

EVALUATING THE INITIAL MANAGEMENT AND REFERRAL PROCESS FOR
PATIENTS WITH DIABETIC FOOT ULCERS

By

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**Evaluating the Initial Management and Referral Process for Patients
with Diabetic Foot Ulcers**

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Abstract

Approximately 10% of the U.S. population is living with diabetes. Diabetic foot ulcers (DFU) are one of the most prevalent and debilitating complications. One in four people with diabetes will develop a DFU at some point in their lifetime. The consequences of non-healing DFUs include risk of amputation, further disease complications, increased risk of mortality, and more frequent and extended hospital stays. Adhering to evidence-based guidelines, which include recommendations for DFU prevention, assessment, and management, is crucial for achieving complete healing and reducing risks for poor outcomes. However, research has consistently shown a significant gap in the use of these guidelines in primary care, where DFU prevention should occur and DFU assessment and management most often begins.

Objective: The purpose of this quality improvement project was to evaluate the initial management and current referral process for DFU patients and make recommendations for improvements based on current evidence-based practice guidelines for DFU management.

Methods: A retrospective chart review was performed at the University of Kansas Hospital's Outpatient Burn and Wound Care Center to evaluate for adherence to evidence-based practice guidelines for initial management and referral for DFU care by referring providers. Factors associated with lack of adherence to guidelines were identified via the collection of variables from 70 randomly selected patient charts, including specific data points related to DFU prevention, assessment, and management. Descriptive statistics were utilized to analyze the data collected using means for continuous variables and frequencies and percentages for categorical variables.

Results: Retrospective data indicates that evidence-based guidelines were poorly implemented for DFU assessment and management in the primary care setting. In a sample of 70 patients, neuropathy assessments were done 21.4% of the time, ischemia assessments 45.7%, and infection assessments 87.1% in the primary care setting. In contrast, all three of these assessments were performed 100% of the time at the specialty wound clinic. Making a referral was the most common management strategy utilized by primary care providers for treating a DFU and was applied 75.7% of the time, although only 23% of these referrals were made to a wound care clinic. Debridement and offloading were infrequently seen in primary care with the former being utilized in 10% of cases and the latter 18.6%. Most often, referrals to wound care were made by a specialist, which was the case 49% of the time. Sixty-one percent of patients required more than one referral before being evaluated by a wound care specialist. Average total duration of a DFU from onset to resolution was 104 days (range 13-248).

Conclusion: The results of this study indicate that the initial management and referral process of DFU's is currently inadequate and not in line with current evidence-based practice guidelines for DFU management. Further research is needed to explore the reasons for provider noncompliance in order to determine appropriate interventions to facilitate improvements in adherence to guidelines.

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Evaluating the Initial Management and Referral Process for Patients with Diabetic Foot Ulcers

The Centers for Disease Control and Prevention (CDC, 2017) estimates that there are 30.3 million people living with diabetes in the United States. If current trends continue, this number is expected to double over the next three decades (Lavigne, Reeves, Sasseville, & Loignon, 2017). The implications of this are significant due to the profound impact diabetes has at the individual, family, community, and population levels.

Although people with diabetes are more susceptible to a multitude of health problems, one of the most prevalent and debilitating complications is the occurrence of diabetic foot ulcers (DFU), estimated to occur in one of every four diabetic patients at some point in their lifetime (Bowling, Rashid, & Boulton, 2015). DFUs are the leading cause of diabetic limb amputations and are associated with an increased risk of death. More than 80 percent of diabetic amputations are preceded by a DFU and 30 percent of these patients die within a year of the limb loss (Lavigne et al, 2017).

According to the American Diabetes Association (ADA, 2015), the overall costs associated with diabetes in the United States are in excess of \$245 billion dollars a year. The portion of these costs that are specifically associated with diabetic limb complications are estimated at \$17 billion each year, making it the most expensive diabetic-associated condition (Barshes et al., 2013). The average cost of managing one severe DFU in the United States is estimated to be more than \$54 thousand dollars a year (Lavigne et al, 2017).

As the incidence of diabetes continues to increase, management in the primary care setting also increases (Smith-Strom, Iversen, Graue, Skeie, & Kirkevold, 2016). Although evidence-based and timely management of DFUs is crucial for achieving complete healing and reducing reoccurrence risks, implementation is often complicated by the many specialties, and in

turn, variations in treatment, involved in the trajectory of care (Edwards et al., 2013). Studies have shown that there is a significant gap in the use of evidence-based guidelines for appropriate assessment, referral, and treatment of DFUs (Edwards et al., 2013). The potential consequences of DFU treatment delay or mismanagement make it imperative that providers become diligent in managing DFUs in accordance with clinical practice recommendations.

Statement of the Problem

Optimal DFU management should involve both the patient and their healthcare providers and starts at the primary care level (Garcia-Klepzig et al., 2018). Research has shown that early specialist referral, evidence-based ulcer management, and transparent communication between all involved parties are key factors for ulcer healing (Chen et al., 2015). The more information a specialist has on a patient's health history and current health status at the time of the initial visit, the more the provider can tailor care that is appropriate to that patient (Garcia-Klepzig et al., 2018).

The Outpatient Burn and Wound Care Clinic (OBWCC) is a specialty medical clinic in Kansas City, Kansas that manages burns or complex and/or chronic wounds for residents of Kansas City and the surrounding areas. Providing care at OBWCC is often complicated as many of the patients seen are suffering from chronic health conditions, are under the care of multiple providers, and/or have limited resources. One of the most common chronic conditions managed at OBWCC is diabetic foot ulcers. OBWCC adheres to the clinical practice guidelines for managing the diabetic foot established by the Society for Vascular Surgery in collaboration with both the American Podiatric Medical Association and the Society for Vascular Medicine (Hingorani et al., 2016). Early and aggressive management of DFUs is crucial in order to give these patients the best chance of making a full recovery. However, valuable time is often lost due

to late and/or inconsistent referral practices from primary care providers to OBWCC. In addition, data that are needed at the initial visit is often incomplete, which further delays the treatment process.

