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IMPROVING SATISFACTION FOR PATIENTS WITH DIABETIC FOOT ULCER USING A DIAGNOSIS SPECIFIC WRITTEN EDUCATION PACKET

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By

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IMPROVING SATISFACTION FOR PATIENTS WITH DIABETIC FOOT ULCER USING A DIAGNOSIS SPECIFIC WRITTEN EDUCATION PACKET

This DNP Project by Douglas William Kozeluh is recommended for approval by the student's Faculty Chair, Committee and Department Head in the School of Nursing

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ABSTRACT

IMPROVING SATISFACTION FOR PATIENTS WITH DIABETIC FOOT ULCER USING A DIAGNOSIS SPECIFIC WRITTEN EDUCATION PACKET

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Diabetes mellitus is a significant health care concern affecting 30.2 million Americans in 2015. One of the most common, costly, and serious sequela of diabetes is diabetic foot ulceration (DFU), which may lead to lower extremity amputation. Up to 50% of DFUs and lower extremity amputations can be prevented through effective patient education (PE). PE provided through written information is one intervention designed to improve patient understanding and self-management practices in order to reduce the risks and complications of DFU. The purpose of this Doctorate in Nursing Practice (DNP) project was to determine if implementation of a DFU specific written education packet led to increased patient satisfaction in an outpatient wound clinic. Ley's cognitive model, used as the theoretical framework, served to describe the relationship between understanding and satisfaction within the PE process. The recruitment of subjects took place at a regional Midwestern outpatient wound care center. Patients included in the project were admitted with a lower extremity wound(s) and had been diagnosed with diabetes mellitus. Non-equivalent control (n = 21) and intervention (n = 11) group data were collected from a convenience sample of patients. Quantitative data were gathered via a Likert scale Patient Satisfaction Survey designed by the health care organization. Data were analyzed using the Wilcoxon Rank Sum test. A greater mean score was achieved in the intervention group compared to the control. However, the findings of this study provided insufficient evidence to support a statistical association

between the provision of this written PE intervention and increased patient satisfaction. Limitations include a small sample size, lack of random sampling, lack of random assignment, and lack of reliability and validity in the Patient Satisfaction Survey. Reflection on these limitations may aid future researchers in designing more robust studies intended to improve quality of care by exploring the effects of PE on satisfaction and understanding.

DEDICATION

This scholarly project is dedicated to my parents, Sara and David Kozeluh, in recognition of their sponsorship, advocacy, and inspiration for the totality of my education. I thank you for instilling in me determination and enthusiasm such that I can achieve any goal. To my brother and closest friend, Craig Kozeluh, who's parallel academic career kept us distant but ultimately brought us closer. To friends, who are too numerous to count, for providing encouragement and an outlet throughout the campaign of life. Lastly, to my loyal companion, Peebs, who spent many hours longing for my affection and days awaiting strolls through the woods.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

Diabetic Foot Ulcer Education Packet.....DFUEP

Diabetic Foot Ulcer .....DFU

Patient Education .....PE

Patient Information Leaflets .....PIL

Wilcoxon Rank Sum .....WRS

Chapter One

Introduction to the Problem

Introduction

Diabetes mellitus is a significant health care concern affecting 30.2 million Americans in 2015 (Centers for Disease Control and Prevention, 2018). As a chronic and progressive disease, it is imperative that the most effective and cost-efficient practice methods be utilized to improve care and reduce morbidity and mortality (American Diabetes Association, 2018). One of the most common and serious sequelae of the disease is diabetic foot ulceration. Of those with diabetes, 15% will develop DFU with 84% of these patients going on to have a minor or major lower extremity amputation with significant loss of quality of life and mortality (Boulton, 2015; Collins & Sloan, 2013; Khoo & Jansen, 2018; Maier, Ilich, Kim, & Spicer, 2013).

DFUs can develop into chronic wounds taking months or years to heal. These complex wounds cause major personal, public health, and social burdens due to long-term treatment costs. Loss of productivity, disability and premature mortality add significant indirect costs. Treatment cost for DFU patients is 5.4 times higher in the first year and 2.8 times higher in the second year compared to the cost of treating diabetics without lower extremity ulceration (Driver, Fabbi, Lavery, & Gibbons, 2010). Successful prevention and management of DFUs requires an interdisciplinary approach including an educational component to improve patient self-management practices. An increase in the complexity of wounds being cared for in home-based settings requires clinicians to better address the educational needs of patients and families who will be treating DFUs at home (Bearden, 2014; Driver et al., 2010; Khoo & Jansen, 2018).

Background and Significance

DFU. Patient self-management education and support are crucial in the prevention of acute complications and reducing the risks associated with long-term complications of diabetes (American Diabetes Association, 2018). Up to 50% of DFUs and amputations can be prevented through effective PE (Yazdanpanah, Nasiri, & Adarvishi, 2015). Providing PE on foot self-management practices has been shown to empower patients to self-manage foot problems reducing complications, occurrence, and recurrence of DFUs (Boulton, 2015; Yazdanpanah et al., 2015). Providing PE can be expensive but must be weighed against the substantial costs incurred by long-term DFU treatment and management of complications (Shanley & Moore, 2015).

Written Information. PE can be effective when provided by a variety of health professionals using different methods; however, using a verbal, face to face component along with written information has been shown to effectively enhance learning. Written information has long been an effective, economical, and simple PE intervention and can be delivered in packets or leaflets to improve knowledge (Sustersic, Gauchet, Foote, & Bosson, 2017; Zirwas & Holder, 2009b). Written PE interventions have been found to be most effective when patients initially seek treatment as they typically have a poor understanding of their condition. The use of written educational materials has been found to improve patient knowledge, satisfaction, and compliance with treatment plans (Sustersic et al., 2017; Zirwas & Holder, 2009b).

Patient Satisfaction. Effective written PE improves patient understanding, leading to greater patient satisfaction. Patient satisfaction is thought to be a major promoter of patient compliance with treatment recommendations and improved outcomes

(Sustersic et al., 2017; Zirwas & Holder, 2009a). Patient satisfaction improves patient compliance and health outcomes while simultaneously maintaining patient retention, improving profitability, and reducing malpractice suits for health care organizations (Stenberg et al., 2018).

Third party payers, governments, and health care providers have begun to recognize the value of patient satisfaction as a quality indicator. As such, patient satisfaction is being appraised by accrediting agencies when assessing the quality of health care organizations. The Centers for Medicare & Medicaid Services (CMS) reimbursement models have recently begun to account for value and quality of care rather than volume alone. These models have included verbiage outlining patient satisfaction as a facet of valuable and quality care. These incentives have motivated the health care industry to gather, analyze, and reflect on satisfaction data to improve their services (Centers of Medicare and Medicaid Services, 2016; Stenberg et al., 2018).

Statement of purpose

The purpose of this DNP project was to determine if implementation of a DFU specific written education packet was associated with increased patient satisfaction in an outpatient wound clinic. Studying the effects of a written PE intervention on satisfaction, has the potential to improve future PE interventions for this population and generate methods to improve the quality of care, reduce costs, and improve health outcomes.

Application of Theoretical Framework

In this DNP project, Ley's cognitive model was used as the theoretical framework. This model describes the relationship between understanding, memory, satisfaction, and compliance as it relates to PE (Ley, 1988). The research questions were

designed based on this model which predicts a significant correlation between understanding and satisfaction. According to the cognitive model, utilizing effective PE interventions to improve patient understanding should have a positive impact on patient satisfaction. To this end, the implementation of a written PE intervention was selected in an attempt to improve patient understanding as a means to improve patient satisfaction (Ley, 1988).

Chapter Two

Literature Review

Introduction

This chapter will provide a review of current literature regarding PE and satisfaction as it specifically applies to care and management of patients with diabetic foot ulcers. The focus of this review will be to review current knowledge about the necessity of PE and the clinical applications that influence patient satisfaction, treatment compliance, and outcomes of care. A discussion of the theoretical framework and its application to this DNP project will also be presented.

Steps in the Research Process

A literature review was undertaken with the use of CINHAL and the Cochrane Database. Literature published within the last ten years were included. Search terms and headings included: patient satisfaction, patient education, patient knowledge, patient adherence, disease management, compliance, self-management, patient information leaflet, chronic disease, written education material, diabetic foot ulcer, wound care, outpatient education, diabetes, and amputation prevention. The reference lists and cited-by lists of relevant articles were also searched.

Diabetes

Diabetes is a significant health care concern; in 2015 it affected 30.2 million Americans (diagnosed and undiagnosed cases) or 9.4% of the population (Centers for Disease Control and Prevention, 2018). As projected by Boyle, Thompson, Gregg, Barker, & Williamson (2010), it is expected that this already staggering prevalence will increase by the year 2050 to 21% of American people. Furthermore, diabetes is the

seventh leading cause of death in the United States and consumed $245 billion health care dollars in 2012 (American Diabetes Association, 2013; Collins & Sloan, 2013).

