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The Influence of Clinically Meaningful Factors on the Performance of the Recommended Annual Diabetic Foot Screening

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A dissertation submitted in partial fulfillment of the requirements for the degrees of Doctor of Philosophy at Virginia Commonwealth University

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List of Abbreviations

ADA- American Diabetes Association
ADFSE- annual diabetes foot screening examination
BRFSS- Behavioral Risk Factor Surveillance System
CAD- coronary artery disease
CDC- Centers for Disease Control and Prevention
CFA- confirmatory factor analysis
CFI- comparative fit index
CMS- Centers for Medicare and Medicaid Services
COPD- Chronic obstructive pulmonary disease
CVA- cerebrovascular accident
DFU- diabetic foot ulcer
EMR- electronic medical record
HgbA1c- glycosylated hemoglobin/hemoglobin A1c
IWGDF- International Working Group on the Diabetic Foot
LEA- lower extremity amputation
MEPS- Medical Expenditures Panel Survey
MI- myocardial infarction
PCMH- patient centered medical home
PN- peripheral neuropathy
PQRI- Physicians Quality Reporting Initiative
PQRS- Physicians Quality Reporting System
PVD- peripheral vascular disease
RMSEA- root mean squared error of approximation
SEM- structural equation modeling
SMBG- self-monitoring blood glucose
T1DM- type 1 diabetes mellitus
T2DM- type 2 diabetes mellitus
VHA- Veterans Health Administration

Abstract

THE INFLUENCE OF CLINICALLY MEANINGFUL FACTORS ON THE PERFORMANCE OF THE RECOMMENDED ANNUAL DIABETIC FOOT SCREENING

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Background: Diabetic foot ulcers are the result of multiple complications from hyperglycemia and lead to poor quality of life and high healthcare costs. The annual diabetes foot screening exam (ADFSE) and prevention interventions can reduce DFUs up to 75%. In 2015, 71% of the US population received the ADFSE.

Objectives: The main objectives of this dissertation were: 1) to determine the association between adherence to diabetes self-management behaviors and the ADFSE, 2) to determine the association between concordant and discordant comorbidities and the ADFSE and 3) to determine the association between the performance of diabetes preventive care processes, number of office visits for diabetes and the completion of the ADFSE.

Methods: Three cross-sectional studies used data from the 2015 Behavioral Risk Factor Surveillance System. Logistic regression models were evaluated to assess the association between the self-management behaviors and the ADFSE. Structural equation modeling (SEM) was used to assess the simultaneous, direct effects of concordant and discordant comorbidity loads on the ADFSE and the performance of diabetes preventive care processes and the number of office visits for diabetes care on the ADFSE.

Results: In 2015, between 78.2% and 80.4% of the US population with diabetes received the ADFSE. Performance of the ADFSE was 77% less likely (OR: 0.33, 95%CI: 0.25-0.44) in those who do not perform self-foot inspections and 40% (OR: 0.59, 95%CI: 0.45-0.76) less likely in those who have never received the pneumococcal vaccination. Receiving the ADFSE was 50-80% less likely in patients who do not self-monitor blood glucose at least one time per day, depending on insulin use and receipt of diabetes education. Neither concordant comorbidities (β=0.226, p=0.086) nor discordant comorbidities (β=0.080, p=0.415) had a direct association with the performance of the ADFSE. The collection of preventive care processes demonstrated a 7% (OR: 1.07, 95% CI: 1.05-1.10) increase in the likelihood the ADFSE was performed

Conclusions: Performance of the ADFSE may be improved through multiple types of interventions. Patient-based interventions to increase adherence to self-management behaviors is one route. Programs to improve overall diabetes care in the clinical setting may also help to further improve completion of the ADFSE.

CHAPTER 1: Background

BACKGROUND

Physiology and Epidemiology of Diabetes Mellitus

According to the estimates by the US Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics, it is estimated that over 30 million people, over the age of 18, are currently living with diabetes in the US (1). Nine percent of US residents have been diagnosed diabetes mellitus but nearly 3.0% of the US population remain undiagnosed (2). The prevalence is expected to increase to 21-33% by 2050 (3). Diabetes is a metabolic disease that affects the body's ability to produce or use insulin. Type 1 diabetes mellitus (T1DM) is characterized by the destruction of pancreatic β-cells and an absolute insulin deficiency, affects 5-10% of the population (4). Seventy-five percent of TIDM cases occur in children and adolescents (5). Type 2 diabetes mellitus (T2DM) is characterized by the combination of insulin resistance in tissues and dysfunctional insulin secretion. T2DM is the cause of 90-95% of cases of diabetes. Both patient populations could experience periods of hyperglycemia, or plasma blood glucose ≥200 mg/dL, which leads to complications. Some of the common complications of diabetes are neuropathy, nephropathy, retinopathy and heart disease (6). These complications are the leading causes of blindness, renal failure and non-traumatic amputations in the US (7). As a consequence of these complications, diabetes remains the 7^{th} leading cause of death in the United States and resulted in almost 80,000 deaths in 2015 (2). The total cost of care for diabetes is estimated to be over $245 billion, which is more than 2.3 times higher than care for those without diabetes (8). Given the expected increase in prevalence, the high mortality rate and high cost of the disease, it is imperative to focus on prevention of diabetes and its complications.

Much of the healthcare costs for diabetes is due to the complications. Neurologic complications include peripheral neuropathy (PN), the loss of sensation beginning in the feet and hands, which can affect 29-60.8% of the diabetes population (9, 10). Peripheral vascular disease (PVD) and cardiovascular disease (CVD) rates are higher in the diabetes population due to the acceleration of atherosclerosis and thrombus formation (6, 11). About 10% and 32% of people with diabetes report PVD and CVD, respectively (9, 12). Retinopathy affects up to 62% of the US diabetes while almost 37% have some degree of chronic nephropathy (8, 10). Finally, the combination of PN and PVD can lead to diabetic foot ulcers (DFU) and lower extremity amputations (LEA).

More than one-quarter of the national spending on neurological, peripheral vascular, cardiovascular and renal conditions are attributed to those with diabetes (13). In 2014, rates of hospitalization per 1,000 persons with diabetes were 18.3 for ischemic heart disease, 11.5 for cerebrovascular accident (CVA) and 5.0 for LEA (8). In addition to hospitalization, more than 14 million people with diabetes visited the emergency department for some type of care. These emergent visits contributed to the average individual annual health care expenditure of $13,700 (8). DFUs and LEAs, the result of neuropathy, PVD and CVD, are the leading causes of hospitalization and cost the US health care system more than $9 billion (14, 15).

The Diabetic Foot

One major complications of diabetes occurs in the foot and is due to the pathophysiology of hyperglycemia. Chronic hyperglycemia leads to both microvascular (PN, retinopathy, and nephropathy) and the macrovascular (CVD, PVD) damage to tissues (16-18). In addition, the immune system response is blunted leading to poor wound healing and increased risk of wound infection (7). The development of the diabetic foot usually begins with PN. Diabetic PN affects the sensory, motor and autonomic branches of the peripheral nervous system (19). Sensory neuropathy results in the loss of ability to detect light touch, vibration, temperature and pain (20). In diabetes, sensory neuropathy typically bilateral and begins in the toes and then moves proximally as the disease progresses. As a result, individuals with sensory neuropathy are unable to detect minor trauma. The nerves innervating the intrinsic muscles of the foot are also damaged by hyperglycemia and result in motor neuropathy. The resulting muscle weakness leads to skeletal deformities such as hammer toes, claw toes and an unstable arch, which, in turn, creates areas of excessive pressure which are prone to tissue injury (7, 19). Finally, autonomic neuropathy leads to impaired blood flow regulation as well as anhidrosis and dry skin that is prone to cracking and fissuring (19). These conditions place the foot at risk for invasion by bacteria and fungus and ultimately wound development.

Diabetic Foot Ulcers

Any injury to the diabetes foot can progress into a DFU. A DFU results from a break in the skin, into or beyond the dermis, which fails to heal in a timely fashion (7, 21). The most common causal pathway for the development of a DFU is through the combination of sensory neuropathy, foot deformities from motor neuropathy and minor traumatic events to the feet (22). An international clinical study found that among patients with a prior DFU nearly 80% had sensory neuropathy, 63% had a foot deformity and 77% reported minor trauma that incited the DFU. Other components of the DFU causal pathway may include: PVD, impaired capillary blood flow, the presence of calluses, and edema. Due to impaired immune system function and the high prevalence of decreased blood flow in the diabetes population, DFUs are difficulty to heal and prone to infection.

The lifetime risk of developing a DFU can be as high as 34% in the diabetes population (23). The incidence of DFU is estimated between 1.9-4.1% annually and if healed, the recurrence rate is as high as 70% (24). Amongst the Medicare population, the incidence rate is higher, at 6.0%, with an annual prevalence of 8.0% (25, 26). The management of DFUs costs the US healthcare system between $9 and $13 billion annually with 77% of the cost is due to inpatient hospital admissions (15, 24).

Lower Extremity Amputation

When medical treatment fails, LEA, the most severe lower extremity consequence of diabetes, is the only option (24). LEAs occur 15 times more often in those with diabetes than in those who do not have diabetes, and 85% of all diabetes LEAs are preceded by a DFU (21). At least 5.0 LEAs per 1,000 persons with diabetes were performed in the US in 2014 (8). LEAs in the Medicare population increase average annual reimbursement to over $54,000 (27).

Perhaps the greatest cost of DFUs and LEAs is mortality. The 5-year mortality rates for diabetes patients is 45-55% and 47% for those with a DFU and LEA, respectively (28). These mortality rates are higher than most cancers, and only pancreatic and lung cancers are more deadly (29). On the contrary, prevention strategies to reduce DFUs and LEAs only cost 10% of the total treatment costs for the conditions, making prevention an ideal target to address this large public health problem (29, 30).

Diabetic Foot Ulcer Prevention and the Recommended Annual Diabetes Mellitus Foot Screening Examination

Evidence has shown that up to 75% of DFUs and 49-85% of LEAs, were preventable through cost effective screening and prevention programs (31, 32). All prevention programs begin with foot screening exam to determine the risk of developing a DFU. The American Diabetes Association (ADA) and the International Working Group on the Diabetic Foot (IWGDF) recommend an annual diabetes foot screening examination (ADFSE) be performed at least once per year on all patients with diabetes over the age of 18 (33-35). Patients with abnormal screenings should have a foot examination on every visit to a health care professional (33, 36).

The ADFSE should include: patient history, general visual foot inspection for dermatologic problems, and musculoskeletal, neurologic and vascular examinations. All portions of the ADFSE can be performed by a variety of health care providers including physicians, nurses, physical therapists and pharmacists, requires minimal specialty equipment and can be performed in less than 5 minutes (37). Despite these national estimates indicate only 71% of the US population received the ADFSE in 2012 (38). Clinical reports of ADFSE completion vary from 12% to 95% adherence (39-46). Prior research has identified race, gender, age, education, insurance and rural residency as factors that influence the performance of the ADFSE (47-49). However, other clinically meaningful patient level factors, such as diabetes self- management behaviors adherence, the influence of comorbidities and factors related to clinical care are still not well understood. Some of these clinically meaningful patient level factors can be explored using a conceptual framework on competing demands presented by Piette and Kerr (50).

Conceptual Model- Piette and Kerr Framework for Competing Demands

The Piette and Kerr framework for competing demands on diabetes care demonstrates that diabetes specific care and health are influenced directly by diabetes self-management behaviors, diabetes medical management as well as comorbidity self-management behaviors and medical management. Further it suggests that these care processes are not only influenced by patients' and clinicians' priorities and resources but also by healthcare organizations. This framework has been utilized in prior research to explore how patient level and clinical factors have influenced the care of patients with diabetes (51-55). This dissertation explored the direct relationships between performance of the ADFSE and three of the major pathways of the Piette and Kerr conceptual model.

Aim 1. To determine whether patient performance of 8 individual diabetes mellitus self-management behaviors are associated with clinicians' decisions to perform the ADFSE.

Aim 2. To assess the simultaneous, direct effects of concordant and discordant comorbidities on the performance of the annual diabetes foot screening exam (ADFSE), using structural equation modeling (SEM), to simulate clinical decision making.

Aim 3. To examine the relationship between the performance of other diabetes preventive care processes, number of office visits for diabetes services and the completion of the recommend ADFSE.

Based on knowledge generated by these studies, clinicians and policy makers will be provided with more information on how to improve the performance of the ADFSE. Improved screening of the diabetes foot will lead to early recognition and better management of diabetic foot problems, and ultimately reduce the major health and economic burdens for patients with diabetes and our society at large.

Diabetes Self-management Behaviors and the ADFSE

Patient participation in the management of diabetes is imperative to achieving good outcomes and preventing complications and is, thus, strongly supported by the ADA and other national and international organizations (56-58). The recommended self-management behaviors and reported rates of patient adherence are listed in Table 1-1. Adherence to these self-management behaviors can result in improved hemoglobin A1c (HgbA1c) control, reduced visceral adipose tissue and plasma triglycerides which, in turn, can reduce the risks of comorbidities and complications associated with diabetes, including DFU and LEA (59, 60). In the conceptual model by Piette and Kerr, diabetes self-management behaviors are characterized as important factors that could directly influence diabetes health care, including performance of the ADFSE (50).

Table 1-1 - Recommended diabetes self-management behaviors and reported rates of adherence (56, 57, 61-64)

Diabetes self-management behavior	Reported rate of adherence
Self-monitoring blood glucose	42-64%
Healthy eating/Diet modification	50-81%
No smoking	75%
Self-foot care	20-60%
Being physical active	50-78%
Receive influenza vaccination	50%
Receive pneumococcal vaccination	43%

A cross-sectional study among patients with T1DM in Pittsburg, Pennsylvania found no association between performing self-monitoring of blood glucose (SMBG) at least once per week and changing insulin dosing based on blood glucose levels (42). However, those who performed SMBG at least once per day had an almost 2-fold increasing odds of receiving the ADFSE (41).

A cross-sectional study among Asian-Americans found no association between tobacco usage and alcohol consumption and the performance of the ADFSE (65). The heterogeneity of the study samples, self-management behaviors and preventive care behaviors studied limits comparability and generalizability to the US population. Thus this dissertation aimed to determine the association between patient adherence to diabetes self-management ADFSE using nationally representative data.

Comorbidities and the ADFSE

The medical management of patient with diabetes is complicated by the presence of other comorbidities and quality of diabetes care must be viewed in this light. Diabetes care comes with a collection of recommended preventive care processes, including the ADFSE. All these processes must be completed in the limited time available during an office visit along with the preventive care processes for other comorbidities. In clinical practice, the number of recommended preventive care processes varies based on each patient's comorbidities.

National estimates showed that amongst those with diabetes in the US, nearly 85% were overweight or obese, 57% had hypertension and over 58% had hypercholesterolemia (66). In those aged over 35, coronary artery disease (CAD) and myocardial infarctions (MI) affect nearly 22% of those with diabetes, while over 9% have suffered a CVA (67). Nearly 10 years ago, 90% of the US diabetes population had at least one other comorbidity and more than a quarter had 5 or more (68). Given these high rates of comorbidities and multiple concurrent comorbidities, it is imperative to understand how they affect diabetes quality of care, in particular, the ADFSE.

The association between comorbidities and diabetes preventive care processes has been explored in multiple studies by operationalizing comorbidities as a total count, individual comorbidities or classified as concordant or discordant with diabetes care processes (52, 54, 55, 68-71). Thus far, the literature has suggested that comorbidity counts, individual comorbidities, and types of comorbidities may all exert an influence on the performance of diabetes preventive care processes. However, no studies in the US have investigated the relationship between comorbidities and the ADFSE. Two international studies found no significant relationship between comorbidities classified as concordant or discordant with diabetes care and the performance of the ADFSE (72, 73). Given the paucity of research regarding the association between comorbidities and the performance of the ADFSE, this dissertation sought to explore these relationships.

Visit Frequency, Competing Demands and the ADFSE

The final pathway of the Piette and Kerr model explored in this dissertation was the association between "Diabetes Medical Management" and overall diabetes care (50). Diabetes medical management can include the provision of preventive care processes, diabetes medication management, management of concurrent comorbidities, patient behavior counseling and other competing demands (45, 74-76). Health care providers are faced with the need to prioritize delivery of preventive care processes during each patient visit which contributes to the observed suboptimal rates of preventive care delivery (74, 77, 78). Further understanding of the influence of these competing demands is necessary to improve the rates of preventive care delivery, including the ADFSE for patients with diabetes.

No available research has explored the influence of clinical competing demands on diabetes care. However, a study utilizing cross-sectional data from Michigan investigated the influence of diabetes preventive care processes on the performance of mammograms and Pap smears in female patients with diabetes (79). Both the performance of mammograms and Pap smears increased significantly as the number of completed diabetes care processes increased. While the individual diabetes care processes were not investigated, this study demonstrated improved diabetes preventive care positively influences other preventive health care processes in the female population. It is possible that completion of other diabetes preventive care processes may help improve rates of completion of the ADFSE. Unfortunately, no published research has directly explored this association.

