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Evaluation of the Prevalence and Treatment Trends of Diabetic Peripheral Neuropathy among Patients with Diabetes in a Rural Population

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EVALUATION OF THE PREVALENCE AND TREATMENT TRENDS OF
DIABETIC PERIPHERAL NEUROPATHY AMONG PATIENTS WITH DIABETES
IN A RURAL POPULATION

by
Lauren Grace Daigle

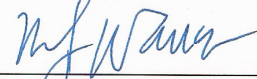
A thesis submitted to the faculty of The University of Mississippi in partial fulfillment of
the requirements of the Sally McDonnell Barksdale Honors College.

Oxford
May 2016


Approved by



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This thesis is dedicated to my high school science teacher, Mrs. Messina. Thank you for teaching me the value of research and for planting a love of science within me when I was a nervous high school freshman. Thank you for believing in me and for teaching me to always set my sights higher and to push myself to be the best that I can be.

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ABSTRACT

LAUREN GRACE DAIGLE: Evaluation of the Prevalence and Treatment Trends of Diabetic Peripheral Neuropathy among Patients with Diabetes in a Rural Population
(Under the direction of Dr. Matthew W. Strum)

Evidence for adherence to the American Diabetes Association's (ADA) screening and treatment guidelines for various health complications of diabetes in rural populations is limited. The ADA recommends annual foot and eye exams and supports the use of the Semmes-Weinstein monofilament (SWM) to detect signs of diabetic peripheral neuropathy (DPN). This study evaluated the prevalence and treatment trends of DPN among patients with diabetes in a rural population. Fifty-two individuals over the age of 18, with known Type 1 or Type 2 diabetes mellitus, were recruited to participate. Participants were asked to respond to a 29-item, multiple choice and freeform question survey about the monitoring and management of their diabetes. A monofilament exam was then performed on each participant using a 10g SWM to detect signs of DPN. Six locations on the foot were tested with the 10g SWM, and a pedal pulse was recorded. The results of the 10g SWM exam were compared to the survey responses for each corresponding participant. Survey responses indicated that 21.2% of participants had been diagnosed with DPN. Although not statistically significant due to limited sample size, 17.3% of participants were identified by the SWM exam to have DPN but were currently undiagnosed by their physician. Furthermore, 12.0% of participants had not had an eye exam in over a year, and 28.8% did not have regular foot exams. Participants

whose physicians performed regular foot exams were 3.0 times as likely to have an eye exam within the last year compared to participants whose physicians did not perform regular foot exams, demonstrating a positive correlation between foot and eye exams. The health consequences of undiagnosed sequelae of diabetes can be devastating. More specific data related to diabetes management and prevention of disease complications (via appropriate screening processes) in underserved areas is warranted; however, this study suggests that rural populations need greater attention and targeted educational programs to enhance the level of care.

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INTRODUCTION

Diabetes mellitus is defined as “a group of diseases that affect how your body uses blood sugar”.¹ Diabetes mellitus is traditionally divided into two different subtypes, type 1 (T1DM) and type 2 (T2DM). T1DM, previously referred to as insulin-dependent diabetes mellitus, is more commonly diagnosed in children and results from defected β cells in the pancreas, preventing the body from making insulin.^{2,3} T2DM, or non-insulin dependent diabetes mellitus, differs from T1DM in that it develops when the body becomes resistant to insulin, and eventually, the production of insulin becomes inadequate. T2DM accounts for 90-95% of all diagnosed cases of diabetes.^{4,5}

Insulin is a hormone that is secreted into the bloodstream by the β cells in the pancreas. Responsible for the uptake of glucose from the blood into cells, insulin lowers the blood glucose concentration. However, in diabetes, blood glucose levels rise as a result of either the lack of insulin (T1DM) or the body's unresponsiveness to insulin, known as insulin resistance (T2DM). In order for insulin to function, it must attach to, and then stimulate, specific receptors on the surface of cells.⁶ This process allows insulin receptor substrate to be moved to the plasma membrane. Glucose is subsequently transported into the cell where activation of several intracellular metabolic processes occurs.⁶

In T2DM, the ability to stimulate the insulin receptor substrate is impaired.⁶ As a result, blood glucose levels rise, causing the β cells to produce more insulin in an attempt

to increase the uptake of glucose into cells. High demand on the β cells to hypersecrete insulin leads to β cell dysfunction and ultimately β cell death.⁶ In contrast, T1DM results from an abnormal immune response against the pancreatic β cells or from defected β cells causing little or no insulin to be produced. Consequently, the insulin necessary to participate in the pathway of glucose uptake into cells is unavailable. As a result, both T1DM and T2DM cause glucose to accumulate in the blood, often having damaging effects on the body.^{3,6}

The risk factors for T1DM include having a family history of T1DM, geography, and age. Individuals with a parent or sibling with T1DM are at an increased risk of developing the condition because they are more likely to possess specific genes associated with diabetes. An increased distance from the equator puts individuals at a higher risk for developing T1DM as well due to less exposure to ultraviolet light and lower vitamin D levels.⁷ T1DM is most common between the ages of four and seven and again between ten and fourteen years of age.⁸

On the other hand, the risk factors for T2DM are quite different. Risk factors include body weight, abdominal fat distribution, physical inactivity, family history, race, age, prediabetes, polycystic ovary syndrome, and gestational diabetes.³ The primary risk factor for developing T2DM is being overweight.³ High levels of fatty tissue cause cells to become more resistant to insulin, consequently increasing blood glucose levels.³ Fat storage distribution also influences risks for T2DM as storing fat primarily in the abdomen puts individuals at a greater risk than storing fat in the hips and thighs.³ Additionally, lack of physical activity increases the risk of T2DM. Physical activity uses glucose for energy and makes cells more sensitive to the presence of insulin.³ Lack of

physical activity consequently decreases the body's sensitivity to insulin and can cause the elevated blood glucose levels indicative of diabetes. A family history of T2DM as well as being male, African American, American Indian, or Asian-American puts individuals at a higher risk for developing the condition due to the presence of certain genetic factors.³ Unlike T1DM, the risk for developing T2DM increases with age, especially after age 45.³ Another risk factor, prediabetes, is when the blood glucose levels are abnormally high, but not high enough to be considered diabetes.³ Prediabetes is often a sign that the body is progressing towards a diabetic state.³ Lastly, polycystic ovary syndrome as well as gestational diabetes in women has been correlated with an increased risk for developing diabetes.³

Diabetes is typically diagnosed through blood tests (See Figure 1).^{9,10} The normal glucose levels for a non-diabetic are 80-120 mg/dL before meals, 160 mg/dL or less two hours after meals, and 100 mg/dL to 140 mg/dL at bedtime.¹¹ Each test has slightly different criteria that must be met. An A1C test is a way to measure blood glucose levels for the past 2 to 3 months without the need for the individual to fast.¹² The Fasting Plasma Glucose test checks fasting blood glucose levels after an individual has not consumed food or drink for 8 hours prior to the test.¹² The Oral Glucose Tolerance Test checks blood glucose levels before and 2 hours after consumption of a sweet drink.¹² Finally, the Random Plasma Glucose Test is a test done on the blood at any time of day when diabetes symptoms are severe.¹² Use of such blood tests can provide the information necessary for a proper diagnosis of diabetes.