The chronic, complex, and progressive nature of diabetes requires ongoing medical care so that both acute and long-term complications of diabetes can be prevented. Patient self-management education and support are crucial components of caring for this population reducing the morbidity and mortality associated with diabetes (American Diabetes Association, 2018). DFUs are a significant complication associated with diabetes and are largely considered preventable medical conditions. Despite this, DFUs remain a significant burden to those living with diabetes, leading to significant morbidity and hospitalization (Boulton, 2015; Yazdanpanah et al., 2015). For the purposes of this DNP project, the term DFU will be defined as a lower extremity wound incurred by a person with diabetes mellitus.

Foot Problems. Of the multitude of long-term complications associated with diabetes, foot conditions are the most common requiring hospital admission. This complication is associated with a high amputation rate yielding a disproportionately elevated morbidity and mortality rate (Boulton, 2015). Persons living with diabetes account for approximately 60% of all non-traumatic lower extremity amputations (Maier et al., 2013). Of those with diabetes, 15% will incur a DFU, of which up to 84% will result in a minor amputation (below the ankle) or a major lower extremity amputation (below and above the knee) (Collins & Sloan, 2013). Major lower extremity amputations have a five year survival rate between 22% and 50% (Khoo & Jansen, 2018).

There are several manifestations of diabetes and risk factors leading to DFUs and lower extremity amputations. The most significant risk factors are (a) poor glycemic

control, (b) peripheral neuropathy, (c) cigarette smoking, (d) foot deformities, (e) pre-ulcerative callus or corn, (f) peripheral arterial disease, (g) history of foot ulcer, (h) previous amputation, (i) visual impairment, and (j) diabetic kidney disease. These contribute significantly to the challenges of DFU healing due to an increased susceptibility to infections, loss of protective sensation, poor ability to heal, and changes in skin integrity (American Diabetes Association, 2018).

DFU Prevention and Management. Both prevention and management strategies for DFUs share the need for similar patient self-management practices and behaviors (Khoo & Jansen, 2018). Management of DFUs requires an interdisciplinary approach; which includes primary care, interventional cardiology, vascular surgery, nephrology, chronic pain management, neurology, podiatry, dietary, and wound care (Khoo & Jansen, 2018).

Patients with diabetes, as well as their health care providers, must be aware of the risk factors and manage them appropriately to reduce complications. Those with risk factors for DFU should be assessed each visit by a health care provider including careful visual inspection of skin integrity, palpation of pedal pulses, and assessment for musculoskeletal deformities. Health care providers should encourage patients to participate in daily and intermittent self-management practices and explain the necessity of ongoing self-management practices such as proper frequency and techniques for foot, skin, and nail care (American Diabetes Association, 2014; Boulton, 2015). Palpation and visual inspections of the feet are required daily because the loss of protective sensation (lack of pain), which delays recognition of foot problems such as blisters, cuts, abrasions, pre-ulcerative lesions, and infections. Any such issues should be promptly seen by or

reported to a medical professional (American Diabetes Association, 2018; Boulton, 2015).

Patients with DFU should be provided PE about the implications of their risk factors and the significance of complications. There are several important education topics which should be discussed during the care of patients with DFU. Topics include risk factor awareness, importance of early identification of complications, treatment options, appropriate DFU dressing instructions, the importance of debridement, need for follow-up appointments, and self-management strategies. Patients and family members caring for a DFU should be educated thoroughly about the early signs and symptoms of foot infection and a deteriorating DFU as it may expedite the need for amputation (Khoo & Jansen, 2018; Yazdanpanah et al., 2015).

Education should be provided regarding footwear and footwear practices. These behaviors include avoiding walking barefoot and inspecting shoes for objects before donning. Off-loading and non-weight bearing are terms used to describe pressure-relieving techniques that are vital to DFU healing and preventing complications. Prescription footwear, ambulatory aids, and application of hard casts are particularly effective at healing wounds. However, these modalities are not always convenient or practical for mobility and compliance with practices and use of devices is often impeded by the desire to participate in an active life style (Khoo & Jansen, 2018; Yazdanpanah et al., 2015).

DFU Management Barriers. There are several identified barriers to the implementation of patient management and prevention strategies for DFUs. Barshes et al. outlines these challenges, “Barriers to implementation include poor access to primary medical care;

patient beliefs and lack of compliance with medical advice; delays in DFU recognition; limited resources and practice heterogeneity of specialists" (Barshes et al., 2013, sec. abstract). Furthermore, patients often fail to take ownership for their illness, deny the seriousness of a DFU, neglect appropriate self-management, remain non-compliant with available treatments and recommendations, and ultimately succumb to preventable life changing complications such as amputation and death (Yazdanpanah et al., 2015).

Patient Education

PE is defined as an intervention that health professionals use to convey information to patients and caregivers using a combination of methods (Shanley & Moore, 2015; Stenberg et al., 2018). Teaching, counseling, and behavior modification methods are used for PE interventions with multiple delivery methods. These planned educational activities are designed to impart knowledge to patients that will facilitate understanding (Friedman, Cosby, Boyko, Hatton-Bauer, & Turnbull, 2011). PE interventions are usually focused on patient's understanding of treatment options, how to manage medical needs, and effective treatment. This new knowledge should allow for more empowered decision making and improve compliance with treatment plans (Shanley & Moore, 2015). Ultimately, effective PE supports patient satisfaction and results in improved compliance with medical treatment and recommendations with the expectation of improved outcomes (Zhang & Chu, 2018; Zirwas & Holder, 2009a). The following paragraphs will discuss these relationships as discovered in the current literature.

Importance in Chronic Disease. At its core, compliance with medical treatment is often attributed to the concept of self-management. Understanding gained through

education is required for self-management of disease (Shanley & Moore, 2015). This concept applies to the management of chronic disease, as these diseases require ongoing use of medical services, medications, and have significant, complex, and severe complications (Stenberg et al., 2018). Chronic diseases when compared to acute illness are more common and costly, are generally preventable, can be effectively controlled, and have a more significant impact on the cost of care and health of the population (Shanley & Moore, 2015; Stenberg et al., 2018; Zhang & Chu, 2018).

PE is considered an essential component in the treatment of chronic wounds, particularly with DFU care. However, it is frequently a neglected aspect of wound management in the clinical setting (Boulton, 2015; Gagliardino et al., 2013; Werdin, Tennenhaus, Schaller, & Rennekampff, 2009; Yazdanpanah et al., 2015). Effective wound care PE has been shown to improve the quality, frequency, efficacy of dressing changes, compliance, and the treatment and prevention of reoccurrence (Werdin et al., 2009).

Impact of Patient Education. Chronic diseases, such as diabetes, that have many serious complications and associated reduced quality of life, require education to promote active participation in self-management practices (Last, 2015; Roque, Cauduro, & Moraes, 2017). Roque et al. (2017) conducted a study assessing the effects of education on foot self-management practices for prevention of lower extremity disease among diabetic insulin users. Positive effects were seen in patient's knowledge of disease, prevention strategies, and participation in such activities (Roque et al., 2017). The researchers highlighted the importance of education in empowering patients to

participate in these practices to reduce DFU occurrence, reoccurrence, and complications (Roque et al., 2017).

PE has been documented as a valuable tool for patients with chronic diseases other than diabetes. Psoriasis is a chronic disease that demands strict compliance with treatment recommendations in order to reduce symptoms, avoid complications, and improve and maintain quality of life (Zschocke, Mrowietz, Karakasili, & Reich, 2014). A literature review written by Zschocke et al. (2014) addressed the challenges of non-compliance for this population and summarized solutions that were found to be effective in the literature. Extensive PE was noted as one of many effective approaches to improve compliance with medical advice and clinical outcomes (Zschocke et al., 2014). Educational strategies recommended for use in clinical practice included: verbal education, written information, group-based learning, audiotapes, videotapes, computer-assisted education, and internet resources (Zschocke et al., 2014).

As stated, the topics of self-management and education also arise in regard to chronic lower extremity ulcers treatment and prevention of reoccurrence. Shanley & Moore (2015) conducted a systematic review outlining the necessity of PE to improve treatment, promote prevention, and reduce reoccurrence of venous leg ulcers. The authors found that enforcing a clear understanding of disease process or strategies that affect healing enabled patients to make informed decisions. Patients who reach this level of understanding are conscious of the implications of complying with treatment plans. Subsequently, they are more capable and motivated to participate in self-management practices that reduce the prevalence of disease complications. As such, PE interventions

should be utilized by clinicians wishing to promote patient understanding and long term compliance with the treatment plan for their condition (Shanley & Moore, 2015).

Adiewere et al. (2018) completed a systematic review and meta-analysis of PE related to preventing incidence and reducing reoccurrence of DFU to decrease amputations. They concluded that for patients with recurrent DFU, foot care practices remain a core component of PE in the prevention of DFU recurrence and amputation. To promote patient compliance with preventive measures, the authors recommend effective PE. The authors advocate for intensive PE in group education sessions as the most effective method of delivery for PE interventions (Adiewere et al., 2018).

Up to 50% of DFUs and amputations can be prevented through effective PE and early identification (Boulton, 2015; Yazdanpanah et al., 2015). A main component to successful and swift healing of DFU is emphasizing the patient's responsibility for foot self-management. To be competent and compliant with foot self-management practices, patients must understand their risk factors and understand strategies to care for DFU. When education is effectively provided to DFU patients with a comprehensive clinical approach, there is a reduction in the frequency and morbidity of limb threatening complications (Yazdanpanah et al., 2015).