Multiple cross-sectional studies have investigated the influence of the number of visits to a health provider on the performance of diabetes preventive care processes. Three studies found a positive association between patients having 4 to 8 office visits and the performance of HgbA1c testing (65, 68, 80). Looking specifically at the performance of the ADFSE, positive associations between number of visits to a health care provider and the ADFSE were found in populations of patients with T1DM, Asian-Americans with diabetes and among participants in the Medical Expenditures Panel Survey (MEPS) (41, 65, 68). Overall, no studies have addressed the influence of both clinical competing demands and the patient visits frequency on the performance of ADFSE.

CHAPTER 2: Description of the dataset

THE BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM

To address the proposed aims, this dissertation used data from the 2015 Behavioral Risk Factor Surveillance System (BRFSS). The BRFSS is a cross-sectional, annual survey administered by the CDC and conducted via land-line and cellular telephones (81). The BRFSS interviews non-institutionalized US residents, over the age of 18 years. The system is designed to collect information on preventive health care practices, health risk behaviors, chronic diseases, injuries and preventable infectious diseases that affect the US adult population. Data is collected by each state's health department, using computer aided telephone interviewing, to provide state-specific information. Data is then compiled into a national database by the CDC. The methods for sample weighting to account for the complex sample design are described elsewhere (82). For this study, the BRFSS sample weighting was utilized to determine nationally representative estimates.

The BRFSS utilizes a disproportionate stratified sample study design to collect the landline samples (81). Since 2008, sampling frames for cellular telephones are obtained from the Telecordia database. The BRFSS questionnaire is comprised of a core component, conducted in every state, and optional modules on specific topics, including diabetes (81). The core component gathers demographic information, health conditions and health behaviors. Each state then determines which optional modules to conduct. The states participating in each optional module are available online (83).

An optional module, asking 10 questions specific to diabetes care is available in the 2015 BRFSS dataset. In 2015, 38 states participated in the diabetes optional module (83). All survey respondents who responded "yes" to the question "Has a doctor, nurse or other health professional every told you that you have diabetes?" in the core component were included in the sample eligible to participate in the diabetes optional module. Respondents indicating the diagnosis of gestational, borderline or pre-diabetes were excluded from the diabetes Module. The diabetes module includes questions about diabetes specific self-management activities and recommended preventive care processes. However, the module did not include information on use of oral medications to manage diabetes. While the module did ask respondents if they used insulin, it did not include information type of insulin use (basal rate vs. basal rate and bolus). A total of 38,224 BRFSS participants were eligible to participate in the optional diabetes module.

CHAPTER 3: Are Diabetes Mellitus Self-management Behaviors Associated with the Receipt of the Recommended Annual Diabetes Foot Screening Examination?

ABSTRACT

Objective: To determine whether patient performance of 8 individual diabetes mellitus self-management behaviors are associated with clinicians' decisions to perform the annual diabetes foot screening exam (ADFSE).

Research Design and Methods: We utilized the 2015 BRFSS data from 38 states (n=14,825) to conduct a cross-section study. Respondents who provided a valid responses for the ADFSE and had at least one visit to a healthcare providers in the past 12 months were included. Eight separate multivariable logistic regression models were evaluated to assess the association between the self-management behaviors and the performance of the ADFSE.

Results: Among adults with diabetes mellitus and at least one visit to a health provider, 78.3% received an ADFSE. The most commonly performed self-management behaviors were performance self-monitoring of blood glucose (SMBG) and self-foot inspections, both at least one time per day. After controlling for covariates, performance of the ADFSE was 77% less likely (OR: 0.33, 95%CI: 0.25-0.44) in those who do not perform self-foot inspections and 40% less likely (OR: 0.59, 95%CI: 0.45-0.76) in those who have never received the pneumococcal vaccination. Patients who do not perform SMBG and do not use insulin or have not had formal diabetes education are 48% less likely (OR: 0.52, 95%CI: 0.38-0.82, OR: 0.52, 95%CI: 0.36-0.74, respectively) to receive the ADFSE. Finally, those who do not practice SMBG and did receive diabetes education are 81% less likely (OR: 0.19, 95%CI: 0.09-0.94) to receive the ADFSE.

Conclusions: Some diabetes mellitus self-management behaviors are associated with the performance of the ADFSE. Future exploration of the casual relationship between diabetes mellitus self-management behaviors and the resultant effects on the performance ADFSE will

provide further information on potential intervention that can increase the performance of this potentially life-saving screening exam.

INTRODUCTION

The lifetime risk of developing a diabetic DFU can be as high as 34% (23). In 2010, more than 77,000 people were hospitalized with an infected DFU and 17% of cases resulted in an LEA (84). The management of DFUs costs the US healthcare system more than $9-13 billion per year, in addition to the baseline cost of the care for diabetes mellitus (15). Despite advances in wound care, more than 60% of DFUs remain unhealed after 20 weeks of standard wound care (85). The 5-year mortality rate for the population with a DFU or LEA resulting from a DFU is between 29% and 50% (28, 86).

Evidence has shown that up to 75% of DFUs and 49-85% of LEAs were preventable through cost effective screening and prevention programs (31, 32). Primary prevention of DFUs in the general US population with diabetes can be effective and cost-saving, however, in 2015 only 71.6% of the US population with diabetes received an ADFSE (87, 88). While the rates of ADFSE performance, based on national surveys, have increased from 64.6% in 2002 to 71.6% in 2015, more than 8.6 million US residents with diagnosed diabetes did not received the ADFSE in 2015 (1, 89). Given the ADFSE is both cost-saving for the US health system and the first step in prevention efforts, it is imperative to identify populations at risk of not being screened and promote effective interventions to increase ADFSE rates (87).

A conceptual model to describe competing demands for diabetes care, developed by Piette and Kerr, describes diabetes self-management behaviors as an important factor that could directly influence the provision of diabetes-specific care, including the ADFSE (50). While previous studies have utilized this framework to explore how patient level and clinical factors influence the care of patients with diabetes, none have explored the role of self-management behaviors on the performance of the ADFSE (51, 52, 54, 55).

Prior studies have found the performance of some diabetes self-management behaviors have positive associations with the performance of diabetes specific screening procedures, such as fasting lipid profiles, urine protein analysis and HgbA1c testing (41, 42, 65). Other studies specifically examined the performance of the ADFSE. Among a small sample of individuals with T1DM, weekly SMBG did not influence the performance of the ADFSE nor other screening procedures. However, when SMBG was performed at least once daily in this study population, the odds of patients receiving the ADFSE nearly doubled (41). A study among a nationally representative sample of Asian-Americans with diabetes mellitus found no relationships between tobacco usage and alcohol consumption and the performance of the ADFSE (65).

Overall the literature on the association between diabetes self-management behaviors and the performance of the ADFSE is limited. The heterogeneity of the study samples, self-management behaviors and preventive care behaviors studied limit comparability and generalizability. Thus, the objective of the current study was to determine whether patient completion of 8 individual diabetes mellitus self-management behaviors are associated with clinicians' decision to perform the ADFSE.

RESEARCH DESIGN AND METHODS

Data Source and Sample

This was a cross-section study using data from the 2015 BRFSS. The BRFSS is designed to collect information on preventive health care practices, health risk behaviors, chronic diseases, injuries and preventable infectious diseases among non-institutionalized US residents, over the age of 18 years (81). The methods for sample weighting to account for the complex sample design are described elsewhere (82).

An optional module, asking 10 questions specific to diabetes care was available in the 2015 BRFSS dataset (90). In 2015, 38 states participated in the Diabetes Mellitus Optional Module (Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, Wyoming) (83). The Diabetes Mellitus Optional Module includes questions about diabetes mellitus specific self-management activities and recommended preventive care processes, including the ADFSE. All survey respondents who responded "yes" to the question "Has a doctor, nurse or other health professional every told you that you have diabetes?" in the core component were included in the sample eligible to participate in the Diabetes Mellitus Optional Module. Respondents indicating the diagnosis of gestational, borderline or pre-diabetes mellitus were excluded from the Diabetes Mellitus Optional Module in the BRFSS survey design. A total of 36,085 of the 2015 BRFSS participants were eligible to participate in the Diabetes Mellitus Optional Module.

To be included in the study sample respondents must have a valid response to the study outcome question, at least one foot and had at least one visit to a health provider for diabetes mellitus care in the past year. One thousand, nine hundred and sixty-five respondents did not provide a valid response to the outcome question and were thus excluded from the study. The BRFSS question "About how often do you check your feet for any sores or irritations?" was used to identify respondents without feet. Three-hundred and forty-nine individuals gave the response of "no feet" were excluded from the analytic sample. Having at least one visit to a health provider for diabetes mellitus care in the past year was determined utilizing the question "About how many times in the past 12 months have you seen a doctor, nurse or other health professional for your diabetes?" The responses were dichotomized to "yes- at least one visit" or "no, no visits." Respondents who had no visits to a health provider or did not provide a valid response were excluded from the study sample (n=3,656). BRFSS respondents who did not provide a valid response for all exposure, covariate and confounding variables were also excluded (n=15,292). After all exclusions were considered, the total sample size for this study was 14,823.

Measures

The primary outcome of this study was defined as having at least one ADFSE in the past year. The study outcome variable was created from the question "About how many times in the past 12 months has a health professional checked your feet for any sores or irritations?" Continuous numerical responses were dichotomized to "yes, at least one time" or "no." The main exposures of interest for this study were self-management behaviors for people with diabetes mellitus that were included in the 2015 BRFSS questionnaire. These behaviors included SMBG, performance of daily self-foot inspections, annual receipt of the influenza vaccine, receipt of a pneumococcal vaccine at any time, meeting aerobic and resistance exercise recommendations, smoking status, and alcohol consumption.

The 2015 BRFSS Diabetes Module asked respondents "About how often do you check your blood for glucose or sugar?" Responses were given as continuous number of times per day, week, month or year. Based on the goal for Healthy People 2020 the variable was dichotomize to "yes, at least one time per day" and "no, less than one time per day" (91). The International Working Group for the Diabetic Foot recommends people with diabetes mellitus , or their caregiver, visually inspect their feet for changes on a daily basis (36). Thus the original, continuous responses to the question "About how often do you check your feet for any sores or irritations?" was dichotomized to "yes, at least one time per day" and "no, less than one time per day." For the receipt of the influenza vaccine in the past 12 months, the question "During the past 12 months, have you had either a flu shot or a flu vaccine that was sprayed in your nose?" was utilized. Receipt of the pneumonia vaccine was determined by the question "Have you ever had a pneumonia shot?" For both vaccination questions the original responses to the questions were either "yes received vaccine" or "no did not receive vaccination." Based on ADA recommendations, the 2015 BRFSS used data collected from multiple questions to calculate a variable to indicate if a respondent "participated in 150 minutes (or vigorous equivalent of minutes) of physical activity per week" (56). These responses were categorized by BRFSS as "yes, performed 150+ minutes of physical activity per week" and "no, did not perform 150 minutes of physical activity per week." The ADA also recommends performance of resistance exercise training 2 days per week (56). The 2015 BRFSS contains the question "During the past month, how many times per week or per month did you do physical activities or exercises to strengthen your muscles?" was used. Responses are given as the number of days per week or month. This study dichotomized responses to "met recommendation" and "did not meet recommendations." The BRFSS contains a calculated variable to indicate if a respondent was a current smoker or not and this was utilized without change (90). Finally, the ADA recommends that males with diabetes mellitus drink no more than 2 alcoholic beverages per day and women no more than one per day (56). The 2015 BRFSS contains a variable that indicates whether a male had more than 14 drinks per week and a women had more than 7 drinks per week and this was used to define a variable for excessive alcohol usage (yes/no) (90).

To increase comparability with existing literature this study utilized covariates similar to variables utilized in prior research (41, 65, 92, 93). These included sex, age, race, education, marital status, annual household income and insurance status. Potential confounders included the number of visits to a health provider for diabetes mellitus care, number of years with diabetes mellitus, self-reported health status and comorbidities including hypertension, hypercholesterolemia, CVD, obesity, and depression. These potential confounders have all been shown to be associated with adherence to self-management in people with diabetes mellitus (41, 51, 65, 94, 95). Previous studies have shown that insulin use and formal diabetes mellitus education modify the association between a diabetes self-management behavior and the performance of diabetes mellitus preventive care processes (65, 93, 94). Thus, this study assessed insulin use and receipt of diabetes mellitus education as potential effect modifiers.

Statistical Analysis

All analyses were conducted with adjustments for the complex sample design of the BRFSS to provide population estimates that represent the 38 states that participated in the 2015 Diabetes Mellitus Optional Module (82). Descriptive statistics for the total study population and stratified by who received and did not received the ADFSE, were calculated for all variables. The sub-populations were compared through chi-squared tests to determine if statistically significant differences existed between the study groups.

Eight separate multivariable logistic regression models were evaluated to assess the association between each of the self-management behaviors and the ADFSE. Hierarchical backward elimination was conducted to identify a parsimonious model for each self-management behavior (96). Initial models contained a single self-management behavior, all covariates, all confounders and both effect modifiers. First, one-way effect modifications, by status of insulin use or receipt of diabetes mellitus education, were assessed. Full and reduced models were compared using the likelihood ratio test where $p<0.05$ was considered a significant difference between models. Significant interactions ($p<0.05$) were retained in the model and the results were stratified by the effect modifier for reporting. Following assessment for effect modification, confounding was assessed using the 10% change-in-estimate method (96).

Sensitivity analyses were conducted for each model to determine the potential for bias due to non-response to the study outcome of interest. For this analysis, the 1,965 respondents, originally excluded for an invalid response to the outcome question, were classified as either all having had the ADFSE or all not having had the ADFSE. The final models for each of the eight self-management behaviors were then re-calculated to determine the odds ratios and 95% CIs assuming the missing respondents did or did not receive the ADFSE. All analyses for this paper were generates using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Table 1 presents the weighted percentages of the characteristics of the study population (n=14,823). In 2015, 78.3% of persons aged 18 years and older, with diagnosed diabetes mellitus and at least one visit to a healthcare provider for diabetes mellitus care received at least ADFSE in the past 12 months. Fifty-one and nine-tenths percent (59.1%) of the population with diabetes mellitus were male, 59.4% were under the age of 65 years and 60.1% were non-Hispanic white. Nearly 95% of people with diabetes mellitus had some form of health insurance. A majority of the study population reported having hypertension (71.9%) and high cholesterol (64.3%), while 24.2% reported some type of CVD and 23.9% reported having depression. A majority of the study population received formal diabetes mellitus education (59.0%), reported time since diagnosis of diabetes mellitus of 10-19 years (34.8%) and "good" or better self-rated health (55.1%).

Table 3-1- Characteristics of persons aged ≥18 years with diagnosed diabetes, 38 states (n=14,823)*							
	Study population		Received annual diabetes foot screening exam in past 12 months				P value‡
			Yes 78.3±1.10%†		No 21.7±1.10 %†		
	%	SE	%	SE	%	SE	
Sex							
Male	51.9	1.3	52.7	1.4	49.1	2.9	0.273
Female	48.1	1.3	47.3	1.4	50.9	2.9	
Age (years)							
18-64	59.4	1.2	58.0	1.4	64.7	2.7	0.0322
≥65	40.6	1.2	42.0	1.4	35.3	2.7	
Race							
Non-Hispanic white	60.1	1.4	61.5	1.5	54.7	3.1	0.0016
Non-Hispanic black	15.0	0.8	15.9	0.9	11.7	1.4	
Hispanic	16.9	1.4	14.6	1.4	25.2	3.5	
Other	5.0	1.1	7.9	1.3	8.4	1.8	
Education							
Less than high school	18.6	1.2	17.7	1.3	22.0	3.2	0.2376
High school graduate	29.5	1.0	29.2	1.1	30.6	2.6	
Some college	31.9	1.2	33.0	1.3	28.1	2.3	
College graduate	20.0	1.0	20.1	1.2	19.3	2.0	
Marital status							
Married	62.5	1.1	62.5	1.2	62.5	2.5	0.9332
Divorced/separated	16.6	0.7	16.6	0.8	16.5	1.6	
Widowed	12.1	0.6	12.2	0.6	11.6	1.2	
Never married	8.8	0.5	8.7	0.6	9.4	1.3	
Annual household income							
<$15,000	15.4	1.0	15.0	1.1	16.4	2.4	0.1546
$15,000-<$25,000	21.9	1.1	20.8	1.1	26.0	3.0	
$25,000-<$35,000	12.3	0.8	12.1	0.8	13.0	1.8	
$35,000-<$50,000	13.1	0.6	13.4	0.7	11.8	1.4	
≥$50,000	37.5	1.3	38.8	1.4	32.8	2.5	
Health insurance							
Yes	93.9	0.8	94.5	0.9	91.8	1.8	0.1350
No	6.1	0.8	5.5	0.9	8.2	1.8	
Use insulin							
Yes	34.0	1.1	36.8	1.3	23.8	2.3	<0.0001
No	66.0	1.1	63.2	1.3	76.2	2.3	
Received diabetes mellitus education							
Yes	59.0	1.2	62.1	1.3	47.7	3.0	<0.0001
No	41.0	1.2	37.9	1.3	52.3	3.0	
Time since diagnosis with diabetes mellitus							
0-4 years	18.4	1.0	16.0	1.0	27.2	2.4	<0.0001
5-9 year	17.4	1.0	17.9	1.1	15.7	1.4	
10-19 years	34.3	1.3	33.8	1.4	36.3	3.2	

20-29 years	15.5	0.9	15.8	1.1	9.5	1.3	
30+ years	15.4	0.7	16.5	0.8	11.3	1.4	
Self-reported health status							
Excellent	2.5	0.3	2.5	0.3	2.3	0.4	0.9722
Very good	16.5	0.8	16.7	0.9	15.8	1.9	
Good	36.1	1.2	35.8	1.3	37.1	2.7	
Fair	30.4	1.2	30.3	1.3	30.8	3.1	
Poor	15.6	1.1	14.7	1.3	13.9	1.6	
Hypertension							
Yes	71.9	1.3	72.7	1.4	68.9	3.0	0.2468
No	28.1	1.3	27.3	1.4	31.1	3.0	
High cholesterol							
Yes	64.3	1.3	64.5	1.5	63.8	3.0	0.8531
No	35.7	1.3	35.5	1.5	36.2	3.0	
Cardiovascular disease							
Yes	24.2	1.0	25.6	1.2	19.0	1.7	0.0019
No	75.8	1.0	74.4	1.2	81.0	1.7	
Depression							
Yes	23.9	1.0	23.5	1.1	25.0	2.1	0.5241
No	76.1	1.0	76.5	1.1	75.0	2.1	
Visits to health provider for diabetes mellitus care							<0.0001
1 visit	16.0	0.9	13.4	0.8	25.4	2.4	
2 visits	23.5	1.2	23.0	1.2	24.5	3.1	
3 visits	16.7	1.0	16.9	1.1	15.6	1.6	
4 visits	27.4	1.1	29.9	1.3	18.5	2.2	
5+ visits	16.4	1.0	16.8	1.2	15.1	1.9	
BMI							
Underweight	0.5	0.1	0.4	0.1	0.5	0.5	0.4907
Normal	12.7	0.8	12.8	0.9	12.3	1.6	
Overweight	32.9	1.3	32.9	1.5	32.8	2.8	
Obese	53.9	1.3	53.9	1.4	53.9	2.9	

* The 38 states include: Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, and Wyoming. † Percentage of population ± SE. ‡ P-values from χ^2 test.