Thus, the purpose of this quality improvement project was to evaluate the current referral process for DFU patients sent to OBWCC and identify strategies for improving upon the current system. The three aims were: (a) Evaluate the quality of the referral process; (b) Identify mechanisms accounting for any potential differences in care related to the referral process; and (c) Make recommendations for improving the referral process based on current evidence-based practice guidelines for DFU management.

Review of Literature

A literature search was performed between September 2018 and January 2019 on the databases of CINAHL, PubMed, the Cochran Library, and the web search engine, “Google Scholar”. Key search terms included “diabetic foot”, “risk for ulceration”, “referral process”, “DFU”, “multidisciplinary teams”, “primary care”, “assessment”, and “treatment”. Inclusion criteria consisted of original research and systematic review articles written in English and that utilized samples consisting of adult participants. Priority was given to articles published within the last ten years.

Diabetic Foot Complications

According to the International Working Group on the Diabetic Foot, the term diabetic foot is “an infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of people with diabetes” (Bus et al., 2015). There are three crucial complications that are frequently seen in the diabetic foot that contribute to DFU formation (Ousey et al., 2018).

The first complication is diabetic peripheral neuropathy (DPN), and it is the most common complication of diabetes that affects the feet and its prevalence is known to increase with diabetes duration (Baker & Kenny, 2016). This condition is reported to be present in 40 to 60% of diabetic patients in the United States and can affect sensory, motor, and autonomic nerve fibers (Barshes et al., 2013). DPN is a loss of protective sensation that results from a patient having a reduced response to touch and painful stimuli in the extremities (Ousey et al., 2018). This condition doubles the risk of a DFU occurring as the sensory pain response that would normally alert the brain of potential dangers to a limb are muted (Barshes et al., 2013). In addition, damage to autonomic nerve fibers results in a loss of sweating that contributes to dry skin, callus formation, and skin cracking; all factors that perpetuate the risk of DFU formation (Ousey et al., 2018).

The second complication is PAD, which eventually presents in 30% of all diabetic patients and nearly half of all DFU patients (Barshes et al., 2013). The progressive sclerosis of involved blood vessels leads to reduced blood supply and tissue ischemia in the extremities and is associated with an increased risk for poor DFU outcomes, including amputation and death (Yazdanpanah, Nasiri, & Adarvishi, 2015).

Finally, the third complication frequently associated with DFU development is structural changes that occur as consequences to a variety of internal factors (e.g., neuropathies, muscle atrophy, reduced mobility in tendons and joints; as well as external factors such as a history of one or multiple minor amputations (Barshes et al., 2013). Changes in structure result in variations in pressure distribution which lead to certain areas of the foot experiencing excess stress during walking. As these areas continue to carry this extra weight, the ongoing trauma makes them increasingly more susceptible to DFU development (Barshes et al., 2013).

Vascular Guidelines for Diabetic Foot Management

Clinical practice guidelines for managing the diabetic foot were published in 2016 by the Society for Vascular Surgery and developed by a multi-disciplinary committee of experts in vascular and internal medicine (Hingorani et al, 2016). The committee spent 3 years reviewing the published literature to develop recommendations for practice based on the best evidence and focusing on five areas of diabetic foot care: prevention, offloading, diagnosis of osteomyelitis, wound care, and peripheral artery disease (PAD; Hingorani et al., 2016). While recommendations related to the prevention and initial assessment of DFUs can mostly be managed in primary care, once a DFU has formed, treatment often requires early specialty involvement. Preventative recommendations include annual foot exams that include testing for diabetic peripheral neuropathy and education on protective foot care practices, as well as maintaining tight glycemic control (hemoglobin A1c < 7%), managing vascular risk factors, utilizing therapeutic footwear, and undergoing ankle-brachial index (ABI) measurements beginning at age 50 (Hingorani et al., 2016).

Once a patient has developed a DFU, appropriate initial assessment is critical for optimal outcomes. Guidelines recommend initial assessment for ischemia, neuropathy, and infection; diagnostics should include ABI and transcutaneous oxygen pressure measurements, and a probe to bone test and plain x-ray (Hingorani et al., 2016). The appropriate treatment pathway, as well as the appropriate specialist to manage the situation, will depend on the findings from this initial assessment; however, all pathways will include some variation of comprehensive wound care and offloading (Hingorani et al., 2016). The crucial common denominator of these various pathways is that evidence-based guidelines consistently recommend that all DFUs should be

referred to a specialist for further management due to the complexity of managing both diabetes and a wound (Ousey et al., 2018).

Assessing for DFU Risk Factors and Complications

There are several factors that must be considered when assessing the feet of a diabetic patient. One crucial area of consideration is individual risk factors that a patient has for developing a DFU that should guide their care (Ousey, et al., 2018). Risk stratification has been found to be effective in identifying and reducing the occurrence of DFUs (Baker & Kenny, 2016). In 2012, Monteiro-Soares and colleagues published an extensive systematic review of variables associated with DFU development; 71 separate studies were ultimately included in the final review. Their findings determined that the patient demographics of age, birth sex and living alone were statistically significant predictors of DFU occurrence (Monteiro-Soares et al., 2012). They also found that duration of diabetes, insulin use, and HbA1c level were significant variables. Foot characteristics that were found to be relevant in predicting DFU occurrence include foot deformity, diagnosis of neuropathy, diagnosis of PAD, a previous history of DFU, and any history of amputation, including minor amputations of the digits or a major amputation of the other limb. Specific wound characteristics that consistently impacted DFU healing included the duration, depth, and area of the ulcer and the presence of either infection or gangrene in the wound.