Types of education interventions. PE can be provided by a variety of health care professionals. These professionals include PE specialists, health care administrators, managers, physicians, nurses, and allied health care professionals (Friedman et al., 2011). There are also a variety of methods available to deliver PE. These include: verbal, graphics, written information, demonstration, audio, computer-aided format, and video (Shanley & Moore, 2015).

The utilization of multiple teaching strategies tends to improve knowledge and satisfaction particularly when verbal communication is one of the strategies used (Friedman et al., 2011). Verbally delivered education (face-to-face with the educator) is the most traditional and most preferred method of education by patients (Alagheband, Miller, & Clarke, 2015; Zirwas & Holder, 2009b). Verbal education is generally easy to understand, allows for patient questions and feedback, and is an excellent way to individualize information. It is also the most effective method for presenting new information.

Regardless of the delivery method, PE must be reinforced by verbal support from the health care provider. Alternatively, verbal information alone has its limitations. It is often time consuming for providers and therefore costly when compared to alternative education strategies. Furthermore, if education is only presented verbally, memory of information may be limited; education that is only provided verbal is also prone to information overload, further limiting memory of the information provided (Zirwas & Holder, 2009b). The combination of written and verbal information provides significantly better knowledge for patients than verbal information alone. Practitioners supplementing their verbal education techniques with written or visual information facilitate memory and compliance with treatment recommendations (Friedman et al., 2011).

Written information. Written information has long been an economical and simple intervention for PE and can include both text and graphics (Shanley & Moore, 2015; Sustersic et al., 2017; Zirwas & Holder, 2009b). It is best provided as standardized instructions with personalized verbal reinforcement and should be kept below the eighth

grade level as patients prefer to have easy reading levels of written information regardless of their actual reading ability (Zirwas & Holder, 2009a). The provision of written education materials as information packages or booklets improves knowledge and reduces confusion for new patients (Friedman et al., 2011).

Sustersic et al. (2017) conducted a systematic review of literature that assessed the use of patient information leaflets (PILs), one example of written education materials. They concluded that in any clinical setting, PILs can improve patient knowledge, patient satisfaction, compliance with treatment, diet, and lifestyle. The authors highlighted the importance of timing of delivery and the quality of PILs. Delivery at the same time as verbal information was preferred so that it may be reviewed with the health care provider. The quality of PILs pertains to the content and the design of the materials. Although time frames of the outcome benefits were not specified, it seemed that benefits were noted more prominently in the short term and for acute conditions when the patient first sought treatment. PILs developed for chronic diseases, invasive procedures, and screening had more variable behavioral outcomes that depended largely on the clinical situation, invasiveness, and the manner and time frame for giving the PILs rather than the quality of the materials (Sustersic et al., 2017).

Cost

DFU Costs. DFUs are a major public health and social concern and a significant burden to individuals as these wounds can be chronic taking months or years to heal. The estimated incidence of DFU for the population living with diabetes is 4% - 6% each year and 15% - 25% for a lifetime (Khoo & Jansen, 2018). There is significant cost associated with DFU. Health care costs are more than five times higher in the first year and nearly

three times higher in the second year compared to the cost of treating diabetics without lower extremity ulceration (Driver et al., 2010). This translates to a cost of approximately $29,000 for the first two years of DFU treatment (Maier et al., 2013). Patients, health systems, third party payers, and ultimately society bears this major financial burden.

Alterations in healthcare policy and reimbursement processes have led to a paradigm shift in health care from hospital-based wound treatment to outpatient and home-based wound care. This has led to an increase in the complexity of wounds being cared for in these settings. As such, clinicians must anticipate, identify, and address the educational needs of patients and families who will be treating wounds once they reach the home setting (Bearden, 2014). Successful prevention and management of DFUs requires an interdisciplinary approach which includes a PE component to improve patient self-management practices. The most effective and cost-efficient PE interventions should be utilized (Driver et al., 2010).

Cost associated with education. Providing education can be expensive and many educational delivery methods are available (Shanley & Moore, 2015). The costs and subsequent economic impacts of implementing PE are just as important to consider as the impact on patient care outcomes (Stenberg et al., 2018). When examining the utility and viability in terms of economics, the cost effectiveness of PE interventions must be considered when deciding which PE interventions are the most appropriate to implement (Shanley & Moore, 2015).

When considering the best ways to allocate time and financial resources for patients and facilities, the impact of cost must be addressed (Stenberg et al., 2018). The

first consideration is the cost to implement the intervention, both to the patient and the service provider. Secondly, there must be an examination of the potential for the intervention to decrease certain costs associated with disease that would otherwise accumulate without such an intervention. PE interventions should be assessed for both merits when being designed. PE interventions that are effective in reducing overall costs of disease and do so at a reasonable cost to patients and health systems, would be favorable, both clinically and economically (Driver et al., 2010; Stenberg et al., 2018).

As previously discussed in this chapter, the costs associated with diabetic foot problems are substantial. These costs of care fall on patients, providers, third-party payers, and health systems, which translates into a significant financial burden on society. Driver et al. (2010) conducted a literature review discussing strategies that seem to have the most influence on reducing the clinical and economic burdens for patients with DFU, namely reduction in amputations, duration of treatment, hospital length of stay, and direct costs of care. Several favorable effects were found in their literature search, which highlighted the most cost-effective treatments as extensive PE, early assessments, and aggressive treatment by a multidisciplinary team (Driver et al., 2010).

Stenberg et al. (2018) conducted a literature review which sought to evaluate the economic impacts of PE interventions for people living with chronic illness. The main diseases included in the review were chronic respiratory conditions, chronic pain, diabetes, and heart disease. PE interventions included face-to-face instruction in an individual or group settings; some sessions were supplemented by phone calls, written materials, and/or multimedia interventions. Their conclusions "strongly suggest that patient education interventions, regardless of study design and time horizon, are

beneficial in terms of decreased hospitalization, visits to Emergency Departments or General Practitioners, increases in quality-adjusted life years, or reduced loss of production" (Stenberg et al., 2018, p. 1032). The literature noted in this review provide reassurance that PE interventions have the potential benefit to significantly reduce health care costs associated with DFUs.

Boren, Fitzner, Panhalkar, and Specker (2009) explored the cost and benefits associated with diabetes education. The literature review compiled relevant studies addressing the economic and financial outcomes associated with educational interventions. Their conclusions indicated that the benefits associated with education for people with diabetes were positive and outweighed the cost of PE interventions.

Patient Satisfaction

Patient satisfaction is an attitude reached by patients as they interact with the health care system (Prakash, 2010). The concept of patient satisfaction for the improvement of care has for decades been the subject of research worldwide (Berkowitz, 2016; Mahomed, St John, & Patterson, 2012; Mathews, Coleska, Burns, & Chung, 2016; Prakash, 2010). Satisfaction is an indicator of quality medical care and is a driver of organizational success (Prakash, 2010). Studies investigating the role of patient satisfaction in the health care industry have categorized it as a pillar of quality of health care (Prakash, 2010).

Recently, health care, particularly the corporate sector, has transitioned into a service focused industry. Patients have begun viewing themselves as customers or consumers of health services. The health industry, third party payers (insurance companies, governments, companies, etc.), and health care providers have begun to

recognize the value of patient satisfaction (Prakash, 2010). There are two primary principles that represent the value of tracking and improving patient satisfaction levels with care received.

The first being that, patient satisfaction is a factor which influences patient compliance with medical advice (Ley, 1988; Prakash, 2010). For example, in a research article by Mathews et al. (2016) the effects of education were studied on medical decision making. The researchers noted that as patient knowledge increased through education, participation in treatment planning increased, and in-turn resulted in improved satisfaction with care and compliance with treatment plan (Mathews et al., 2016).

Secondly, in and of itself, patient satisfaction is a desirable goal for health care organizations. This is underscored by several factors. Patient satisfaction maintains loyalty and retention of patients. This allows for consistent profitability and preservation of market share. Health care providers serving patients who report being satisfied with care are able to reduce their risk of malpractice suits. Furthermore, accreditation agencies set benchmarks for health organizations based on quality of care and service, using satisfaction as a quality performance indicator. Accreditation by these agencies is required in some quality-based reimbursement models. Accreditation and the reporting of quality ratings may also provide an advantage over other organizations in competitive markets. Patient satisfaction has garnered high value within the health care industry under these principles (Grepperud, 2015; Prakash, 2010).

Patient satisfaction has also stepped into the spotlight as an emerging component in reimbursement models (CMS, 2016; Prakash, 2010; Zirwas & Holder, 2009a). In alignment with the ideals brought forth by the Affordable Care Act (ACA), the Centers of

Medicare and Medicaid Services (CMS) have undertaken a variety of strategies to redirect the United States health care system (CMS, 2016). At the heart of this paradigm shift is the intention to transition CMS payments to a value and quality based reimbursement system, rather than one dictated by volume (CMS, 2016). The document titled 'Quality Strategy 2016' outlines the strategies, objectives, and desired outcomes to accomplish this mission (CMS, 2016). A primary goal highlighted by this document is to improve effective communication, care coordination, and satisfaction with health care services (CMS, 2016). To incentivize health systems to share this goal, reimbursement models are implemented that focus on improved quality outcomes related to communication, care coordination, and satisfaction. The integration of evidence-based PE, particularly self-management education programs, are highlighted as desired outcomes (CMS, 2016).