Examining the population who received the ADFSE, we found that 52.7% were male and 58.0% were under the age of 65 and 94.5% had some form of health insurance. The distribution of race in those who received the ADFSE was: 61.5% non-Hispanic white, 15.9% non-Hispanic black, 14.6% Hispanic and 7.9% reported another race. A majority of patients who received the ADFSE received at least some college level education (53.1%), were married (62.5%), reported an annual household income over $35,000 (52.2%), have had diabetes more than 10 years (66.1%), reported at least "good" self-rated health (55.0%) and reported 3 or more visits to a healthcare provider for diabetes care (63.6%). Among those who received the ADFSE, 72.7% had hypertension, 64.5% have high cholesterol, 25.6% report CVD, 23.5% have depression and 86.8% were overweight or obese.

The population who did not receive the ADFSE were 49.1% male, 64.7% were under the age of 65 and 91.8% had health insurance. Upon examining race, of those who did not receive the ADFSE 54.7% were non-Hispanic white, 11.7% were non-Hispanic black, 25.2% were Hispanic and 8.4% were of other races. A majority of the population who did not receive the ADFSE had less than a high school level education or only graduated from high school (52.6%), were married (62.5%), and had an annual income less than $35,000 (55.4%), have had diabetes over 10 years (57.1%), reported at least "good" self-rated health (55.2%) and reported having 3 or more visits to a healthcare provider for diabetes care (50.1%). When comorbidities are explored, 68.9% had hypertension, 63.8% have high cholesterol, 10% report having CVD, 25.0% have depression and 86.7% are overweight or obese.

Table 2 presents the reported performance of recommended diabetes self-management behavior in the study population. The two most often performed behaviors were SMBG at least one time per day (89.9%) and self-foot exam at least one time per day (87.4%). The two least commonly performed behaviors are currently smoking (13.4%) and drinking excessive amounts of alcohol (2.1%). The rates of performance of the other diabetes self-management behaviors were: 59.0% received the influenza vaccine in the past 12 months, 61.6% have received a pneumococcal vaccine, 44.2% met aerobic activity recommends and 19.6% met resistance training recommendations.

Table 3-2- Reported performance of recommended diabetes mellitus self-management behaviors in persons aged ≥18 years with diagnosed diabetes, 38 states (n=14,823)*							
	Study population		Received annual diabetes foot screening exam in past 12 months				P value‡
			Yes 78.3±1.10%†		No 21.7±1.10 %†		
	%	SE	%	SE	%	SE	
Perform self-monitoring of blood glucose ≥1 time per day							0.0004
Yes	89.9	0.7	91.2	0.8	85.4	1.5	
No	10.1	0.7	8.8	0.8	14.6	1.5	
Perform self-foot exam ≥1 time per day							<0.0001
Yes	87.4	0.7	90.7	0.7	75.3	2.1	
No	12.6	0.7	9.3	0.7	24.7	2.1	
Receive influenza vaccine in past 12 months							0.0272
Yes	59.0	1.3	60.5	1.4	53.5	2.9	
No	41.0	1.3	39.5	1.4	46.5	2.9	
Ever receive pneumococcal vaccine							<0.0001
Yes	61.6	1.3	64.7	1.4	50.3	2.9	
No	38.4	1.3	35.3	1.4	49.7	2.9	
Met aerobic activity recommendations§							0.0217
Yes	44.2	1.3	45.7	1.4	38.7	2.7	
No	55.8	1.3	54.3	1.4	61.3	2.7	
Met resistance training recommendations‖							0.0193
Yes	19.6	1.0	20.8	1.2	15.2	1.9	
No	80.4	1.0	79.2	1.2	84.8	1.9	
Current smoking status							0.8249
Yes	13.4	0.9	13.3	1.1	13.8	1.6	
No	86.6	0.9	86.7	1.1	86.2	1.6	
Excessive alcohol consumption¶							0.0323
Yes	2.11	0.3	2.3	0.4	1.3	0.3	
No	97.9	0.3	97.7	0.4	98.7	0.3	

* The 38 states include: Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, Wyoming.. † Percentage of population ± SE. ‡ P-values from χ^2 test. § ≥150 minutes of moderate aerobic exercise per week. ‖ Perform resistance training ≥2 days per week. ¶ Males- no more than 2 and women no more than 1 alcoholic beverage per day.

When only those who received the ADFSE are examined, 91.2% complete SMBG at least one time per day and 90.7% perform a self-foot check at least one time per day. This population reports rates of smoking (2.3%) and excessive alcohol consumption (13.3%) at higher rates than the general population with diabetes. Of the ADFSE recipients 60.5% received the influenza vaccine in the past 12 months, 64.7% received the pneumococcal vaccine, 45.7% performed the recommended amount of aerobic activity and 20.8% performed the recommended amount of resistance training.

Reported rates of SMBG at least one time per day (85.4%) and self-foot exams at least one time per day (75.3%) were lower among those who did not receive the ADFSE. The other rates of completion were also lower in the population who did not receive the ADFSE. The influenza vaccine was received by only 53.5% and pneumococcal vaccine was received by 50.3% of those who did not also receive the ADFSE. Finally, only 38.7% and 15.2% of patients performed the recommended amounts of aerobic and resistance training, respectively.

Table 3 shows the results from the 8 multiple logistic regression models to describe the association between each diabetes mellitus self-care behaviors and the performance of the ADFSE. The status of insulin use was found to modify the association between receipt of the influenza vaccine ($p=0.006$), performance of the recommended dosage of aerobic exercise ($p=0.036$) and avoidance of excessive alcohol consumption ($p=0.034$) and performance of the ADFSE.

The receipt of the influenza vaccine and the performance of the recommended dosage of aerobic exercise did not demonstrate significant associations with the performance of the ADFSE, in either subpopulation. A positive association was found in the population that do not use insulin and consume an excessive quantify of alcohol. Among those who do not use insulin and do consume an excessive amount of alcohol there is more than 3 times increased odds (OR: 3.14, 95%CI: 1.45-3.91) ADFSE is performed compared to those who do not use insulin and avoid excessive alcohol usage.

Table 3-3- Multiple Logistic Regression Model Estimates of Odds Ratios (OR) and 95% CI for the association between patient performance of 8 individual diabetes mellitus self-management behaviors on the performance of the recommended annual diabetes foot screening examination (n=14,823)			
Recommended self-management behavior	Effect modification	**Self-management behavior**	
		Met recommendation	Did not meet recommendation OR (95% CI)
Self-monitor blood glucose ≥1/per day*	Use insulin	Reference	1.67 (0.79-2.43)
	Do not use insulin	Reference	**0.52 (0.38-0.82)**
	Had diabetes mellitus education	Reference	**0.19 (0.09-0.94)**
	No diabetes mellitus education	Reference	**0.52 (0.36-0.74)**
Perform self-foot check ≥1/per day†	None	Reference	**0.33 (0.25-0.44)**
Received influenza vaccine ≤12 months*	Use insulin	Reference	1.78 (0.86-2.50)
	Do not use insulin	Reference	0.90 (0.68-1.19)
Ever receive pneumococcal vaccine*	None	Reference	**0.59 (0.45-0.76)**
Perform ≥150 minutes of moderate aerobic exercise per week*	Use insulin	Reference	1.60 (0.75-2.36)
	Do not use insulin	Reference	0.90 (0.69-1.18)
Perform resistance training ≥2 days per week*	None	Reference	**0.71 (0.51-0.98)**
No smoking*	None	Reference	0.95 (0.69-1.30)
Avoid excessive alcohol consumption‡	Use insulin	Reference	0.86 (0.31-1.87)
	Do not use insulin	Reference	**3.14 (1.45-3.91)**
Bolded ORs and 95% CI indicate significance at p<0.05. All models adjusted for covariates: sex, age, race, education, marital status, annual household income and insurance status. *Adjusted for covariates only. † Adjusted for covariates and duration of time with diabetes mellitus. ‡ Adjusted for covariates and number of visits to a health provider for diabetes mellitus care.			

Both status of insulin use (p=0.0108) and of the receipt of formal diabetes education (p=0.0336) were found to be significant effect modifiers of the relationship between performance of SMBG at least one time per day and the receipt of the ADFSE. Among those who used insulin, performance of SMBG was not significantly associated with the performance of the ADFSE (OR: 1.67, 95%CI: 0.79-2.43). For the group that does not use insulin, those who do not perform SMBG at least one time per day were nearly 50% less likely to receive the ADFSE (OR: 0.52, 95%CI: 0.38-0.82) compared to those who do perform SMGB at least one time per day. When effect modification based on receipt of formal diabetes education was explored, both statuses demonstrated a significant association between performance of SMBG at least one time per day and performance of the ADFSE. Among those who receive formal diabetes education, those who do not perform SMBG at least one time per day were more than 20% less likely to receive the ADFSE (OR: 0.19, 95% CI: 0.09-0.94) compared to those who do perform the behavior. Finally, those who do not receive formal diabetes and do not perform the SMBG activity nearly 50% less likely to receive the ADFSE (OR: 0.52, 95%CI: 0.36-0.74) compared to those who perform SMBG at least one time per day.

No statistically significant one-way effect modifications were demonstrated between the remaining four self-management behaviors (perform daily self-foot check, receipt of pneumococcal vaccine, resistance exercise and smoking status) and performance of the ADFSE. The model results demonstrated that not performing daily self-foot checks, non-receipt of the pneumococcal vaccination and not performing the recommended dosage of resistance exercise all have a negative association with the receipt of the ADFSE. Those who do not perform a daily self-foot check are 67% less likely (OR: 0.33, 95%CI: 0.25-0.44) to receive the ADFSE compared to those who do perform a daily self-foot check. Those who do not receive a pneumococcal vaccination are nearly 40% less likely (OR: 0.59, 95%CI: 0.45-0.76) to receive the ADFSE compared to those who have received the vaccination. And those who do not perform resistance training at least 2 times week, are almost 30% less likely (OR: 0.71, 95%CI: 0.51-0.98) to receive the ADFSE, compared to those who perform the recommended dosage of resistance training. Finally, no significant association (OR: 0.95, 95%CI: 0.69-1.30) was found between current smoking status and receipt of the ADFSE.

Finally, Table 4 presents the results of the sensitivity analysis for non-response bias. The results demonstrfate no significant non-response bias.

Table 3-4- Multiple logistic regression model estimates of odds ratios (OR) and 95% CI to assess for outcome non-response bias in estimates for the influence of patient performance of 8 individual diabetes mellitus self-management behaviors on the performance of the recommended annual diabetes foot screening examination.			
	Model estimate OR (95% CI)	Assuming all non-responders received ADFSE OR (95% CI)	Assuming no non-responders received ADFSE OR (95% CI)
Perform self-monitoring of blood glucose ≥1 time per day			
Use insulin, received diabetes mellitus education	0.62 (0.17-1.27)	0.54 (0.15-1.96)	0.51 (0.11-2.40)
No insulin use, received diabetes mellitus education	1.67 (0.54-5.15)	1.43 (0.53-3.86)	1.34 (0.44-4.14)
Use insulin, no diabetes mellitus education	0.19 (0.07-0.50)	0.22 (0.10-0.48)	0.21 (0.08-0.56)
No insulin use, no diabetes mellitus education	0.52 (0.36-0.74)	0.57 (0.40-0.80)	0.57 (0.39-0.82)
Perform self-foot exam ≥1 time per day	0.33 (0.25-0.44)	0.39 (0.30-0.51)	0.40 (0.30-0.51)
Receive influenza vaccine in past 12 months			
Use insulin	1.78 (0.86-2.50)	1.38 (0.81-1.91)	1.39 (0.83-1.91)
No insulin use	0.90 (0.68-1.19)	0.84 (0.64-1.10)	0.86 (0.66-1.12)
Ever receive pneumococcal vaccine	0.59 (0.45-0.76)	0.58 (0.45-0.74)	0.59 (0.46-0.75)
Met aerobic activity recommendations*			
Use insulin	1.60 (0.75-2.36)	1.50 (0.92-1.98)	1.53 (0.96-2.00)
No insulin use	0.90 (0.69-1.18)	0.90 (0.69-1.16)	0.92 (0.71-1.18)
Met resistance training recommendations†	0.71 (0.51-0.98)	0.72 (0.55-1.00)	0.76 (0.57-1.01)
Current smoking status	0.95 (0.69-1.30)	0.94 (0.69-1.28)	0.93 (0.69-1.25)
Excessive alcohol consumption ‡			
Use insulin	0.86 (0.31-1.87)	0.66 (0.33-1.34)	0.69 (0.36-1.36)
No insulin use	3.14 (1.45-3.91)	2.16 (1.12-2.81)	2.14 (1.12-2.79)
* ≥150 minutes of moderate aerobic exercise per week. † Perform resistance training ≥2 days per week. ‡ Males- no more than 2 and women no more than 1 alcoholic beverage per day			

CONCLUSIONS

The results of this study support the hypothesis that a positive association exists between the performance of some diabetes mellitus self-management behaviors and the receipt of the ADFSE among the US population with diabetes mellitus. The daily performance of SMBG and self-foot checks, receipt of the pneumococcal vaccination, and performance of resistance training at least two days per week were all significant and positively associated with the performance of the ADFSE. In contrast, a negative association between receipt of the ADFSE and those who avoid excessive alcohol. While this association is opposite of that found among the other significant self-management behaviors, it may be explained by the development of PN among those who consume excessive alcohol, providing a different trigger for a foot inspection (97).

We also found some associations between self-management behaviors and receipt of the ADFSE were modified by status of insulin use and receipt of formal diabetes mellitus education. Our results are consistent with findings from prior literature (65, 93, 94). In the early 2000s national estimates from BRFSS data demonstrated the receipt of the ADFSE varied among sub-population based on both insulin use and receipt of formal education (93). In this study, the rates of performance of the ADFSE were higher among those who used insulin compared to those who did not use insulin as well as among those who received formal diabetes mellitus education compared to those who did not. Rates of performing self-management behaviors were also higher in the sub-populations that used insulin and received formal education. Among Asian-Americans with diabetes mellitus use of insulin was also found as an effect modifier (65). Those who use insulin in the Asian-American population were more likely to receive preventive care processes, including the ADFSE, compared to those who did not use insulin. Given the consistency of effect in this study and other literature, it is apparent that future research should continue to explore the underlying causes for such variations and develop effective intervention programs that target at the subgroups of patients who are currently not benefiting from the ADFSE.