The risk factor history should then be combined with an appropriate assessment of diabetic foot etiology to determine the appropriate course for managing diabetic foot care (Armstrong, Boulton, & Bus, 2017). Jung and colleagues (2016) were able to demonstrate this point by applying a predictive model for delayed wound healing using only information that was collected and documented in the electronic health record (EHR) during routine care in outpatient

wound centers. Utilizing basic patient demographic information, as well as quantitative and categorical information on 180,696 separate wounds, the model was able to predict which wounds would most likely be slow to heal with a high level of confidence. The results underscored the point that early, accurate predictions about wounds can be garnered from appropriate history and assessment, and this information can be used by providers to make accurate referral and/or treatment decisions. As per established guidelines, physical assessment should include checks for DPN, PAD, and structural deformities, the three hallmark complications of the diabetic foot (Hingorani et al., 2016). The presence of any of the three warrant, at minimum, referral and evaluation by a specialist. According to the guidelines, a diabetic patient that is negative for all three of these complications and has no DFU or amputation history can continue with annual foot evaluations by their preferred provider (Hingorani et al., 2016)

The presence of DPN is easily assessed for by testing patient response to sensory stimulation on the plantar surface of the feet using a 10-g monofilament, the Ipswich Touch Test, or a 128-Hz tuning fork (Baker & Kenny, 2016). All three of these tests are evidence-based and reliable mechanisms for assessing for the loss of protective sensation (Baker & Kenny, 2016). It is also important to note that they are each easily implemented using standard equipment found in any primary care office. Research has shown that up to 90% of patients with peripheral sensory neuropathy are unaware that they have it, making identification of the condition and patient education on foot-protective behaviors crucial aspects of DFU prevention (Barshes et al., 2013). Guidelines state that patients that are positive for this complication require foot evaluations to be increased from annually to semiannually (Hingorani et al., 2016).

A first step in assessing for PAD is to palpate pedal pulses (Baker & Kenny, 2016). Diminished or absent pulses along with the presence of easily identifiable clinical features such as: dependent rubor, very dry skin, diminished or absent hair growth on lower legs and feet, and persistent blanching, are highly indicative of PAD and warrant further and more in-depth evaluation of the vessels (Bowling et al., 2015). Finally, structural deformities can be easily identified, if providers are performing regular diabetic foot checks in accordance with clinical practice guidelines (Ousey et al., 2018). In addition, the impact of such deformities on DFU occurrence can be mitigated by primary prevention through collaboration with orthotics to incorporate the use of specialized footwear to make weight distribution more uniform (Barshes et al., 2013). If either PAD and/or any structural deformities are present along with DPN, timing of diabetic foot assessments by a provider should be increased from semiannually to quarterly (Hingorani et al., 2016).

Primary Care Management of DFU

With the ever-increasing demands on the healthcare system along with the high prevalence of diabetes, it is becoming more commonplace for primary care providers (PCP) to manage diabetic care themselves. In turn, PCPs are more frequently becoming the first-line healthcare provider monitoring for and managing DFUs. Published guidelines recommend referral occur within 24 hours of DFU identification or as early as possible following assessment and identification of a DFU (Ousey et al., 2018). However, research studies have shown that general practitioners are inconsistent in adhering to these evidence-based practice guidelines for DFU prevention and management (Sanders et al., 2013).

In the landmark Eurodiale Study that looked at PCP management strategies for patients presenting with a new DFU in fourteen different clinics and spanning ten countries, large

variations were found between individual providers (Prompers, et al., 2008a). The researchers determined that 27% of patients presenting to their PCP with a DFU were treated for greater than 3 months before being referred to a specialist; results also revealed that 77% of patients treated had either inadequate offloading or were not instructed by their PCP to offload at all. After following the care of 1232 new DFU patients, the Eurodiale Study concluded that treatment of DFUs in primary care is often not in line with current evidence-based guidelines that stress both early specialist referral and offloading of the ulcerated foot.

A study by Manu (2008) that looked at referral patterns for DFU patients from their PCP to a specialist came to similar conclusions when results showed that 48% of patients were referred to a specialist more than a month after DFU onset. A mixed-methods study revealed similar results, finding the average delay in DFU referral to a specialist was 20.5 days (Sanders et al., 2013). An observational study by Spanos (2017) that aimed to assess factors associated with the DFU healing process found that referral delay was one of three key factors that contributed to delayed healing and limb loss. The mean time until referral was 23.8 days and there was no time difference found between patients that presented as a self-referral versus a provider-referral (Spanos et al., 2017). Ellis, Ballance, Lunt, and Lewis (2010) looked at the outpatient care provided to patients for the six months before and the six months after a hospitalization for a DFU occurred. Despite these patient's high-risk status, study results found that 51% of them were not referred to a specialist for foot care either before or after their hospital admission.

Research has also found that primary care providers admit to being unsure about DFU management. In 2018, Garois-Klepzig published a study that evaluated the perceptions of PCPs regarding their own ability to appropriately manage DFUs. These researchers found that up to

40% of PCPs did not feel that they were adequately trained in DFU treatment protocols, including when and where to refer and appropriate testing to order. The authors recommended that establishment of clear and specific competencies for each of the different types of health professionals involved in DFU management would be beneficial for maximizing efficiency and fluidity of care for these complex patients (Garois-Klepzig, 2018). A study by Smith-Strom (2016) also yielded support for this conclusion by using an interpretive description study design to analyze an integrated wound-care pathway. This research revealed three themes as essential for good DFU outcomes: competent wound management by healthcare professionals, continuity of care, and easy access to care.

