MANAGEMENT OF COMORBID DEPRESSION IN VETERANS WITH DIABETES

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Submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice in the Doctor of Nursing Practice Program in the School of Nursing.

Chapel Hill
2017

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ABSTRACT

Letha M. Joseph: Management of Comorbid Depression in Veterans with Diabetes
(Under the direction of Diane Berry)

Objective: Patients with diabetes have an increased risk of developing depression. Comorbid depression in patients with diabetes affects their health-related quality of life, diabetes self-management, and health care utilization. The purpose of this study was to examine the feasibility of screening for depression in patients with diabetes while they were hospitalized for medical illness.

Methods: The electronic health records of 193 patients admitted to medical units at a local facility from July 2016 to December 2016 were assessed for the presence of diabetes. Twenty-one patients with type 2 diabetes and with glycated hemoglobin above 7% were consented and screened for depression using the Patient Health Questionnaire (PHQ-2). Seven patients with positive symptoms for depression were enrolled in the study. The researcher alerted the medical provider via the electronic medical record about the patients with depression symptoms and the provider discussed options for management of depression with the patient and initiated treatment. The patients answered the PHQ-9, the Veterans RAND-12 and the Stanford Diabetes Questionnaire at baseline and at eight weeks and 12 weeks after discharge from the hospital. Five patients completed the study. At the completion of the study, the hospitalist team providers and the patients answered survey questions about the process.

Results: The process of screening for depression at admission, notifying the provider by way of electronic medical record that the patient screened positive for depression with suggestions for medication and psychiatric counseling was feasible and acceptable to providers. Patients also felt

the program was acceptable and helped them get the assistance they needed for depression. Statistics are not reported due to the small sample size.

Conclusion: The results suggest that screening for depressive symptoms while admitted with medical illness was feasible and acceptable to patients and providers. A randomized controlled pilot study will be conducted next to establish efficacy.

To my family, Thomas, Leo, and Geo, who provided support and encouragement on this journey. To my parents and siblings who supported me spiritually from the other side of the globe. And especially to Thomas, my husband, I could not have done this without making many of the sacrifices that you graciously understood. Thank you for all of your support along the way.

ACKNOWLEDGEMENTS

I want to acknowledge and thank my doctoral committee members for their expertise, time and support in outlining and conducting this study. Thank you to Dr. Diane Berry, my committee chair, for her encouragement, psychological support and positive energy, editing assistance and guidance throughout the process. Thank you to Dr. Ann Jessup and Dr. Jean Davison my committee members, for their encouragement, practical tips and guidance throughout the process. Thank you to Dr. Brian Schneider, my site mentor and Dr. Jack Twersky, the collaborating physician at the site for their assistance in securing approval from the facility and for facilitating the implementation. Also thank you to the hospitalist team providers at the Durham VA Medical Center for following up the participants and providing valuable feedback on depression screening in patients with diabetes. Your feedback will impact the management of patients with diabetes in the Durham VA Medical Center. And finally, I want to thank the University of North Carolina, for awarding me the graduate merit doctoral assistantship for academic year 2015-16 that enabled me to pursue this advanced degree.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
CCM	Chronic Care Model
CDC	Centers for Disease Control
CHAP	Community Healthcare Access Program
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CPRS	Computerized Patient Record System
DNP	Doctorate in Nursing Practice
DVAMC	Durham Veterans Affairs Medical Center
GDP	Gross Domestic Product
HbA1c	Hemoglobin A1c
HIPAA	Health Insurance Portability and Accountability Act
HRQoL	Health Related Quality of Life
I CARE	Integrity, Commitment, Advocacy, Respect, Excellence
ICCC	Innovative Care for Chronic Conditions
IRB	Institutional Review Board
MCBS	Medicare Current Beneficiary Survey
MCS	Mental Component Summary
PCS	Physical Component Summary
PHQ	Patient Health Questionnaire
SD	Standard Deviation
US	United States
VAMC	Veterans Affairs Medical Center
VR-12	Veterans RAND-12
WHO	World Health Organization