Given the ADFSE is intended to prevent DFUs and, ultimate, LEAs, it is important to consider if the diabetes mellitus self-management behaviors found to be associated with the performance of the ADFSE in this study, also influence the rates of DFUs and LEAs in the US. A 2014 study conducted by Margolis, et al. found LEA rates in the US may be explained, in part, by variations in patient health behaviors, including diabetes mellitus self-management behaviors and receipt of cancer screenings (92). Our results indicate that performance of some diabetes mellitus self-management behaviors, may influence the performance of the ADFSE. It is possible that the ADFSE is a link between the self-management behaviors and the lower rates of LEAs. However, as proposed by Margolis, et al. our results may also be an indication of the level of health literacy among patients with diabetes mellitus. Patients with diabetes mellitus that have a higher level of health literacy are more likely to complete recommended self-management behaviors and gain more benefit from healthcare interventions (98, 99). Thus, it is possible, that those with higher health literacy ensure the receipt of the ADFSE and follow DFU prevention recommendations resulting in lower rates of LEAs. Further research is needed to assess the role health literacy plays in DFU and LEA prevention and management.

As with other observational studies, this study is limited by the self-reported nature of the data which may introduced of recall, misclassification and possibility social desirability biases. The cross sectional nature of the data also limits the determination of causality. One major limitation is the survey question utilized to define this study's outcome measure. The comprehensive ADFSE involves multiple components including a neurologic and vascular exam as well as visual inspection of the feet. The BRFSS question only asks "has a health professional checked your feet for any sores or irritations?" This implies a visual exam was completed but there is no indication if the neurologic and vascular exams were completed. Thus, the outcome may be an overestimation of the true rate of the complete clinical ADFSE (40). Another major limitation is the inability to discern if a participant has T1DM or T2DM. Given the differences in disease management these populations should be considered separately in future analyses (4). Prior research has also identified provider type can influence the performance of preventive health services but this data is not available in the BRFSS data (100-102).

Despite these limitations, this was the first study, to our knowledge, to systematically explore the association between individual diabetes mellitus self-management behaviors and receipt of the recommended ADFSE using a large, population based data set representing a majority of US states. Thus, it provides results that are generalizable to the US population with diabetes mellitus within the 38 states captured in the BRFSS Diabetes Mellitus Optional Module. The main outcome of this study, the performance of the ADFSE, is based upon the same BRFSS survey question utilized by Healthy People 2020 to report national rates of completion of the ADFSE increasing the external validity of our study (91). Research has also found good agreement between self-report of the ADFSE on the BRFSS and chart audits increasing the internal validity (43, 103).

In conclusion our study provides support to the Piette and Kerr conceptual model which, in part, considers the influence of patient self-management behaviors on the clinical care of patients with diabetes mellitus. We found that five diabetes mellitus self-management behaviors are positively associated with the performance of the ADFSE, an effective and cost-effective screening exam that is known to reduce DFUs and LEAs. Future research must focus on demonstrating a causal relationship among diabetes mellitus self-management behaviors, performance of the ADFSE and ultimately, the prevention of DFUs and LEAs in the US population with diabetes mellitus. If this causal relationship can be proven, existing programs aimed at improving self-management in patients with diabetes mellitus, such as Lifestyle Redesign® with an occupational therapist, could offer a solution to the problem of DFUs and LEAs (104). The reduction of DFUs and LEAs in the ever increasing US population with diabetes mellitus would improve the quality of life of patients and reduce the financial burden on both patients and the US healthcare system.

CHAPTER 4: The Association Between Comorbidities and the Performance of the Recommended Annual Diabetes Foot Screening Examination

ABSTRACT

Objective: This study aimed to assess the simultaneous, direct effects of concordant and discordant comorbidities on the performance of the annual diabetes foot screening exam (ADFSE), using structural equation modeling (SEM), to simulate clinical decision making.

Research Design and Methods: We used the 2015 BRFSS data from 38 states (n=20,882) to conduct a cross-sectional study. Respondents who provided a valid response regarding receipt of the ADFSE and had at least one visit to a health care provider in the past 12 months were included. SEM was used to assess the simultaneous, direct effects of concordant and discordant comorbidity loads on the performance of the ADFSE.

Results: In 2015, 78.2% of patients with diabetes received the ADFSE. Hypertension (71.0%) was the most commonly and renal disease (8.2%) was the least commonly reported comorbidities. On average, patients with diabetes have 4.8 comorbidities. The final SEM model demonstrated that neither concordant comorbidities (β=0.226, p=0.086) nor discordant comorbidities (β=0.080, p=0.415) had a direct association with the performance of the ADFSE.

Conclusions: The burden of concordant and discordant comorbidities are not associated with the performance of the ADFSE. This may be a reflection of recent changes in the US healthcare system, such as the introduction of clinical practice guidelines and incentive payments for quality of care, including the performance of the ADFSE in the US population with diabetes. However, in light of the burden DFUs and LEAs place on patient quality of life and the financial burden on the US healthcare system, identification of other influential factors and development of interventions to increase the rate of the ADFSE in the US may be the only way to reduce the rates of DFUs and LEAs in the US and the world.

INTRODUCTION

The management of patients with DFUs costs the American health care system $9-13 billion dollars annually and significantly increases utilization of emergency, inpatient and outpatient medical services (15). When treatment fails patients must undergo an LEA, with more than 85% of all amputations in the US being preceded by a DFU (21). With the prevalence of diabetes expected to increase and affect 21-34% of the US population by 2050, and the lifetime incidence of a DFU in this population as high as 34%, the costs of DFU management and rates of LEAs will likely increase (3, 23). However, evidence has shown that up to 75% of DFUs and more than 49% of LEAs are preventable through cost-effective, comprehensive screening exams and prevention programs (31, 32). It is essential that all individuals with diabetes receive the recommended ADFSE (33, 36). Despite the known benefits, in 2015, only 71.6% of the US population with diabetes received the ADFSE (88).

The management of patients with diabetes includes 11 recommended preventive care processes, including the ADFSE, that are now a incorporated in quality of care processes measures in the US (105, 106). Table 1 presents the 11 recommended diabetes care processes and the reported rates of completion in the US in 2015. However, the medical management of patients with diabetes is further complicated by the presence of other comorbidities. Therefore, quality of care for patients with diabetes must also consider the management of comorbidities. . As discussed in the Piette and Kerr conceptual framework on competing demands of chronic comorbid conditions in diabetes care the need to complete diabetes care processes, including the ADFSE, competes with the need to complete self-management and clinical screenings for other comorbidities (50). Within the time of an often brief clinical visit, health care providers must prioritize required preventive care processes along with management of patient comorbidities and other patient reported symptoms. Often the care of more complex or serious medical conditions, such as cancer, renal failure or symptomatic depression, preclude the performance of preventive care, such as the ADFSE (50).

Table 4-1- Recommended diabetes preventive care processes and Healthy People 2020 reported results(62, 105, 106)

Preventive care process	Healthy People 2020 report year	US diabetes population receiving preventive care process
HgbA1c measurement at least twice a year	2007	64.8%
LDL cholesterol measurement every 1-2 years	NR*	NR*
At least annual blood pressure measurement	NR*	NR*
Annual urinary microalbumin measurement	2012	42.4%
Annual diabetes foot examination	2007	70.2%
Annual dilated eye examination	2008	53.4%
Annual dental examination	2014	54.5%
Annual flu vaccination	NR*	NR*
Annual pneumococcal vaccination	NR*	NR*
Hepatitis B vaccination series	NR*	NR*
Annual evaluation of footwear	NR*	NR*

* NR- no report: not included in Healthy People 2020 or not specifically reported for diabetes population

A majority of patients with diabetes must also manage at least one other chronic comorbid medical condition, such as hypertension or CAD (66). National estimates, published in 2014, indicate that amongst those with diabetes in the US, nearly 85% were overweight or obese, 57% had hypertension and over 58% had hypercholesterolemia. In those aged 35 and over with diabetes, CAD and MI affect nearly 22%, while over 9% have suffered a CVA (67). A study from 2015 reported nearly 90% of patients with diabetes had at least one other comorbidity (107). The study also reported 37% of patients with diabetes had one to two other comorbidities while 43% had three to four. Given these high rates of comorbidities and multiple concurrent comorbidities, it is imperative to understand how they compete with diabetes quality of care, in particular, the ADFSE.

Prior research has explored the relationships between individual comorbidities or the total number of comorbid conditions with the performance of a number of the recommended diabetes preventive care processes. Studies have found individual comorbidities have differential effects on diabetes preventive care processes (55, 70). A study utilizing a total count of comorbidities found patients with more than five comorbidities had an increased odds of receiving HgbA1c testing and annual dilated eye exams (68). Piette and Kerr introduced a system to classify comorbidities as either concordant or discordant with diabetes disease management and preventive care processes (50). Using this classification scheme studies have again found differential effects on recommended diabetes preventive care processes (52, 71). While studies demonstrated both positive and negative associations between individual comorbidities and total number of comorbidities, to date, no US study has explored the relationship between comorbidities and the ADFSE.

Thus far, the literature has suggested that the counts, individual comorbidities, and types of comorbidities may all exert an influence on the performance of some of the recommended diabetes preventive care processes. There is also a lack of research among the US population exploring the relationship between comorbidities and the ADFSE. Thus, we proposed to address this gap in the literature for the ADFSE while considering the number and types of comorbidities, as well as the individual contribution of specific comorbidities to simulate the clinical decision making process. Health care providers must consider comorbidity interrelatedness, or the interaction of medical conditions and treatments, when conducting clinical exams (108). Therefore, this study aimed to assess the simultaneous, direct effects of concordant and discordant comorbidities on the performance of the ADFSE, using structural equation modeling (SEM), to simulate clinical decision making.

RESEARCH DESIGN AND METHODS

Data Source and Sample

This study utilized data from the 2015 BRFSS (81). The BRFSS is an annual cross-section survey, administered by the CDC that interviews non-institutionalized US residents, over the age of 18. The BRFSS is designed to collect data on preventive health practices, health risk behaviors, and chronic disease that affect the US adult population. The methods for sample design and sampling weighting to account for complex sample design are described elsewhere (82).

The 2015 BRFSS included an option module focused on diabetes which included 10 questions specific to diabetes care. In 2015, the 38 states that participated in the Diabetes Optional Module included: Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, Wyoming. This module was administered to all respondents, in participating states, who answered "yes" to the question "Has a doctor, nurse or other health professional every told you that you have diabetes?" in the BRFSS core component. Respondents indicating the diagnosis of gestational, borderline or pre-diabetes were excluded from the Diabetes Optional Module in the BRFSS survey design. A total of 36,085 of the 2015 BRFSS participants were eligible to participate in the Diabetes Optional Module.

The inclusion criteria for this study required respondents have at least one foot, have had at least one visit to a health care provider for diabetes specific care within in the past 12 months and provided valid responses to all exposure and confounding variables. The BRFSS contains a question requesting respondents indicate “About how often do you check your feet for any sores or irritations?” (90). Those who gave a response of “no feet” (n=349) were excluded from the analytic sample. The question “About how many times in the past 12 months have you seen a doctor, nurse or other health professional for your diabetes?” was utilized to identify all respondents who had at least one visit to a healthcare provider for diabetes care. Those who reported having no visits or did not provide a valid response to this question were excluded from the analytic sample (n=3,656). Finally respondents who did not provide valid answers to all exposure and confounding variable questions were also excluded (n=11,198). The final analytic sample size for this study was 20,882.

Measures

The ADA and the IWGDF recommend patients with diabetes receive the ADFSE at least one time per year and this was defined as the outcome for this study (33, 36). The outcome was operationalized using the BRFSS question “About how many times in the past 12 months has a health professional checked your feet for any sores or irritations?” The respondents provided the number of times, on a continuous scale from 1-76, or “none.” The responses were dichotomized, for this study, to “at least one ADFSE” and “none.”

The main exposures of this study are two latent variables, “diabetes concordant comorbidity burden” and “diabetes discordant comorbidity burden.” These latent variables are measured by observed variables for individual comorbid medical conditions. The 2015 BRFSS contains information on the diagnoses of hypertension, high cholesterol, MI, CAD, CVA, asthma, cancer, pulmonary diseases, orthopedic conditions, depressive disorder, renal disease, diabetic retinopathy and overweight or obese. The assignment of indicators, the individual comorbidities, to each of the latent variables will be based upon the classifications from a Delphi study by Magnan et al. from 2015 (53). The concordant comorbidities will be defined by indicators for the presence or absence of hypertension, high cholesterol, MI, CAD, CVA, renal disease, retinopathy and overweight or obese. The discordant comorbidities will be defined by indicators for asthma, respiratory diseases, cancer, orthopedic diseases, and depressive disorders.

The indicator for hypertension was derived from the survey question "have you ever been told by a doctor, nurse or other health professional that you have high blood pressure?" (90). Respondents answering "yes" were categorized as having hypertension. For consistency with prior studies, female respondents indicating hypertension only during pregnancy and all respondents indicating "borderline high" or "pre-hypertension" will be categorized as not having hypertension (109-111).

All cancer diagnoses, including skin cancer, were combined into one variable, consistent with the results of a Delphi study conducted by Magnan, et al. (53). Respondents answering "yes" to either "have you ever been told by a doctor, nurse or other health professional that you had skin cancer?" or "Ever told you had any other types of cancer?" will be classified as having cancer. Respondents answering "no" to both questions will be considered to never have had cancer.

The BRFSS created variables to identify adults who currently have asthma and another which calculated BMI (90). The variable to identify adults who have been told they currently have asthma categorized respondents as either "yes, currently have asthma" or "no." The calculated variable for BMI was retained as a continuous variable for the analysis. Respondents with calculated BMI equal to or more than 25.0 will be classified as overweight/obese. Respondents with BMI less than 25.0 will be classified as not overweight/obese.

Finally, the indicators for high cholesterol, MI, CAD, CVA pulmonary diseases, orthopedic conditions, depressive disorder, renal disease and diabetic retinopathy were constructed from a series of questions with the stem "have you ever been told by a doctor, nurse or other health professional that you had [chronic condition]?" (90). A response of "yes" to each condition was categorized as having the chronic condition and responses of "no" as not having the chronic condition. The BRFSS question for pulmonary diseases included the diagnoses of chronic obstructive pulmonary disease (COPD), emphysema and chronic bronchitis. The question for orthopedic conditions includes the diagnoses of rheumatism, polymyalgia rheumatica, osteoarthritis, tendonitis, bursitis, bunion, tennis elbow, carpal tunnel syndrome, tarsal tunnel syndrome and joint infections.

Potential confounders for the study, based on prior research, included: respondents age (<65/≥65 years old), gender (male/female), race (White non-Hispanic, Black non-Hispanic, Hispanic, or other), education (did not graduate high school, graduated from high school , attended college or technical school, or graduated from college or technical school), marital status (married/member of an unmarried couple, divorced/separated, widowed or never married), annual household income (<$15,000, $15,000- <$25,000, $25,000- <$35,000, $35,000- <$50,000, ≥$50,000), insurance status (insured/uninsured), insulin use (yes/no) and receipt of a diabetes education course (yes/no) (47, 51, 52, 54, 55, 71).

Statistical Analysis

Descriptive statistics for the outcome, all exposures and potential confounders were calculated. This included analyses stratified based on receipt of the ADFSE. All proportions and means were weighted to provide population level estimates based on the complete sample design of the BRFSS. Chi-squared or student's t-test were utilized to compare groups.

SEM methods, using the two step approach, were used to assess the simultaneous, direct effects each of the latent variables, concordant and discordant comorbidities, have on the performance of the ADFSE. First, confirmatory factor analysis (CFA) was conducted to assess the goodness-of-fit of the measurement model. A good model fit was defined by a root mean squared error of approximation (RMSEA) less than 0.05 and a Comparative Fit Index (CFI) greater than 0.95 (112). If a CFA model was found to not be a good fit of the data, standardized solutions for between each indicator and the associated latent variable were calculated to determine the correlations. Indicators with poor correlation ($p<0.2$) to the latent variable were removed from the model. The reduced CFA model was then reanalyzed for goodness-of-fit. Once the measurement model demonstrated a good fit with the data, final correlations and variance explained by each indicator were determined.

Once an acceptable measurement model was determined through CFA, probit structural regression modeling was undertaken to assess the full model 1. First, potential confounders were determined by calculating the odds ratio and 95% CI between each potential confounder and the outcome. Confounders were included in the final model if the bivariate association was significant ($p<0.05$). The final model, with confounders, was assessed using structural regression modeling. Model goodness-of-fit was first assessed utilizing RMSEA less than 0.05 and CFI greater than 0.95.

All analyses were conducted with adjustment for the complex sample design of the BRFSS. Proportions and means represent national estimates and include standard error estimations (82). Data analyses were generates using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and MPlus version 9 (Muthén & Muthén, Los Angeles, CA, USA).

RESULTS

In 2015, 78.2% of the US population with diabetes and at least one visit to a health care provider for diabetes care reported receipt of the ADFSE. The demographic characteristics of the total study population (n=20,882), and the study population stratified by receipt of the ADFSE, are presented in Table 2. In 2015, a majority of the US population with diabetes were male (53.8%), under the age of 65 (59.6%), non-Hispanic white (58.9%) and were married or a member of an unmarried couple (61.7%). A majority of the population reported at least some education at the college level (51.0%). 37.5% had an annual household income over $50,000. Over 93% of the population with diabetes reported having some form of health insurance coverage in 2015. Only 33% reported using insulin and more than 58% reported receipt of formal diabetes education.