Research has also shown that when primary care providers have received adequate training on screening for diabetic foot complications and are familiar with clinical practice guidelines for management and referral, DFU outcomes improve considerably (Lazzarini, O'Rourke, Russell, Derhy, & Kamp, 2012). A three-year study of three different and diverse practice sites found the surveillance of diabetic patients deemed "high risk" for DFU improved 34% after providers received formal training in diabetic foot assessment and DFU referral and management guidelines (Lazzarini et al., 2012). In addition, appropriate treatment according to risk improved 15% and documentation of evidence-based diabetic foot management improved between 13-66%. The National Diabetes Foot Care Audit (NDFCA), measures the care structures, patient management, and care outcomes of 19,453 patients to date with DFUs, reports that patients, initially seen by providers that referred to a specialist within 24 hours of DFU diagnosis, experienced fewer severe ulcers and had better outcomes at 12-weeks post-diagnosis (NHS Digital, 2018).

Delayed Referral Impact on Healing

There is a positive correlation between delays in specialist management and delayed DFU healing (Edwards et al., 2013; Lavigne et al., 2017; Smith-Strom et al., 2017). Other significant consequences include the risk of amputation as well as financial burden. It has been well established that the longer a DFU remains unhealed, the greater the risk for infection, and, in turn, amputation (Rogers et al., 2010). The costs associated with wound care directly, as well as indirectly in the loss of productivity that DFU patients and their family members experience, is detrimental to not only these patients as individuals, but to society, as a whole (Sen et al., 2009).

Time. Wounds assessed and managed in the primary care setting and not treated in adherence with evidence-based practice guidelines have average healing times of more than 5 months while those that follow published guidelines have an average healing time of 5 weeks (Lavigne et al., 2017). Research by Smith-Strom (2017) looked at how DFU healing times were affected by delayed referral to a specialist. Researchers from this study found that patients that were referred to a specialist 52 days or more after DFU onset had a 58% decreased healing rate compared to those that were referred earlier. Edwards (2013) found that DFU management that did not adhere to evidence-based guidelines resulted in wounds with an average healing time of 22 weeks; in contrast, wounds that were admitted into specialist care had an average healing time of 12 weeks. This study also found that the use of evidence-based wound management increased significantly in the specialty care setting compared to the primary care setting. The findings from each of these studies further demonstrates the critical importance of adhering to practice guidelines that emphasize early referral to a specialist for optimal DFU healing (Edwards et al., 2013; Lavigne et al., 2017; Smith-Strom et al., 2017).

Infection. Another consequence of delayed referral is the increased risk of infection and, in turn, amputation. The longer a DFU is present, the greater the risk of infection and in fact, 60% of DFUs have some clinical signs of infection upon presentation to a provider (Barshes et al., 2013). Due to diabetic foot pathology, infection often spreads rapidly, resulting in gross amounts of tissue destruction that is high risk for requiring amputation (Manu et al., 2018). DFU infection results in 85% of diabetic limb amputations and is also a major cause of diabetic hospital admissions (Lavigne et al., 2017). Greater than 1 million people with diabetes suffer limb loss each year, which translates to one amputation every 20 seconds (Hingorani et al, 2016).

In a study that assessed factors associated with the DFU healing process, for each additional day of delay in referral, the odds risk for a major amputation increased by 3.5% (Spanos et al., 2017). Prognosis is often bleak for patients following a major lower-extremity amputation (LEA). The five-year survival rate following an LEA is only 50% and these patients also have about a 50% chance of developing a DFU in the contralateral limb within the five years following the initial amputation (Sen et al., 2009). Evidence has shown that limb loss has a larger negative impact on quality of life than any other complication of diabetes with loss of mobility, loss of independence, depression, and anxiety all being prominent consequences (Barshes et al., 2013).

However, research studies that have demonstrated adoption of better and more rapid referral practices have yielded encouraging results. A retrospective study followed the care of 648 DFU patients over the course of a ten-year period in order to compare the frequency of LEAs before and after clinical practice guidelines for wound care were implemented at the facility (Wang et al., 2016). The first two years of the study, before practice changes were implemented, major amputation rates were 9.5% the first year and 14.5% the second; after

implementation, major amputation rates declined to less than 5% for every year thereafter. In a similar study, data were collected retrospectively for a two- year period before a multidisciplinary foot team was introduced to help meet clinical practice recommendations for DFU care, at which point, data were then collected prospectively for the next eleven years (Krishnan, Nash, Baker, Fowler, & Rayman, 2008). Over the course of the study, the incidence of total amputations fell 70% and the incidence of major amputations fell 82%.

Cost. Another consequence for the individual as well as the public, is the financial impact of DFUs, which is made even more burdensome when mismanagement occurs. The cost of managing diabetic foot disease in the United States is estimated to be more than 6 billion dollars a year (Hingorani et al., 2016). One-third of the total financial burden of diabetes management is attributed to DFUs (Ousey et al., 2018). The direct cost associated with managing one DFU, considering both in- and outpatient management, ranges from \$5,218 to \$23,372 per occurrence, which averages out to \$13,179 per episode (Prompers et al., 2008b). Diabetes-related amputations make up approximately 3 billion of the total expenditure for diabetic foot disease management (Sen et al., 2009). Patients lose more than 2 million workdays annually due to DFUs (Edwards et al., 2013). Communities incur the consequences associated with this absence from the workforce as does society, as a whole (Edwards et al., 2013).

