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Implementing a Three-Minute Foot Exam for Diabetic Patients in Primary Care

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Abstract

Problem- One in four U.S. Veterans have Diabetes Mellitus, and one in four U.S. Veterans with diabetes will develop a diabetic foot complication. There is currently no protocol for healthcare providers to perform foot screenings on diabetic patients at each visit. Utilizing a foot screening at each visit for high risk diabetic patients may help to recognize problems sooner, making treatment easier and less aggressive.

Methods- This quality improvement initiative was a retrospective and prospective record review before and after evidence based three-minute foot exams were implemented. A convenience sample of 50 patient medical records were reviewed to collect demographical, clinical indicators, and to establish the frequency of foot exams, education, detection of complication and treatment or referral with the current standard of care. A convenience sample of 20 patients, who were seen in a primary care face to face visit, had a retrospective chart review to collect the same data set as the standard of care baseline group.

Results- No differences between the standard group and the intervention group were found in comparing age, gender, war era, agent orange exposure, or Hbg-A1C lab values. The Fisher's Exact test showed statistical significance of documented foot exams and documented patient education in the intervention group, pre- and post-implementation with a p value of 0.001. Two patients (10%) had an undiagnosed diabetic foot complication identified on the foot exam and treatment or referral initiated.

Implications for Practice- Implementing an easy to use foot exam for diabetic patients at every visit is significant in improved patient outcomes. Timely recognition of diabetic foot complications also entails easier and less aggressive treatment.

Implementing a Three-Minute Foot Screening for Diabetic Patients in Primary Care

Introduction

Foot health is an important aspect of overall health and well-being. A diabetic patients' foot health can have a great impact on their life. Diabetes Mellitus (DM) has been, and continues to be, a major health issue. More than 600 million people are estimated to be suffering from DM in the next 20 years and currently one in eleven people have the disease worldwide (Allen, Van der Does, Albertine, & Gunst, 2016, p 1). A diagnosis of DM can lead to further complications in a patient's health, especially with their feet including diabetic foot ulcers, peripheral neuropathy, and amputations. These complications can be treated early if recognized by medical professionals during primary care visits.

DM refers to a disease process that affects how the body uses blood glucose. The body processes digested food into glucose, which in-turn supports the body and is an important source of energy for the cells of muscles and tissues (Mayo Clinic, 2019). Since there is an alteration in how the body uses glucose in DM, patients may develop a multitude of health issues and comorbidities, specifically in their feet (Mayo Clinic, 2019).

Specific complications associated with Diabetes Mellitus involving the feet include neuropathy, peripheral vascular disease (PVD), skin changes, calluses, foot ulcers, poor circulation, and amputation (Mayo Clinic, 2019). The American Diabetes Association (ADA) published *Standards of Medical Care in Diabetes for primary care providers* (2019). These standards are updated and published annually. The ADA professional practice committee, including healthcare providers from

multiple disciplines, developed the standards (American Diabetes Association, 2019).

The ADA's standards are based on evidence-based recommendations and are graded on an A, B, C, or E system (ADA, 2019). There are well conducted cohort studies that provide sufficient evidence to recommend annual foot examinations for all diabetic patients (ADA, 2019). The ADA also recommends a foot screening at every visit for diabetic patients who have evidence of sensory loss, previous ulceration, and/or previous amputation. This recommendation is based on supportive evidence, albeit from poorly controlled studies (ADA, 2019).

Diabetic foot complications are associated with loss of function, morbidity, and mortality (Allen, Van der Does, Albertine, & Gunst, 2016, p 1). Utilizing a foot screening at each visit for high risk diabetic patients may catch problems sooner, making treatment easier and less aggressive.

According to the Centers for Disease Control (CDC), diabetes and the associated complications cost the United States around \$327 billion in 2017 (Centers for Disease Control, 2018) and that number is only expected to rise. As high as 25% of patients with diabetes have a lifetime risk of developing a foot ulcer (Boulton et al., 2008). Currently, the ADA (2019) recommends at least annual diabetic foot screenings, as well as more frequent screenings for patients at high risk for complications.