Motivated by financial reimbursement, quality standards, accreditation, and competitive marketing needs, the health care industry increasingly appraises the gathering, analyzing, and monitoring of patient satisfaction data (Prakash, 2010). To fulfill the underlying need for improved quality and value of care outlined by the ACA, it is crucial that evidence-based practice methods targeting patient satisfaction are integrated into health care settings (Prakash, 2010).

Theoretical Framework

As previously discussed in this chapter, PE interventions are a vital pathway towards understanding and have effects on patient satisfaction which in turn improves compliance with treatment plans. Therefore, patient satisfaction is of value to those interested in improving patient care. This DNP project implemented a PE intervention

and evaluated its effectiveness by measuring patient satisfaction. To design this study and better understand the relationships of interest, Ley's cognitive model was used as the theoretical framework (1988).

Ley's cognitive model is a framework which includes the key concepts of the PE process. The cognitive model contains four interrelated core components beginning with understanding and followed by memory, satisfaction, and compliance. Ley describes a patient's understanding as their knowledge of illness, details for treatment regimen, and rationale of treatment (1988).

The cognitive model predicts significant correlations between understanding, memory, satisfaction, and compliance. The model explains the direct and indirect relationships between the four components (See Figure 1). Within the cascade of effects seen in this model, the relationship between understanding and satisfaction is of interest to this project. Understanding has direct effects on memory, satisfaction and compliance. Understanding has an indirect effect, through satisfaction, on compliance. Similarly, understanding has indirect effects, through memory, on satisfaction and compliance. Finally, satisfaction has a direct effect on compliance (Ley, 1988).

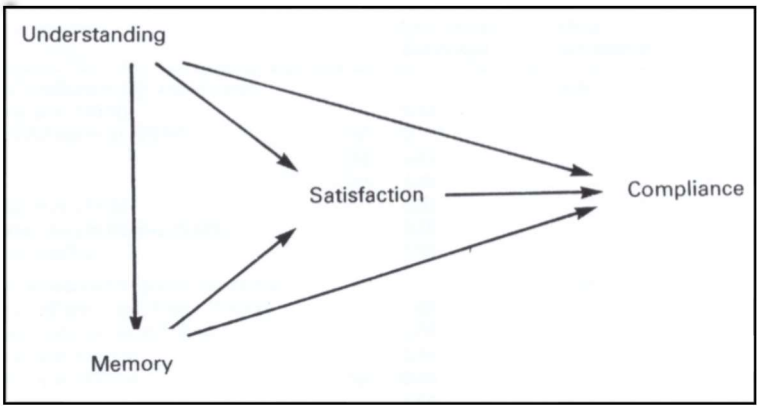

Figure 1. Ley's Cognitive Model. Reprinted from *Communicating with patients: Improving communication, satisfaction and compliance*, by P. Ley, 1988, New York, NY, US: Croom Helm. Copyright 1988 by Croom Helm. Reprinted with permission (See Appendix A).

Ley developed the cognitive model with the belief that through improved communication, patients can gain greater understanding, and subsequently greater patient satisfaction can be achieved (1988). For this reason, the implications of the cognitive model rest heavily on use of PE interventions that effectively achieve patient understanding. As such, this DNP project framework was fashioned based on the relationship and direct effects of understanding on satisfaction. Moreover, through PEs effect on satisfaction, there may be further effect on compliance and outcomes.

According to the cognitive model, effective PE interventions utilized to improve patient understanding should have a positive impact on patient satisfaction. To this end, the provision of a written PE intervention was selected to improve patient understanding with satisfaction as the measured outcome. Memory and compliance were not measured or assessed in this DNP project; however, it is worth highlighting the expected interactions these concepts have with satisfaction as valuable outcomes predicted by this model.

Literature Summary

DFUs are a common complication of diabetes and often fail to heal, requiring lower limb amputations and high mortality rates (Khoo & Jansen, 2018; Yazdanpanah et al., 2015). DFUs cause significant cost to patients, health care organizations, and society. More importantly, they are detrimental to patient quality and length of life (Yazdanpanah

et al., 2015). There are several important PE topics to be provided to those being treated for DFU. Patients should be made aware of their risk factors and how to manage them appropriately to reduce complications with self-management practices. These self-management strategies include proper foot care and inspection, reportable symptoms to health care providers, appropriate footwear practices, risks of amputation and other complications. Other topics include risk factor awareness, glucose control, importance of early identification of complications, treatment options, appropriate DFU dressing instructions, the importance of debridement, and need for follow-up appointments (Khoo & Jansen, 2018; Yazdanpanah et al., 2015).

Patient non-compliance is often a factor that complicates successful and timely healing of DFU. PE is an intervention found frequently throughout the literature that improves satisfaction with care and correlates to improved understanding, satisfaction, outcomes, and compliance with treatment plans, particularly when verbal education is combined with written or visual information (Friedman et al., 2011; Sustersic et al., 2017; Zirwas & Holder, 2009a). When effectively implemented, PE engages patient participation in medical decision making contributing to increased satisfaction (Heng, Tham, Eng, Ling, & Menon, 2013; Mathews et al., 2016). This connection between education and satisfaction is thought to be a major promoter of patient compliance with treatment and improved outcomes (Mathews et al., 2016; Prakash, 2010; Sustersic et al., 2017; Zschocke et al., 2014).

The literature suggests that written materials can be an effective PE intervention and are cost effective and efficient PE interventions for DFU that use multiple teaching strategies are effective, particularly when implemented within a setting that provides an

interdisciplinary wound care team (Driver et al., 2010; Sustersic et al., 2017; Zirwas & Holder, 2009b).

The significance of this DNP project is highlighted by these themes and the recognition that patients and families are increasingly expected to care for more complex wounds at home (Bearden, 2014). The research questions for this project were derived from this literature review and the theoretical framework, which surmise that effective PE provides the corner-stone of understanding, leading to increased patient satisfaction (Zirwas & Holder, 2009a). Research questions can be found in the following chapter and will describe the methods utilized to carry out the study framework.

Chapter Three

Methods

Purpose

There is a multitude of information that patients with DFU must understand and apply as self-management practices. PE supplemented by written education materials can be effective at improving understanding and satisfaction. The purpose of this DNP project was to determine if implementation of a DFU specific written education packet was associated with improved patient satisfaction in an outpatient wound clinic.

Sample and Setting

The recruitment of subjects took place at a regional outpatient wound care center located in the Midwest. Patients included in the study were admitted to this wound clinic with a lower extremity wound and had been diagnosed with diabetes mellitus. Exclusion criteria were: (a) adults with decisional impairments, (b) <18 years of age, and (c) non-English speaking. All qualified patients were invited to participate during a study time frame of three months. A control and intervention group comprised this study, which are described in the procedure section below.

Cursory review of the EMR was used to estimate that 20 existing patients in the practice would meet study criteria for a control group. Based on historical numbers, it was estimated that over three-months 20 new patients might enter the practice who met study criteria for an intervention group. For a population of 40, with confidence level of 95% and confidence interval of five, a sample size of at least 36 would be appropriate (Creative Research Systems, 2012).

Project Approval.

Approval by the health system's Institutional Review Board (IRB) and the university IRB was obtained. A full waiver of informed consent was approved by both IRBs (see appendix B and C respectively). Consent was implied through completion of the Patient Satisfaction Survey.

Design and Procedures

This DNP project utilized a quasi-experimental designed that collected quantitative data from non-equivalent comparison groups using survey method. Patients completed paper surveys in the clinic office. The completed surveys were collected by the registered nurse (RN) and recorded by the researcher.

Control Group. The control group was made up of current patients, i.e., patients admitted to the clinic and seen prior to the project start date. The control group was identified by searching the electronic medical records on the project start date for study inclusion criteria. All patients have an electronic medical record that includes data such as age, diagnosis, and wound location. Once identified, subject names were added to a control group list. Patients were invited to participate in the study at their soonest follow up appointment and the Patient Satisfaction Survey was offered and completed. Names of subject in the control group were marked complete on the list once the Patient Satisfaction Survey was completed, eliminating any chance of omission or duplication of data. The list was destroyed following completion of data collection. Patient identifiers were not linked to data.

The control group received the clinic's standard PE without the diabetic foot ulcer education packet (DFUEP). The standard PE was provided by two staff RNs at the

clinic, who had similar education and wound care experience. One of the RNs was the researcher. education included:

- The standard PE provided at the initial visit and reinforced at each visit.
- PE provided as verbal instructions.
- Demonstration used to instruct on proper dressing change technique at each visit.

This educational process was not dictated by a specific procedure. As such, it was unstructured and informal in that it was left to RN's discretion as no written PE materials were provided to the control group.

Intervention Group. In the intervention group the patient education was formalized into a process with the use of a PE information packet specific to the treatment of DFU. The intervention group was made up of patients admitted after the project start date who met study criteria. These newly admitted patients had not received education from staff or been seen at this clinic site previously. The intervention and data collection took place during patients scheduled visits over three months. The intervention was provided in the form of a DFUEP to the intervention group in addition to the clinic's standard PE (verbal and demonstration education).