Healthcare systems have implicated the up-front costs and low reimbursement rates associated with chronic wound management as major barriers to the use of evidence-based guidelines (Edwards et al., 2013). However, the long-term financial strain to the economy brought on by DFUs, as well as the personal tragedy and loss experienced by the patient and their community, in fact makes the utilization of DFU clinical guidelines a cost-effective health care expenditure (Hingorani et al., 2016). The Eurodiale Study provided strong evidence to

illustrate this point when they used prospective data to perform a cost analysis, of the patients treated during the study, in relation to outcome (Prompers et al., 2008b). The highest total costs were incurred in patients who underwent major amputations (\$28,513), after that were those whom were still not healed after twelve months (\$20,064), while the lowest costs were associated with patients whose ulcers healed, with an average total cost of \$8,729 (Prompers et al., 2008b). In addition, this study also found that resource utilization and costs increased with the severity of the DFU, with the total cost per patient being over four times higher when infection and PAD were also present.

Theoretical Framework

The development of this project was guided by the Donabedian framework, which has been well established as a useful conceptual model for appraising healthcare quality. The model was developed by Avedis Donabedian and introduced in his landmark article, “Evaluating the Quality of Medical Care” in 1966. This model consists of a three-part approach made up of three factors: structure, process, and outcome (Liu et al., 2013). Structure represents the attributes of an organization where care takes place, a broad concept that encompasses not only the setting itself but also the organization of care and the skills and qualifications of the health care providers (Liu et al., 2013). Process refers to the actions that are carried out in providing care while outcomes consists of the result for the patient, (Liu et al., 2013). According to Donabedian, these three factors impact each other in that the structure of healthcare influences the processes that will be performed, which in turn influences the outcomes that will occur (Liu et al., 2013).

Methods

This quality improvement (QI) project was conducted at University of Kansas Hospital’s OBWCC. A retrospective chart review was conducted to evaluate for adherence to evidence-

based practice guidelines for initial management and referral for DFU care by referring providers. Factors associated with lack of adherence to guidelines were identified via the collection of variables, including specific data points related to DFU prevention, assessment, and management. Characteristics from the following four categories were also collected from each chart: demographics (age, gender, lives alone, insurance, smoking), diabetes (duration, insulin use, HbA1c), foot (deformity, DFU history, amputation history, PAD diagnosis, neuropathy diagnosis), and wound (duration, depth, area, infection, gangrene presence at time of referral). Recommendations for improving practice were then guided by analysis of the data collected.

Human Subject Protection

The University of Kansas Internal Review Board (IRB) designation as quality improvement was obtained in April of 2019, prior to initiation of this project. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects the privacy of patients' health information (Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 2013). The project leader and practice personnel involved with this project carefully adhered to patient rights set forth by HIPAA and reinforced by the standards of care for practice at OBWCC. All data collected from patient health records for the project were aggregated and did not include any potential patient identifiers. Patient confidentiality was assured by coding the patient charts using individual identification numbers. A list of the patient charts and their assigned identifying numbers was kept in a secured location. All electronic files containing identifiable information was password protected. Only the de-identified patient number was used to enter and manage all study data in REDCap.

Setting

Data were collected from the OBWCC that is part of the University of Kansas Hospital network and located on the Kansas/Missouri state line. The OBWCC treats over 300 patients each month with approximately one-third of these patients being seen for DFU management. DFU patients seen at the clinic are referred from surrounding primary care and specialist facilities, the KU Emergency Department or emergency departments in the surrounding area or are a self-referral. The OBWCC is staffed by one nurse practitioner, a physician's assistant, two physicians, and three full time nurses. Except for the physician's assistant, all care providers have over a decade of wound care experience and all nurses are Wound Care Certified. For the purposes of this DNP project, the project leader collaborated directly with the clinic's nurse practitioner, whom was also a committee member for this project.

Sample

A convenience sample of 70 patient charts was selected from the OBWCC. Appropriate sample size was determined by reviewing the sample size used in published research that utilized a similar study design and plan for analysis to the one planned for this project; sample size of these various studies ranged between 49 and 105 participants (Edwards et al., 2013; Ellis et al., 2010; Sanders et al., 2010; Smith-Strom et al., 2017). The average of all samples reviewed was calculated to be 70.

Charts retrieved included patients that have presented to the clinic in the last 36 months with a DFU that was new to OBWCC and initially evaluated at a primary or urgent care clinic. Inclusion criteria for patient charts included: at least 18 years of age, medical diagnosis of diabetes, presence of one or more open foot ulcers on foot or ankle, and an ICD-10 code consistent with a DFU diagnosis. Exclusion criteria included patients that did not have enough

medical records from their referring provider available in their chart to allow for accurate evaluation of initial DFU management. In cases where multiple ulcers were present, the largest ulcer was chosen as the object of the study.

Data Collection

Designated practice personnel at OBWCC compiled a list of all patient charts from the previous 24 months containing one or more ICD-10 diagnostic codes consistent with the diagnosis of a DFU. The project leader used the first 70 charts that fit the designated inclusion/exclusion criteria to be included in the chart review and assigned each of them a unique identification number. The project leader completed a retrospective chart analysis. Data from each chart was recorded in a table designed by the project leader and containing relevant variables determined by evidence obtained from the literature review and professional recommendations of the project committee (See Appendix). Factors associated with lack of adherence to guidelines, specifically DFU prevention, assessment, and management, were collected. Dichotomous data points (yes/no) included whether the patient had a history of the following: annual foot exams, use of therapeutic footwear, HbA1c testing, Semmes-Weinstein testing, vascular studies, or ABI testing. Variables concerning DFU assessment guidelines at initial evaluation and at the OBWCC included if the wound was physically assessed for the presence of neuropathy, ischemia, or infection and if appropriate testing was ordered (yes/no): plain x-ray, ABI, probe to bone, and/or TcPO₂. To review adherence to DFU management guidelines, charts were reviewed for the occurrence of debridement, offloading orders, antibiotic orders, and referral to a specialist at both the initial encounter and at the first OBWCC visit.

