shoes that fit properly.
- Cover small blisters with a bandage, and cover large ones with a gauze pad held with adhesive or paper tape.
 You also can buy special blister bandages in different sizes at a drugstore.
- If your blister is infected, your doctor may need to drain the fluid from the blister and give you antibiotics.

Ingrown toenail

Ingrown toenails happen when the edges of your toenails grow into your skin.



- Ingrown toenails can form if you wear shoes that are too tight or cut into the corners of your toenails when you trim them.
- To prevent ingrown toenails, wear shoes that fit properly.
- If your toenail edges are sharp, smooth them with a nail file or emery board instead of cutting them.
- If you go to a salon for a pedicure, make sure they do not cut into the corners of your toenails. Never treat ingrown toenails at home.
 Your doctor may remove part of your toenail to help it heal or keep it from growing back into your skin.
 If your toe is infected, you may need antibiotics.

Bunion

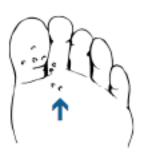
A bunion is a bump at the outside edge of your big toe. As the bump gets worse, it can be filled with extra bone and fluid.



- Bunions form when your big toe slants toward your small toes. High heels, pointed shoes, or shoes that are too tight or narrow may cause bunions. Bunions often run in families.
- To prevent bunions, wear shoes that fit well.
- Your doctor may suggest using padded shoe inserts to prevent a bunion from getting worse and using medicine to reduce pain and swelling. You may need surgery to remove a bunion that causes frequent pain.

Plantar warts

Plantar warts are small, fleshcolored growths on the bottoms of your feet. Sometimes you see tiny, black dots in the warts.



- Plantar warts are caused by a virus that enters your feet through small breaks in your skin. The warts can be painful and make it hard to walk.
- To prevent plantar warts from spreading, avoid contact with your warts and wash your hands after touching them.
- Keep your feet clean and dry.
- Don't go barefoot in public areas.
- Your doctor may remove plantar warts with minor surgery, laser treatment, liquid nitrogen, or medicines.

Hammertoe

Hammertoes are toes that curl under your feet.



- Hammertoes form when one or both joints of the small toes bend from weakness in your foot muscle. Diabetic nerve damage may cause the weakness.
- You may get sores on the bottoms of your feet and on the tops of your toes that can become infected.
- The shape of your feet may change.
- You can have problems walking and finding shoes that fit well.
- Avoid high heels or shoes with pointed toes.
- Your doctor may give you an orthotic, or insert, to place in your shoe. Medicines can reduce pain and swelling. If your hammertoe becomes rigid and painful, or if an open sore has formed, you may need surgery to correct your toe.

Dry and cracked skin

Dry and cracked skin is rough, scaly, and flaking. Your skin may be gray if you have dark skin. Your skin may be red or itch.



- Dry and cracked skin can be caused by high blood glucose, nerve damage, or poor blood flow.
- Cracks allow infection to start.
- Keep your feet moist with lotion or petroleum jelly.
- Do not soak your feet because your skin could become drier.
- If you cannot treat your dry and cracked skin at home, see your doctor. You may need a prescription ointment or cream.

Athlete's foot

Athlete's foot is a fungus that causes itching, burning, redness, and cracking of your skin. The fungus grows on the soles of your feet and in between your toes.



- To prevent athlete's foot, keep your feet as dry as you can.
- Try not to wear the same shoes all the time. Try to wear socks that do not trap moisture, such as cotton or wool socks.
- Wear waterproof shoes or flip-flops in public showers.
- If you go to a salon for a pedicure, ensure the tools are sterilized or bring your own tools.
- See your doctor to make sure you have athlete's foot. You can buy sprays and creams to treat fungus at a drugstore; however, your doctor may prescribe a stronger oral medicine.

Fungal infection

Fungal infection of the toenails makes them thick, hard to cut, and appear yellow, green, brown, or black. A nail may also fall off.



- To prevent a fungal infection of the toenails, keep your feet as dry as you can.
- Try not to wear the same shoes all the time. Try to wear socks that do not trap moisture, such as cotton or wool socks.
- Wear waterproof shoes or flip-flops in public showers.
- If you go to a salon for a pedicure, ensure the tools are sterilized or bring your own tools.
- See your doctor to make sure you have a fungal infection of the toenails.
 Your doctor may prescribe an oral medicine to treat them. Sometimes, a doctor may remove the nail surgically or chemically or perform laser treatment. A laser beam can go deep into the nail tissue and kill the fungus; however, doctors are still studying how well this treatment works.