CHAPTER 1: INTRODUCTION

Background and Significance

According to the Centers for Disease Control and Prevention (CDC), more than 29 million people in the United States (U.S.) suffer from diabetes (CDC, 2014). The incidence of depression in patients with diabetes is higher than the incidence of depression in patients without diabetes (Hasan, Mamun, Clavarino, & Kairuz, 2015). The presence of diabetes almost doubles the odds of developing depression (Hsu et al., 2012; Vamos, Mucsi, Keszei, Kopp, & Novak, 2009). Depressive symptoms in adults with diabetes negatively affect their self-management and adherence to diabetes treatment, which lead to poor glycemic control, and microvascular and macrovascular complications (Egede & Ellis, 2008; Ford, 2008; Gonzalez et al., 2007; Katon et al., 2008). Poor clinical outcomes in diabetes care in patients with depression is well documented in the literature (Shah, Mezzio, Ho, & Ip, 2015; Waitzfelder et al., 2010). According to the Reasons for Geographic and Racial Differences in Stroke (REGARDS) study, comorbid stress and depression are common among patients with diabetes and are associated with poor cardiovascular outcomes (Cummings et al., 2016). Singh and colleagues (2015) also identified a strong association between depression and the progression of diabetes to cardiovascular disease. Patients with diabetes and comorbid depression have a two-fold higher risk of having a myocardial infarction compared with patients who have either diabetes or depression alone (Scherrer et al., 2011). Zhang and colleagues (2005) argued that comorbid depression in patients with diabetes was associated with increased mortality, whereas depression did not increase mortality in patients without diabetes. Van Dooren and colleagues (2013) reported that depression is associated with nearly 1.5-fold increased risk for mortality in patients with diabetes. Bogner and colleagues (2007) reported a reduction in five-year all-cause mortality in older adults

with diabetes when they received appropriate management of their comorbid depression. Gonzalez et al. (2007) noticed that even minor depression could affect diabetes self-management. However, Li et al. (2009) reported that nearly 45% of patients with diabetes suffer from undiagnosed depression.

Routine screening and management of depressive symptoms may improve diabetes care outcomes. The American Diabetes Association's (ADA) Foundation of diabetes self-management includes routine depression screening and management of depressive symptoms using a stepwise collaborative care approach (ADA, 2016). Patients with co-morbid depression report more diabetes-related symptoms and utilize health care services more frequently than patients with diabetes who do not have any depressive symptoms (Molosankwe, Patel, Gagliardino, Knapp, & McDaid, 2012). Vamos et al., (2009) reported more frequent and prolonged hospitalizations and extended illnesses for patients with diabetes and comorbid depression compared with patients with diabetes alone. The Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project reported 30-day all-cause readmission rates of 20.3% among patients with diabetes and related complications (Elixhauser & Steiner, 2013). Unidentified or poorly managed depression may be contributing to this high utilization of health care services. The ADA (2016) identifies hospitalization as a potential opportunity for depression screening and initiating collaborative depression management as part of comprehensive diabetes care.

Problem Statement

Unidentified depression exists in patients with diabetes. Comorbid depression affects diabetes self-management and leads to poor diabetes outcomes and high utilization of healthcare services. Routine screening during hospitalization to identify comorbid depression provides an opportunity to initiate collaborative depression management. Despite evidence-based recommendations, routine depression screening and management are not always included in the management of patients with diabetes admitted to inpatient medical units.

Purpose

The purpose of this clinical demonstration study was to explore the feasibility of depression screening and follow-up for patients with diabetes during their hospitalization and to evaluate the effect of depression management in depressive symptoms, health-related quality of life, diabetes self-management and all-cause 30-day readmission rates of patients with diabetes. The following clinical questions were addressed:

- Was it feasible to screen for depressive symptoms in patients with diabetes who were admitted to the Durham Veterans Affairs Medical Center (DVAMC) with medical problems?
- Was it feasible for inpatient medical providers to initiate management and follow-up for identified depressive symptoms in these patients?
- Would patients with diabetes who also had depression be able to manage their diabetes better if they received treatment for their depression?
- Would patients with diabetes who also had depression have a better quality of life if they received treatment for their depression?
- Would management of depression among hospitalized patients with diabetes reduce emergency department visits for non-emergent conditions and re-hospitalizations for ambulatory care sensitive conditions?
- What were the challenges identified by inpatient medical providers in initiating management and follow-up for depressive symptoms?

CHAPTER 2: REVIEW OF LITERATURE

Search Strategy

Databases used for this literature search included PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Academic search premier, Social work abstracts, and Applied Social Sciences Index and Abstracts. This literature search was limited to manuscripts published in English from January 1, 2005, to August 30, 2015. Search terms included *diabetes, depression, prevalence, management, diabetes distress, emotional problem, and mental health.* Inclusion criteria included studies examining the prevalence of depression among adults with known diabetes, studies on the effects of depression on glycemic control, and the effects of collaborative depression management. Exclusion criteria included studies limited to pharmacotherapy; studies comparing the prevalence of depression in patients with chronic diseases in general, studies examining the effect of race and ethnicity in depression, studies comparing the utility of different depression screening tools, and studies conducted among adolescents.