At higher risk of developing Diabetes Mellitus than the general population, United States Veterans are among a vulnerable population (U.S. Department of Veteran Affairs, 2017). DM is a major health issue faced by Veterans, along with

other mental, social, and physical disabilities. According to the Veterans Health Administration (VHA), nearly one in four Veterans who are receiving care from the VHA has diabetes (U.S. Department of Veteran Affairs, 2017).

The Institute of Medicine published a report in 2000, *Veterans and Agent Orange: Herbicide/Dioxin Exposure and Type 2 Diabetes*, discussing an association between exposure to herbicides and type 2 diabetes (U.S. Department of Veteran Affairs, 2015). As a result of this report, Veterans who were potentially exposed to Agent Orange or other herbicides during military service are eligible to receive VA health care and disability compensation (U.S. Department of Veteran Affairs, 2015). Many U.S. Veterans who served in the Vietnam War were exposed to Agent Orange and the St. Louis VHA's patient population is largely from the Vietnam War era.

Annual foot screenings provide opportunities to prevent, address, and treat complications early. Primary care physicians, nurse practitioners, and registered nurses in outpatient offices at a VHA in a large midwestern city perform annual diabetic foot screenings. There is currently no protocol for healthcare providers to perform foot screenings on diabetic patients at each visit. Implementing a foot care protocol for each visit could promote prevention and timely recognition in the development of foot ulcers and other complications that could lead to a reduction in occurrence and severity of foot complications in diabetic patients (Cousart & Handley, 2017). Miller et al. (2014), created a three-minute foot care exam for diabetic patients that can be utilized in many healthcare disciplines, including primary care.

This project was a quality improvement initiative. The objective was to

implement Miller et al.'s (2014) three-minute foot screening for diabetic patients in a primary care office at the VHA. The goal was to increase the frequency of diabetic foot exams performed on diabetic patients. Outcome measures included use of the three-minute foot screen, complications documented (ulcers, infection, neuropathy, etc.), treatment and referrals given if needed.

To determine the relationship between the three-minute foot exam for diabetic patients in a primary care clinic and complications noted, treatment, and referrals given, this study explored the study question: In diabetic United States Veterans receiving care at a VHA Primary Care Clinic, does the use of the three-minute foot exam at every visit, compared to only using the annual comprehensive foot exam, result in timely recognition of associated diabetic foot complications?

Literature Review

The University of Missouri-St. Louis (UMSL) Library search tool was utilized to gather evidence-based research data. Included in the UMSL library search tool are search engines such as Medline, EBSCO Host, Cochrane, PubMed, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). Google Scholar and Google search were also utilized. Key words that proved useful in the literature search included diabetes, foot care, foot screen, foot program, veteran, diabetic complications, three-minute foot screen, three-minute foot exam, Ipswich touch test, and primary care.

In conducting a literature search, articles from years 2004-2020 were included. Exclusion criteria included inpatient diabetic care. Inclusion criteria included research related to Diabetes Mellitus, Diabetes Mellitus complications, foot

care/screening, and primary care of diabetic patients. After review of the literature, eleven studies/articles were selected to be included in the literature review for this project, along with information gathered from websites including ADA, CDC, and U.S. Department of Veterans Affairs.

The annual diabetic foot exam has several key components, including a health history. Risk factors the provider should inquire about include previous amputation, past foot ulcer history, peripheral neuropathy, foot deformity, peripheral vascular disease, poor glycemic control, and cigarette smoking (Boulton et al., 2008). A thorough foot exam with careful inspection is also a key component of the diabetic annual foot exam. The provider should assess the patient's skin, looking inter-digitally, as well as under the foot and behind the heel, noting skin discoloration, ulceration, calluses, or areas of erythema (Boulton et al., 2008). Musculoskeletal assessments include looking for bone deformities. Neurological assessment includes testing for sensory loss, ideally with two clinical tests. A popular way to test for sensory loss is the use of monofilaments on the patient's 1st, 3rd, and 5th metatarsal heads and plantar surface of the distal hallux (Boulton, et al., 2008). Other clinical tests to assess for sensory loss include tuning forks, pinprick sensation, ankle reflexes, and vibration perception threshold testing. Vascular assessment should also be completed by assessing the posterior tibial pulses and the dorsalis pedis pulses, noting diminished or absent pulses.