Signs of infection on your feet include

- pus
- redness
- increasing pain
- warm skin

Call or see your doctor right away if you have any of these signs.

How can diabetes change the shape of my feet?

Nerve damage from diabetes can lead to changes in the shape of your feet. The damaged nerves cannot send messages to your foot muscles about movement. Your foot muscles become weak and imbalanced. The bones of your feet and toes may shift.

Nerve damage from diabetes also causes **Charcot's** foot, a problem in which the joints and soft tissue in your foot are destroyed.

In the early stages of Charcot's foot, your joints are stiff and collect fluid. The problem can quickly worsen. Your bones can slip out of place, making your foot look deformed. You might not sense pain, so you may keep walking on your foot, making the problem worse. Without knowing it, you could injure and damage the joints or break a bone in your foot.

The symptoms of Charcot's foot appear quickly and include

- warm, red skin
- swelling
- pain

Your doctor may first treat Charcot's foot by placing your foot in a cast and asking you to walk only with crutches or use a wheelchair. You may need surgery to correct the placement of the bones.



Charcot's foot

How can special shoes or shoe inserts help my feet?

Special shoes or shoe inserts can be made to fit softly around and protect sore feet or feet that have changed shape. Medicare Part B insurance and other health insurance programs may help pay for these shoes or inserts. Ask your doctor whether your special shoes or inserts are covered by your insurance.

How often should I have a foot exam?

See your doctor at least once a year for a foot exam, or more often if you have foot problems. During the exam, your doctor will

- look at your feet for signs of problems, especially if you have nerve damage
- · test the sense of feeling in your feet
- test how well blood is flowing to your legs and feet

- · show you how to care for your feet
- decide if special shoes or shoe inserts would help your feet stay healthy
- · trim your toenails if you cannot trim your own

Help your doctor care for your feet during every checkup. Start every checkup by taking off your shoes and socks. Tell your doctor about any foot problems you are having. If needed, your doctor may send you to a foot doctor, called a **podiatrist**.



Start every checkup by taking off your shoes and socks.

How does smoking affect my feet?

Smoking can narrow and harden the blood vessels that nourish your nerves with oxygen and nutrients. Nerve damage and poor blood flow can cause serious foot problems.

Smoking and diabetes are a dangerous mix. Smoking raises your risk for many diabetes problems. If you quit smoking,

- you will lower your risk for heart attack, stroke, nerve disease, kidney disease, and amputation
- your cholesterol and blood pressure levels might improve
- your blood circulation will improve

If you smoke, stop smoking. Ask for help so that you don't have to do it alone. You can start by calling 1–800–QUITNOW or 1–800–784–8669.



How can I keep my feet healthy?

You can keep your feet healthy by taking these steps:

- · If you smoke, get help to quit.
- See your doctor at least once a year for a foot exam, or more often if you have foot problems.
 Have your doctor check the sense of feeling in your feet and how well blood is flowing to your feet.
- Keep your blood glucose numbers as close to your target as possible. Your doctor will work with you to set your target blood glucose numbers and teach you what to do if your numbers are too high or too low.
- Check your feet every day for cuts, sores, blisters, redness, calluses, infected toenails, or other problems. You may have serious foot problems, even though you feel no pain. Checking every day is even more important if you have nerve damage or poor blood flow. If you have trouble bending over to see your feet, use a mirror to help.



Check your feet every day.

You also can ask a family member or friend to help you. Call or see your doctor right away if you have any foot problems.

- Wash your feet every day in warm, not hot, water. Test the temperature with your elbow or with a thermometer—90 to 95 degrees is safe. Do not soak your feet because your skin could dry out. Dry your feet well. Be sure to dry between your toes. Use talcum powder or cornstarch to keep the skin between your toes dry.
- Keep your skin soft and smooth. Rub a thin layer of lotion, cream, or petroleum jelly on the tops and bottoms of your feet after you wash and dry them. Do not put any between your toes because you might get an infection.
- Smooth corns and calluses.
 Rub gently, only in one direction, to keep from tearing your skin. Do not cut corns and calluses.
 Don't use razor blades, corn plasters, or liquid corn and callus removers—they can damage your skin.