Prevalence of Comorbid Depression

The relationship between diabetes and depression has been noted in the literature for over 300 years, and evidence suggests a bi-directional relationship between depression and type 2 diabetes (Egede & Ellis, 2010; Mezuk, Eaton, Albrecht, & Golden, 2008; Semenkovich, Brown, Svrakic, & Lustman, 2015). To date, there have been multiple competing theories on the reason why patients with diabetes develop depression. Behavioral health has applied Beck's cognitive theory to conceptualize the development of depression (Beck, 2008). Daily challenges related to

lifestyle modification, blood glucose monitoring and adherence to medication and diet place a huge demand on patients. Patients' struggle to maintain adherence may lead to frustration and negative thoughts. Inability to generate better outcomes such as weight loss or lower blood glucose levels may aggravate these thoughts. Some individuals may use their defense mechanisms and social and spiritual support systems to control these negative thoughts. Uncontrolled negative thoughts can lead to helplessness and hopelessness (Henkel, Bussfeld, & Möller, 2002; Joiner et al., 2001). People with a pessimistic explanatory style may view the cause of negative outcomes as internal and develop depression when dealing with negative experiences. As per Aaron Beck's cognitive theory of depression (Beck, 2008), negative thoughts lead to dysfunctional belief themes or schemas such as the person is defective or inadequate, everything results in failure, and the future is hopeless which constitute the negative cognitive triad. Individuals who cannot process this cognitive triad develop depression.

Also, others theorize that patients diagnosed with diabetes experience lifestyle alterations as a result of economic concerns, the duration of diabetes, the complications of diabetes, and poor quality of life, and these cumulative effects contribute to the risk of developing depression (Hamer, Batty, & Kivimaki, 2011). All patients with diabetes do not develop depression; however, negative affect, negative life experiences and diabetes-related concerns predict future chances for developing major depression (Naranjo, Fisher, Areán, Hessler, & Mullan, 2011).

Theories in Psychoneuroimmunology explain mechanisms by which experiences in the external social environment transduce to the internal biological environment and contribute to a depression pathogenesis (Nouwen, 2015). There are several common neuroendocrine and neurotransmitter abnormalities related to both diabetes and depression (Nouwen, 2015; Siddiqui, Jha, Waghdhare, Agarwal, & Singh, 2014). According to Social Signal Transduction Theory of

Depression (Slavich & Irwin, 2014), social stressors such as social rejection, isolation, exclusion and social adversity up-regulate the immune system, which leads to the production of pro-inflammatory cytokines. These cytokines signal the brain to induce behavioral and emotional changes leading to depression. These mechanisms explain how social stressors and chronic inflammation in patients with diabetes increase vulnerability to comorbid depression.

As compared to adults without diabetes, the prevalence of depression is significantly higher among patients with diabetes (Ali, Stone, Peters, Davies, & Khunti, 2006; de Groot, Doyle, Hockman, Wheeler, & al, 2007; Nouwen et al., 2010). However, there is no established association between severity of diabetes and extent of depressive symptoms. So symptoms of depression could be due to diabetes burden rather than impaired glucose metabolism (Knoll et al., 2007). Lopez-de-Andrés et al. (2015) evaluated the prevalence of depression among hospitalized patients with diabetes from 2001 to 2011 and reported an increased prevalence of depression even though there were improvements in their health profile and a decreased length of stay during that period. Patients with comorbid depression can have serious complications of diabetes as compared to patients who have diabetes alone. Depression affects patients' health-related quality of life, self-care, and ability to communicate effectively with health care providers or seek resources to manage their diabetes (Katerndahl, Calmbach, & Becho, 2012), which affects their diabetes care outcomes.

Effects of Comorbid Depression

Comorbid depression affects various aspects of diabetes self-management. Poor self-management and poor outcomes in these patients are well-documented (Lin et al., 2010; Shah, Mezzio, Ho, & Ip, 2015; Solis, 2011; Vickers, Nies, Patten, Dierkhising, & Smith, 2006; Waitzfelder et al., 2010). There is a reciprocal relationship between depressive symptoms and self-efficacy in patients with diabetes (Adam & Folds, 2014) and these patients often perceive an