Table 2.1—Criteria for the diagnosis of diabetes
FPG \geq 126 mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.*
OR
2-h PG \geq 200 mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.*
OR
A1C \geq 6.5% (48 mmol/mol). The test should be performed in a laboratory using a method that is NGSP certified and standardized to the DCCT assay.*
OR
In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose \geq 200 mg/dL (11.1 mmol/L).
*In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

FIGURE 1: Criteria for the Diagnosis of Diabetes. From Standards of Medical Care in Diabetes—2016

Some common symptoms of diabetes include excessive thirst and hunger, fatigue, blurry vision, slow healing bruises, weight loss, and pain or numbness in the hands and feet.¹³ As the condition progresses, other organs may be affected and other symptoms may occur.¹³

Diabetes is the seventh leading cause of death in the United States today.⁵ Roughly 29.1 million Americans had diabetes in 2014, with 1.7 million new diagnoses.^{5,14} There are 21.0 million diagnosed cases of diabetes and 8.1 million undiagnosed cases. Diabetes affects various ethnicities differently.⁵ Diabetes is most prominent among American Indians/Alaska Natives, non-Hispanic blacks, Asian Americans and Hispanics.

Roughly 16% of the American Indians/Alaska Natives population has diagnosed diabetes, making it the ethnicity with the highest percentage of diagnosed diabetes.⁵ The differences in genetic factors as well as lifestyles impact the prevalence of diabetes among various ethnicities.⁵ More importantly, 86 million adult Americans have prediabetes, and as many as 1 in 3 Americans are expected to have diabetes in 2050 if trends continue.^{5,14}

On a more local level, approximately 11.7% of adult Mississippians had a diagnosis of diabetes in 2012.⁵ The Mississippi State Department of Health reported that, in 2012, Mississippi ranked first in the nation for cases of diagnosed diabetes while Louisiana ranked second.^{5,15} Statistics show that 11.5% of the adult population in Louisiana had a diagnosis of diabetes in 2012.⁵ Diabetes is clearly a condition that holds great prevalence throughout the U.S. and particularly in the Southeast. A significant portion of the United States' population is affected by diabetes, costing over \$245 billion per year in healthcare.⁵ In Mississippi, the estimated cost of diabetes is \$1.7 billion per year.¹⁵

Uncontrolled or long-term diabetes can lead to microvascular complications. These include retinopathy, nephropathy, and neuropathy. The most prominent and common health complication associated with diabetes is diabetic neuropathy. The American Diabetes Association (ADA) defines diabetic neuropathy as “the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after exclusion of other causes”.¹⁶ Excess blood glucose can injure the capillaries that provide blood to nerves and interferes with the ability of nerves to transmit signals.¹⁷ There are four main types of diabetic neuropathies: peripheral neuropathy, autonomic neuropathy,

radiculoplexus neuropathy and mononeuropathy.¹⁷ The most common form is diabetic peripheral neuropathy.¹⁷ Symptoms of diabetic peripheral neuropathy include tingling, burning, pain, and loss of feeling that starts at the tips of the fingers and toes.^{16,17} Symptoms tend to be worse at night and are often lessened by movement, walking or standing.¹⁶ However, problems balancing and walking are also commonly seen in individuals with diabetic peripheral neuropathy.¹⁶ Diabetic peripheral neuropathy may affect one or more nerves and over time can lead to the complete loss of feeling in entire limbs.^{16,17} The nerve damage that often results from diabetes puts the feet at an increased risk for foot complications.³ Minor cuts and blisters can become infected and amputations of extremities may be necessary in severe cases.³ More serious foot problems such as deformities and bone and joint pain can also result. Diabetic neuropathies affect as many as 50% of patients with diabetes to some degree.¹⁸ Of these individuals with diabetic peripheral neuropathy, there were 73,000 non-traumatic lower-limb amputations performed in 2010.^{5,19,20}

Because diabetic peripheral neuropathy has no known cure, treatment tends to focus on managing symptoms and slowing the progression of the disease.¹⁷ Wearing proper footwear, maintaining a healthy blood pressure, eating healthy, exercising, avoiding alcohol and smoking, as well as keeping the blood glucose within a target range can help to delay the progression of diabetic peripheral neuropathy.¹⁷ Diabetic peripheral neuropathy and its complications were estimated to cost between 4.6 and 13.7 billion dollars annually in the United States. In fact, up to 27% of the medical costs of diabetes in the United States is attributed to diabetic peripheral neuropathy.²¹

Due to the high potential for serious health problems caused by diabetic peripheral neuropathy, the ADA recommends that diabetic patients receive a comprehensive foot exam at least once per year.²² All patients should be screened for diabetic peripheral neuropathy beginning at diagnosis of T2DM and 5 years after the diagnosis of T1DM. Foot exams should check for various dermatologic conditions such as skin color, thickness, dryness, and cracking.^{19,22} The presence of ulcers, blisters and calluses should also be checked.²² In addition, a musculoskeletal assessment should be performed to look for deformities such as claw toes, prominent metatarsal heads, and charcot joints.^{19,22} Pedal pulses may also be checked in some instances. The presence of any of these conditions should be noted, and the patient should be referred to a physician if the results seem indicative of possible diabetic peripheral neuropathy.¹⁹ Patients with insensate feet, ulcers, and foot deformities should be examined at every physician visit rather than just once a year.¹⁰

One other common and accurate way to test for diabetic peripheral neuropathy is through Semmes-Weinstein monofilaments (SWM). These are typically made of fine nylon and designed “such that the amount of pressure on the plantar surface of the great toe is a function of the instrument, and not of the examiner”.¹⁶ SWM are single-fiber nylon threads, and each generates a buckling stress.¹⁶ Each monofilament “is marked with a number that represents the decimal log of 10 times the force in milligrams ranging from 1.65 (000.45 g) to 6.65 (447 g) of linear force.”¹⁶ To test for neuropathy, the monofilament is gently placed perpendicularly on the surface of the foot until the monofilament buckles.¹⁶ This action is repeated several times on various areas of the foot: the 1st, 3rd, and 5th metatarsal heads, and the plantar surface of the distal hallux.¹⁶