- Trim your toenails each week or when needed.
 Have your doctor trim your toenails if
 - · you can't see well
 - · you can't reach your feet
 - · your toenails are thick or yellowed
 - · you have an ingrown toenail

If you can see and reach your toenails, trim them with clippers after you wash and dry your feet. Trim toenails straight across and smooth them with an emery board or a nail file. Do not cut into the corners of your toenail.



Trim toenails straight across and smooth them with an emery board or a nail file.

• Wear shoes and socks at all times to protect your feet. Do not walk barefoot—not even indoors because it is easy to step on something and hurt your feet. Always wear socks, stockings, or nylons with your shoes to help prevent blisters and sores. Choose clean, lightly padded socks that fit well. Socks that have no seams are best. Do not wear socks or knee-high stockings that are too tight below your knee. Check the inside of your shoes before you put them on to be sure they don't have any sharp edges or objects in them and the lining is smooth.



Check the inside of your shoes before you put them on.

• Wear shoes that fit well. Shoes that fit well can help prevent serious foot problems. Shop for shoes at the end of the day because your feet are slightly bigger then—feet tend to swell during the day. When buying shoes, make sure they feel good from the start and have room for your toes. Don't buy shoes with pointed toes or high heels. They put too much pressure on your toes. Avoid open-toed shoes or sandals. Athletic or walking shoes are good for daily wear. They support your feet and allow air to move around inside the shoe. Never wear vinyl or plastic shoes because they don't stretch or allow air to move around inside the shoe. Break in shoes slowly. Wear them 1 to 2 hours each day for the first few weeks.



Inside view of a properly fitted shoe



Inside view of a poorly fitted shoe

 Protect your feet from heat and cold. Wear shoes on hot pavement or at the beach. Put sunscreen on the tops of your feet to prevent sunburn. Keep your feet away from radiators and open fires. Do not put hot water bottles or heating pads on your feet. Wear socks at night if your feet get cold. In winter, wear lined boots to keep your feet warm. Check your feet often in cold weather to prevent frostbite.



Wear shoes on hot pavement or at the beach.

- Keep the blood flowing to your feet. Put your feet up when you are sitting. Wiggle your toes for 5 minutes two or three times a day. Move your ankles up and down and in and out to improve blood flow in your feet and legs. Do not cross your legs for long periods of time.
- Choose physical activities that are easy on your feet. Walking briskly, dancing, swimming, and bicycling are good forms of physical activity that are easy on your feet. Avoid activities that are hard on your feet, such as running and jumping. Wear athletic shoes that fit well and provide good support.



Walking briskly is good physical activity that is easy on your feet.

Pronunciation Guide

For More Information

To find diabetes educators (nurses, dietitians, pharmacists, and other health care providers), contact

American Association of Diabetes Educators

200 West Madison Street, Suite 800

Chicago, IL 60606

Phone: 1-800-338-3633

Internet: www.diabeteseducator.org

To find dietitians, contact

Academy of Nutrition and Dietetics

120 South Riverside Plaza, Suite 2000

Chicago, IL 60606-6995

Internet: www.eatright.org

Click on "Find a Registered Dietitian."

To learn more about foot problems from diabetes, contact

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Information Clearinghouse National Institutes of Health

1 AMS Circle

Bethesda, MD 20892-3675

Phone: 1-877-22-NIAMS (1-877-226-4267)

or 301–495–4484 TTY: 301–565–2966 Fax: 301–718–6366

Email: NIAMSinfo@mail.nih.gov

Internet: www.niams.nih.gov

To get more information about taking care of diabetes, contact

National Diabetes Information Clearinghouse

1 Information Way

Bethesda, MD 20892-3560 Phone: 1-800-860-8747

TTY: 1-866-569-1162

Fax: 703–738–4929

Email: ndic@info.niddk.nih.gov

Internet: www.diabetes.niddk.nih.gov

National Diabetes Education Program

1 Diabetes Way

Bethesda, MD 20814-9692

Phone: 1-888-693-NDEP (1-888-693-6337)