This DFUEP consisted of a folder containing written materials pertinent to the disease process, identification of early symptom and risk factors for complications, treatment options, and self-management principles of DFU treatment and prevention (see appendix D). In addition, the clinic staff continued to provide verbal instructions, demonstration as needed, and reinforced education at each visit. The written materials used in the intervention were developed by Restorix Healthcare based on synthesized literature and the expert experience of the organization's medical staff (M. Smith,

personal communication, 2018). Permission for the use and reprinting of these education materials was granted (see Appendix E).

PE was provided by the same two staff RNs at the clinic throughout the project. These nurses had similar education and wound care experience. The clinic management decided to make a practice change for the clinic's education process. The new education process was being implemented with diagnosis specific education materials for patients with DFU at the clinic. The procedure was discussed between the two staff RNs and management to reach a consensus. This included:

- The standard PE was provided at the initial visit and reinforced at each visit.
- PE was provided as verbal instructions.
- Demonstration was used to instruct on proper dressing change at each visit.
- In addition, written PE materials specific to the DFU were provided to the intervention group at their admission visit with the DFUEP (See appendix D).

The DFUEP was handed to the patient and briefly reviewed with the patients in the exam room which allowed for a more structured and formal education process. Patients took materials home and were encouraged to use them as a reference for managing DFU and caring for their feet.

After receiving the DFUEP and the clinic's standard PE, the names were added to the intervention group list with date-of-admit. This list ensured that patients who received the intervention were offered the opportunity to take the Patient Satisfaction Survey at a subsequent visit, seven to 30 days after the admission date. The list of participant names was destroyed following completion of the data collection. Patient identifiers were not linked to data.

Measures

The Patient Satisfaction Survey was used to collect quantitative data for this project (See appendix F). The Patient Satisfaction Survey was developed by Restorix Health based on synthesized literature, internal assessment of performance improvement needs, and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) (M. Smith, personal communication, 2018). Permission was obtained for the use of this tool (see appendix E). The survey was used in this study because it was the survey used to measure satisfaction at all of the clinics managed by the company throughout the country. This allows for potential comparison of data across clinics and does not overburden patients or create survey fatigue. Although reliability and validity data associated with the Patient Satisfaction Survey are not available, it is very similar to the CHAPS survey which lends support to the content of the survey and facilitates generalization of results.

Data were gathered with the same Patient Satisfaction Survey for the intervention and control groups. Patients in the study received and completed the Patient Satisfaction Survey with 22 items. Items one through 21 used Likert scale answers (one = never, two = sometimes, three = usually, four = always). Optimal responses were four (always). The Patient Satisfaction Survey items could be analyzed to address three subcategories. Items one through eight were designated to measure satisfaction with "timeliness /courtesy/ appearance". Items nine through 19 were related to "active participation/treatment". Items 20 and 21 were listed as "general". Item 22 used a numeric rating scale and asked patients to rate the facility on 0-10 scale where 0 is the worst facility and 10 is the best facility. There are no guidelines for scoring this survey other than the higher the score the more satisfied the patient was with their experience.

Data Analysis

A statistician was consulted for the DNP project. The data set was entered into an Excel file and then transferred into R programming with no patient identifiers attached to ensure anonymity. Descriptive and inferential statistics were analyzed with the use of the Wilcoxon Rank Sum (WRS) test for comparison of the two independent groups. Research questions included:

1. What was the level of satisfaction among DFU patients who received an educational packet specific to their diagnosis?
2. What was the level of satisfaction among DFU patients who did not receive an educational packet specific to their diagnosis?
3. Was there an increase in the overall level of satisfaction between DFU patients who had received an educational packet specific to their diagnosis and those who did not?
4. Was there an increase in the levels of satisfaction pertaining to education between DFU patients who have received an educational packet specific to their diagnosis and those who did not?

Descriptive statistics were compiled in tables in the results section to address research questions one and two. The statistical test used to answer research questions three and four in this DNP project was the WRS test. This nonparametric test was used to determine if there was an association between survey scores and the intervention because the control and intervention groups data were not normally distributed (J. Rich, personal communication, 2018).

Chapter Four

Results

Introduction

This chapter will review the research findings of this DNP project beginning with a review of the research questions and study design. A review of the data and relevant statistical findings will follow. Also included is a discussion of the data analysis, limitations of the project, and recommendations for future research. Lastly, the conclusions reached through this DNP project will be outlined.

This DNP project sought to answer four research questions. For patients receiving DFU care in an outpatient wound clinic: What was the level of satisfaction among DFU patients who received an educational packet specific to their diagnosis? What was the level of satisfaction among DFU patients who did not receive an educational packet specific to their diagnosis? Was there an increase in the overall level of satisfaction between DFU patients who had received an educational packet specific to their diagnosis and those who did not? Was there an increase in the levels of satisfaction pertaining to education between DFU patients who have received an educational packet specific to their diagnosis and those who did not?

Sample

Thirty-two patients from an outpatient wound care facility were recruited for this study; the sample size was $n = 21$ patients for the control group and $n = 11$ for the intervention group.

Control group. For the control group a total of 35 patients met study criteria at the start date of the project. However, only 21 patients completed the Patient Satisfaction

Survey; there were 14 patients who did not. Reasons for not completing the survey at next scheduled appointment include: deceased (one), lost to follow up (12), and declined (one). This represents a 60% participation rate (21/35).

Intervention group. For the intervention group, Patient Satisfaction Surveys were given at follow up appointments within 30 days of receiving the intervention. Throughout the study time frame, 16 patients met the study criteria for the intervention group and received the intervention. A total of 11 subjects completed the survey following the intervention; five subjects did not. Reasons for not completing the survey include: deceased (three) and lost to follow up (two). This represents a 69% participation rate (11/16).

Data analysis

Items were analyzed as a total and as an aggregation of items assessing specific qualities related to PE. Summary statistics were compiled using base R functions and are displayed in tables in the following sections. The statistical test used for this analysis was WRS, which is a nonparametric test used to compare the control to the intervention group (J. Rich, personal communication, 2018). The results specific to the research questions are broken down into two parts, descriptive data analysis and WRS tests.

Research question one and two asked, *what was the level of satisfaction among DFU patients who receive an educational packet specific to their diagnosis* and w*hat was the level of satisfaction among DFU patients who do not receive an educational packet specific to their diagnosis?* To address these questions, the total survey score, aggregated across all 22 items, was analyzed with a maximum possible score of 94. Control (n = 21) and intervention (n = 11) scores are compared. Median scores for control and

intervention groups were 92 and 93, respectively. Table 1 displays the descriptive statistics.

Table 1

Total Patient Satisfaction Survey Scores (out of 94)

Group	n	Median	Mean (±SD)
Control	21	92	90.57± 3.85
Intervention	11	93	91 ± 6.16

Research question three asked, *was there an increase in the overall level of satisfaction between DFU patients who had received an educational packet specific to their diagnosis and those who did not?* To address this question the WRS test with a one-sided alternative was used to assess for statistical significance. Total satisfaction survey scores for the intervention group were slightly higher than for the control. With a test statistic of W = 94 and an approximate p-value of 0.19, there is little to no evidence that the intervention group was associated with a higher overall median survey satisfaction score than the control group.

Research question four asked, *was there an increase in the levels of satisfaction pertaining to education between DFU patients who have received an educational packet specific to their diagnosis and those who did not?* To address this question the WRS test with a one-sided alternative was used to assess for statistical significance. Only Patient Satisfaction Survey items that specifically addressed components of PE were used. The items were reviewed by the researcher and selected based on their specific qualities and components relating to PE. This aggregate included:

- Item 10 – *I feel I am an active participant in the treatment of my wound*.
- Item 11 – *I was taught all I needed to care for myself at home*.

- Item 12 – *I received written information about my symptoms or health problems prior to leaving*.
- Item 17 – *The center team explained things in a way I could understand*.
- Item 19 – *My different nurses, technicians and/or doctors were consistent with each other in providing me information and care*.
- Item 20 – *I felt all worries or concerns were discussed with me by center team* (see appendix F).

There was a possible maximum score of 24. For both aggregates, the control (n = 21) and intervention (n = 11) scores were compared with descriptive statistics. In the intervention group the median score (24) improved by 2 when compared to the control median (22). Table 2 displays the descriptive statistics.

Table 2

PE Aggregate Patient Satisfaction Survey Scores (out of 24)

Group	n	Median	Mean (SD)
Control	21	22	22.52 ± 1.57
Intervention	11	24	22.55 ± 2.81

With a test statistic of W = 94.5 and an approximate p-value of 0.19, there is little to no evidence that the intervention group was associated with a higher median score than the control group for the aggregate of Patient Satisfaction Survey items that specifically addressed components of PE.

Discussion

The purpose of this DNP project was to determine if the provision of a DFU specific written education packet led to increased patient satisfaction in an outpatient

wound clinic. The descriptive statistics represented an increase in patient satisfaction, albeit small, from the control to intervention groups. However, findings from this research did not show a statistically significant difference between the intervention and control groups ($p = 0.19$). In addition, further analysis comparing the aggregate of Patient Satisfaction Survey items that specifically addressed components of PE also failed to show significant difference ($p = 0.19$) between the intervention and control groups.