Providers may feel that performing a comprehensive annual diabetic foot exam may take too much time for their busy schedules in a primary care office. Diabetic foot evaluations are completed 12% to 20% of the time (Miller et al., 2014). In a

study by Cousart and Handley (2017), the researchers evaluated whether all aspects of a diabetic foot exam could be incorporated within a 15-minute office visit. The researchers performed a patient history, foot care and patient education on 31 patients with an average time spent of 10 minutes. This data shows that for annual foot care visits, it is feasible to perform a comprehensive foot exam in a traditional office visit time frame.

Current practice recommendations include a visual foot assessment and patient education at every visit, which can prevent up to 85% of diabetes-related amputations (Sanchez, 2008). According to the CDC (2011), more than 60% of nontraumatic lower extremity amputations (LEA) occur in United States diabetics. In patients who have had a history of prior amputation or ulceration, the risk for developing foot ulceration is 36 times greater than the general population (CDC, 2011). To increase diabetic foot screenings in a primary care office, Persaud et al. (2018) recommends an easy and rapid clinical tool for assessing foot health.

Three-Minute Diabetic Foot Exam

With a typical comprehensive diabetic foot exam, certain equipment and training is required. Miller et al. (2014) set out to develop a less complicated diabetic foot exam that could be completed by healthcare professionals. This exam takes three-minutes to complete and consists of three components: discussing a patient's health history, assessment of the feet, and patient education.

Obtaining a brief patient history can help the healthcare provider recognize patients at risk for diabetic foot complications. According to Miller et al. (2014), obtaining the patient's history should only take about one minute. During this

history, the healthcare provider should ask the diabetic patient about previous leg/foot ulcers or wounds, lower extremity amputations (including toes), prior stenting or leg bypass surgery, and smoking/nicotine use (Miller et al., 2014). Inquiring about cigarette and nicotine use is important due to the associated increased risk of peripheral artery disease (PAD). Asking the patient if they experience burning or tingling in their lower extremities, changes in skin color, or a loss of lower extremity sensation which indicates neuropathy which also increases the diabetic patient's risks for foot complications (Centers for Medicare & Medicaid, 2017).

Performing the physical examination is the next step in the three-minute diabetic foot exam. Miller et al. (2014) recommends that patients with confirmed diabetes should receive a foot inspection at every visit. Due to neuropathy, patients may not know that there is an issue with their feet such as infection, skin breakdown, ulcer formation, or inadequate vascular perfusion. Foot complications that the patient may not recognize, may be found on assessment by a health care provider. The physical examination should take one minute. Visual inspection of the legs, feet and toes should include looking for: color changes, signs of fungal infection, calluses, and open wounds. Assessing the patient's vascular status can be done by checking for temperature difference between the left and right foot and assessing hair growth (Miller et al., 2014). When palpating the dorsalis pedis and posterior tibial pulses, the provider should note diminished or absent pulses.

Neurologic examination of the feet during the annual comprehensive foot exam is typically done with the use of monofilaments. The Ipswich Touch Test (IpTT) is

utilized in the three-minute diabetic foot exam. Instead of monofilaments, the index finger of the provider is used for the neurologic exam. Since there is no equipment for the IpTT, the test can be performed in a variety of settings and by a variety of healthcare providers, including nurses and home caregivers (Madanat et al., 2014). Performing the IpTT involves using the providers index fingertip to lightly touch the first, third, and fifth toes for one to two seconds (Rayman et al., 2011). Baker and Kenny (2016) add that the provider should instruct the patient to close their eyes during the IpTT and respond if/when they feel sensation. In a study comparing the IpTT to monofilaments, Rayman et al., 2011 concluded that the two tests showed similar sensitivity and specificity. The IpTT is a quick, reliable, and inexpensive test to identify patients at risk for diabetic foot complications.