TTY: 1-866-569-1162 Fax: 703-738-4929

Email: ndep@mail.nih.gov Internet: www.ndep.nih.gov

www.yourdiabetesinfo.org

American Diabetes Association

1701 North Beauregard Street

Alexandria, VA 22311

Phone: 1-800-DIABETES (1-800-342-2383)

Email: askADA@diabetes.org Internet: www.diabetes.org

JDRF

26 Broadway, 14th Floor New York, NY 10004

Phone: 1-800-533-CURE (1-800-533-2873)

Fax: 212–785–9595 Email: info@jdrf.org Internet: www.jdrf.org

More in the Series

The Prevent Diabetes Problems Series includes seven booklets that can help you learn more about how to prevent diabetes problems:

- Prevent diabetes problems: Keep your diabetes under control
- Prevent diabetes problems: Keep your eyes healthy
- Prevent diabetes problems: Keep your feet healthy
- Prevent diabetes problems: Keep your heart and blood vessels healthy
- Prevent diabetes problems: Keep your kidneys healthy
- Prevent diabetes problems: Keep your mouth healthy
- Prevent diabetes problems: Keep your nervous system healthy



For free single copies of these booklets, write, call, fax, or email the

National Diabetes Information Clearinghouse

1 Information Way

Bethesda, MD 20892–3560 Phone: 1–800–860–8747 TTY: 1–866–569–1162

Fax: 703-738-4929

Email: ndic@info.niddk.nih.gov

These booklets are also available at www.diabetes.niddk.nih.gov.

Acknowledgments

Publications produced by the Clearinghouse are carefully reviewed by both NIDDK scientists and outside experts. The National Diabetes Information Clearinghouse (NDIC) thanks David G. Armstrong, D.P.M., M.D., Ph.D., professor of surgery and director, Southern Arizona Limb Salvage Alliance (SALSA), University of Arizona, for reviewing the updated version of this publication.

The NDIC also thanks the following people who helped review or field-test the original version of this publication:

For the American Association of Diabetes Educators Lynn Grieger, R.D., C.D.E. Arlington, VT Celia Levesque, R.N., C.D.E. Norwalk Hospital Montgomery, AL Teresa McMahon, Pharm.D., C.D.E.

Seattle, WA Barbara Schreiner, R.N.,

M.N., C.D.E. Galveston, TX

For the American Diabetes Association

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The National Diabetes Education Program is a federally funded program sponsored by the U.S. Department of Health and Human Services' National Institutes of Health and the Centers for Disease Control and Prevention and includes over 200 partners at the federal, state, and local levels, working together to reduce the morbidity and mortality associated with diabetes.

National Diabetes Information Clearinghouse

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The National Diabetes Information Clearinghouse (NDIC) is a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The NIDDK is part of the National Institutes of Health of the U.S. Department of Health and Human Services. Established in 1978, the Clearinghouse provides information about diabetes to people with diabetes and to their families, health care professionals, and the public. The NDIC answers inquiries, develops and distributes publications, and works closely with professional and patient organizations and Government agencies to coordinate resources about diabetes.

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This publication may contain information about medications and, when taken as prescribed, the conditions they treat. When prepared, this publication included the most current information available. For updates or for questions about any medications, contact the U.S. Food and Drug Administration toll-free at 1–888–INFO–FDA (1–800–463–6332) or visit www.fda.gov. Consult your health care provider for more information.





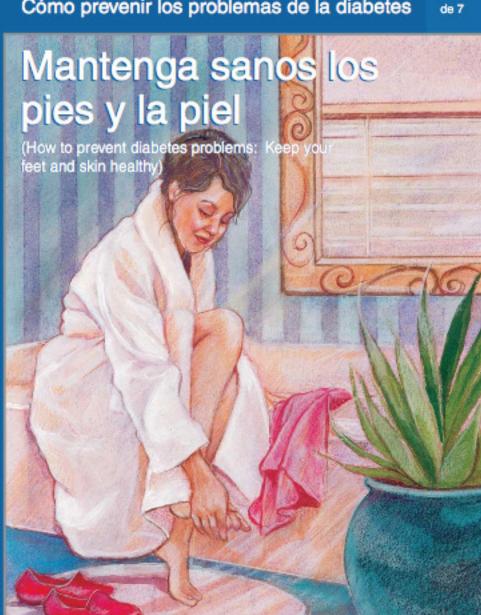
NIH Publication No. 14-4282 February 2014



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5ta de una serie

Cómo prevenir los problemas de la diabetes





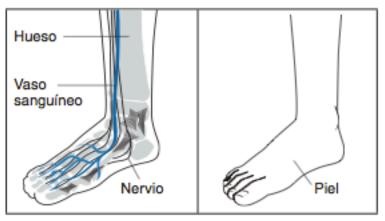


National Diabetes Information Clearinghouse

¿En qué consisten los problemas de la diabetes?