There is a large body of evidence from research articles, literature reviews, and systematic reviews predicting that written PE interventions should increase patient satisfaction. This DNP project implemented an educational delivery method that combined verbal and written methods, which is supported by the reviewed literature. Stenberg et al. (2018) found strong support for PE in terms of reducing patients medical needs and improved quality of life, particularly for those patients with chronic disease. Sustersic et al. (2017) using systematic literature reviews investigated the best use of written education materials. They concluded that, regardless of the clinical situation, written PE materials can improve patient knowledge and patient satisfaction. Moreover, when written PE materials are delivered to patients with chronic diseases, the quality of the educational materials was less important than the timing and manner of delivery. It is specifically important to deliver written PE at the same time as verbal education. Friedman et al. (2011) conducted a systematic review that supported the use of written PE materials, noting positive effects on patient knowledge and patient satisfaction particularly when combined with other teaching methods. Zirwas & Holder (2009) state in a literature review that successful education results in increased patient satisfaction.

This project was implemented in a wound clinic that has an interdisciplinary staff and resources that includes RNs, a nurse practitioner, and physicians. Specialties available include podiatry, infectious disease, endocrinology, vascular surgery, interventional cardiology, and general surgery. Driver et al. (2010) noted that the ideal clinical setting to implement PE for the management of DFU is with an interdisciplinary wound care team. Mathews et al. (2016) conducted research showing that as patient knowledge increased through education, participation in treatment planning increased, and in-turn improved patients' satisfaction with care. Furthermore, Ley's cognitive model (1988) predicts that enhanced patient understanding yields greater levels of patient satisfaction can be achieved.

Failure to show statistically significant results in this DNP project contradicts this literature. However, after accounting for the limitations, this can be interpreted as a lack of evidence rather than evidence of no effect. Meaning that the intervention could have shown significant effects in this study had it not been for the limitations. The following section will review these limitations and discuss the recommendations for future research.

Limitations

This DNP project utilized a convenience sample, which did not allow for random assignment into groups. Regarding sampling, there were different time periods when data were collected for the control and intervention groups. Therefore, the study design was unable to account for any confounding variables (e.g., patient demographics, clinic staff, clinic access, referral sources etc.) that could have impacted patients within each period. The PE intervention in this project was delivered one on one, which is an instructional method used in much of the supporting literature. However, Adiewere et al.

(2018) noted that the best PE process for patients with DFU was provided in group education settings. This was not a format conducive for this project setting and may have limited the impact of this project.

This project involved a small total sample size (n = 32) and the sample size of the intervention group was much smaller than that of the control group. If the project contained similar group sizes, results may have been different. Furthermore, sample size poses some challenges to the effectiveness of this study design. Descriptive statistics may have hinted at some effects, but the small sample size could have hampered the statistical significance. Finally, the Patient Satisfaction Survey did not have any established reliability and validity data which further limits this study. Also, the researcher provided interventions and collected surveys which may have influenced results, however any influence would have been equally distributed to both control and intervention groups.

Recommendations for future research

Overall, there is little evidence to support that the intervention of providing patients with written information on lower extremity wound care improved patient satisfaction in this project. Despite this, future research could be directed by the results of this study. For example, it might be worthwhile to redesign the data collection methods to fashion a more robust study. If repeated, ensuring for randomization of assignment and sampling might show a stronger effect of the intervention on patient satisfaction. Including a component of group education methods as identified in the literature may provide improved statistical outcomes. Also, an increased sample size would allow for the use of parametric statistical methods, such as a t-test, that have more

robust properties than nonparametric alternatives, like the WRS. There were time constraints for data collection which further contributed to the small sample size and should be accounted for in future research. Furthermore, if repeated, demographic data should also be collected such as age and education level, which may help in refining the written PE materials. Finally, a reliable and valid patient satisfaction tool should be used to measure satisfaction.

Conclusions

This DNP project examined if the provision of a DFU specific written education packet led to increased patient satisfaction in an outpatient wound clinic. The literature review and Ley's cognitive model predicted that effective PE interventions improve patient understanding and should have had a positive impact on patient satisfaction. To this end, the provision of a written PE intervention was selected in an attempt to improve patient understanding with patient satisfaction as the measured outcome. Ley's cognitive model predicts that patient memory and compliance are expected to improve as understanding and satisfaction increase (Ley, 1988). Although memory and compliance were not measured or assessed in this DNP project, it is worth highlighting these expected benefits. In this study, a greater mean score was achieved in the intervention group compared to the control. However, there was insufficient evidence to support a statistical association between the intervention and increased patient satisfaction.

A reflection on the limitations of this DNP project may provide future researchers with similar aims the ability to design more robust studies. Future research studying the effects of PE methods on patient satisfaction may lead to an overall higher quality of care through improved patient understanding of treatment plans, a sense of

involvement in decision making, and greater awareness of the implications of compliance.

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Appendix A

Cognitive Model Reprint Permission

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Douglas Kozeluh <dkozeluh@nmu.edu>

Permissions
2 messages

Douglas Kozeluh <dkozeluh@nmu.edu> Tue, Dec 4, 2018 at 7:43 AM
To: mpkbookspermissions@tandf.co.uk

Taylor & Francis Group
I am seeking permission to use a figure in the final project for my graduate program. It is a Doctorate in Nursing Practice project from Northern Michigan University. The figure is from the paper back book: Communicating with patients: Improving communication, satisfaction and compliance.

Ley, P. (1988). Communicating with patients: Improving communication, satisfaction and compliance. New York, NY, US: Croom Helm.

ISBN listed on inside cover is: 0-7099-4174-9

The figure, 5.1 found on page 73, is a visual representation of Ley's Cognitive Model, which I used as the theoretical framework for this project. I would like to include a photo copy of the figure or re-creation within the written document, also in a presentation. This will aid readers in understanding the model and to better understand the concepts pertaining to the project.

If you are not able to offer this permission, please, direct me to an appropriate contact if you are aware of one.

Kind regards,

Douglas W. Kozeluh

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Dear Douglas

Communicating with the patient by P. Ley and M. S. Spelman. (Staples 1967)

Thank you for your enquiry.

I am unable to trace the above title on our system. It may be that it was out of print by the time we acquired the Croom Helm titles? Therefore we are not in a position to grant formal permission. However, we have no objections to the proposed use as outlined in your request.

If you do decide to use the figure, please provide full acknowledgement to the original source.

We trust this meets your requirements.

Kind regards

Annette

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Appendix B

Health System IRB Approval

UP HEALTH SYSTEM
MARQUETTE
A Duke LifePoint Hospital

April 11, 2018

Douglas W. Kozeluh
2180 Grove Street
Marquette, MI 49855

RE: Improving satisfaction for patients with diabetes and lower extremity wounds using a diagnosis specific written education packet
UPHS-M IRB Study #0873-2018

Study approval period: April 11, 2018 to March 11, 2019

Dear Mr. Kozeluh

Review of the above-referenced study by the UP Health-System Marquette's (UPHS-M) Institutional Review Board (IRB) was completed at the April 11, 2018 meeting. I am pleased to advise you that the rights and welfare of the human subjects appear to be adequately protected and the IRB has approved this study for a period of one year. Documentation specifically reviewed was the following:

- Study Protocol
- Retrospective Data Collection Study Form
- Patient Satisfaction Survey
- Educational Tools

You are reminded that the next Board approval for this study will be set for one calendar year (date indicated above) or upon completion of the project-whichever comes first. If you plan to continue this project beyond one year, please make provisions for obtaining appropriate IRB approval prior to March 11, 2019. If this study is completed before one year, notification of completion and results need to be sent to the IRB for review. Any changes in procedures involving human subjects must be reviewed by the IRB prior to initiation of the change. The IRB must also be notified promptly of any problems (unexpected side effects, complaints etc.) involving human subjects during the course of this study.

Thank you for bringing this project to our attention and we look forward to working with you in the future.

Sincerely,

Rudy Evonich, MD
Chairman UPHS-M IRB
OHRP IRB #00001757

RE/ssh

580 West College Avenue • Marquette, MI 49855
UPHealthSystem.com

Appendix C

University IRB Approval

NORTHERN MICHIGAN UNIVERSITY

Douglas Kozeluh <dkozeluh@nmu.edu>

Kozeluh Reciprocal IRB Approval: HS18-955
1 message

Janelle Taylor <jantaylo@nmu.edu> Thu, Apr 26, 2018 at 9:27 AM
To: dkozeluh@nmu.edu, Katherine Menard <kmenard@nmu.edu>
Cc: Derek Anderson <dereande@nmu.edu>

Memorandum

TO: Douglas Kozeluh
Nursing Department

CC: Katie Menard
Nursing Department

FROM: Dr. Robert Winn
Interim IRB Administrator

DATE: April 26, 2018

SUBJECT: IRB Reciprocal Approval
NMU Proposal Number: HS18-955
"Improving satisfaction for patients with diabetes and lower extremity wounds using a diagnosis specific written education packet"
IRB Approval Dates: 4/26/18 – 4/25/19
Proposed Project Dates: 4/25/18 – 7/30/18

This IRB proposal "Improving satisfaction for patients with diabetes and lower extremity wounds using a diagnosis specific written education packet" has been approved under the reciprocal review process.