These four monofilament testing sites have been shown to identify 90% of patients with an insensate site.²⁴ To test for complete loss of protective sensation, a 10g SWM should be used.¹⁶ Several studies have shown that use of the 10g SWM is highly predictive of future ulcerations, and its efficacy in screening for sensory loss has been confirmed in several studies.²³ When conducting a monofilament test for neuropathy, the sensation of pressure using the 10g SWM should first be demonstrated for the patient on a proximal site such as the arm.²³ The patient should close their eyes and respond with “yes” during the test whenever they feel the monofilament being applied.²³ If the patient does not feel the monofilament after it buckles, then the test site is considered to be insensate.²⁵

Diabetes affects millions of Americans and is associated with many health complications that have various effects on the body. Diabetic peripheral neuropathy is one of the more common diabetes-related health complications and can have detrimental effects on an individual, so it is important that patients with diabetes receive foot exams regularly. Performing a foot exam using a 10g SWM is an accurate and simple way to test for possible diabetic peripheral neuropathy. Since many rural populations do not have easy access to healthcare, these populations have been shown to often have untreated health conditions. However, data showing how diabetes in particular is monitored and managed in rural populations is limited. As a result, this study sought to test a rural population of people in a local community pharmacy using a 10g SWM to determine the prevalence of diabetic peripheral neuropathy as well as how often it goes undiagnosed by physicians in a rural population. The study also aims to analyze whether the treatment trends of diabetic peripheral neuropathy are correlated with those of diabetic retinopathy, another common sequelae of diabetes. By determining whether a

correlation exists, hopefully physicians can develop better treatment plans to improve patient care. The results of the study showing the prevalence of diabetic peripheral neuropathy will be shared with physicians to hopefully raise awareness for diabetic peripheral neuropathy and to help combat the adverse health risks associated with the condition.

MATERIALS AND METHODS

This study, “Evaluation of the Prevalence and Treatment Trends of Diabetic Peripheral Neuropathy among Patients with Diabetes in a Rural Population” was reviewed by the Institutional Review Board (IRB) at the University of Mississippi and approved. Patients of Prairieville Pharmacy, located in Prairieville, Louisiana were recruited as subjects. The pharmacist at Prairieville Pharmacy asked patients taking medications commonly used to treat diabetes if they would be willing to participate. Patients over the age of 18, with known diabetes mellitus, were eligible to participate. Each participant was given a randomized code to keep his or her anonymity. The participant was asked to complete a survey on Qualtrics asking various questions about how his or her diabetes is monitored and managed, as well as other questions to gauge the participant’s knowledge about his or her diabetes. Then, the participant was asked to remove his or her shoes and socks on both feet. The investigator wore latex gloves, and used a new pair of latex gloves between each participant. The investigator performed a monofilament exam on the participant using a 10g Semmes-Weinstein monofilament (SWM). The 10g SWMs were purchased through Medical Monofilament. A new 10g SWM was used for each participant. The investigator first demonstrated for each participant how the 10g SWM would be used and how it felt by applying the 10g SWM to the participant’s forearm. Then, six sites on each foot were tested: the first, third, and fifth metatarsal heads; the plantar surface of the distal hallux and fifth phalanx; and the

dorsum pedis. (See Figure 2: Semmes-Weinstein Monofilament Test). The investigator touched the 10g SWM to the same six sites on each foot in random order by applying just enough pressure to cause the 10g SWM to buckle. The six testing sites were chosen based on literature evaluations of the most accurate testing sites for detecting diabetic peripheral neuropathy. The participant was asked to close his or her eyes and to respond “yes” any time he or she felt the 10g SWM on his or her foot. If a participant did not respond “yes” when the monofilament was applied to a particular site, the test site was considered to be insensate. The number of “yes” responses was recorded on the participant’s Qualtrics survey. Next, the investigator checked for a bilateral pedal pulse in each participant. The bilateral pedal pulse was recorded as either “present” or “absent” for each participant. The pedal pulse must have been detected on both feet in order to be considered present. The presence or absence of the bilateral pedal pulse was recorded on the participant’s Qualtrics survey. At the end of each participant’s time, a total of twelve sites were evaluated with the 10g SWM. Each participant was offered a copy of the results from his or her monofilament exam to take to his or her physician. The investigator discarded the 10g SWM and latex gloves into the proper trash receptacle.