Data regarding independent risk factors for DFU occurrence were also collected from each chart in the categories of demographics, diabetes, foot characteristics, and wound

characteristics. These factors included the demographics of age, birth sex, living alone, insurance, and smoking. In the category of diabetes, duration of disease, insulin use, and the results of the patient's most recent HbA1c were collected. Foot characteristics collected included whether the patient had a history of DFUs, amputations, or foot deformities and any clinical diagnosis of PAD or DPN. Finally, data points relating to the current wound included how long the patient had the DFU before they went to a provider (patient delay), depth and area of the wound at first provider assessment, and whether or not the wound was infected or gangrene was present at initial assessment.

To evaluate referral practices for DFU management, data were collected on how long the patient was treated from time of initial DFU assessment to initial specialist referral (professional delay), whom referred the patient (primary care provider, another specialist, self-referral by the patient), provider type (MD, APRN, PA), and how many providers were seen in the referral trajectory before being seen at the OBWCC. The duration of time it took the OBWCC to heal the DFU was also recorded (time-to-heal) as well as the total duration of DFU presence (patient delay + professional delay + time-to heal).

Analysis

Data were entered and stored in the secure web application, REDCap. Findings were described using means and standard deviation for continuous variables and frequencies and percentages for categorical variables. The project leader was responsible for collecting, de-identifying, entering, and transferring for analysis, all patient data from each chart used.

Results

The study sample consisted of 70 patients with an average age of 59 years and a range of 32 to 88 years (see Table 1). Most of the patients did not have demographic factors that placed

them in a high-risk category for DFU development. Birth sex was the only demographic category where a majority of patients were found to be high risk. Male birth sex is considered a risk factor for DFU occurrence and represented 49 (70%) of the sample. Other high-risk demographic categories for DFU development included living alone 27 (39.1%), no health insurance coverage 4 (5.7%), and smoking 15 (21.4%). The sample included an average diabetes duration of 13 years and a range of 3 months to 37 years. Most patients included were positive for both diabetes risk factors for DFU development, insulin use 51 (72.9%) and a HbA1c greater than seven 63 (90%). The most common high-risk foot characteristic seen was a history of DFUs 51 (72.9%). This was followed by DPN diagnosis 45 (64.3%), foot deformities 42 (60.9%), amputation history 37 (52.9%), and PAD diagnosis 25 (35.7%).

Table 1

Sample Risk Factor Characteristics.

Demographics

Age Mean	59 year
Male	49(70%)
Lives alone	27(39.1%)
No insurance	4(5.7%)
Smoking	15(21.4%)

Diabetes Variables

Duration Mean	13 years
Insulin use	51(72.9%)
HbA1c > 7	63(90%)

Foot Variables

Deformity	42(60.9%)
DFU history	51(72.9%)
Amputation history	37(52.9%)
PAD Diagnosis	25(35.7%)
Neuropathy Diagnosis	45(64.3%)

Note: $n = 70$ for all characteristics.

Out of the total sample ($n = 70$), variables related to DFU prevention measures, varied greatly, as shown in Table 2. The prevention variable seen the most was a history of HbA1c testing, utilized by 65 (92.9%) of charts reviewed. A history of Semmes-Weinstein testing was

documented for 40 (57.1%) charts and a history of vascular studies for 31 (44.3%). Both preventative foot care education and a history of annual foot exams were documented in 27 (38.6%) of the charts sampled. The DFU prevention measure utilized the least was a history of ABI testing, which was performed in 24 (34.3%) of the charts reviewed.

Table 2

Patients that Received Primary Prevention in Accordance with Vascular Guidelines.

History of annual foot exams	27(38.6%)
Preventative foot care history	27(38.6%)
HbA1c history	65(92.9%)
Semmes-Weinstein history	40(57.1%)
ABI history	24(34.3%)
Vascular studies history	31(44.3%)

Note: n =70 for all characteristics.

Based on vascular guidelines, each chart was reviewed for how the DFU was assessed and managed in primary care and at the OBWCC, utilizing the same criteria; this data were then compared, as shown in Table 3. The OBWCC assessed for both ischemia and infection and measured wound depth for all 70 charts (100%). For these same assessments, primary care assessed for ischemia for 32 (45.7%) patients, performed infection assessments on 61 (87.1%) of them and documented a measurement for wound depth in 11 (15.7%) of the charts reviewed. The OBWCC was found to have performed a neuropathy assessment on 68 (97.1%) of the charts sampled. In primary care, neuropathy assessments were only documented as completed 15 (21.4%) times. Wounds seen at the OBWCC were charted as infected for 19 (27.1%) charts and gangrene was noted as being present 9 (12.9%) times. In primary care DFU assessments, wound infection was reported 40 (57.1%) times and gangrene noted as being present for 2 (2.9%) charts. Additional testing to further assess the DFU was ordered by the OBWCC on 46 (65.7%) of the charts reviewed, while similar testing was only ordered by primary care providers on 20 (28.6%) charts.