Among those who received the ADFSE in 2015, 54.1% were male and 58.2% were under the age of 65. When race was examined, those who received the ADFSE were 60.5% non-Hispanic white, 16.7% non-Hispanic blacks, 14.8% Hispanic and 8.0% of other reported races. Of those who received the ADFSE 47.9% had less than high school level or had graduated high school while 52.1% had at least some college education, 48.4% earned less than $35,000 in annual household income, and 93.9% had some form of health insurance. A majority of people who received the ADFSE were married or a member of an unmarried couple (61.7%), 17.1%

Table 4-2- Demographic characteristics of persons aged ≥18 years with diagnosed diabetes, 38 states* (n=20,882)

	Population estimate		Received annual diabetes foot screening exam in past 12 months				P value‡	Bivariate analysis
			Yes 78.18±0.93%†		No 21.82±0.93%†			Odds ratio (95% CI)
	%	SE	%	SE	%	SE		
DEMOGRAPHIC CHARACTERISTICS								
Sex								
Male	53.8	1.0	54.1	1.3	53.0	2.5	0.6991	Ref
Female	46.2	1.0	45.9	1.3	47.0	2.5		1.04 (0.84-1.30)
Age (years)								
18-64	59.6	1.0	58.2	1.1	64.8	2.2	0.0095	Ref
≥65	40.4	1.0	41.8	1.1	35.2	2.2		0.76 (0.61-0.93)
Race								
Non-Hispanic white	58.9	1.1	60.5	1.0	53.5	2.2	0.0012	Ref
Non-Hispanic black	15.8	0.7	16.7	1.0	12.9	2.2		0.88 (0.67-1.15)
Hispanic	16.9	1.0	14.8	1.0	24.2	2.2		1.85 (1.32-2.60)
Other	8.3	0.9	8.0	1.0	9.4	2.2		1.33 (0.76-2.33)
Education								
Less than high school	18.8	1.0	17.9	1.0	21.9	2.4	0.2316	1.36 (0.95-1.94)
High school graduate	30.2	0.9	30.0	1.0	30.7	2.2		1.14 (0.87-1.49)
Some college	31.3	1.0	31.9	1.1	29.2	2.3		1.01 (0.76-1.35)
College graduate	19.7	0.8	20.2	0.9	18.2	1.6		Ref
Marital status								
Married/couple	61.7	0.9	61.7	1.0	61.8	2.2	0.8703	Ref
Divorced/separated	17.1	0.6	17.1	0.6	17.4	1.4		1.02 (0.81-1.29)
Widowed	11.7	0.5	11.9	0.5	10.9	0.9		0.91 (0.72-1.16)
Never married	9.4	0.5	9.3	0.5	9.0	1.4		1.06 (0.76-1.49)
Annual household income								
<$15,000	15.5	0.8	15.3	0.9	16.3	1.9	0.2939	1.21 (0.86-1.68)
$15,000-<$25,000	22.2	0.9	21.5	0.9	25.0	2.4		1.32 (0.97-1.79)
$25,000-<$35,000	11.8	0.6	11.6	0.7	12.6	1.5		1.23 (0.89-1.71)
$35,000-<$50,000	13.0	0.5	13.2	0.6	12.1	1.2		1.03 (0.78-1.37)
≥$50,000	37.5	1.0	38.4	1.1	34.0	2.4		Ref
Health insurance								
Yes	93.4	0.6	93.9	0.7	92.4	1.4	0.3018	Ref
No	6.4	0.6	6.1	0.7	7.6	1.4		1.27 (0.81-2.00)
Use insulin								
Yes	32.6	0.9	35.7	1.0	21.6	1.8	<0.0001	Ref
No	67.4	0.9	64.3	1.0	78.4	1.8		2.02 (1.60-2.54)
Received diabetes education								
Yes	58.3	1.0	61.3	1.1	47.6	2.5	<0.0001	Ref
No	41.7	1.0	38.7	1.1	52.4	2.5		1.74 (1.40-2.16)

* In 2015, the 38 states that participated in the Diabetes Optional Module included: Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, Wyoming. † Percentage of population ± SE. ‡ P-values from χ^2 test.

were divorced or separated from a spouse, 11.9% were widowed and 9.3% were never married. Finally, among those who received the ADFSE, 35.7% used insulin, 64.3% did not use insulin, 61.3% received formal diabetes education and 38.7% did not receive formal education.

Examining those who did not receive the ADFSE, 53.0% were male and64.8% were under the age of 65. Among those who did not receive the ADFSE, 53.5% were non-Hispanic white, 12.9% were non-Hispanic black, 24.2% were Hispanic and 9.4% were of other reported races. A majority of people who received the ADFSE received at least some college level education (52.1%) and were married or a member of an unmarried couple (61.8%). Of those who received the ADFSE, 53.9% had less than $35,000 in annual household income but 92.4% had health insurance. Finally, among patients who did not receive the ADFSE, 21.6% used insulin and 47.6% had received formal diabetes education. There were no statistically significant differences in the receipt of the ADFSE based on sex, education level, marital status, annual household income or health insurance status.

Table 3 describes the comorbid conditions reported by person over the age of 18 with diagnosed diabetes. The reports indicate the US population with diabetes have an average of 4.8 comorbid conditions of which 2.9 are considered to be concordant and 1.9 are discordant for the purposes of this study. Being overweight or obese is the most commonly reported comorbidity (86.8%) while renal disease is the least commonly reported comorbid condition (8.3%). The proportion of the population with the remaining concordant comorbid conditions are: 64.4% have hypercholesterolemia, 13.3% reported a prior MI, 14.1% have CAD, 8.2% report a prior CVA, and 19.3% report retinopathy. For the discordant comorbid conditions, the population reports 11.1% currently have asthma, 12.8% have COPD, 20.0% report a history of cancer, 46.3% report an orthopedic condition and 23.3% report depression.

Table 4-3- Reported comorbid conditions in persons aged ≥18 years with diagnosed diabetes, 38 states* (n=20,882)							
	Population estimate		Received diabetes foot screening exam in past 12 months				P value[†]
			Yes 78.18±0.93%[†]		No 21.82±0.93%[†]		
	%	SE	%	SE	%	SE	
CONCORDANT COMORBID CONDITIONS							
Hypertension							
Yes	71.0	1.0	72.2	1.1	66.5	2.7	0.0396
No	29.0	1.0	27.8	1.1	33.5	2.7	
Hypercholesterolemia							
Yes	64.4	1.1	64.6	1.1	63.6	2.6	0.7414
No	35.6	1.1	35.4	1.1	36.4	2.6	
Prior myocardial infarction							
Yes	13.3	0.6	13.8	0.6	11.6	1.2	0.1155
No	86.7	0.6	86.2	0.6	88.4	1.2	
Coronary artery disease							
Yes	14.1	0.7	15.0	0.8	10.8	1.1	0.0036
No	85.9	0.7	85.0	0.8	89.2	1.1	
Prior cerebrovascular accident							
Yes	8.2	0.6	8.1	0.6	8.6	1.3	0.7238
No	91.8	0.6	91.9	0.6	91.4	1.3	
Retinopathy							
Yes	19.3	0.8	20.5	0.9	15.1	1.5	0.0040
No	80.7	0.8	79.5	0.9	84.6	1.5	
Renal disease							
Yes	8.3	0.4	8.9	0.5	6.3	1.0	0.0455
No	91.7	0.4	91.1	0.5	93.7	1.0	
Overweight/obese							
Yes	86.8	0.6	86.8	0.7	86.8	1.4	0.9984
No	13.2	0.6	13.2	0.7	13.2	1.4	
DISCORDANT COMORBID CONDITIONS							
Current asthma							
Yes	11.1	0.5	11.4	0.6	9.9	1.2	0.2753
No	88.9	0.5	88.6	0.6	90.1	1.2	
Chronic obstructive pulmonary diseases							
Yes	12.8	0.7	13.5	0.8	10.2	0.9	0.0068
No	87.2	0.7	86.5	0.8	89.8	0.9	
Any cancer history							
Yes	20.0	0.8	19.4	0.8	22.5	2.1	0.1499
No	80.0	0.8	80.6	0.8	77.5	2.1	
Orthopedic issues							
Yes	46.3	1.0	46.3	1.1	46.4	2.4	0.9712
No	53.8	1.0	53.7	1.1	53.6	2.4	
Depression							
Yes	23.3	0.8	22.9	0.9	24.7	1.9	0.3726
No	76.7	0.8	77.1	0.9	75.3	1.9	
	Population mean		Received diabetes foot screening exam in past 12 months				P value[‡]
			Yes		No		
	Mean	SE	Mean	SE	Mean	SE	

Total comorbid conditions	4.77	0.04	4.80	0.04	4.63	0.10	<0.0001
Total concordant conditions	2.85	0.03	2.90	0.03	2.70	0.07	<0.0001
Total discordant conditions	1.91	0.02	1.01	0.02	1.94	0.05	<0.0001

Looking specifically at the population who received the ADFSE, they have an average of 4.8 comorbid conditions with 2.9 concordant and 1.0 discordant condition. Overweight or obese status (86.8%) remains the most common comorbid condition and renal disease (8.9%) remains the least common comorbid condition reported. The remaining concordant medical conditions are reported at rates of: 64.6% for hypercholesterolemia, 13.8% reported having a prior MI, 15.0% report CAD, 8.1% report prior CVA, and 20.5% reported retinopathy. Among the discordant medical conditions, those who received the ADFSE reported rates of: 11.4% for having current asthma, 13.5% report having COPD, 19.4% report a history of cancer, 46.3% have an orthopedic condition and 22.9% report depression.

Among those that did not receive the ADFSE, the study population reported an average of 4.6 comorbid conditions of which an average of 2.7 are concordant conditions and an average of 1.9 are discordant conditions. The proportions of concordant comorbid conditions of the study population who did not receive the ADFSE are: 66.5% with hypertension, 63.6% have hypercholesterolemia, 11.6% report a prior MI, 10.8% have CAD, 8.6% report a prior CVA, 15.1% have retinopathy, 6.3% have renal disease and 86.% are overweight or obese. Discordant comorbid conditions are reported at rates of 9.9% with current asthma, 10.2% with COPD, 22.5% have a history of cancer, 46.4% report an orthopedic condition and 24.7% have depression and did not receive the ADFSE.

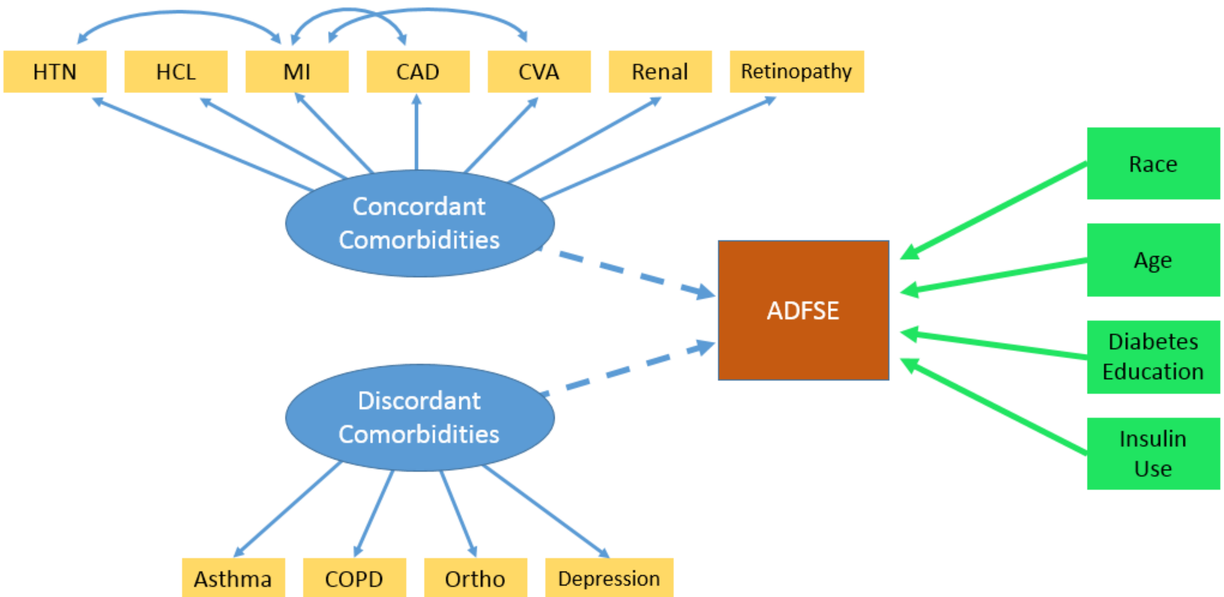
The final CFA model demonstrated a good fit between the proposed model and the observed data based on an RMSEA of 0.011 (90%CI: 0.009-0.013) and a CFI of 0.959. Standardized and unstandardized parameter estimates are presented in Table 4. The proportion of the latent factor variance explained by each indicator is also included in Table 4. None of the indicators for concordant comorbidities had a variance greater than 37% explained by the latent factor. For discordant comorbidities, only COPD (59.3%) had over half of its variance explained by the latent factor. This indicates poor convergent validity between the indicators and latent factors.

Table 4-4- Unstandardized coefficients, standardized coefficients and percentage of variance explained for the final CFA model.

Indicator	Latent variable	Unstandardized coefficient (B)	Standardized coefficient (β)	Percentage of variance explained
Hypertension	Concordant	1.00	0.59±0.04	34.8
Hypercholesterolemia	Concordant	0.73±0.08	0.43±0.04	18.5
Myocardial infarction	Concordant	0.88±0.09	0.52±0.04	27.0
Coronary artery disease	Concordant	1.06±0.09	0.62±0.03	38.4
Prior cerebrovascular accident	Concordant	0.87±0.08	0.51±0.03	26.0
Renal disease	Concordant	0.87±0.08	0.51±0.03	26.0
Retinopathy	Concordant	0.59±0.07	0.34±0.04	11.6
Current asthma	Discordant	1.00	0.57±0.04	32.5
Chronic obstructive pulmonary diseases	Discordant	-1.35±0.15	-0.77±0.06	59.3
Orthopedic disease	Discordant	-1.05±0.08	-0.60±0.03	36.0
Depression	Discordant	-0.97±0.07	-0.55±0.03	30.3

The final SEM model, presented in Figure 1, demonstrated a good fit between with the observed date. The model fit statistics were: χ^2=(df=93)=645.238, p<0.0001, RMSEA=0.017 (90%CI: and CFI=0.807. Given a low CFI value the null model RMSEA was examined and found to be 0.0346. The low null model RMSEA (<0.158) indicates the CFI is not informative for this model (113). Table 4 presents the unstandardized probit estimates (β), SEs, and p-values for regression pathways of the final SEM model. After controlling for age, race, insulin use and receipt of formal diabetes education the direct effects of concordant comorbidities (β=0.226, p=0.086) and discordant comorbidities (β=0.080, p=0.415) on the performance of the ADFSE were not significant. Thus, neither concordant nor discordant comorbidities significantly contribute to the probability that the ADFSE is performed.

Figure 4-1- Final SEM model. RMSEA=0.017, null model RMSEA=0.035.



Solid pathways indicate statistically significant model pathways. Dashed pathways indicate non-significant pathways. HTN – hypertension. HCL-hypercholesterolemia. MI- myocardial infarction. CAD-coronary artery disease. CVA-cerebrovascular accident. Renal- renal disease. COPD- chronic obstructive pulmonary disease. Ortho-orthopedic conditions. ADFSE- annual diabetes foot screening exam.

Table 4-5- Unstandardized estimates (β), standard error (SE) and p-values for regression pathways of the final SEM model.

Pathway	Unstandardized coefficient (β)	SE	P-value
Concordant comorbidities → ADFSE	0.23	0.13	0.09
Discordant comorbidities → ADFSE	0.08	0.10	0.42
Race → ADFSE	-0.09	0.04	0.02
Age → ADFSE	0.154	0.06	0.02
Insulin use → ADFSE	0.35	0.07	<0.0001
Diabetes education → ADFSE	0.27	0.6	<0.0001

CONCLUSIONS

The current findings of this study indicate that there are no simultaneous, direct associations between concordant nor discordant medical comorbidities and the performance of the ADFSE. These results may suggest that the competing demands of chronic comorbid conditions in diabetes care have little influence on the decision of a health care provider to perform the ADFSE. Our results are similar to two international studies which also demonstrated no association between concordant and discordant conditions and the performance of the ADFSE (72, 73).