Patient Education is the final step in the three-minute diabetic foot exam. Karadag et al. (2019) advises daily foot care practices by diabetic patients at home to prevent or detect foot complications. Healthcare providers should educate patients on how to inspect their feet at home. Patients should be encouraged to visually inspect each foot and between toes for wounds, calluses, ulcers, swelling, or discoloration. Patients should be taught to use a mirror or ask another person to inspect hard to see places on the feet. Miller et al. (2014) mentions that a common barrier to prevention is lack of knowledge. It is imperative to educate the patient on diabetic foot care to reduce the likelihood of diabetic foot complications.

Throughout the literature review, many studies mention the recommendation of at least annual comprehensive foot exams for diabetic patients. Healthy people 2020 has a goal of reaching 76.7% of all diabetics receiving an annual foot exam (Healthy

People 2020, 2019). Although the ADA also recommends a foot exam at every visit for all diabetic patients, there was a lack of studies directly reviewing this recommendation. Healthy People 2020 does not have an objective for foot exams at every visit for diabetics. Many studies refer to providers stating there is not enough time during office visits to perform foot exams. Many studies utilized Miller et al.'s (2014) three-minute foot exam protocol. The idea of utilizing a three-minute foot exam, which can be performed by a variety of healthcare workers, could eliminate the time constraint, and improve patient care.

The Plan-do-study-act (PDSA) cycle is a four-step process that can be repeated as many times as needed, for continual learning and improvement (The W. Edwards Deming Institute, 2019). The PDSA cycle was modified by Dr. Deming from 1950 to 1993 (Moen & Norman, 2010). The four-step process is laid out in a circular, continuous design. The first step involves identifying a goal. The goal was to perform the three-minute diabetic foot exams on 80% of diabetic patients seen in a primary care clinic, at each visit. The second step was to implement the plan; educate staff on the three-minute foot exam for diabetic patients and encourage them to perform the exam on all diabetic patients at each visit. Studying the outcomes to test the validity of the plan was the third step. Outcomes to be measured included how often the three-minute foot exam was performed, foot complications (ulcers, neuropathy, other wounds) found and documented, and how often the patient's exam resulted in treatment or referral for a diabetic foot complication. To close the cycle, the project was discussed with key stakeholders and will be evaluated as to whether the facility will continue the implementation.

Method

This was a quality improvement initiative utilizing retrospective and prospective record review before and after evidence based three-minute foot exam was implemented. Data was collected by completing a retrospective chart review and a prospective chart review. Data from two months prior to implementing the three-minute foot exam, and data from two months after implementing the three-minute foot exam, was reviewed.

This project took in a Veteran's Health Administration (VHA) primary care clinic. The primary care clinic is in a large city in a midwestern state and sees patients local to the area. The patient population seen at this primary care clinic include United States Veterans, primarily from the Vietnam War era.

Convenience sampling was used to select participants. Participants were diabetic U.S. Veterans receiving care in the primary care clinic. Inclusion criteria included patients over the age of 18 with a previous diagnosis of Diabetes Mellitus. For this project, participants must have had Hemoglobin A1C greater than 6.4 and be taking oral diabetes medication and/or insulin. Patients who have bilateral lower extremity amputations were excluded. A retrospective chart review on 50 patients was completed to create a standard group, establishing a baseline. An intervention group of 20 patients had a retrospective chart review and prospective chart review after implementation.

To complete this project, approval from the VHA was received. A doctoral committee including a doctorally prepared Nursing Graduate Professor, a doctorally

prepared faculty member, and a doctorally prepared Nurse from the project site approved the project. Human subject approval from UMMSL's IRB was obtained and the VHA research department deemed the project QI and did not require IRB submission.

Data Collection and Analysis

Data was collected from the Computerized Patient Records System (CPRS) Electronic Health Record (EHR) utilized by the VHA. No identifying patient information such as social security number, name, or date of birth was collected. Data collection was kept on a password protected computer. Health indicators utilized in a documentation tool included age, gender, diagnoses, exposure to agent orange, and war era. Data for outcome measures collected included documentation of the three-minute foot exam, foot complications identified during the exam, treatment given for complications, and referrals to higher level of care.