For DFU management, primary care offices tended to favor prescribing antibiotics, as was seen in 39 (55.7%) of the charts sampled, and making referrals, which was the most common management strategy for primary care, utilized 53 (75.7%) times. Debridement and offloading were infrequently seen in the management of DFUs in primary care with the former performed only 7 (10%) times and the latter 13 (18.6%). In contrast, in DFU management at the OBWCC, vascular guidelines were much more closely adhered to. Offloading was utilized in all 70 (100%) charts reviewed and debridement in 59 (84.3%) of them. Antibiotics were prescribed by the OBWCC 15 (21.4%) times and referrals were made for 29 (41.4%) charts included in the sample.

Table 3

Comparison of DFU Assessment and Management: Primary Care vs OBWCC.

<u>DFU Assessment</u>	<u>Primary Care</u>	<u>OBWCC</u>
Neuropathy assessment	15(21.4%)	68(97.1%)
Ischemia assessment	32(45.7%)	70(100%)
Infection assessment	61(87.1%)	70(100%)
Depth measured	11(15.7%)	70(100%)
Wound infected	40(57.1%)	19(27.1%)
Gangrene present	2(2.9%)	9(12.9%)
Tests ordered	20(28.6%)	46(65.7%)
<u>DFU Management</u>		
Debridement	7(10%)	59(84.3%)
Offloading	13(18.6%)	70(100%)
Antibiotic prescribed	39(55.7%)	15(21.4%)
Referral	53(75.7%)	29(41.4%)

Note: n = 70 for all characteristics.

Each chart in the sample was reviewed for who made the referral to the OBWCC and classified into one of four categories: primary care provider, specialty provider, self-referral by the patient, or other (see Table 4). The most common scenario was a referral to the OBWCC by a specialty provider, which occurred in 34 (49%) of the charts reviewed. The patient made their own referral in 18 (26%) charts and the primary care provider initiated the referral in 16 (23%)

cases. There were 2 (3%) charts where the referral to OBWCC came from someone that did not fit into one of the three main categories described above and were thus designated as ‘other’. Each referral was then further examined to determine the credentials of the provider that made the referral to the OBWCC: medical doctor (MD), advanced practice registered nurse (APRN), physician assistant (PA), or other. Referring providers were found to be MDs in 46 (66%) of the charts examined. 18 (26%) charts fell into the other category, which included referrals from a variety of disciplines including physical therapy, chiropractic care, and osteopathic medicine. APRNs were found to be the referring provider in 5 (7%) charts and a PA made the referral in 1 (1%) of the charts examined.

The total sample was also examined for how many providers were seen from initial diagnosis of the DFU to being seen at the OBWCC. Thus, every chart saw at least 2 providers, with the initial provider representing the first and the OBWCC representing the last provider. 27 (39%) of the charts reviewed fit this exact scenario, seeing two providers, one that made the initial DFU diagnosis and then referred to the OBWCC. The most commonly seen scenario was three providers, which occurred in 31 (44%) cases. Four providers were consulted in 9 (13%) of the charts reviewed, while 3 (4%) patients saw 5 or more providers before being referred to the OBWCC.

Table 4

Referral Characteristics.

PCP 16(23%)	Provider type that referred to OBWCC		
	Specialty 34(49%)	Patient(self-referral) 18(26%)	Other 2(3%)
	Referring provider credentials		
MD 46(66%)	APRN 5(7%)	PA 1(1%)	Other 18(26%)
	Number of providers seen from initial diagnosis to being seen at OBWCC		
Two 27(39%)	Three 31(44%)	Four 9(13%)	Five or more 3(4%)

Finally, the total sample was reviewed for total duration of treatment, from DFU onset to complete healing, as shown in Table 5. 18 charts were removed from the final analysis due to DFU healing not occurring or healing not confirmed by the chart. Twelve charts were removed due to the DFU resulting in an amputation, 5 charts were left out due to the patient dying before the DFU was resolved and 1 chart was lost to follow up after treatment was initiated at the OBWCC. The remaining 52 charts were found to have an average patient delay in seeking initial treatment for a DFU of 25 days (range 0-180). Professional delay, which was defined as how long it took for a patient to see a specialist after the initial DFU diagnosis, had a mean of 20 days (range 1-89). Time-to-heal was defined as the time span from the first visit with a specialty provider till the DFU was designated in the chart as being resolved and averaged 59 days (range 7-186). Overall, the average total duration of a DFU from onset of the ulcer until resolution was 104 days (range 13-248).

Table 5

Total Duration of Treatment.

<u>Patient delay</u>	+	<u>Professional delay</u>	+	<u>Time-to-heal</u>	=	<u>DFU duration</u>
25 days		20 days		59 days		104 days
(range 0-180)		(range 1-89)		(range 7-186)		(range 13-248)

Note: n = 52 for all characteristics.

Discussion

The primary aim of this quality improvement project was to evaluate the initial management and referral process for DFU patients. Prior to data collection, the OBWCC was unaware of the guidelines and processes being used to manage DFUs by the various primary care providers initially seeing these patients. This retrospective chart review found that the initial evaluation and referral process for DFU patients is often not in line with evidence-based

guidelines. Apart from HbA1c and Semmes-Weinstein testing, primary prevention measures recommended by vascular guidelines to prevent DFUs had a less than fifty percent implementation rate for the total sample. This was the case even though all patients in the sample, in addition to being diabetic, also had at least one, and often, multiple risk factors that made them high risk for DFU occurrence. Poor levels of implementation of evidence-based guidelines for DFU assessment, as were found in this sample, have also been reported in other studies (Edwards, et al., 2013; Spanos, et al., 2017). Edwards and colleagues (2013) determined that less than one-third of their sample had received any prevention services despite the presence of risk factors for DFU development documented in the EMR. Spanos and colleagues (2017) also found that less than half of the DFU patients in their sample had received any type of preventative services. These findings are significant as prevention of the risks associated with the diabetic foot and recognition of the risk for ulceration are crucial for minimizing DFU development.