Los problemas de la diabetes surgen cuando hay demasiada glucosa en la sangre por mucho tiempo. Los niveles altos de glucosa en la sangre, también llamado azúcar en la sangre, pueden dañar muchos órganos del cuerpo como el corazón, los vasos sanguíneos, los ojos y los riñones. La enfermedad del corazón y de los vasos sanguíneos puede causar ataques al corazón o derrames cerebrales. Usted puede hacer mucho para prevenir o retrasar los problemas de la diabetes.

Este librito contiene información sobre los problemas de los pies y de la piel causados por la diabetes. Obtendrá información sobre lo que puede hacer cada día y durante cada año para mantenerse sano y prevenir los problemas de la diabetes.



Los niveles altos de glucosa en la sangre pueden provocar problemas de los pies y de la piel.

¿Qué debo hacer diariamente para mantenerme sano a pesar de la diabetes?



Siga el plan de comidas saludables que elaboraron usted y su médico o dietista.



Realice actividad física durante 30 minutos casi todos los días. Pregunte a su médico qué actividades son las mejores para usted.



Tome sus medicamentos según las indicaciones.



Mídase los niveles de glucosa en la sangre todos los días. Cada vez que lo haga, anote el resultado en la hoja de registro.



Revísese los pies diariamente para ver si hay cortaduras, ampollas, llagas, hinchazón, enrojecimiento o si tiene las uñas doloridas.



Cepíllese los dientes y use hilo dental todos los días.



Controle su presión arterial y colesterol.



No fume.

¿Cómo es que la diabetes puede dañar los pies?

Los niveles altos de glucosa en la sangre causados por la diabetes provocan dos problemas que pueden dañar los pies.

- Daño a los nervios. Uno de los problemas es el daño a los nervios de las piernas y los pies. Cuando los nervios están dañados, es posible que no sienta dolor, calor ni frío en las piernas y los pies. Cuando no tiene sensación en estas áreas, una llaga o cortadura de los pies puede empeorarse porque no sabe que la tiene. La falta de sensación surge por el daño a los nervios, que también se llama neuropatía diabética. Este daño puede provocar una lesion o una infección.
- Mala circulación de la sangre. El segundo problema ocurre cuando no hay suficiente flujo de sangre en las piernas y los pies. La mala circulación impide la curación de las llagas o las infecciones. Este problema se llama enfermedad vascular periférica (PVD por sus siglas en inglés). Cuando una persona tiene diabetes, fumar empeora los problemas de la circulación.

Estos dos problemas juntos pueden causar problemas de los pies. Por ejemplo, los zapatos pueden causarle una ampolla cuando no le calzan bien. Pero debido al daño en los nervios del pie, no nota el dolor causado por la ampolla. Luego, la ampolla se infecta. Si los niveles de glucosa en la sangre son altos, el exceso de glucosa alimenta los microbios que causan la infección. Los microbios se multiplican y la infección empeora. La mala circulación de la sangre en las piernas y los pies retrasa la curación de la infección. En algunos casos las infecciones extensas nunca sanan. Este

tipo de infección podría causar gangrena. Cuando hay gangrena, se mueren la piel y el tejido alrededor de la llaga. El área se pone negra y huele mal.

Para evitar que la gangrena afecte más piel y tejido, puede que el médico necesite realizar una cirugía para cortar un dedo del pie, el pie entero o incluso parte de la pierna. Esta cirugía se llama amputación.



Asegúrese de usar zapatos que le calcen bien.

¿Qué puedo hacer para cuidarme los pies?

- Lávese los pies todos los días con agua tibia.
 Toque el agua con el codo para asegurarse de que no esté demasiado caliente. No remoje los pies. Seque los pies completamente, especialmente entre los dedos.
- Revísese los pies todos los días para ver si tiene alguna cortadura, lesión, ampolla, enrojecimiento, callosidad u otros problemas.