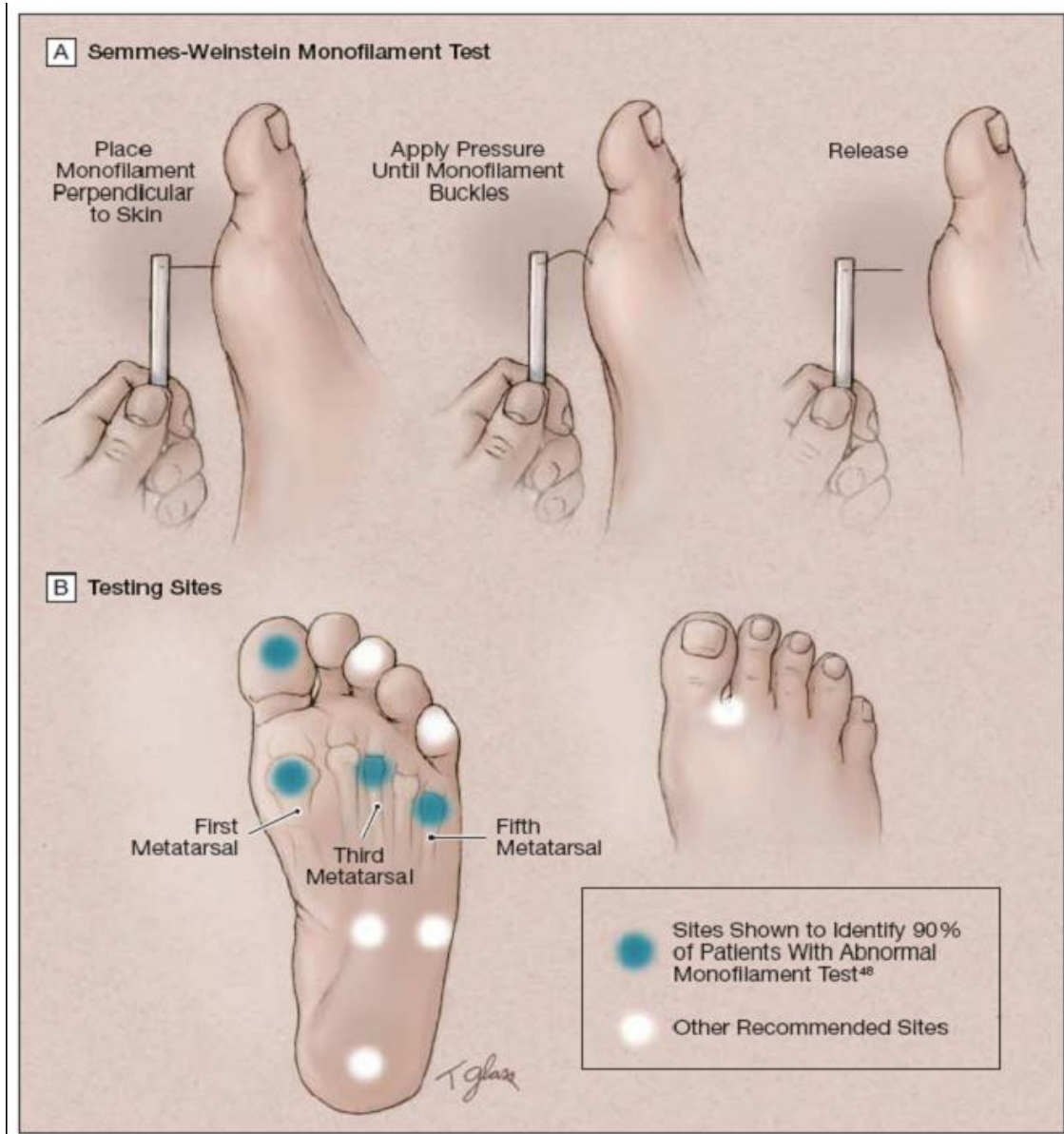


FIGURE 2: Semmes-Weinstein Monofilament Test. From American Medical Association—2005

OBSERVATIONS

Throughout the study, various observations were noted. Roughly the same number of sensate test sites was observed on each foot, suggesting that the degree of feeling on each foot was approximately equal for most participants. The dorsum pedis was the site most commonly felt by participants. The first, third, and fifth metatarsal heads as well as the plantar surface of the distal hallux and fifth phalanx were distributed fairly equally in terms of how often participants responded “yes” to feeling the 10g SWM. Participants with structural deformities in the bones of their feet had more insensate test sites than participants without structural deformities in their feet. Also, there was a general trend that participants with thick, callused skin on their feet had more insensate test sites compared to participants without calluses. In addition, participants who reported having physicians that provided regular foot exams tended to behave more confidently about how they would perform on the monofilament exam compared to participants whose physicians rarely performed foot examinations.

RESULTS

Prevalence of Diabetic Peripheral Neuropathy in a Rural Population as Detected by 10g Semmes-Weinstein Monofilament Exam

Using the software, SPSS, the data collected were transferred from the Qualtrics survey software to an SPSS document. To determine the prevalence of diabetic peripheral neuropathy in the sample of participants, the results of the 10g SWM were analyzed with SPSS. The number of “yes” responses to the monofilament exam was counted for each participant. Participants were considered to test negative for diabetic peripheral neuropathy if they had 10 or more “yes” responses. In other words, if the participant felt 9 or less of the 12 testing sites on the foot, he or she was classified as having diabetic peripheral neuropathy. Descriptive statistics were used to determine the frequency of participants who felt 9 or less of the testing sites using the 10g SWM. It was found that 15 of the 52 participants, or 28.8%, of the participants tested positive for diabetic peripheral neuropathy using the 10g SWM.

Next, the results of the survey question in which participants were asked to report whether or not they had ever been diagnosed with diabetic peripheral neuropathy were analyzed. Participants who answered that they were unsure if they had ever been diagnosed with diabetic peripheral neuropathy were classified as not having a diagnosis of diabetic peripheral neuropathy. The results showed that 11 of the participants, or 21.2%, reported a previous or current diagnosis of diabetic peripheral

neuropathy. (See Figure 3: Proportion of Participants Reporting a Diagnosis of Diabetic Peripheral Neuropathy)

Then, a cross-tabulation was done to compare the survey responses with the results of the 10g SWM exam. The cross-tabulation identified 9 participants, or 17.3%, who tested positive for diabetic peripheral neuropathy from the 10g SWM exam that reported never being diagnosed with diabetic peripheral neuropathy in their survey responses. Additionally, 5 participants, or 9.62%, reported a previous or current diagnosis of diabetic peripheral neuropathy but tested negative for diabetic peripheral neuropathy based on their results of the 10g SWM exam. A McNemar test was used to compare the proportion of participants who reported a previous diagnosis of diabetic peripheral neuropathy to those who tested positive for diabetic peripheral neuropathy from the 10g SWM exam. A p-value of 0.424 was determined using a binomial distribution and a two-tailed analysis, and thus concluded to be insignificant since $p > 0.05$.

Therefore, it can be concluded that there was no statistically significant difference between the proportion of participants who reported having a previous diagnosis of diabetic peripheral neuropathy and the proportion of participants who tested positive for diabetic peripheral neuropathy based on their results from the 10g SWM exam. (See Figure 4: Comparison of Diagnosis of Diabetic Peripheral Neuropathy by Physician and Results of the 10g Semmes-Weinstein Monofilament Exam)