Preliminary work for the project included a literature review and approval from necessary groups. Education was given to the primary care clinic staff on Miller et al.'s (2014) three-minute foot exam for diabetic patients and how a foot exam at every visit for a diabetic patient improves patient outcomes. Healthcare providers that performed the three-minute foot exam included RNs and LPNs. The healthcare providers demonstrated their understanding of the three-minute foot exam to the researcher by the teach-back method. Staff members who performed the three-minute foot exam received a verbal consent from each patient by asking permission to perform the exam. The primary care clinic started performing the three-minute foot exam on all diabetic patients at every visit, starting in July 2020. The clinic staff

performed the three-minute foot exam for two months. The researcher compared data from before implementation, including how often a foot exam was documented and performed, how often wounds were documented during the exam, and treatment or referral of diabetic foot complications; and after implementation, including how often foot exams were documented and performed, how often wounds are documented during the exam, and treatment or referral of diabetic foot complications.

Results

In the standard group, the retrospective data concluded with N=50. Sample included patients aged 35-83 with a mean of 67 years; 2 females (4%) and 48 males (96%). Of the 50 patients in standard group, 18 (36%) had a documented foot exam for their primary care visit. None of the 50 patients had diabetic foot complications documented, therefore no treatment or referrals were documented.

The intervention group concluded with N=20. The retrospective chart review involved reviewing the same clinical measures as the standard group. Sample included patients aged 40-82 years with a mean of 68 years; 1 female (5%) and 19 males (95%). Of the 20 patients in the prospective chart review, 20 (100%) had a documented foot exam for their primary care visit; 2 (10%) patients had diabetic complications/wounds documented and each had an accompanying treatment/referral documentation.

A Fisher's Exact Test showed there was a statistical significance comparing pre-implementation foot exams documented and post-implementation foot exams documented in the intervention group, based on an alpha value of 0.05, $p < .001$. A

Fisher's exact test was conducted to examine whether documented education in the Intervention Group were independent. The results of the Fisher exact test were significant based on an alpha value of 0.05, $p < .001$.

When comparing Age in the Standard Group to the Intervention Group, the result of the two-tailed independent samples t -test was not significant based on an alpha value of 0.05, $t(68) = -0.51$, $p = .612$. This suggests the mean of Age was not significantly different between the two groups. When comparing the HgbA1C in the Standard Group to the Intervention Group, the result of the two-tailed independent samples t -test was not significant based on an alpha value of 0.05, $t(68) = -1.11$, $p = .269$. This finding suggests the mean of HgbA1C was not significantly different between the two groups. The result of the two proportions z -test for nominal data (sex, agent orange exposure, war era) was not significant. These findings suggest there is no difference between the Standard Group and Intervention Group.

Discussion

The goal of this quality improvement initiative was an increase in frequency of foot exams on diabetic patients. The result of the implementation did find that more complications were discovered when completing the foot exam on each diabetic patient at each visit. This allowed providers to treat and/or refer patients depending on how severe the foot complication/wound was. Finding diabetic foot complications in earlier stages can decrease costs to the patient and the facility. Diabetic foot complications cost the United States anywhere from \$9 to \$13 million a year (Raghav et al., 2018).

Completing the three-minute foot exam did not add a significant amount of

time to the patient visit. RNs and LPNs were able to complete the exam while obtaining vital signs and other check in procedures. All patients gave verbal consent to allow staff to complete the foot exam.

Limitations to this quality improvement initiative included the COVID-19 pandemic. Many clinics switched primarily to virtual tele-health appointments, which delayed this project. When the clinics started to re-open, many patients opted to stay with virtual appointments and face-to-face appointments were kept to around 6-8 per day.

Conclusion

Implementing an easy to use foot exam for diabetic patients at every visit is significant in improved patient outcomes. More diabetic foot complications/wounds were discovered utilizing the three-minute foot exam compared to the annual comprehensive foot exam, which decreases costs to the patient and the facility. Timely recognition of diabetic foot complications also means easier and less aggressive treatment for patients.

Recommendations for sustainability of this project include staff and patient education. Staff should be regularly educated on the risks of diabetic foot complications and what to look for. Patients should be educated at each visit on appropriate foot care, and signs they need to watch for, and when to alert their provider. Due to the COVID-19 pandemic, this project implementation time was shorter than anticipated. It is recommended that more trials be implemented in order to see outcomes that result from larger numbers of participants.

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