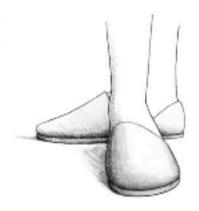
Es especialmente importante revisarse los pies diariamente si tiene daño en los nervios o mala circulación. Si no puede doblarse o levantar el pie para revisarlo, use un espejo. Si su vista no es buena, pida a otra persona que le revise los pies.



Revísese los pies todos los días para ver si hay problemas.

- Si tiene la piel seca, úntese crema humectante después de lavarse los pies y secarlos. No se ponga crema humectante entre los dedos de los pies.
- Use una piedra pómez o una lima de cartón para limar suavemente los callos y callosidades. Límeselos después de bañarse o ducharse.
- Córtese las uñas de los pies una vez por semana o cuando sea necesario. Córtese las uñas cuando estén suaves después del baño. Córtelas siguiendo el contorno del dedo y procure que no queden demasiado cortas. Límese las uñas con una lima de cartón.

- Siempre use pantuflas o zapatos para protegerse los pies de las lesiones.
- Siempre use calcetines o medias para evitar las ampollas. No use calcetines ni medias cortas que le queden demasiado apretadas debajo de las rodillas.



Siempre use pantuflas o zapatos para protegerse los pies.

- Use zapatos que le pies.

 calcen bien. Compre
 su calzado por la tarde, cuando los pies estén más hinchados. Use los zapatos nuevos con cautela hasta que se suavicen. Úselos de 1 a 2 horas al día durante las primeras 3 semanas.
- Antes de ponerse los zapatos, toque el interior de los mismos y asegúrese de que no tengan bordes cortantes u objetos que puedan lastimarle los pies.

¿Cómo me puede ayudar el médico a cuidarme los pies?

- Informe al médico inmediatamente de cualquier problema que tenga en los pies.
- Su médico debería hacerle un examen completo de los pies cada año.
- Pida al médico que le revise los pies cada vez que acuda a una cita para controlar su diabetes.

Asegúrese de quitarse los zapatos y calcetines antes de que el médico entre a la sala de exploración para que no se le olvide revisarle los pies.



Quítese los zapatos y calcetines para que el médico le revise los pies.

- Pida al médico que le revise para ver qué tan bien los nervios de los pies están transmitiendo las sensaciones.
- Pida al médico que le revise la circulación de la sangre en las piernas y los pies.
- Pida al médico que le muestre cómo debe cortarse las uñas de los pies. Pregunte qué tipo de crema humectante debe usar para la piel de las piernas y los pies.
- Si no puede cortarse las uñas de los pies usted mismo o si tiene algún problema de los pies, pida al médico que le envíe a un médico especialista en pies. Este tipo de médico se llama podiatra (podólogo).

¿En qué consisten los problemas comunes de los pies causados por la diabetes?

Todas las personas pueden tener callos, ampollas y otros problemas de los pies. Si usted tiene diabetes y sus niveles de glucosa en la sangre permanecen altos, estos problemas de los pies pueden causar infecciones.



Callo y callosidad.

Los callos y las callosidades son capas gruesas de piel que aparecen cuando hay demasiada fricción y presión en un solo punto. Los callos y las callosidades pueden infectarse.



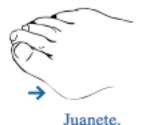
Ampolla.

Las ampollas pueden formarse cuando los zapatos ejercen presión en un solo punto. Cuando los zapatos no calzan bien o cuando se usan sin calcetines, se puede formar una ampolla. Las ampollas pueden infectarse.



Las uñas encarnadas ocurren cuando la orilla de una uña se clava en la piel y crece. La piel puede ponerse roja e infectarse. Las uñas se pueden encarnar cuando se cortan demasiado

profundamente las esquinas de las uñas de los pies. Las uñas también se pueden encarnar cuando los zapatos están muy apretados. Si las orillas de las uñas están filosas, límeselas con una lima de cartón.