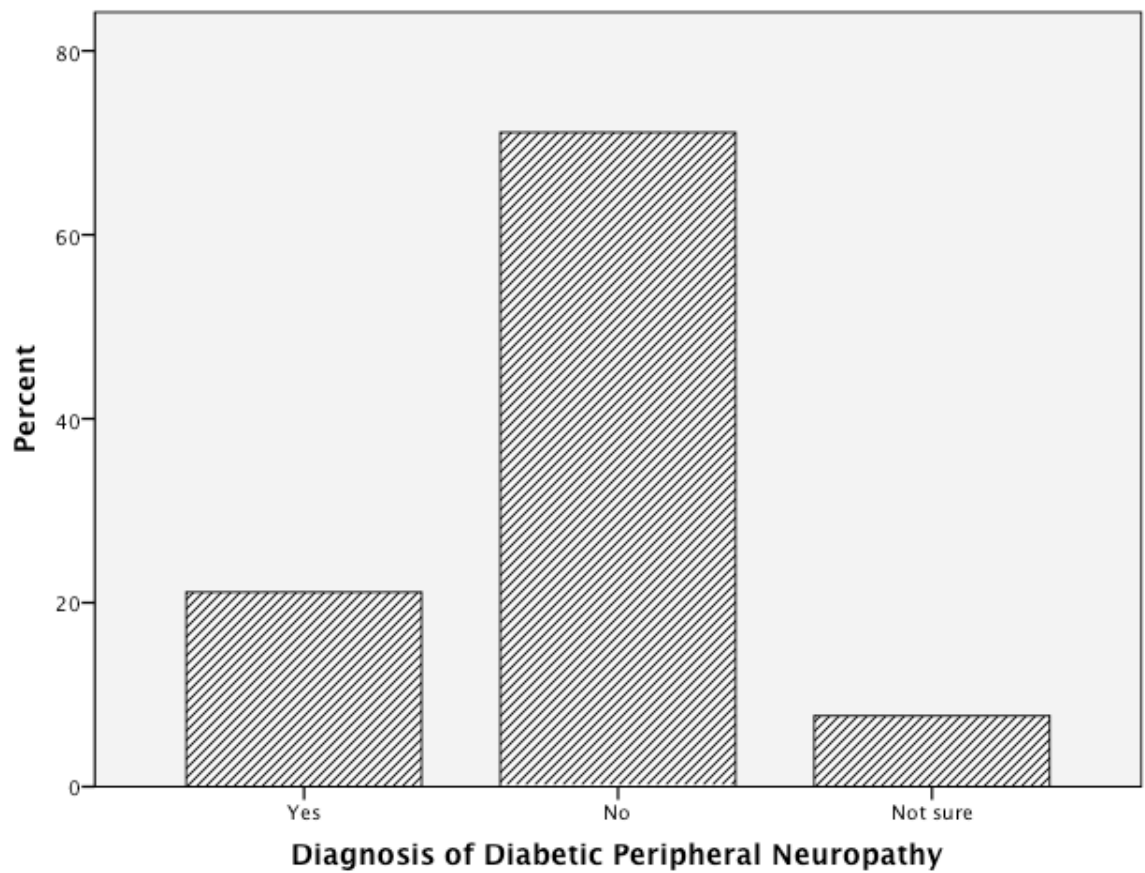


FIGURE 3: Proportion of Participants Reporting a Diagnosis of Diabetic Peripheral Neuropathy

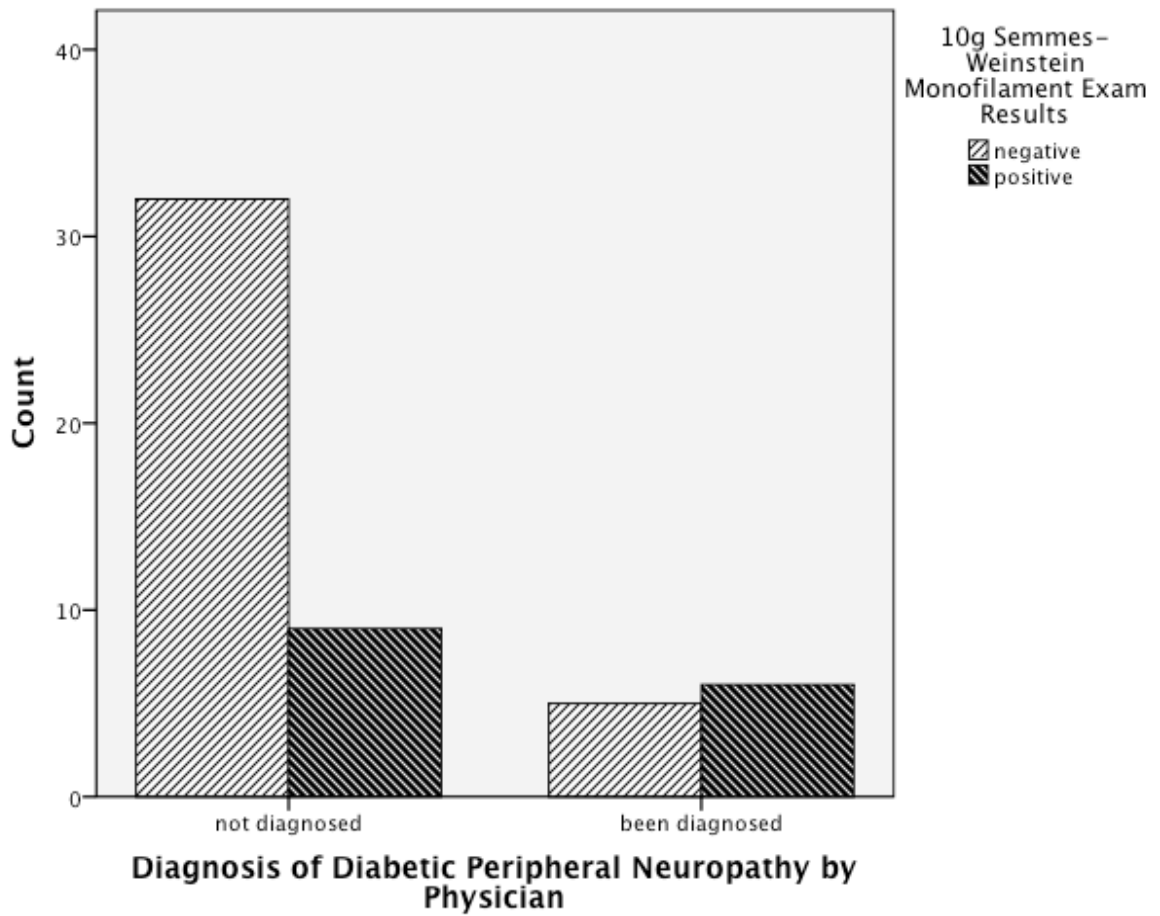


FIGURE 4: Comparison of Diagnosis of Diabetic Peripheral Neuropathy by Physician and Results of the 10g Semmes-Weinstein Monofilament Exam

Relationship between Frequency of Foot and Eye Exams Among Patients with Diabetes in a Rural Population

The ADA recommends that patients with diabetes receive a comprehensive foot and eye exam at least once per year, and more often if the patient is at an increased risk for, or has been diagnosed with diabetic peripheral neuropathy or diabetic retinopathy. To evaluate adherence to the ADA's recommendations for patients with diabetes having an annual eye exam, data were collected through the Qualtrics survey software regarding the last time participants received an eye exam. Through SPSS, survey responses were grouped into having an eye exam "within the last year," "over a year ago," or "unknown." Descriptive statistics were done that showed that 11.5% of participants had not had an eye exam in over a year, and 3.8%, or 2 participants, were not sure of how long it had been since their last eye exam.