However, our results differ from US studies conducted in the mid-2000s through 2011. While the ADFSE was not included in the studies, researchers found that increasing numbers of total comorbidities and concordant comorbidities improved performance of some diabetes quality care processes while discordant conditions reduced performance of at least one care process (52, 54, 68). To understand the difference between these results and those of these prior US studies, one must consider the full conceptual model of Piette and Kerr, including the role of healthcare organizations the management of patients with diabetes (50). Healthcare organizations place controls on clinical care, such as clinical practice guidelines and reimbursement strategies that directly influence how health care providers prioritize care in the clinical environment. In 1995, the ADA, the Centers for Medicare and Medicaid Services (CMS) and the National Committee on Quality Assurance introduced the Diabetes Quality Improvement Program (DQIP) which included eight process and outcomes measures (114). The DQIP program was adopted by CMS, the Veterans Health Administration (VHA) and other commercial health plans and some progress was made toward improving diabetes quality of care. The studies which found associations between concordant and discordant conditions and diabetes quality of care were conducted while the DQIP was being utilized (52, 54, 68). Our study, utilized data that was collected after the initiation of the CMS Physicians Quality Reporting Initiative (PQRI) was begun in 2009. The PQRI program was introduced to improve overall quality of care in the US and began the transition from fee-for-service to a pay-for-performance reimbursement model in the CMS patient populations (115). Health care providers are financially incentivized, through a reward and penalty system, for addressing pre-defined quality care measures, including the ADFSE for patients with diabetes (106). These financial incentives for the Medicare and Medicaid populations, may explain the null findings of this study which were based on data collected in 2015. Given the null findings included people with insurance other than Medicare and Medicaid, our results may be a reflection of a shift in clinical practice toward preventive care.

Another possible explanation for our null findings was the use of dichotomous indicators for the comorbidities. While the CFA model demonstrated a good fit with the data, there was poor convergent validity between the indicators and the latent factors defined in this study. The use of dichotomous variables limits the ability to define the severity and level of control of a disease. Disease severity, level of control and patient symptoms may influence the performance of screening exams, such as the ADFSE, during clinic visits and should thus be considered in research (108). Future research using clinical measures of severity and disease control, such as blood pressure measurements rather than a dichotomous indicator for presence of hypertension, may help increase convergent validity and thus improve final model fit. However, the issue of convergent validity may also be an indication that our proposed latent variables of concordant and discordant comorbidities are not a good statistical representation of the concept of comorbidity interrelatedness. A 2018 study by Magnan, et al. utilized exploratory factor analysis to stratify patients by clusters of chronic conditions (116). All five of the clusters explored increased the odds that diabetes preventive care processes were performed. However, the

ADFSE was not included. This and other statistical models will need to be explored in future research.

Despite these potential issues with the statistical model, our study has many notable strengths. First, it is the first study to utilize a large, nationally representative sample to explore the simultaneous relationship between types of comorbidities and the performance of the ADFSE. Second, the use of SEM methods allows for the assessment of the simultaneous effects of comorbidities that are concordant and discordant with diabetes care, while accounting for demographic and other characteristics. This is an improvement from prior studies that used statistical models that could only address count or category of comorbidity. Health care providers rarely have the luxury to consider each comorbidity in isolation and thus models which address only count or individual comorbidities are not an ideal representation of the clinical decision making process. Our model introduced, to a degree, the comorbidity interrelatedness that health care providers must consider in all clinical decision making processes (108).

While the use of a large, national data set was a strength of this study, the use of the BRFSS and the cross-sectional study design have additional limitations. First, the BRFSS is based on self-report and this may introduce recall, misclassification and social desirability bias into the results. The BRFSS also does not differentiate between individuals with type 1 diabetes and type 2 diabetes. Given the differences in disease etiology, medical management strategies and comorbidity profiles for these two populations, it would be prudent to explore the populations separately, but this is not possible with BRFSS (4). In addition, the BRFSS does not contain measures of severity for diabetes nor for the other comorbidities explored in this study. Both Piette and Kerr and Zulman, et al. suggested disease severity be included in the understanding of diabetes management (50, 108). Conditions that are controlled, or require minimal management, may not influence the performance of the ADFSE and result in overestimation of the contribution of a comorbidity. However, if a condition is dominant or severe, such as active cancer or end-stage COPD, the patient and health care provider may opt to forgo diabetes screenings to focus on the dominant condition. Unfortunately, the 2015 BRFSS does not contain data on disease severity. This lack of information could result in inaccurate estimates of the association between comorbidities and the ADFSE.

Given the current and potential future burden of DFUs and LEAs on the US population with diabetes and the burden on the US healthcare system it is important to understand the factors that influence the performance of the ADFSE. Our study gives an indication there may be a shift occurring the US health system where factors other than patient level comorbidities are influencing the performance of this cost-effective and efficient screening exam for the population with diabetes. The Piette and Kerr conceptual model includes the influence of healthcare organizations as well as health care provider's resources and priorities in care. It will be important to explore all of these factors simultaneously with patient level factors and priorities in future research on the ADFSE and other diabetes preventive care processes. It is predicted that more than 64 million Americans will have diabetes in 2050 and up to 34%, or 21 million people, will have a DFU during their lifetime (3, 23). Given the high cost of care and impact on patient quality of life, DFUs and LEAs must be reduced in the US population with diabetes. Identification of influential factors and development of interventions to increase the rate of the ADFSE to 100% in the US may be the only way to reduce the rates of DFUs and LEAs in the US and the world.

CHAPTER 5: The Associations Between Visit Frequency and Competing Demands on the Performance of the Recommended Annual Clinical Diabetic Foot Screening

ABSTRACT

Objective: This study to examine the relationship between the performance of other diabetes preventive care processes, the number of office visits for diabetes care and the completion of the annual diabetes foot screening exam (ADFSE).

Research Design and Methods: We used the BRFSS data from 38 states (n=19,056) to conduct a cross-sectional study. Respondents who provided a valid response regarding receipt of the ADFSE and had at least one visit to a health care provider in the past 12 months were included. Structural equation modeling was used to assess the simultaneous, direct effects of the performance of other diabetes preventive care processes and the number of office visits for diabetes care on the completion of the ADFSE.

Results: In 2015, 80.4% of the US population received the ADFSE. On average, patients with diabetes received 3.9 diabetes preventive care processes. The collection of preventive care processes demonstrated a 7% (OR: 1.07, 95%CI: 1.05-1.10) increase in the likelihood the ADFSE was performed for each unit increase in processes performed. The number of visits to a healthcare provider for diabetes care was found to have a non-significant association with the ADFSE (OR=1.00, 95%CI=1.00-1.00, p=0.56).

Conclusions: The completion of increasing numbers of diabetes preventive care processes are positively associated with the performance of the ADFSE. This may be due, in part, to the recent implementation of electronic medical records and financial incentives to healthcare providers to improve overall quality of care in the US healthcare system. Further, research should continue to explore other approaches which may positively influence the completion of the ADFSE and help reduce the development of DFUs in the US population.

INTRODUCTION

More than one-third of the cost of care for patients with diabetes, over $38 billion, in the US is a result of management of DFUs (117). The cost of managing a patient an active DFU is estimated to be $28,000-$31,000 annually, nearly twice as much as those who have diabetes alone (15). When a DFU fails to heal, the ultimate consequence for a patient is LEA. Between 2007 and 2010, up to 5% of patients with diabetes underwent an LEA to resolve a non-healing DFU (15). Despite medical advances in wound care, the 5-year mortality rate for patients with a DFU or a LEA is between 45% and 72% (28, 86). However, cost effective ADFSE and patient education prevention programs can prevent up 75% of DFUs and 85% of LEAs (31, 32). Despite the benefits of performing the ADFSE, less than three-quarters of the US population with diabetes received this life-saving screening exam in 2015 (88).

The ADFSE is one of 11 recommended preventive care processes endorsed by the ADA and CMS which should be performed at least annually for patients with diabetes (114). Between 2009 and 2012, 86% of the population with diabetes underwent blood cholesterol testing but only 50% received the recommended twice annual HgbA1c blood test (118). Historically, provision rates of these preventive care screening processes remain suboptimal due to competing demands. These competing demands including such as provider preferences and expertise, visit length and, patient concerns, financial constraints and comorbidities (74, 77, 101, 102). The Piette and Kerr conceptual model explores competing demands for diabetes care and presents "diabetes medical management" as one factor that has direct influence on diabetes care (50). While research has explored competing demands from concurrent comorbidities, little is known about the influences of the frequency of outpatient visit for diabetes care and other diabetes preventive care processes on the performance of the ADFSE (52, 54, 55, 71) .

Prior research has demonstrated two to four health care visits per year increased the likelihood that diabetes preventive care processes, such as HgbA1c testing and retinal exams, were completed (41, 65, 76, 80). That same frequency of visits to a health provider increased the odds the ADFSE was performed (41, 65, 76). A 2005 study demonstrated that performance of mammograms and Pap smears increased significantly as the number of completed diabetes care processes increased (79). To date, no studies have addressed the influence of both the patient visits frequency and clinical competing demands on the performance of the ADFSE. Thus, this study aims to examine the relationship between the performance of other diabetes preventive care processes, the number of office visits for diabetes care and the completion of the ADFSE.

RESEARCH DESIGN AND METHODS

Data Source and Sample

This study used data from the 2015 BRFSS, an annual, cross-sectional survey conducted by the CDC (81). The BRFSS surveys non-institutionalized US residents, over the age of 18 years, to collect information on preventive health care practices, health risk behaviors, chronic diseases, injuries and preventable infectious diseases that affect the US adult population. The methods for sample weighting to account for the complex sample design are described elsewhere (82).

In 2015, 38 states participated in the BRFSS Diabetes Optional Module which contained 10 questions specific to diabetes specific self-management activities and recommended preventive care processes. Survey respondents who answered “yes” to the question “Has a doctor, nurse or other health professional every told you that you have diabetes?” were included in the sample eligible to participate in the Diabetes Optional Module (n=36,085). Respondents with “pre-diabetes,” “borderline diabetes,” and “gestational diabetes” were excluded from participation in the Diabetes Optional Module.

Inclusion in this study also required respondents to have at least one foot, at least one visit to a health care provider for diabetes care in the past 12 months and provide valid responses to all outcome, exposure and confounder variables. Respondents with no feet (n=328) were identified by the answer of “no feet” to the survey question “About how often do you check your feet for any sores or irritations?” Having at least one visit to a health provider for diabetes care in the past year was determined utilizing the question “About how many times in the past 12 months have you seen a doctor, nurse or other health professional for your diabetes?” Respondents reporting no visits, “don’t know/not sure” and those who refused to answer the question were excluded from the study sample (n=4,121). Finally, an additional 12,580 respondents were excluded from the study sample due to invalid responses to the outcome, exposure and confounding variables. The final study sample size was 19,056.

Measures

The primary outcome of this study was defined as having at least one ADFSE in the past 12 months. The 2015 BRFSS Diabetes Optional Module asks “About how many times in the past 12 months has a health professional checked your feet for any sores or irritations?” Responses were continuous between 1 and 76, “none,” “don’t know,” or refused to answer. The responses were dichotomized to “yes, at least one time” or “no.” Respondents providing answers of “don’t know” or those who refused to answer were be considered “missing” and excluded from the data analysis.

This study's main exposure variables included the number of visits to a health care provider for diabetes care and a latent variable to represent the competing demands of diabetes preventive care processes. The 2015 BRFSS collected information on five of the recommended processes which included: HgbA1c and cholesterol blood tests, retinal exams, and receipt of influenza and pneumonia vaccinations. The number of visits for diabetes care was operationalized using the questions "About how many times in the past 12 months have you seen a doctor, nurse or other health professional for your diabetes?" Responses were reported as a continuous number of visits for diabetes care (1-76 visits) or no visits and were retained as a continuous variable in the statistical model.

The five preventive care processes were defined based on frequency recommendations by the ADA (4, 33, 119, 120). Responses to the question "About how many times in the past 12 months has a doctor, nurse, or other health professional checked you for "A one C"?" were dichotomized to "at least 2 HgbA1c tests per year" and "less than 2 HgbA1c tests per year." The 2015 BRFSS asks respondents "Have you EVER had your blood cholesterol checked?" Participants who respond "no" were classified as "not adherent to cholesterol screening guidelines." For those who answered "yes" to this questions, the follow-up question "About how long has it been since you last had your blood cholesterol checked?" was asked. Respondents answering "in the last year" and "in the last 2 years" were categorized as "yes, adherent to cholesterol screening guidelines." Those who responded "in the last 5 years" or "5 or more years ago" were categorized at "not adherent to cholesterol screening guidelines." Adherence to the recommendation for comprehensive eye exams was determined by the question "When was the last time you had an eye exam in which the pupils were dilated?" Responses of "in the past month," "in the past year," and "in the past 2 years" were dichotomized to "yes, adherent with recommended retinal exams." Respondents indicating "2 or more years ago" and "never" were dichotomized to "no, not adherent with recommended retinal exams." Receipt of an annual influenza and pneumococcal vaccinations, were determined by the question "During the past 12 months, have you had either a flu shot or a flu vaccine that was sprayed in your nose?" and "Have you ever had a pneumonia shot?" The BRFSS collected "yes" and "no" responses and no recoding was required.

Potential confounders for this study were based on prior studies and included: gender (male or female), respondent age (<65 year or ≥65 years), race (White non-Hispanic, Black non-Hispanic, Hispanic, or other), education (did not graduate from high school, graduated from high school , attended college or technical school, or graduated from college or technical school), marital status (married, divorced, widowed or never married), annual household income (<$15,000, $15,000- <$25,000, $25,000- <$35,000, $35,000- <$50,000, or ≥$50,000), insurance status (insured or uninsured), insulin use (yes or no) and receipt of a diabetes education course (yes or no) (65, 68, 77, 79, 80, 101, 121, 122).

Statistical Analysis

Descriptive statistics for all outcome, exposure and potential confounder variables were calculated with adjustment for the complex sample design of the BRFSS to provide population level proportions. Descriptive statistics were also provided for the sample stratified by receipt or non-receipt of the ADFSE. Chi-squared and student's t-test were utilized to compare groups.

The SEM two step approach was used to assess the simultaneous, direct effects of the latent variables for competing demands and the number of health care visits have on the performance of the ADFSE. CFA was conducted to determine the goodness-of-fit for the measurement model for the latent variable. The latent variable indicators were: HgbA1c and cholesterol blood tests, retinal exams, and receipt of influenza and pneumonia vaccinations. Good model fit was defined by an RMSEA less than 0.05 and CFI of greater than 0.95 (113). Standardized solutions were calculated for factor loading estimates. Indicators with poor correlations ($r<0.2$) to the latent construct were be removed from the model. Model fit was be reassessed for any trimmed model. Unstandardized and standardized solutions were calculated for each indicator along with variance explained.

Potential confounding variables were determined by calculating the odds ratio and 95% CI between each potential confounder and the outcome. The final model included confounders that had a significant ($p<0.05$) bivariate association with the outcome. The final structural model, including the latent variable, number of visits for diabetes care and significant confounders, was assessed for goodness-of-fit. An RMSEA of less than 0.05 and a CFI greater than 0.95 . Data analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) and MPlus version 9 (Muthén & Muthén, Los Angeles, CA, USA).

RESULTS

Table 1 presents the descriptive statistics for the total population and stratified based on receipt of the ADFSE. In 2015, 80.4% of the US population received the ADFSE. The sample was 51.0% male, 57.4% under the age of 65 and 62.7% non-Hispanic white. A majority of the population reported having at least some college education (54.0%), were married or in a member of an unmarried couple (62.5%) and reported an annual household income over $35,000 (52.5%). Over 95% of the population had some form of health insurance, only 34.5% reported

Table 5-1- Demographic characteristics of persons aged ≥18 years with diagnosed diabetes, 38 states* (n=19,056)								
	Population estimate		Received annual diabetic foot screening exam in Past 12 months				P value‡	Bivariate analysis
			Yes 80.4±0.9%†		No 19.6±0.9%†			Odds ratio (95% CI)
	%	SE	%	SE	%	SE		
DEMOGRAPHIC CHARACTERISTICS								
Sex								
Male	51.0	1.1	51.6	1.2	51.6	2.4	0.2357	1.14 (0.92-1.41)
Female	49.0	1.1	48.4	1.2	48.4	2.4		
Age (years)								
18-64	57.4	1.0	56.9	1.2	61.7	2.4	0.0763	0.82 (0.66-1.02)
≥65	42.2	1.0	43.1	1.2	38.3	2.4		
Race								
Non-Hispanic white	62.7	1.2	63.2	1.3	60.3	2.7	0.0029	ref
Non-Hispanic black	15.0	0.7	16.1	0.8	10.6	1.2		0.69 (0.53-0.90)
Hispanic	14.3	1.0	12.8	1.1	20.4	2.9		1.67 (1.11-2.50)
Other	8.0	1.0	7.8	1.1	8.6	1.7		1.16 (0.69-1.94)
Education								
Less than high school	16.0	0.9	16.0	1.0	16.0	2.2	0.7040	0.94 (0.63-1.41)
High school graduate	30.3	0.9	30.0	1.0	31.7	2.3		1.00 (0.75-1.33)
Some college	32.9	1.0	33.2	1.1	30.1	2.0		0.86 (0.66-1.12)
College graduate	21.1	0.9	20.8	1.0	22.1	1.9		ref
Marital status								
Married/couple	62.5	0.9	62.7	1.0	61.4	2.2	0.7042	ref
Divorced/separated	16.5	0.6	16.1	0.6	18.0	1.5		1.14 (0.89-1.46)
Widowed	12.2	0.5	12.2	0.6	11.9	1.1		1.00 (0.78-1.27)
Never married	8.9	0.5	8.9	0.6	8.7	1.1		0.99 (0.72-1.37)
Annual Household Income								
<$15,000	14.2	0.8	13.8	0.9	16.0	2.2	0.4751	1.30 (0.89-1.89)
$15,000-<$25,000	21.3	0.8	21.3	0.9	21.2	2.1		1.11 (0.83-1.49)
$25,000-<$35,000	12.1	0.6	11.7	0.7	13.5	1.7		1.29 (0.92-1.80)
$35,000-<$50,000	13.7	0.6	13.7	0.6	13.7	1.4		1.11 (0.84-1.48)
≥$50,000	38.8	1.1	39.6	2.2	35.5	2.2		ref
Health insurance								
Yes	95.1	0.5	95.3	0.6	94.1	1.0	0.2613	ref
No	4.9	0.5	4.7	0.6	5.9	1.0		1.28 (0.83-2.00)
Use insulin								
Yes	34.5	1.0	37.2	1.1	23.3	2.0	<0.0001	ref
No	65.5	1.0	62.8	1.1	76.7	2.0		1.95 (1.54-2.48)
Received diabetes mellitus education								
Yes	60.3	1.0	63.0	1.1	48.9	2.4	<0.0001	ref
No	39.7	1.0	37.0	1.1	51.1	2.4		1.78 (1.44-2.21)

* The 38 states include: In 2015, the 38 states that participated in the Diabetes Mellitus Optional Module included: Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, Wyoming. † Percentage of population ± SE. ‡ P-values from χ^2 test.

using insulin for management of diabetes, and 60.3% report having received formal diabetes mellitus education.