Los juanetes se forman cuando el dedo gordo del pie está inclinado hacia los otros dedos y, como resultado de eso, la sección del hueso que está en la base del dedo gordo aumenta de tamaño. Los

juanetes pueden ponerse rojos, causarle dolor e infectarse. Los juanetes se pueden formar en uno o en ambos pies. Los zapatos con punta estrecha pueden causar juanetes. Los juanetes por lo general son más frecuentes en algunas familias. Se pueden eliminar con cirugía.



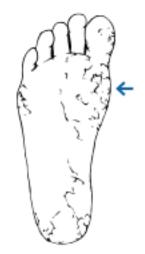
Las verrugas plantares son causadas por un virus. Las verrugas generalmente se forman en la planta del pie.



Dedo en martillo.

Los dedos en martillo se forman cuando un músculo del pie se debilita. La debilidad puede ser causada por el daño en los nervios causado por la diabetes. El músculo débil hace que los

tendones del pie se vuelvan más cortos y que los dedos se doblen hacia abajo. También puede llegar a tener llagas en la planta del pie y arriba de los dedos. Los pies pueden cambiar de forma. Los dedos en martillo pueden hacer que sea difícil caminar y encontrar zapatos que calcen bien. Los dedos en martillo por lo general son más frecuentes en algunas familias. Los zapatos demasiado chicos también pueden causar los dedos en martillo.



Piel seca y agrietada.

La piel seca y agrietada ocurre cuando los nervios en las piernas y los pies no reciben el mensaje de mantener la piel húmeda y suave. La piel seca puede agrietarse. Las agrietas permiten que los microbios entren en la piel, lo que causa infección. Si los niveles de glucosa en la sangre son altos, el exceso de glucosa alimenta los microbios y hace que la infección empeore.



Pie de atleta.

El pie de atleta es un hongo que causa comezón, enrojecimiento y agrietamiento de la piel. La piel agrietada entre los dedos permite que los microbios entren en la piel, lo que causa

infección. Si los niveles de glucosa en la sangre son altos, el exceso de glucosa alimenta los microbios y hace que la infección empeore. La infección puede pasar a las uñas de los pies volviéndolas más gruesas, amarillas y difíciles de cortar.

Hable con el médico inmediatamente si tiene algún problema de los pies.

¿Cómo pueden los zapatos especiales ayudar a mantener sanos los pies?

Se pueden hacer zapatos especiales que queden cómodos cuando los pies están doloridos o cuando hayan cambiado de forma. Estos zapatos especiales ayudan a proteger los pies. Es posible que Medicare y otros programas de seguro médico cubran los zapatos especiales. Hable con el médico para que le diga dónde y cómo comprarlos.

¿Cómo es que la diabetes puede dañar la piel?

La diabetes puede dañar la piel de dos maneras.

 Cuando los niveles de glucosa en la sangre son altos, el cuerpo pierde líquido. Cuando hay menor cantidad de líquido en el cuerpo, la piel puede ponerse seca. La piel seca puede dar comezón y, al rascarse, puede causarle dolor. La piel seca se puede partir. Cuando la piel se parte permite la entrada de microbios que causan infección. Si los niveles de glucosa en la sangre son altos, el exceso de glucosa alimenta los microbios y hace que la infección empeore.

Es posible que se reseque la piel de las piernas, de los pies, de los codos y de otras partes.

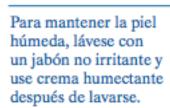
 El daño a los nervios puede reducir la cantidad de sudor. El sudor ayuda a mantener la piel suave y húmeda. Una reducción de la cantidad de sudor en las piernas y los pies puede resecar la piel.



Tomar líquidos contribuye a que la piel esté húmeda y sana.

¿Qué puedo hacer para cuidarme la piel?

- Después de lavarse con un jabón no irritante, asegúrese de enjuagarse y secarse bien. Seque bien los lugares donde el agua puede esconderse, como debajo de los brazos y los senos y entre las piernas y los dedos de los pies.
- Después de lavarse, use una crema humectante para mantener la piel húmeda.
 Pida al médico que le recomiende una crema de ese tipo.
- Beba mucho líquido, como agua, para que la piel esté húmeda y sana.
- Use ropa interior de algodón puro. El algodón permite que el aire circule mejor entre la ropa y la piel.



labón Suave

CREMA

HUMECTANTE

- Revísese la piel después de lavarse. Asegúrese de que no tenga áreas secas, rojas ni doloridas que puedan infectarse.
- Hable con el médico si tiene algún problema de la piel.