Next, to analyze adherence to the ADA's recommendation that patients with diabetes have an annual foot exam, data were collected through the Qualtrics survey software regarding whether or not the physician managing the participant's diabetes performs regular examinations of the participant's feet. Participants were first asked whether or not their physician performs regular examinations of their feet to check for bone deformities, slow healing wounds, and loss of feeling. Then, participants were asked how frequently their doctor performed such foot exams. Survey responses were categorized through SPSS into either "yes, participant has foot exam at least once annually" or "no, participant does not receive annual foot exam." The results showed that 71.2% of participants receive an annual foot exam, and 28.8% of participants do not receive an annual foot exam.

Then, to determine whether there was a relationship between how frequently participants received foot and eye exams, a cross-tabulation was performed using the categories of survey responses mentioned above. An odds ratio was calculated to be 3.0, meaning that participants whose physicians performed regular foot exams were 3.0 times as likely to have an annual eye exam compared to participants whose physicians did not perform regular foot exams. By running a Pearson chi-square test, a two-sided p-value of 0.20 was obtained, and thus insignificant because the p-value was greater than 0.05.

It can be concluded that there was no statistically significant relationship between the frequency of having foot and eye exams. However, because there was a general trend that participants who receive annual foot exams are more likely to have an annual eye exam, the results may be significant from a clinical perspective. (See Figure 5: Comparison of the Proportion of Participants who had an Eye Exam within the Last Year Given that their Physician Performs Regular Foot Examinations)

Effect of Attending Diabetes Self-Management Class on Adherence to ADA's Recommendations for Foot and Eye Exams

To determine whether or not attending diabetes self-management class affects adherence to the ADA's guidelines for foot and eye exams, the proportion of participants who have attended diabetes self-management class was first determined. A survey question was developed through Qualtrics in which participants were asked whether they had ever attended a diabetes self-management class. The results were analyzed using SPSS to show that 38.5% of participants had never attended a diabetes self-management class, while 61.5% of participants had attended a diabetes self-management class.

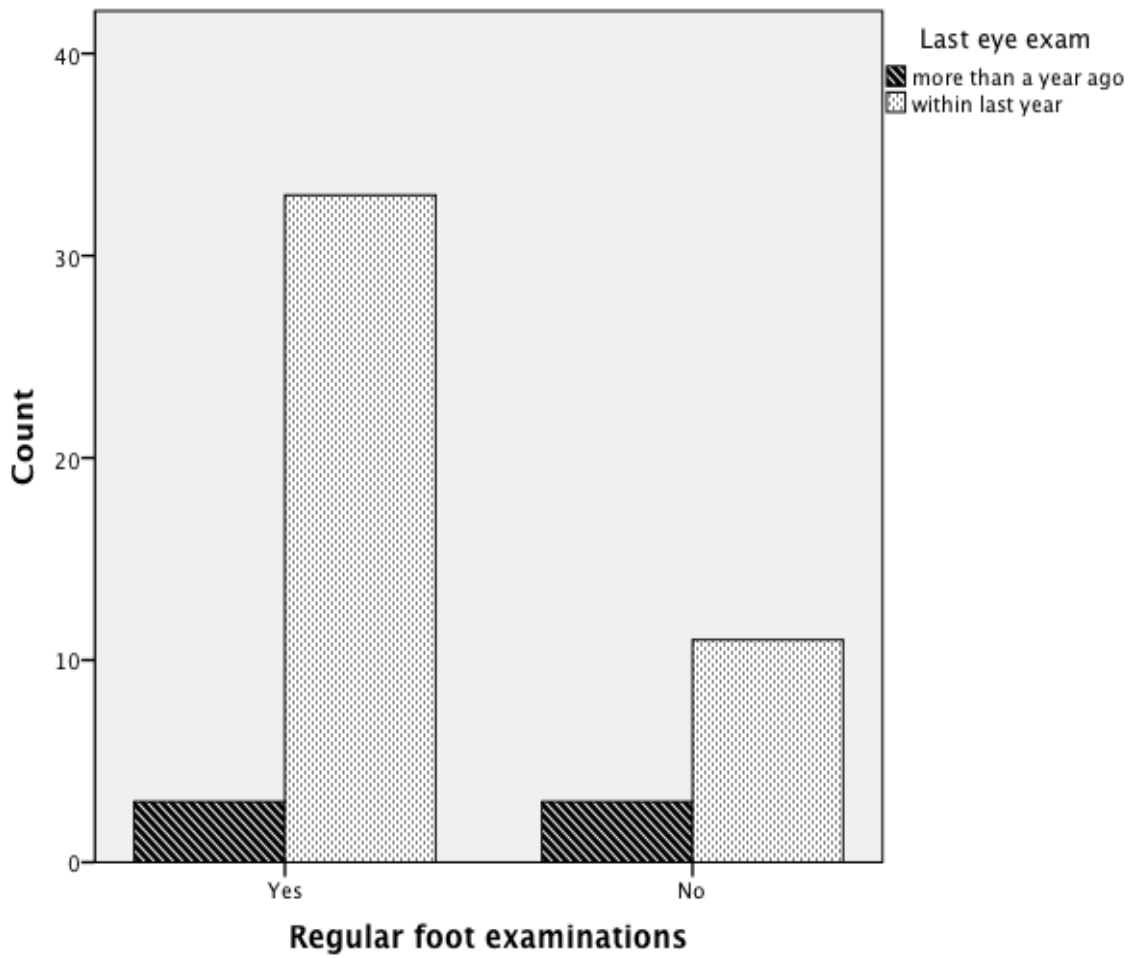


FIGURE 5: Comparison of the Proportion of Participants who had an Eye Exam within the Last Year Given that their Physician Performs Regular Foot Examinations

Next, a cross-tabulation was performed to determine whether attending a diabetes self-management class impacted adherence to the ADA's eye exam guidelines. Two participants were excluded from this analysis because they were unsure of the timing of their last eye exam. Out of the 31 participants included who had attended a self-management class, 90.3% had an eye exam within the last year. Out of the 19 participants who had not attended a self-management class, 84.2% had an eye exam within the last year. A Fisher's Exact Test was performed, and a two-sided p-value of 0.661 was obtained. Since $p > 0.05$, the results were not statistically significant.

Then, another cross-tabulation was done to evaluate whether attending a diabetes self-management class impacted adherence to the ADA's foot exam guidelines. Out of the 32 participants who had attended a self-management class, 78.1% reported having regular foot exams performed by their physician. Of the 20 participants who had never attended a self-management class, 60.0% reported having regular foot exams performed by their physician. A Fisher's Exact Test was done, and a p-value of 0.213 was obtained using a two-tailed analysis. Therefore, the results were not statistically significant since p was greater than 0.05. Although the effect of attending a diabetes self-management class was not statistically significant, there is a general trend that participants who attended a self-management class were more adherent to the ADA's recommendations for foot and eye exams.