inadequate control over their diabetes (Egede & Ellis, 2010). DiMatteo, Lepper, and Croghan (2000) identified a three-fold risk for non-adherence among patients with diabetes and comorbid depression as compared to those who have diabetes alone. Even minor depression is associated with poor self-management (Gonzalez et al., 2007), which leads to physical disability (Deschênes, Burns, & Schmitz, 2015; Lysy, Da Costa, & Dasgupta, 2008). Richardson et al. (2008) suggested that there is a longitudinal relationship between depression and poor glycemic control and confirmed the association between depression and high glycated hemoglobin (HbA1c) levels over time. Comorbid depression may act as a catalyst in the progression of diabetes and development of cardiovascular complications (Cummings, et al., 2016; Singh et al., 2015). Increased risk of mortality in patients with diabetes and comorbid depression is well supported (Coleman, Katon, Lin, & Von Korff, 2013; Katon et al., 2008; Kimbro, Steers, Mangione, Duru, & Ettner, 2014; Park, Katon, & Wolf, 2013; Sullivan et al., 2012). Bogner and colleagues (2007) reported a reduction in five-year mortality with appropriate management of underlying depression in older adults with diabetes.

Patients with diabetes and comorbid depression have a higher risk for missed preventive self-care practices (Egede, Grubaugh, & Ellis, 2010) leading to a higher risk for retinopathy (Sieu et al., 2011), lower limb amputations (Williams et al., 2011), and hypoglycemic episodes (Katon et al., 2013). Also, patients with diabetes exhibit hyperglycemia associated brain injury, cognitive decline and memory impairment (Weinstein et al., 2015), which increases their risk of dementia. Köhler and colleagues (2015) reported a high risk of dementia in patients with depression. However, patients with diabetes and comorbid depression have an increased risk for dementia compared to patients with either of these disease conditions alone (Katon et al., 2015).

The presence of depression has a significant economic impact on diabetes care. Patients with diabetes and comorbid depression tend to report poor health-related quality of life (Egede & Hernández-Tejada, 2013; Katerndahl, et al., 2012) and more physical symptoms which lead to more hospitalizations for ambulatory care sensitive symptoms (Davydow et al., 2013; Subramaniam et al., 2009). Public health research also endorses increased physical symptoms, higher utilization of healthcare services and preventable hospitalizations among these patients (Smith, Gariepy, & Schmitz, 2014). A higher number of office visits, emergency room visits, hospitalizations and prescription usage led to higher health care costs in this patient population (Kalsekar et al., 2006). Simon and colleagues (2005) reported a 50-75% increase in health care costs in patients with diabetes and depression. According to a multi-morbidity disease cluster cost analysis in the Veterans' Health Administration, diabetes with depression accounts for the highest healthcare expenditures (Egede et al., 2015).

Globally, after controlling for gross domestic product (GDP) per capita, the U.S. has the highest diabetes-related health care costs (Seuring, Archangelidi, & Suhrcke, 2015). In regards to health care spending, loss of productivity related to physical or psychological symptoms increases the financial burden. Egede (2004) analyzed the 1999 National Health Interview Survey for the prevalence of functional disability. According to this analysis, the prevalence of functional disability was 24.5% for participants without diabetes or depression, 51.3% for those with major depression, 58.1% for those with diabetes and 77.8% of participants with diabetes and depression (Egade, 2004). In 2012, the estimated total cost of diabetes in the United States was $245 billion, which included an estimated $176 billion in direct health care costs and $69 billion related to reduced productivity (Economic Costs of Diabetes, 2013). Simon et al. (2007) analyzed the economic benefit of symptom-free days and reported a cost benefit of $952 per

patient over a 24-month period when patients received adequate management for their comorbid depression.

According to Schierhout and colleagues (2013), depression in patients with diabetes is often unidentified or inadequately treated. The unidentified depression may be related to several factors. Comorbid depression may be considered as secondary to medical illness and viewed as less severe. Providers might focus on physical illness and ignore depressive symptoms. The overlap of physical symptoms may make the diagnosis of comorbid depression challenging. Patients may think it is normal to feel sad while having a chronic illness such as diabetes and may not consider it as depression and may not report to their providers. Li et al. (2009) analyzed data from the Behavioral Risk Factor Surveillance System and reported that nearly 45% of patients with diabetes had undiagnosed depression. The ADA (2016) supports routine screening for depression as part of standard diabetes management. Screening for depression at the time of diagnosis of diabetes, during routine follow-up visits, on initiation of insulin, during hospitalization, and at the onset of any complications can identify the symptoms of depression (ADA, 2016).