The study is approved by UP Health System – Marquette as protocol number 0873-2018.

Include the NMU proposal number (HS18-955) and the contact information of the NMU researcher and the NMU IRB Administrator on all research materials and on any correspondence regarding this project at Northern Michigan University.

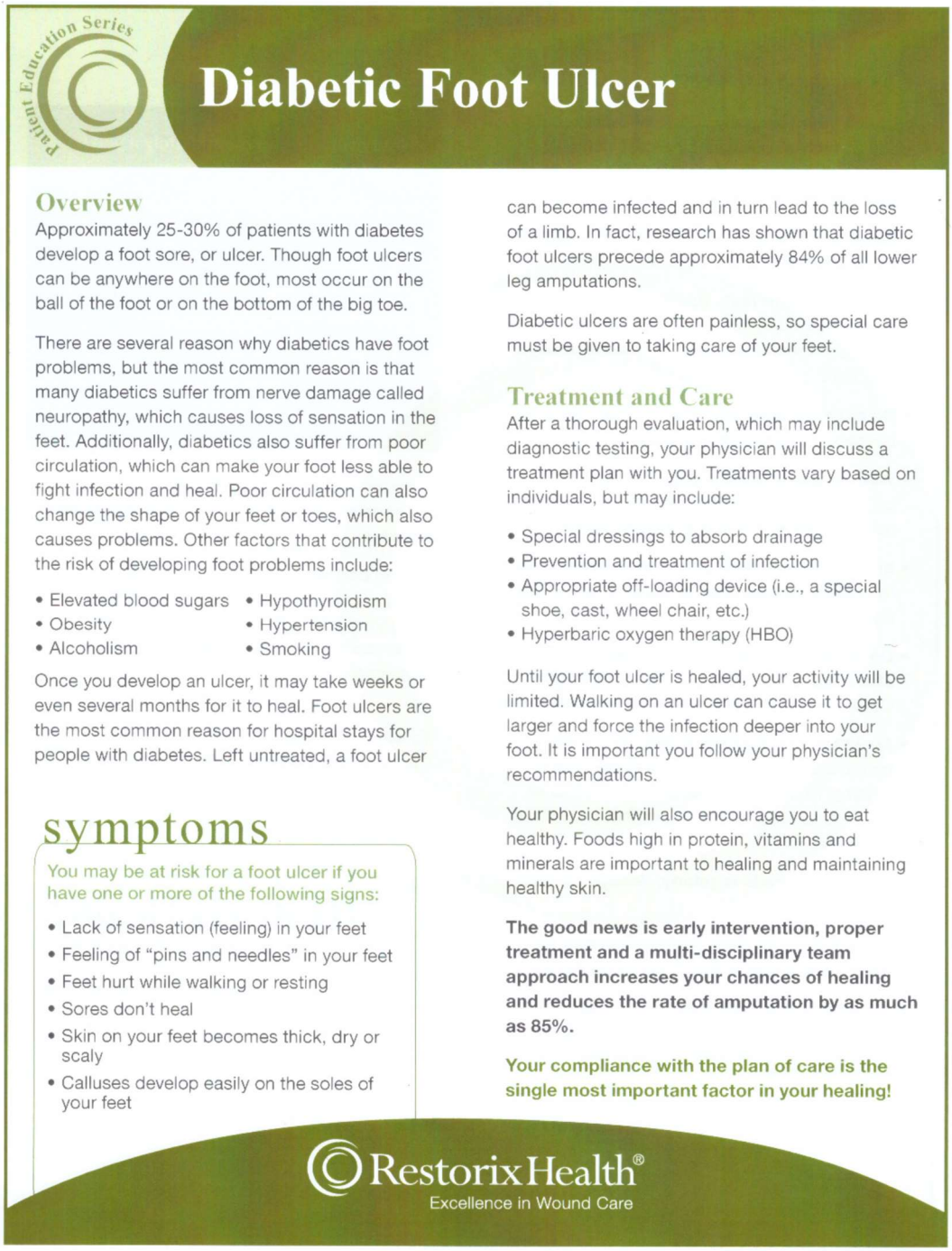
Any changes or revisions to your approved research plan must be approved by the Institutional Review Board (IRB) prior to implementation.

If you do not complete your project within 12 months from the date of your approval notification, you must submit a Project Renewal Form for Research Involving Human Subjects. You may apply for a one-year project renewal up to four times.

All forms can be found at the NMU Grants and Research website: http://www.nmu.edu/grantsandresearch/node/102

Appendix D

Education Materials



Patient Education Series

Diabetic Foot Ulcer

Overview

Approximately 25-30% of patients with diabetes develop a foot sore, or ulcer. Though foot ulcers can be anywhere on the foot, most occur on the ball of the foot or on the bottom of the big toe.

There are several reason why diabetics have foot problems, but the most common reason is that many diabetics suffer from nerve damage called neuropathy, which causes loss of sensation in the feet. Additionally, diabetics also suffer from poor circulation, which can make your foot less able to fight infection and heal. Poor circulation can also change the shape of your feet or toes, which also causes problems. Other factors that contribute to the risk of developing foot problems include:

- Elevated blood sugars
- Obesity
- Alcoholism
- Hypothyroidism
- Hypertension
- Smoking

Once you develop an ulcer, it may take weeks or even several months for it to heal. Foot ulcers are the most common reason for hospital stays for people with diabetes. Left untreated, a foot ulcer can become infected and in turn lead to the loss of a limb. In fact, research has shown that diabetic foot ulcers precede approximately 84% of all lower leg amputations.

Diabetic ulcers are often painless, so special care must be given to taking care of your feet.

symptoms

You may be at risk for a foot ulcer if you have one or more of the following signs:

- Lack of sensation (feeling) in your feet
- Feeling of "pins and needles" in your feet
- Feet hurt while walking or resting
- Sores don't heal
- Skin on your feet becomes thick, dry or scaly
- Calluses develop easily on the soles of your feet

Treatment and Care

After a thorough evaluation, which may include diagnostic testing, your physician will discuss a treatment plan with you. Treatments vary based on individuals, but may include:

- Special dressings to absorb drainage
- Prevention and treatment of infection
- Appropriate off-loading device (i.e., a special shoe, cast, wheel chair, etc.)
- Hyperbaric oxygen therapy (HBO)

Until your foot ulcer is healed, your activity will be limited. Walking on an ulcer can cause it to get larger and force the infection deeper into your foot. It is important you follow your physician's recommendations.

Your physician will also encourage you to eat healthy. Foods high in protein, vitamins and minerals are important to healing and maintaining healthy skin.

The good news is early intervention, proper treatment and a multi-disciplinary team approach increases your chances of healing and reduces the rate of amputation by as much as 85%.

Your compliance with the plan of care is the single most important factor in your healing!

Restorix Health®
Excellence in Wound Care

Education Materials

Caring for Your Feet

- **Check your feet daily.** Look for blisters, cuts and scratches. Use a long handled mirror or place a mirror on the floor to see the bottom of your feet. Always check between your toes.
- **Keep your feet clean.** Wash daily, dry carefully–especially between the toes.
- **Moisturize your feet.** Apply a moisturizer as recommended by your physician, but never apply between toes as that can lead to a fungal infection.
- **Do not walk barefoot.** That includes on sandy beaches and pool/patio areas.
- **Wear properly fitted shoes.** Shoes should be comfortable when purchased. Do not wear narrow, pointed toe or high-heeled shoes.
- **Inspect the inside of your shoes daily.** Check for foreign objects, tears or rough areas on the inside of the shoe.
- **Do not wear shoes without socks or stockings.** Wear clean, properly fitted socks. Cotton or cotton blend socks are recommended.
- **Avoid temperature extremes.** Test water temperature with your hand or elbow prior to bathing. Do not soak your feet in hot water or apply a hot water bottle. If your feet feel cold at night wear socks.
- **Trim you toenails regularly.** Always cut your nails straight across.
- **Do not use over the counter remedies for corns.** See a podiatrist to have these evaluated.
- **Avoid crossing your legs.** This causes pressure on the nerves and blood vessels, resulting in less blood flow to your feet.

important

Notify your doctor immediately if you have any of the following symptoms:

- You have a fever of 101 degrees or higher
- You have an increase in leg/foot pain
- A discolored drainage is noted from the ulcer or a bad odor is noted from the ulcer site
- Increased swelling of your foot/leg
- Feet or leg becomes cold, pale, blue or existing numbness increases

The most important thing you can do to lower your risk of developing a foot ulcer is to **manage your diabetes**.

With proper self-care, most symptoms can be reduced and foot ulcers minimized. Early recognition of an ulcer and immediate care under your physician's direction can prevent complications.

To learn more about RestorixHealth Wound Care Centers, please call 914.372.3150 or visit our website at:

www.restorixhealth.com

RestorixHealth®
Excellence in Wound Care

155 White Plains Road, Suite 222 | Tarrytown, NY 10591

RestorixHealth®
Excellence in Wound Care

XXXXXXXXXX 2/20/14

Education Materials

UP HEALTH SYSTEM
MARQUETTE
A Duke LifePoint Hospital

WHAT IS A WOUND HEALING CENTER?