Examining the study population who received the ADFSE in 2015, 51.6% were male and 56.9% were under the age of 65. Race was distributed as follows: 63.2% non-Hispanic white, 16.1% non-Hispanic black, 12.8% Hispanic and 7.8% reported other races. A majority of the population who received the ADFSE had at least some college level education (54.0%), were married or a member of an unmarried couple (62.7%) and reported over $35,000 in annual household income (53.5%). Ninety-five and half percent (95.5%) reported having some form of health insurance, 37.2% used insulin and 63.0% received formal diabetes education and also received the ADFSE in 2015.

Among the population that did not receive the ADFSE, 51.6% were male, 61.7% were under the age of 65. Exploration of the distribution of race in those who did not receive the ADFSE 60.3% were non-Hispanic white, 10.6% were non-Hispanic black, 20.4% were Hispanic and 8.6% reported another race. Similar to the population that received the ADFSE, of those who were not 52.2% were married or a member of an unmarried couple, 49.2% reported an annual household income over $35,000 and 94.1% reported having health insurance. However, only 23.3% who used insulin and 48.9% who received formal diabetes education did not receive the ADFSE.

Table 2 displays the proportion of the total population, and the population stratified by ADFSE receipt in 2015, who reported completion of the 5 diabetes preventive care processes. On average, the population received 3.9 of the preventive care practices and had an average of 4.0 visits to a health care provider for diabetes care in the past 12 months. In the population overall, 81.4% received at least 2 HgbA1c tests in the past 12 months and 98.4% received a cholesterol blood test in the past 2 years. Comprehensive visions exams were completed by 88.7% of the study population in the past 12 months. Vaccine receipt was not completed at similar rates of the other preventive care processes. In 2015, 59.5% received an influenza vaccine in the past 12 months and 64.4% have ever received the pneumococcal vaccine.

Table 5-2- Reported completion of diabetes preventive care processes in persons aged ≥18 years with diagnosed diabetes, 38 states* (n=19,056)

	Population estimate		Received annual diabetes foot screening exam in past 12 months				P value†
			Yes 80.4±0.9%†		No 19.6±0.9%†		
	%	SE	%	SE	%	SE	
At least 2 HgbA1c tests in past 12 months							<0.0001
Yes	81.4	0.8	83.4	0.9	73.0	1.9	
No	18.6	0.8	16.6	0.9	27.0	1.9	
Cholesterol blood test in past 2 years							
Yes	98.4	0.4	98.5	0.5	97.9	0.5	0.3336
No	1.6	0.4	1.5	0.5	2.1	0.5	
Comprehensive vision exam in last 12 months							
Yes	88.7	0.6	90.9	0.6	80.0	1.9	<0.0001
No	11.3	0.6	9.1	0.6	20.0	1.9	
Received influenza vaccine in past 12 months							
Yes	59.5	1.1	60.6	1.2	54.9	2.4	0.0314
No	40.5	1.1	39.5	1.2	45.1	2.4	
Ever receive pneumococcal vaccine							
Yes	64.4	1.1	67.2	1.2	52.9	2.4	<0.0001
No	35.6	1.1	32.8	1.2	47.1	2.4	

	Population Mean		Received annual diabetes foot screening exam in past 12 months				P value‡
			Yes		No		
	Mean	SE	Mean	SE	Mean	SE	
Visits for diabetes care	3.95	0.13	4.09	0.15	3.41	0.15	<0.0001
Number of diabetes preventive care processes completed	3.92	0.01	4.01	0.03	3.59	0.05	<0.0001

* The 38 states include: In 2015, the 38 states that participated in the Diabetes Mellitus Optional Module included: Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Vermont, Utah, Virginia, Washington, Wisconsin, Wyoming.
† Percentage of population ± SE. ‡ P-values from χ^2 test.

When the population was stratified, the group who received the ADFSE receive an average of 4.0 diabetes preventive care processes and reported an average of 4.1 visit to a healthcare provider for diabetes care. Of this population, 83.4% received the recommend number of HgbA1c tests, 98.5% received a cholesterol blood test in the last 2 years and 90.9% received a comprehensive vision exam in the past year. Finally, 60.6% received the influenza vaccine in the past 12 months and 67.2% have receipted a pneumococcal vaccine as well are receiving the ADFSE in 2015.

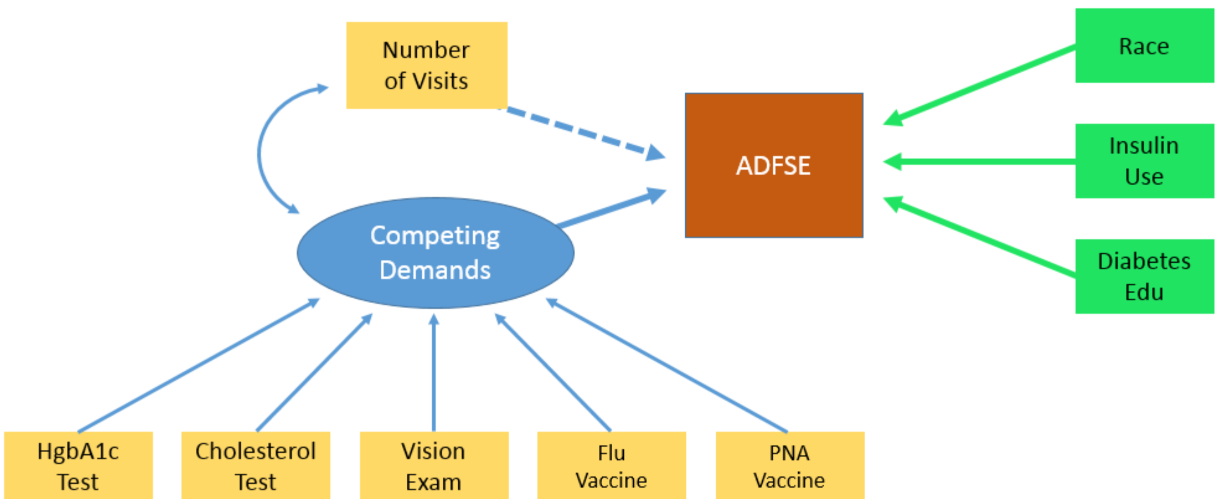
The population who did not receive the ADFSE reported receiving an average of 3.6 diabetes preventive care processes and attended an average of 3.4 visits to a healthcare provider for diabetes care. This group reported receipt of diabetes care processes as: 73.0% had 2 HgbA1c tests in the past 12 months, 97.9% have had a cholesterol blood test in the past 2 years, 80.0% have had a comprehensive vision exam in the last 12 months, 54.9% reported receipt of the influenza vaccine in the past 12 months and 52.9% have received the pneumococcal vaccine.

The fit statistics for the CFA model were: χ^2 (df=5)=18.133, p=0.0028, RMSEA=0.01 (90%CI: 0.006-0.018), CFI=0.95. The RMSEA and CFI statistics indicate the measurement model is a good fit of the data. Table 3 presents the unstandardized coefficients, standardized coefficients and the percentage of variance the latent variable explains for each indicator. The latent variable for competing demands explains over 56% of the variance for the indicator for receipt of a comprehensive vision exam in the past 2 years. However, the latent variable only explains 21% of the variance for the indicator for receipt of 2 HgbA1c blood tests in the past 12 months.

Table 5-3- Final CFA model unstandardized coefficients, standardized coefficients and percentage of variance explained for each indicator. RMSEA=0.01. CFI=0.95				
Indicator	Latent variable	Unstandardized coefficient (B)	Standardized coefficient (β)	Percentage of variance explained for the indicator
At least 2 HgbA1c tests in past 12 months	Competing demands	1.00	0.46±0.04	21.2%
Cholesterol blood test in past 2 years	Competing demands	1.42±0.26	0.65±0.12	42.3%
Comprehensive vision exam in last 12 months	Competing demands	0.75±0.14	0.34±0.05	56.3%
Received influenza vaccine in past 12 months	Competing demands	1.08±0.14	0.49±0.05	24.0%
Ever receive pneumococcal vaccine	Competing demands	1.51±0.18	0.69±0.05	47.6%

Figure 1 presents the results of the full SEM model including odds ratios (OR), 95%CI and p values for each of the paths. The full SEM model fit statistics were: χ^2 (df=21)=268.654, p<0.0001, RMSEA=0.018 (90%CI: 0.016-0.021), CFI=0.832. The null model RMSEA was found to be 0.038 and indicates the CFI may not be ideal to measure the fit of this model (113). There was a significant association (P<0.001) between the competing demands latent variable and performance of the ADFSE. For every unit increase in competing demands, there was a 7% (OR: 1.07, 95%CI: 1.05-1.10, p<0.0001) increase in the likelihood the ADFSE was performed. No significant association was present between the number of visits for diabetes care and the performance of the ADFSE (OR=1.00, 95%CI=1.00-1.00, p=0.56).

Figure 5-1- Final SEM model. RMSEA=0.036.



Solid pathways indicate statistically significant model pathways. Dashed pathways indicate non-significant pathways. ADFSE- annual diabetes foot screening exam. Flu- influenza. PNA- pneumococcal.

Table 5-4- Odds ratios (OR), 95% confidence intervals (95% CI)) and p-values for regression pathways of the final SEM model.

Pathway	OR	95% CI	P-value
Competing demands → ADFSE	1.07	1.05-1.10	<0.0001
Number of visits to healthcare provider → ADFSE	1.00	1.00-1.00	0.56
Race → ADFSE	0.98	0.97-0.99	0.16
Insulin use → ADFSE	1.07	1.05-1.09	<0.0001
Diabetes education → ADFSE	1.07	1.05-1.09	<0.0001

CONCLUSIONS

The results of this study found that over 80% of patients with diabetes who had at least one visit to a health care provider received the ADFSE. This rate is exceeds the goal of Healthy People 2020, but our rate does not include those without a visit to a health provider, and may help contribute to lower rates of DFUs and LEAs in the future (91). We also found a positive association between the performance of an increasing number of other diabetes preventive care process, often defined as improved quality of care, and the performance of the ADFSE. Our results suggest that completion of multiple preventive care processes recommended for patients with diabetes is not competing with the performance of the ADFSE but rather improves performance of the ADFSE. Unlike prior research, our study did not find a significant association between the number of visits to a health care provider for diabetes care and the performance of the ADFSE.

Recent changes in the payments systems in and the structure of the US healthcare systems may help explain our finding of the positive association between improved diabetes quality of care and the performance of the ADFSE. Incentive programs by CMS to implement meaningful use of electronic medical records (EMR), including development of chronic disease registries, began in the US in 2011 (123). Since that time research has demonstrated that the use of a diabetes registry in clinical practice improved rates of completion of diabetes preventive care processes and reduced hospital utilization in this patient population. A systematic literature review found that the utilization of clinical decision support systems within EMR also demonstrated improvements in the quality of care provided to patients with diabetes (124). CMS has also provided 1.5% Medicare payment bonuses to providers who participated in the Physician Quality Reporting System (PQRS) from 2007 through 2015 (125). The PQRS system included a Diabetes Measure which included addressing HgbA1c control, influenza vaccine, vision exams, management of nephropathy, exam for PN and smoking cessation interventions at specified intervals of patient visits (106). Participation in the PQRS system was associated with improvements in the provision of the ADFSE along with other quality of care measures in patients with diabetes (126). The use of inventive payments to improve diabetes quality of care is one likely explanation for our positive finding between the performance of diabetes preventive care processes and the performance of the ADFSE.

The introduction of patient centered medical home (PCMH) model into the US healthcare system may also explain the positive association between completion of increasing numbers of diabetes preventive care processes and the performance of the ADFSE (127). PCMHs strive to provide accessible, patient-centered, coordinated and comprehensive clinical care. Data collected by the MEPS, a nationally representative survey, revealed patients who belong to a PCMH had higher rates of completion of ADA recommended diabetes preventive care processes compared to those patient who did not belong to a PCMH (118). The VHA has also implemented the PCMH model and demonstrated improvements diabetes quality of care (128). Specifically, the ADFSE completion rates have increased. In 2013, nearly 20% of US primary providers reporting belonging to a PCMH model (129).

This study has many strengths including being the first study, to our knowledge, to explore the simultaneous association between competing demands of diabetes care and the number of visits for diabetes care. Our study also utilized a large, national data set which provided results that are generalizable to the US population with diabetes. In addition, the BRFSS is also used to inform Healthy People 2020 which increases the external validity of our results (62). The main outcome of our study, self-report of the ADFSE, has been validated in prior studies, which reduces the risk of misclassification bias in our results (43, 103).

Despite these strengths, our study has several limitations. The self-report nature of the BRFSS data may introduce recall and social desirability bias into our results while the cross sectional design limited determination of causality. Another major limitation is the inability to differentiate patients with type 1 diabetes and type 2 diabetes in the study sample. Given the differences in disease management, prioritization of preventive care processes, and the management of other comorbidities, the joint analysis of both populations may cancel out a difference in effect (4). In addition, the BRFSS does not have information on the number of visits respondents make to other health care providers for management of medical issues other than diabetes. Diabetes specific preventive care processes may have been completed in these visits but not accounted for in our analysis.

In conclusion our study sought to explore the relationship between competing demands and the number of visits for diabetes care and the performance of the ADFSE. Improving overall diabetes quality of care can potentially improve the rates of ADFSE completion. Thus programs to aid health care providers in completion of diabetes preventive care processes, such as use of EMR, financial incentives to complete preventive screenings and the PCMH model, should be further explored to determine their effect on increasing the rates of the ADFSE and ultimately, the reduction of DFUs and LEAs. While the benefit of ADFSE on the prevention of these life threatening complications are well known, efforts must be made to increase their application in the US clinical care environment. Reports from 2017 estimate that between 1.0 million to 3.5 million people in the US have had a DFU at some point in their lifetime and more than 100,000 underwent an LEA (8, 23). These numbers can only be reduced with provision of evidence-based screening and prevention practices.

CHAPTER 6: Summary

SUMMARY

DFUs and LEAs continue to be a major public health problem and result in decreased quality of life for patients and high costs of care for the US healthcare system (8, 15, 24, 130). Rates of DFUs and LEAs can be reduced through comprehensive screening and prevention programs (32, 33). The ADA and the IWGDF recommend patients with diabetes receive a comprehensive diabetic foot exam at least once a year (33-35). However, population estimates from 2012 demonstrated that only 71% of the US population received the ADFSE (38). Clinical reports of completion of the ADFSE vary from 12% to 95% (39-46). Prior research has identified age, race, gender, education, insurance and rural residency are factors that are associated with the performance of the ADFSE (47-49). However, little research has explored the association between clinically meaningful factors and the performance of the ADFSE. The aim of this dissertation was to examine the associations between clinically meaningful factors and the performance of the ADFSE. The Piette and Kerr conceptual framework on competing demands of chronic comorbid conditions in diabetes care was utilized to guide the analyses (50). Our studies found between 78.2% and 80.4% of patient with diabetes, who had at least one visit to a healthcare provider for diabetes care, received the ADFSE in 2015.