Cómo obtener más información

Nota: Si quiere ponerse en contacto con una de las siguientes organizaciones, es posible que necesite la ayuda de un intérprete o algún familiar o amigo bilingüe. No todas las organizaciones ofrecen asistencia en español.

Educadores en diabetes (enfermeras, dietistas, farmacéuticos y otros profesionales médicos)

Para localizar un educador
en diabetes en su área, llame
gratis a la American Association
of Diabetes Educators
al 1–800–832–6874.
O visite el sitio web en
www.diabeteseducator.org
y haga clic en "Find a
Diabetes Educator".

Dietistas

Para localizar un dietista en su área, comuníquese con la American Dietetic Association en www.eatright.org y haga clic en "Find a Nutrition Professional".

Dependencias gubernamentales

El National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), que en español se llama Instituto Nacional de Artritis y las Enfermedades Musculoesqueléticas y de la Piel, forma parte de los National Institutes of Health (NIH), que en español se llaman Institutos Nacionales de la Salud. Para obtener más información sobre los problemas de los pies y de la piel, escriba al NIAMS Information Clearinghouse, 1 AMS Circle, Bethesda, MD 20892–3675; o llame gratis al 1–877–226–4267; o visite el sitio web en www.niams.nih.gov/Portal_En_Espanol/default.asp.

Para obtener más información sobre el control de la diabetes, comuníquese con:

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Otras publicaciones de esta serie

La serie "Cómo prevenir los problemas de la diabetes" consta de siete libritos que le pueden ayudar a prevenir los problemas causados por esta enfermedad.



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Estos libritos también están disponibles en Internet en www.diabetes.niddk.nih.gov/spanish/indexsp.asp (en inglés: www.diabetes.niddk.nih.gov).

Agradecimientos

El National Diabetes Information Clearinghouse, que en español se llama Centro Coordinador Nacional de Información sobre la Diabetes, desea agradecer a todas las personas que ayudaron con la revisión o la evaluación pública de la versión en inglés de este librito.

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El National Diabetes Information Clearinghouse (NDIC) es el Centro Coordinador Nacional de Información sobre la Diabetes, un servicio del National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Este Instituto forma parte de los National Institutes of Health, que a su vez dependen del Department of Health and Human Services de los Estados Unidos. Fundado en 1978, el NDIC proporciona información sobre la diabetes a las personas con diabetes y a sus familiares, así como a los profesionales de la salud y al público en general. El NDIC responde a preguntas, produce y distribuye publicaciones y colabora estrechamente con organizaciones profesionales, gubernamentales y de pacientes para coordinar los recursos sobre la diabetes.

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Esta publicación puede contener información sobre medicamentos. Durante la preparación de este librito, se incluyó la información más actualizada disponible. Para recibir información al día, o si tiene preguntas sobre cualquier medicamento, comuníquese con la U.S. Food and Drug Administration (FDA). Llame gratis al 1–888–463–6332 (INFO–FDA), o visite su sitio web en www.fda.gov (en español: www.fda.gov/oc/spanish/ default.htm). Consulte a su médico para obtener más información.



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NIH Publication No. 09–4282S

Enero 2009

APPENDIX G INTERVIEW QUESTIONS FOR NURSES

Interview Questions for Nurse

- 1. Do you feel that you have the skills to provide the screening adequately?
- 2. What aspects of the protocol were easy to implement?
- 3. What were some of the challenges to implementation of the diabetic screening clinic?
- 4. How would you improve the protocol?

APPENDIX H INTERVIEW QUESTIONS FOR PATIENTS

Interview questions to ask the patients who part take in diabetic foot screening

- 1. Do you feel that the foot screening has improved your care of your feet?
- 2. What new practices have you implemented since your last visit?
- 3. How satisfied are you with the screening?
- 4. What would you change, if anything, about the screening?

APPENDIX I

DATA FORM

Data Form Utilizing the 60-Second Tool

Pte#	Age	Last foot screening	Gender	Years w DM	Previous Ulcers	Previous Amputation	Pulses	Stiffness	Active DM Ulcers	Ingrown toe nails	Callus	Fissure	Neuropathy	Referred	Total score