DISCUSSION

Regularly testing for and monitoring the common health complications of diabetes mellitus plays a vital role in patient health care. Nearly half of all patients with diabetes are affected by diabetic neuropathies, a condition that can be deadly and debilitating without proper management. Ensuring that all patients with diabetes receive the proper care for such health complications as outlined by the American Diabetes Association is necessary and important. This is especially true in populations that have limited access to or education about diabetes management, such as in a rural setting. This study aimed to evaluate the prevalence of two of the common health complications of diabetes and to determine how well these conditions were being tested for and monitored in a rural population. By asking participants to provide information about their diabetes management and then checking their feet for neuropathy with the monofilament test, the investigator was able to compare their current understanding of their health with the results from a reliable test for diabetic peripheral neuropathy. Almost one-third of all participants showed signs of diabetic peripheral neuropathy through the monofilament test. With such a high percentage of participants affected, these results confirm the importance of testing for diabetic neuropathies. More importantly, over half of all participants identified by the 10g SWM to have diabetic peripheral neuropathy were undiagnosed by the physician managing their diabetes. Although not statistically significant, these results are of clinical significance since they provide evidence that a

considerable number of patients with diabetes in this rural population are not receiving proper care for these serious health conditions. With a larger sample size, the results could become statistically significant as well.

This study also analyzed whether there is a relationship between how frequently patients with diabetes have foot and eye exams. Knowing if there is a relationship can be helpful so that physicians may understand whether improving one area of patient care may have similar effects on other areas of patient care as well. The investigator first identified that over a quarter of all participants did not receive annual foot exams, and roughly 15% did not have annual eye exams. These results indicate that while the majority of patients with diabetes in this particular rural population were adherent to the ADA's recommendations for foot and eye exams, improvements are still necessary. More specific data related to diabetes management and prevention of disease complications in underserved areas is warranted; however, this study suggests that rural populations need greater attention and targeted educational programs to enhance the level of care.

The results also showed that participants who receive annual foot exams were three times as likely to have annual eye exams. Although these results were not statistically significant due to a limited sample size, the results hold some degree of clinical significance. Understanding the relationship between the management of health complications of diabetes is important. The results suggest that improvements in one area of patient care may positively affect other areas of patient care. This is especially helpful in rural populations where access to health care is often more limited. Encouraging adherence to one aspect of the ADA's guidelines for managing the complications of

diabetes can increase adherence to other aspects as well, leading to an overall improvement in patient health outcomes.

Another aspect of diabetes care analyzed by this study was whether attending a diabetes self-management class improved patient adherence to receiving annual foot and eye exams. The results showed that only about sixty percent of participants had ever attended a self-management class. Since such a low percentage of participants have received proper education about managing their diabetes, improvements in patient education in this rural populations are needed. Education about proper management of diabetes is crucial so that patients may understand what signs and symptoms to watch for and how to prevent some of the debilitating sequelae of diabetes.

Although the results were not statistically significant, it was found that there was a roughly six percent increase in the number of participants who had annual eye exams in the participants who had attended a diabetes self-management class compared to participants who had not attended a self-management class. Additionally, there was about a twenty percent increase in the number of participants who had annual foot exams in participants who had attended a self-management class compared to those who had not attended a self-management class. If a larger sample size had been used, these results could have been statistically significant. Regardless, these results certainly appear to possess significance clinically since there was an observed general trend that participants who have proper education about how to manage their diabetes have improved adherence to the ADA's guidelines for foot and eye exams. Understanding that education improves patient self-management provides support that educating patients and providing them with educational opportunities is valuable and can lead to improved health outcomes.

Proper management of diabetes includes more than just maintaining blood glucose levels. Patients with diabetes should be aware of the effects of diabetes on several other body systems. Patients and physicians should work together to ensure that patients are properly educated about the importance of having annual foot and eye exams. Furthermore, physicians should understand the importance of regularly examining their patients for potential complications of diabetes. Patients in rural populations are often at an increased risk for health complications due to limited access to health care facilities and fewer educational opportunities. Although greater patient care may be needed across all populations, it can be concluded from this study that patients in rural populations may be in need of additional improvements in patient care. In the rural population included in this study, there were a considerable number of patients who did not have regular foot and eye exams and who had undiagnosed diabetic peripheral neuropathy. The results verify the need for continued work toward greater diabetes care and provide insight into the value of diabetes self-management education.

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APPENDICES

Appendix A: Patient Survey

We will be looking at patients with diabetes. We want to see how many people have lost some feeling in their feet and how often they have their feet looked at by a doctor. To find this out, we want you to answer some questions that deal with your medical history in regards to diabetes, diabetes complications, and foot-care. Your name will not be recorded for any reason. The only information recorded will be whether you are male or female, your age, and your ethnicity. You may skip any questions that you do not feel comfortable answering. If you start the study and decide that you do not want to finish, you may stop at any time. Whether or not you choose to participate or to withdraw will not affect you in any way. Thank you in advance for your time!

1. Have you ever been diagnosed with diabetes?
 - a. Yes
 - b. No

2. If yes, what type of diabetes were you diagnosed with?
 - a. Type 1
 - b. Type 2
 - c. Gestational
 - d. I don't know

3. How many years have you been diagnosed with diabetes?

4. Does your physician perform regular examinations of your feet to check for bone deformities or slow-healing wounds?
 - a. Yes
 - b. No

5. Have you ever had a monofilament exam?
 - a. Yes
 - b. No
 - c. Not sure

6. If yes, about how many times have you had a monofilament exam? (skip to question 7 if you answered "no" to question 5)
 - a. One time
 - b. A few times
 - c. Once a year

- d. More than once a year
7. Have you ever been diagnosed with peripheral neuropathy?
- a. Yes
 - b. No
 - c. Not sure
8. If so, at what age were you first diagnosed with peripheral neuropathy?
- _____
9. Do you check your feet regularly for blisters, ulcers, calluses, and ingrown toenails?
- a. Yes
 - b. No
10. How long does it typically take for your foot wounds to heal?
- a. 2-4 days
 - b. About 1 week
 - c. About 2 weeks
 - d. Longer than 2 weeks
11. When was the last time you had an eye exam? _____
12. Has your doctor ever made you pee in a cup?
- a. Yes
 - b. No
13. Do you have microalbuminuria (protein in the urine)?
- a. Yes
 - b. No
14. Do you currently take medication for diabetes management?
- a. Yes
 - b. No
15. If yes, what type of diabetes medications do you take? Circle all that apply.
- a. Oral (pill)
 - b. Injection
 - c. Insulin
16. Do you take insulin?
- a. Yes
 - b. No
17. Do you take your medications as instructed?
- a. Yes
 - b. No

18. During the past 24 hours, how many different kinds of medication have you taken (including diabetic and non-diabetic medications)?