The treatment of a DFU is truly important since the sooner it begins, the better the outcome is likely to be. Data from this study illustrated that initial assessment and management of DFU patients is inadequate. While DFU evaluation at the OBWCC was in-line with evidence-based practice guidelines, care prior to often was not. For example, while over seventy-five percent of PCP's that diagnosed a DFU did make a referral to someone, it was concerning that in many cases a complete wound assessment was not done on the patient to determine the appropriate specialist referral. Less than half of providers were performing an initial assessment for ischemia that, based on guidelines, would be crucial for determining if the patient needed to be seen by a vascular specialist or at least have vascular testing ordered. Less than a quarter of PCP's measured wound depth, which would help determine if a patient needed an orthopedics

referral. The comparison of DFU evaluation between primary care providers and the OBWCC illustrated a concerning trend that much of the work that should be done during an initial DFU work up was being delayed until the patient began treatment at the OBWCC. Other studies have reported similar findings (Smith-Strom et al., 2017; Spanos et al., 2017; Wells & Evans, 2012). Smith-Strom (2017) found that DFU duration before initiating care with a wound specialist influenced healing time and that the time delay from DFU onset to referral by a PCP was the primary contributor to this association. Spanos and colleagues (2017) discovered that nearly half of their total sample received a late referral to wound care by their PCP. Similarly, Wells and Evans (2012) determined that 40% of PCPs in their sample did not refer DFU patients to a specialty provider for treatment. Delayed referrals, referrals to the wrong specialist, and delays in testing are all crucial time delays for appropriate DFU treatment that could end up costing a patient one of their limbs.

The most common initial management for a DFU was an assessment for infection only, followed by management with an antibiotic, either due to active infection or as a precaution if no infection appeared to be present, and then a referral to another provider. The type of specialty referred to varied greatly and was not always supported by assessment findings. Some of the specialty referrals that were seen during this study included wound care, podiatry, vascular, orthopedics, infectious disease, and the emergency department. While DFU care once the patient reached the OBWCC was, overall, in line with evidence-based practice guidelines, improvements need to be made in getting these patients into specialty care more quickly. Many of the patients in this study saw multiple providers before being treated at the OBWCC and the average DFU duration was 104 days.

It is evident, based on the findings of this study, that DFU patients being referred to the OBWCC are high risk for inadequate initial DFU evaluation and referral. DFUs need to be routinely screened for and acted upon when found. The literature review illustrates the relationship between prompt DFU intervention and improved health outcomes. Therefore, it is recommended that an education tool for DFU prevention and evaluation tailored for primary care providers be developed. While beyond the scope of this project, development of such a tool could be an area of interest for future studies.

Summary

This project was a quality improvement study, conducted in collaboration with the OBWCC, to evaluate the assessment and referral of DFU patients initiating care at the OBWCC. This project was a retrospective chart review implemented over a six-month period, with three months for project implementation and three months allowed for analysis and dissemination of the data. This study found that initial assessment and management, as well as the referral process for DFU patients, is not in line with current evidence-based practice guidelines for DFU management. Further research is needed to explore interventions that will increase provider awareness and compliance with these guidelines. Improvements in compliance have the potential to significantly improve the care, management, and quality of life of patients with a DFU diagnosis.

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Appendix

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Evaluating the Initial Management and Referral Process for Patients with Diabetic Foot Ulcers
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DFU Variables

Record ID _____

Risk Factor Variables: Demographics

Gender Male
 Female

Age _____

Lives alone Yes
 No

Insurance Yes
 No

Smoking Yes
 No

Risk Factor Variables: Diabetes characteristics

Diabetes Duration _____

Insulin use Yes
 No

HbA1c > 7 Yes
 No

Risk Factor Variables: Foot characteristics

Deformity Yes
 No

DFU history Yes
 No

Amputation history Yes
 No

PAD Diagnosis Yes
 No

DPN Diagnosis Yes
 No

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Risk Factor Variables: Wound characteristics

Duration of ulcer before seen by provider (patient delay)

Depth

Area

Infection

 Yes
 No

Gangrene

 Yes
 No**Vascular Guideline Variables: DFU Prevention History**

Is there a history of annual foot exams?

 Yes
 No

Is there a history of diabetic footwear?

 Yes
 No

Is there a history of HbA1c testing?

 Yes
 No

Is there a history of Semmes-Weinstein testing?

 Yes
 No

Is there a history of ABI?

 Yes
 No

Is there a history of vascular studies?

 Yes
 No**Vascular Guideline Variables: DFU Assessment at First Visit**

Assessment for neuropathy performed?

 Yes
 No

Assessment for ischemia performed?

 Yes
 No

Assessment for infection performed?

 Yes
 No

TcPO2 ordered?

 Yes
 No

Plain x-ray ordered?

 Yes
 No

ABI ordered?

 Yes
 No

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PTB ordered? Yes
 No

Vascular Guideline Variables: Initial DFU Management

Was offloading performed or ordered? Yes
 No

Was debridement performed or ordered? Yes
 No

Was an antibiotic prescribed? Yes
 No

Was referral to specialist ordered? Yes
 No

Referral Variables: HCP-related factors (prior to OBWCC visit)

Duration of ulcer from initial visit till seen at
OBWCC (professional delay) _____

Whom referred? PCP
 Specialist
 Patient
 Other

Provider type? MD
 APRN
 PA
 Other

of providers in referral trajectory _____

Delay and Duration characteristics

Duration of ulcer (time-to-heal) _____

Total duration of treatment (patient delay +
professional delay + time-to-heal) _____