Chapter 3, titled “Are diabetes mellitus self-management behaviors associated with the receipt of the recommended annual diabetes foot screening examination?” examined the relationship between 8 individual diabetes self-management behaviors and the performance of the ADFSE. The eight diabetes self-management behaviors included: performing SMBG at least one time per day, performing a self-foot inspection at least one time per day, receipt of the influenza vaccine in the past 12 months, receipt of the pneumococcal vaccine at any time, meeting aerobic and resistance training exercise recommendations, smoking status and alcohol consumption. Logistic regression models were used to assess the association between an individual self-management behavior and the receipt of the ADFSE. One-way interactions with insulin use status and receipt of formal diabetes education were also examined to determine if these variables modified the association between a self-management behavior and performance of the ADFSE. Insulin use was found to modify the association between receipt of the influenza vaccine, performance of the recommended dosage of aerobic exercise and avoidance of excessive alcohol consumption. However, the receipt of the influenza vaccine and the performance of the recommended dosage of aerobic exercise did not demonstrate significant associations with the performance of the ADFSE when the effect modification by insulin use was considered. Among those who do not use insulin and do consume an excessive amount of alcohol there is more than 3 times increased odds ADFSE is performed compared to those who do not use insulin and avoid excessive alcohol usage. Both status of insulin use and of the receipt of formal diabetes education were found to be significant effect modifiers of the relationship between performance of SMBG at least one time per day and the receipt of the ADFSE. Among the groups who do not use insulin and did and did not receive formal diabetes education, those who do not perform SMBG at least one time per day were over 48% less likely to receive the ADFSE compared to counterparts who did perform the recommended self-management behavior. These results suggest that patient education programs which educate patients on and encourage performance of self-management behaviors may help improve the rates of performance of the ADFSE in the US population with diabetes.

Chapter 4, entitled "The association between comorbidities and the performance of the recommended annual diabetic foot screening examination" examined the simultaneous, direct effects of concordant and discordant comorbidities on the performance of the ADFSE. SEM methods were employed to simulate clinical decision making which allows for consideration of multiple types of information to be considered in parallel. No significant simultaneous, direct associations between concordant nor discordant medical comorbidities and the performance of the ADFSE were found. These results may indicate that decisions about performance of the ADFSE are not influenced by patients' comorbidity profiles. They may also be a reflection of changing payment models and quality reporting requirements which been implemented over the past decade within the US healthcare system.

The last chapter, Chapter 5, titled "The associations between visit frequency and competing demands on the performance of recommended annual clinical diabetic foot screening" examined the associations between the performance of other diabetes preventive care processes, the number of office visits for diabetes care and the completion of the ADFSE. SEM method were utilized to explore these associations simultaneously. The number of visits to a healthcare provider for diabetes care was found to have a non-significant association with the ADFSE in our model. The model demonstrated a positive association between the performance of an increasing number of other diabetes preventive care process, often defined as improved quality of care, and the performance of the ADFSE. Our results suggest that completion of multiple preventive care processes recommended for patients with diabetes is not competing with the performance of the ADFSE but rather improves performance of the ADFSE. These results suggest that programs which encourage healthcare providers to improve overall quality of care to patients with diabetes may be one way to improve the performance of the ADFSE. Implementation of patient programs to increase patient activation and participation in their own care, and empowering patients to request providers perform all recommended preventive care, may also help improve the performance of the ADFSE.

IMPLICATIONS FOR PUBLIC HEALTH

Diabetes is predicted to affect more than one-quart of the US population by 2050 (3). By this time, as many as 44 million US residents will develop a DFU in their lifetime (3, 23, 131). Given the poor quality of life and high cost of care with a DFU, immediate action is needed to reduce the rates of DFUs and LEAs in those with diabetes (15, 130, 132). While recent population level intervention to improve overall diabetes care in the US have made headway, further work is required to ensure the problems of the diabetic foot are also addressed (133).

First, public awareness of the complication of the diabetic foot, DFUs and LEAs needs to increase in the US. While November is “National Diabetes Awareness Month”, The Save a Leg, Save a Life Foundation began the “White Sock Campaign” in 2013 (134, 135). The “White Sock Campaign” was designed to raise awareness of the complications of diabetes and PAD. At this time the campaign needs to extend beyond the walls of medical buildings and into the public domain to increase awareness of patients, family members, and caregivers of those with diabetes. National education programs, such as those successfully used in research studies, designed to increase patient and caregiver awareness of the diabetes foot and provide strategies to help reduce the risk of DFUs are also necessary to empower the population to combat this growing public health problem (31, 32).

Second, all healthcare providers should be trained and encouraged to administer the ADFSE during every patient interaction, or at regular intervals during periods of care. The exam can be performed by a variety of healthcare providers such as physician podiatrists, nurses, physical therapists and pharmacists (37). The exam requires less than 5 minutes to complete and is low cost, requiring only a 3.06 Semmes-Weinstein monofilament. With more healthcare providers performing the ADFSE, more patients at risk for DFU development can be identified and referred to appropriate prevention and treatment programs. However, the number of these programs remains suboptimal in the US, and internationally, due to lack of time in the clinical setting, inconsistent healthcare provider training and reimbursement concerns (136). Policy makers and health insurance providers will need to make DFU prevention a priority and implement changes to support healthcare providers and provide patients with evidence based care.

FUTURE RESEARCH

Future research is necessary to ensure that 100% of the US population with diabetes receives the ADFSE. While this dissertation found positive associations between the ADFSE and various clinically relevant factors, the cross-sectional nature of the data precludes the ability to determine causality. Longitudinal data, from EMRs, national registries or prospective studies, will be required to explore whether diabetes self-management behavior and performance of other diabetes preventive care processes lead directly to improved rates of performance of the ADFSE.

Additional studies on these topics will also benefit from exploring T1DM and T2DM populations separately and provider type (eg- general practice vs. endocrinology). Given the differences in disease etiology, age of onset differences, and differences in health care service utilization it will be important for future studies to ensure each patient group receives appropriate research consideration (4, 137). Prior research has also identified provider type can influence the performance of preventive health services (77, 100-102, 137). Specific to diabetes preventive care, endocrinologists were more likely to administer HgbA1c test and retinal exams compared to primary care physicians (100). Prioritization of the multiple recommended diabetes preventive care processes also differs by provider type (77).

Exploration of the effect modification by status of insulin use and diabetes education is also required in future research. It is possible that some portion of the effect modification by insulin use, found in this dissertation, may be due to the differences in the management of T1DM and T2DM mentioned previously (4). These effect modifications may also be explained by other physiologic measures, such as HgbA1c level, blood cholesterol levels or blood pressure that are used to determine relative control of diabetes and associated comorbidities (120). The effect modification based on receipt of diabetes education which was observed in this dissertation should also be further explored. One prior study has demonstrated that while diabetes education and knowledge improve patient performance of self-management behaviors, it does not have an association with completion of preventive care nor control of metabolic measures (94). It is possible that diabetes education is a proxy for a yet unexplored variable that may explain group differences. Finally, while not explored in this dissertation, future research will also need to determine if effect modification by status of insulin use or formal diabetes education, exists when other pathways of the Piette and Kerr model are examined (50).

Ultimately, future research will also need to firmly establish if the positive findings of this dissertation will reduce the rates of DFUs and LEAs in the US. DFU and LEA rate reductions have resulted from comprehensive programs that began with the ADFSE and then provided appropriate interventions and follow up (31, 32, 138-142). Margolis, et al. utilized the BRFSS and demonstrated a negative association between receipt of colorectal cancer screening and LEAs suggesting that receipt of preventive care processes may reduce LEAs (92). However, this study did not find any significant associations between the examined diabetes self-management behaviors, some of which were explored in this study, and LEAs. Regardless, a causal link must be established between diabetes self-management behaviors and the performance of other diabetes preventive care processes, the ADFSE and reduction in rates of DFUs and LEAs to ensure early interventions at the prevention level will result in a positive outcomes on quality of life for patients with diabetes and reduce the burden on the healthcare system.

CHAPTER 7: References

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Vita

Trisha Arlene Sando was born on December 12, 1978 in Palo Alto, California. She graduated from Thousand Oaks High School in 1997. She received her Bachelors of Science in Biology from The California Institute of Technology in 2001. Trisha earned her Doctor of Physical Therapy degree from University of Southern California in 2005. She obtained her Certified Wound Specialist credential in 2008. In 2015, Trisha earned her Masters of Science in Wound Healing and Tissue Repair from Cardiff University, Wales. She has worked as a Physical Therapist in both wound care and acute care physical therapy since 2005.

RESEARCH EXPERIENCE

Research Assistant 2014-present

Virginia Commonwealth University- Division of Epidemiology
Richmond, VA
Epidemiologic studies on diabetic foot screening, physical therapy services for stroke survivors and caregiver burden

Research Assistant- Part-time 2003-2004

University of Southern California- Division of Biokinesiology and Physical Therapy
Motor Control and Development Laboratory
Los Angeles, CA
Data collection of ingestive behavior in MAO knockout mice

Research Assistant- Full-time 2001-2002

Arbor Vita Corporation
Sunnyvale, CA
Molecular biology- gene cloning, protein production and functional analysis, immunobiology

Undergraduate Researcher/ SURF student 2000-2001

California Institute of Technology- Division of Biology
Strauss Virology Laboratory
Pasadena, CA
Molecular studies of Yellow Fever Virus

CLINICAL EXPERIENCE

Physical Therapist December 2015-present

Virginia Commonwealth University Medical Center
Inpatient acute care

Physical Therapist April 2015-March 2016

Genesis Rehab Services
Long term care

Physical Therapist November 2013-July 2014
Cross Country TravCorps
Antelope Valley Hospital- Lancaster, CA
Inpatient acute care

Physical Therapist February 2013-October 2013
Cross Country TravCorps
Olive View Medical Center- Sylmar, CA
Inpatient acute care

Physical Therapist July 2005-January 2013
USC University Hospital/Keck Hospital of USC- Department of Physical Therapy
Wound care, Inpatient acute care

TEACHING EXPERIENCE

Instructor Fall 2017
VCU Department of Physical Therapy
Richmond, VA
Kinesiology Laboratory

Clinical Instructor 2005-2012
USC University Hospital/Keck Hospital of USC
Los Angeles, CA
Wound care, Inpatient acute care

Teaching Assistant 2005-2010
California Institute of Technology – Division of Biology
Pasadena, CA
Bi 145a, Bi 145b- Human Physiology

Tutor Spring 2004
University of Southern California- Division of Biokinesiology and Physical Therapy
Los Angeles, CA
Neuroscience

Teaching Assistant Spring 1999, 2000, 2001
California Institute of Technology- Division of Biology
Pasadena, CA
Biology 1 (BI1)- Fundamentals of Modern Biology

PROFESSIONAL LICENCES AND CERTIFICATION

Physical Therapy Licensure
California # 30442 2005-present
Texas #1235866 2013-2015

Virginia #2305209239 2015-present

Certified Wound Specialist 2008-present
American Board of Wound Management
CWS ID# 3381

Clinical Instructor Credential 2009-present
American Physical Therapy Association

Basic Life Support for Health Care Providers 2002-present
American Heart Association

PUBLICATIONS

Cohen, SA., Cook, S.K., Hall, L., **Sando, T.A.**, Sabik, N. "What aspects of rural life contribute to rural-urban health disparities in older adults? Evidence from a national survey." *The Journal of Rural Health*. 2017.

Cohen, S.A., Cook, SK., Kelley, L., Foutz, JD., **Sando, TA.**. "A Closer Look at Rural-Urban Health Disparities: Associations Between Obesity and Rurality Vary by Geospatial and Sociodemographic Factors." *The Journal of Rural Health.* Vol 33, Issue 2. (2017). Pg 167-179.

Cohen, S.A., Cook, S., Kelly, L., **Sando, TA.,** Bell, A.E. "Psychosocial factors of caregiver burden in child caregivers: results from the new national study of caregiving." *Health and Quality of Life Outcomes* Vol 13. Issue 1 (2015): 120.

Corver, J., Lenches, E., Smith, K., Robison, R., **Sando, T**., Strauss, E., Strauss, J. "Fine Mapping of a cis-Acting Sequence Element in Yellow Fever Virus RNA That Is Required for RNA Replication and Cyclization". *Journal of Virology*. Vol. 77, Issue 3. Feb. 2003. Pg 2265-2270.

PEER REVIEWED ABSTRACTS/CONFERENCES

Randolph, B., Goldberg, L., **Sando, T**. The Use of Supine Ergometry to Facilitate Conservative Treatment of Ileus in the Critically Ill Patient: A Case Series. American Physical Therapy Association- Combined Sections Meeting. Febuary 21-24, 2018. New Orleans, LA.

Sando, TA., Perera, R., Lu, J. The Influence of Comorbid Conditions on the Performance of Annual Comprehensive Foot Examinations in the US Population with Diabetes Mellitus. Symposium on Advanced Wound Care. April 5-9, 2017. San Diego, CA.

Sando, TA. Regional Variations in Three Activity Limitations in the US Population. American Physical Therapy Association- Combined Sections Meeting. February 15-18, 2017. San Antonio, TX.

Cohen, SA., Cook, S., Hall, L., **Sando, TA**. What Aspects of Rural Life Contribute to Rural-urban Health Disparities in Older Adults? Evidence from a National Survey. American Public Health Association Annual Conference. October 29-November 2, 2016. Denver, CO.

Cohen, SA., Kelley, L., Cook, SK., **Sando, TA.** Geographic Variability in Rural-Urban Disparities in Obesity Among Older Adults: Why Place and Policy Matter. AcademyHealth Annual Research Meeting. June 26-28, 2016. Boston, MA.

Sando, TA.¸ Cohen, SA. Predictive Factors of Daily Self-foot Inspection in the US Population with Diabetes Mellitus. Symposium on Advanced Wound Care. April 13-17, 2016. Atlanta, GA.

Sando, TA., Ratliff, S., Cohen, SA. Patient Reports of Post-CVA Functional Impairments are the Driving Force Behind Post-Acute Therapy Referrals. American Physical Therapy Association- Combined Sections Meeting. February 17-20, 2016. Anaheim, CA.

Sando, TA., Bareis, N., Cohen, SA. Psychiatric Medication Use is Associated with Increased Impairments in the Vestibular and Proprioception Systems. American Physical Therapy Association- Combined Sections Meeting. February 17-20, 2016. Anaheim, CA.

Sando, T., Cohen, SA. Predictive Factors of Diabetic Foot Screening Rates in the United States. American Public Health Association Annual Conference. October 31-November 4, 2015. Chicago, IL.

Sando, T., Cohen, SA. Do functional mobility and activity of daily living deficits after a cerebrovascular accident influence the referral to physical and occupation therapy? American Public Health Association Annual Conference. October 31-November 4, 2015. Chicago, IL.

Cook, S., Cohen, SA., **Sando, TA.,** Kelley, L. Demographic and socioeconomic modifiers of the association between caregiving intensity and caregiver health: Evidence from a national caregiving survey. American Public Health Association Annual Conference. October 31-November 4, 2015. Chicago, IL.

Cohen, SA., Kelley, L., Cook, S., Foutz, J., **Sando, TA**. Geographic variation in rural-urban obesity rates in older adults: Evidence from a national survey. American Public Health Association Annual Conference. October 31-November 4, 2015. Chicago, IL.

Sando, T., Cohen, SA. Diabetic foot screenings: Who are we missing? Symposium on Advanced Wound Care- Spring 2015. April 29-May 3, 2015. San Antonio, TX.

Cohen, S., **Sando, T**., Phillips, A., Kelley, L., Sherif, Y., Brown, M. Associations between caregiving intensity and caregiver burden in "sandwiched" caregivers: Results from the new National Study of Caregiving. American Public Health Association Annual Conference. November 15-19, 2014. New Orleans, LA.

Phillips, A., Cohen, S., **Sando, T**. Emerging caregiver burden domains in the new National Study of Caregiving: Results, reliability, and applications. American Public Health Association Annual Conference. November 15-19, 2014. New Orleans, LA.

Sando, T. Treatment of a Complex Wound Surrounding Infected Total Artificial Heart Drivelines. Symposium on Advanced Wound Care. September 27-30. Las Vegas, NV.

AWARDS AND HONORS

Phi Kappa Phi Scholarly Achievement Award — 2017
Virginia Commonwealth University
School of Medicine

Honor Society of Phi Kappa Phi — 2016

C. C. Clayton Award — 2016
Virginia Commonwealth University
School of Medicine

Erickson Foundation Research Award in Positive Aging — 2015
American Public Health Association- Section on Aging and Public Health
"Geographic variation in rural-urban obesity rates in older adults: Evidence from a national survey"

Summer Undergraduate Research Fellowship — 2000
California Institute of Technology

COMMITTEE AND COMMUNITY SERVICE

Committee Member- Educating the Generalist — May 2015-present
Association for the Advancement of Wound Care

Committee Member- PhD Curriculum Committee — September 2017-present
Virginia Commonwealth University, Division of Epidemiology

Committee Member- MPH Assessment Committee — September 2016-August 2017
Virginia Commonwealth University, Division of Epidemiology

Volunteer Physical Therapist- CARES Pro-Bono Clinic — 2017
Virginia Commonwealth University
School of Allied Health, Department of Physical Therapy

PROFESSIONAL ORGANIZATION MEMBERSHIPS

Member — December 2014-present
Wound Healing Society

Member August 2014-July 2016

American Public Health Association

Member April 2013-present

Association for the Advancement of Wound Care

Member 2002-present

American Physical Therapy Association

Section Membership: Acute Care (2008-present), Education (2012-present), Research (2016-present), Clinical Electrophysiology and Wound Management (2017-present)