As a comprehensive wound healing center, we treat all wounds, but specialize in those that have become chronic and difficult to heal.
Our approach to wound care is aggressive and comprehensive, coordinating traditional and advanced therapies that aid and accelerate the healing process.
Our center is staffed by multidisciplinary team with advanced training in wound care and hyperbaric medicine.

Every year, chronic wounds and other conditions keep millions of Americans like you from enjoying their best quality of life.

We treat all chronic wounds associated with, but not limited to:

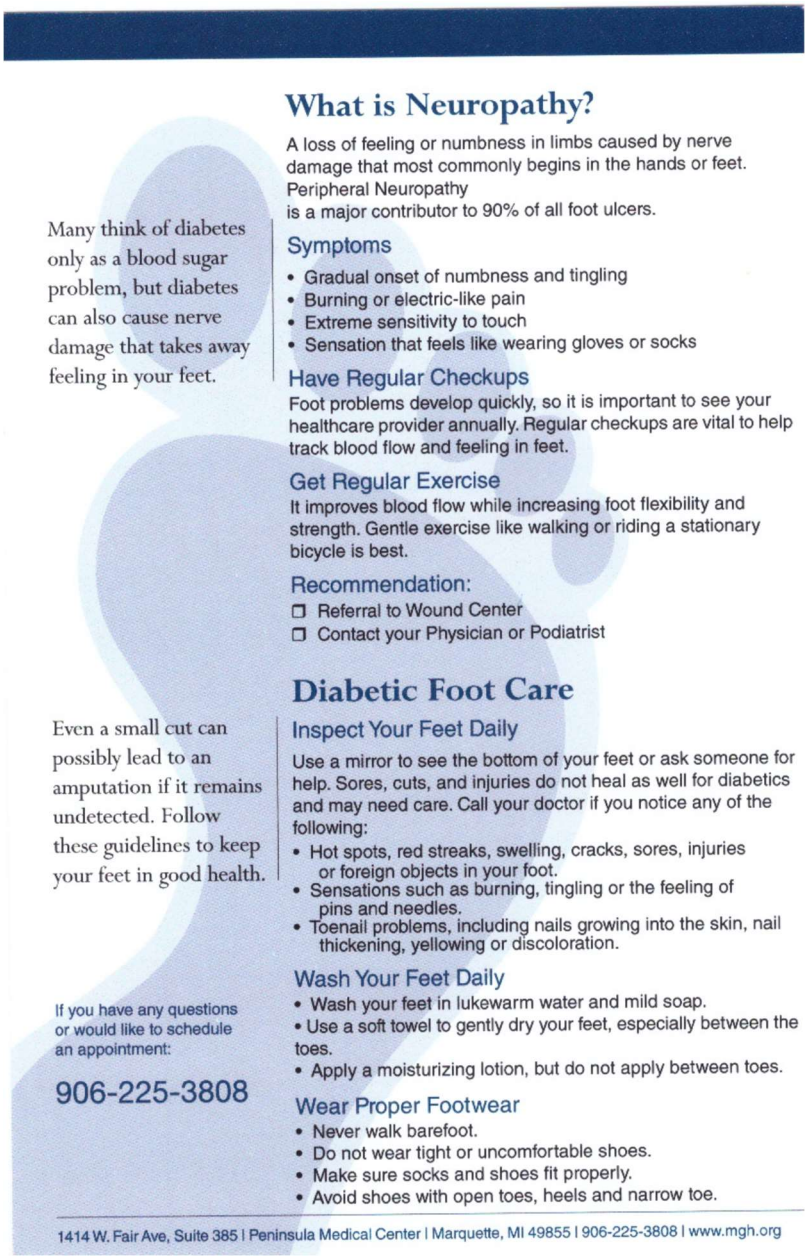
- Diabetic Foot Ulcers
- Venous Ulcers
- Pressure Ulcers
- Surgical Wounds
- Traumatic Wounds
- Arterial Ulcers
- Radiation Wounds
- Compromised Skin Grafts and Flaps
- Crush Injuries

For more information please call:

906-225-3808

1414 W. Fair Ave, Suite 385 | Peninsula Medical Center | Marquette, MI 49855 | 906-225-3808 | www.mgh.org

Education Materials



What is Neuropathy?

A loss of feeling or numbness in limbs caused by nerve damage that most commonly begins in the hands or feet. Peripheral Neuropathy is a major contributor to 90% of all foot ulcers.

Many think of diabetes only as a blood sugar problem, but diabetes can also cause nerve damage that takes away feeling in your feet.

Symptoms

- Gradual onset of numbness and tingling
- Burning or electric-like pain
- Extreme sensitivity to touch
- Sensation that feels like wearing gloves or socks

Have Regular Checkups

Foot problems develop quickly, so it is important to see your healthcare provider annually. Regular checkups are vital to help track blood flow and feeling in feet.

Get Regular Exercise

It improves blood flow while increasing foot flexibility and strength. Gentle exercise like walking or riding a stationary bicycle is best.

Recommendation:

- ❒ Referral to Wound Center
- ❒ Contact your Physician or Podiatrist

Diabetic Foot Care

Even a small cut can possibly lead to an amputation if it remains undetected. Follow these guidelines to keep your feet in good health.

Inspect Your Feet Daily

Use a mirror to see the bottom of your feet or ask someone for help. Sores, cuts, and injuries do not heal as well for diabetics and may need care. Call your doctor if you notice any of the following:

- Hot spots, red streaks, swelling, cracks, sores, injuries or foreign objects in your foot.
- Sensations such as burning, tingling or the feeling of pins and needles.
- Toenail problems, including nails growing into the skin, nail thickening, yellowing or discoloration.

Wash Your Feet Daily

- Wash your feet in lukewarm water and mild soap.
- Use a soft towel to gently dry your feet, especially between the toes.
- Apply a moisturizing lotion, but do not apply between toes.

Wear Proper Footwear

- Never walk barefoot.
- Do not wear tight or uncomfortable shoes.
- Make sure socks and shoes fit properly.
- Avoid shoes with open toes, heels and narrow toe.

If you have any questions or would like to schedule an appointment:

906-225-3808

1414 W. Fair Ave, Suite 385 | Peninsula Medical Center | Marquette, MI 49855 | 906-225-3808 | www.mgh.org

Appendix E

Education Materials and Survey Permission

Gmail

Douglas Kozeluh <dwkozeluh@gmail.com>

Education Materials

2 messages

Douglas Kozeluh <dwkozeluh@gmail.com> Sat, Dec 8, 2018 at 5:56 PM
To: Maureen Smith <Maureen.Smith@restorixhealth.com>

Maureen,
We spoke a few weeks ago regarding the satisfaction survey and the education materials for DFU developed by Restorix and its application to the research I am doing at the UPHS - Marquette wound care center for my Doctorate in Nursing Practice at Northern Michigan University. I would like to include a copy of the survey and the education material in the appendix of the written document. I am requesting permission to do so.

Sincerely,
Douglas Kozeluh, RN
715-482-3684
dkozeluh@nmu.edu

Maureen Smith <Maureen.Smith@restorixhealth.com> Mon, Dec 10, 2018 at 3:43 PM
To: Douglas Kozeluh <dwkozeluh@gmail.com>

You are welcome to use them. All the best.

Appendix F

Patient Satisfaction Survey

	Patient Satisfaction Survey	4	3	2	1
TIMELINESS /COURTESY/ APPEARANCE		**Always**	**Usually**	**Sometimes**	**Never**
1	Scheduling my appointment went smoothly.				
2	I was treated promptly.				
3	The staff kept me informed about any delays to my appointment starting on time.				
4	The nurses and/or technician(s) treated me with courtesy and respect.				
5	The doctor treated me with courtesy and respect.				
6	The front office staff was helpful.				
7	I found the directions and signage to get me to the center easily.				
8	The center was clean and comfortable.				
ACTIVE PARTICIPATION/TREATMENT		**Always**	**Usually**	**Sometimes**	**Never**
9	I felt the center staff were concerned with my comfort.				
10	I feel I am an active participant in the treatment of my wound.				
11	I was taught all I needed to care for myself at home.				
12	I received written information about my symptoms or health problems prior to leaving.				
13	I felt comfortable with the privacy I had in the treatment or HBO room.				
14	The center team listened carefully to me.				
15	I felt any wound pain I experienced during procedures in the wound center was handled well.				
16	I felt staff worked together to provide care to me.				
17	The center team explained things in a way I could understand.				
18	I had trust and confidence in the center team treating me.				
19	My different nurses, technicians and/or doctors were consistent with each other in providing me information and care.				
GENERAL		**Always**	**Usually**	**Sometimes**	**Never**
20	I felt all worries or concerns were discussed with me by center team.				
21	If an issue occurred while I received treatment at the center, the issue was resolved to my satisfaction.				

Using a number between 0 and 10, where 0 is the worst facility and 10 is the best facility, what number would you use to rate this facility? (circle one) 1 2 3 4 5 6 7 8 9 10