19. If you have taken medication in the last 24 hours, how many of the medications you have taken have been prescribed by your physician (including diabetic and non-diabetic medications)?

20. Have you ever attended diabetes self-management class?

- a. Yes
- b. No

21. What kind of physician do you see for your diabetes?

- a. Primary care physician/family doctor
- b. Endocrinologist
- c. Other

22. Do you know your last A1C (hemoglobin A1C)

- a. Yes
- b. No

23. If so, what was your last A1C (hemoglobin A1C)? _____

24. Do you smoke?

- a. Yes
- b. No

25. If so, about how many cigarettes do you smoke per day? _____

26. How many years have you smoked? _____

27. Age category:

- a. 18-25
- b. 26-30
- c. 31-35
- d. 36-40
- e. 41-45
- f. 46-50
- g. 51-55
- h. 56-60
- i. 61-65
- j. 66-70
- k. 71-75
- l. 76-80

m. 81+

28. Gender

- a. Male
- b. Female

29. Ethnicity:

- a. Caucasian
- b. African American/Black
- c. Hispanic/Latino
- d. Pacific Islander
- e. Native American/Alaskan
- f. Asian
- g. Other

Thank you for your participation!

Appendix B: Monofilament Exam Form

Insert your Health Center's Name Here

Diabetes Foot Screen

Adapted from LEAP Program 5/01

History of plantar ulceration? Yes No Date _____

Monofilament Exam: + = can feel the 10 gram nylon filament - = cannot feel the 10 gram nylon filament

Draw in:



Callus



Pre-Ulcer



Ulcer (note width/
depth in cm.)

Date: _____



Right Left

Date: _____



Right Left

Date: _____



Right Left

Is the patient:

able to see bottom of his/her feet?
wearing properly fitting shoes?

Yes / No
Yes / No

Yes / No
Yes / No

Yes / No
Yes / No

Foot Exam Results:

Normal / Abnormal

Normal / Abnormal

Normal / Abnormal

If **Abnormal** (circle which foot)

Foot ulcer Right / Left

Right / Left

Right / Left

Abnormal shape Right / Left

Right / Left

Right / Left

Toe deformity Right / Left

Right / Left

Right / Left

Thick or ingrown toenails Right / Left

Right / Left

Right / Left

Callus buildup Right / Left

Right / Left

Right / Left

Swelling Right / Left

Right / Left

Right / Left

Elevated skin temp Right / Left

Right / Left

Right / Left

Muscle weakness Right / Left

Right / Left

Right / Left

RISK CATEGORY

0 1 2 3

0 1 2 3

0 1 2 3

0 No loss of protective sensation


1 loss of protective sensation with no weakness, deformity, callus, Pre-ulcer, or history of ulceration

2 Loss of protective sensation with weakness, deformity, pre-ulcer, or callus but no history of ulceration

3 History of plantar ulceration/Charcot Foot

Referral made? Date and place referred: _____

Appendix C: Patient Consent Letter

	The University of Mississippi Institutional Review Board
Protocol #	<u>15-054</u>
Approval date	<u>04-14-15</u>
Expiration date	<u>04-13-16</u>
Signature	<u>Ashley Crumby</u>

CONSENT FORM

Consent to Participate in an Experimental Study

Title: Evaluation of the Prevalence and Treatment Trends of Peripheral Neuropathy among Diabetics in a Rural Population

Investigator

Lauren Daigle
Department of Pharmacy Practice
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(225) 588-9484

Advisor

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Department of Pharmacy Practice
201 Faser Hall
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INCLUDE THE FOLLOWING ONLY IF YOU ARE COLLECTING DATA EXCLUSIVELY FROM ADULTS

By checking this box I certify that I am 18 years of age or older.

Description

We will be looking at patients with diabetes. We want to see how many people have lost some feeling in their feet and how often they have their feet looked at by a doctor. To find this out, we want you to answer some questions and to allow me to perform a foot exam. The questions I want to ask you deal with your medical history in regards to diabetes, diabetes complications, and foot-care. The questions will be completed online and will remain secret. The second part of the study is the foot exam. We will ask you to remove your shoes and socks, have a seat, and close your eyes. A monofilament exam uses a piece of fishing line to check the feeling in your foot. We will touch portions of your foot with fishing line. These touches will be completely painless. You will be asked to reply "yes" when you feel the touch. The questions and the foot exam will take between 10-15 minutes to finish. We will explain the activity to you and you can ask any questions.

Risks and Benefits

You may feel uncomfortable because you may not do as well on the foot exam as you would like. We do not think that there are any other risks. We will discuss the results of your foot exam and what the results may mean for you in regards to having or developing peripheral neuropathy.

Cost and Payments

The questions and foot exam will take 10-15 minutes to complete. There are no other costs for helping us with this study. We will provide you with a copy of your exam results so that you may discuss them with your physician.

UM Protocol #15-054

Confidentiality

Your name will not be recorded for any reason. The only information recorded will be whether you are male or female and your age.

Right to Withdraw

You do not have to take part in this study. If you start the study and decide that you do not want to finish, all you have to do is to tell Lauren Daigle in person, by letter, or by telephone at the Department of Pharmacy Practice, 201 Faser Hall, The University of Mississippi, University MS 38677, or (225) 588-9484. Whether or not you choose to participate or to withdraw will not cause you to lose any benefits to which you are entitled.

The researchers may terminate your participation in the study without regard to your consent and for any reason, such as protecting your safety and protecting the integrity of the research data

IRB Approval

This study has been reviewed by The University of Mississippi's Institutional Review Board (IRB). The IRB has determined that this study fulfills the human research subject protections obligations required by state and federal law and University policies. If you have any questions, concerns, or reports regarding your rights as a participant of research, please contact the IRB at (662) 915-7482.

Statement of Consent

I have read the above information. I have been given a copy of this form. I have had an opportunity to ask questions, and I have received answers. I consent to participate in the study.

Signature of Participant Date

Signature of Investigator Date

**NOTE TO PARTICIPANTS: DO NOT SIGN THIS FORM
IF THE IRB APPROVAL STAMP ON THE FIRST PAGE HAS EXPIRED.**

UM Protocol #15-054