Effect of Collaborative Management of Co-Morbid Depression

The effect of depression management on improvement in HbA1c has not been established (Georgiades et al., 2007; Katon et al., 2004; Wang, Tsai, Chou, & Chen, 2008). However, Nicolau and colleagues (2013) reported improved health-related quality of life with improvement in comorbid depression. Outcomes of successful diabetes management depend not only on improved physiological indicators but also on symptom relief, improvement in social functioning, mental health and physical well-being (Safa et al., 2007). Therefore, improvement in health-related quality of life is an important indicator of successful diabetes self-management. Chronic disease management has several dimensions and self-management is one of the four

strategic goals listed in Department of Health and Human Services' framework for improving health status with chronic diseases (Parekh, Goodman, Gordon, & Koh, 2011). Since patients with comorbid depression report more diabetes symptoms and utilize emergency room services more often for non-urgent medical conditions (Georgiades et al., 2007; Katon et al., 2006; Simon et al., 2007), management of depressive symptoms may improve diabetes symptoms and decrease emergency room visits and hospitalizations for non-urgent medical conditions. Additionally, there is evidence of improved mortality rates in patients with diabetes who received management for their comorbid depression (Bogner et al., 2007; Bogner et al., 2016). Providers who are involved in the management of diabetes can identify and initiate management for comorbid depression. As Knowles et al. (2015) describe, collaborative management initiated by medical providers is an opportunity for patients to overcome the stigma associated with depression and seek professional support for their depressive symptoms.

Gaps in the Literature

A Cochrane Review on the effect of depression management in patients with diabetes and depression (Baumeister, Hutter, & Bengel, 2012) found that there was moderate improvement in glycemic control and depressive symptoms. However, the effect of management of comorbid depression on quality of life, self-management and diabetes complications has not been sufficiently studied. The review concluded that evidence was sparse and inconclusive due to a lack of well-designed studies. Generation of evidence by future well-designed studies exploring the effect of management of depressive symptoms on glycemic control, self-management, and quality of life is a priority. Additionally, future research needs to generate evidence on interventions capable of improving depression, diabetes-dependent quality of life and glycemic control.

Gaps in Clinical Practice

Existing barriers in implementing depression care account for gaps in practice. Several barriers exist in implementing routine depression screening and integrating collaborative depression care into diabetes self-management. Osborn, Kozak, & Wagner (2010) identified various factors related to provider and patients which were potential barriers in integrating depression management in diabetes care. System level concerns such as time constraints, competing for clinical expectations, general practitioners' reluctance in initiating depression care and difficulty in collaborating with mental health care are potential barriers. The indication of depression management is strong enough to overcome the system barriers. The stigma associated with mental illness may prevent patients from reporting these symptoms and seeking professional help. In hospitalized patients, inpatient providers can address depression and arrange primary care follow-up, which may decrease patient resistance in seeking professional help. A patient-centered approach focused on potential benefits regarding the quality of life and improvement in physical and emotional symptoms may reduce patient resistance to depression management (Riley, McEntee, Gerson, & Dennison, 2009).

CHAPTER 3: THEORETICAL FRAMEWORK

Diabetes is a chronic disease. The World Health Organizations' (WHO) Innovative Care for Chronic Conditions (ICCC) framework emphasizes the importance of prepared and motivated patients as micro-level building blocks in the successful management of any chronic disease and conceptualizes patient's quality of life as a primary outcome of disease management (WHO, 2002). According to the Chronic Care Model (CCM), better chronic disease outcomes are achieved when productive interactions took place between prepared and proactive practice team and empowered and prepared patients (Bodenheimer, Wagner, & Grumbach, 2002). Self–management support is one of the six key areas identified in CCM to improve chronic disease management (Baptista et al., 2016).

The success of diabetes management depends on effective self-management. Self-management is one of the four strategic goals listed in Department of Health and Human Services framework for improving health status with chronic diseases (Parekh, Goodman, Gordon, & Koh, 2011). Self-management refers to the dynamic, interactive, and daily processes in which individuals engage to manage a chronic illness (Ruggiero et al., 1997). Grey, Knafl, & McCorkle (2006) defined self-management as a cluster of daily activities of an individual intended for managing a disease condition. Self-management is a broad term which depicts the complex nature of living with a chronic condition such as diabetes. Self-management incorporates the individual's utilization of health care, lifestyle modification and efforts to monitor and manage disease (Grey, Knafl, & McCorkle, 2006).

This study was based on the hypothesis of the existence of unidentified comorbid depression among patients with diabetes as a barrier to their self-management. The Revised Self and Family Management Framework explains the importance of reducing and eliminating potential barriers to improving outcomes of chronic disease management.

The Revised Self and Family Management Framework

According to the Revised Self and Family Management Framework (Grey, Schulman-Green, Knafl, & Reynolds, 2015), various factors affect self-management of a chronic disease such as diabetes and influence disease management outcomes. Identification of those facilitators and barriers may help the clinicians empower patients in employing successful self-management strategies. Various tasks and skills related to self-management are identified as processes in this framework. Effective self-management results in proximal outcomes which lead to distal outcomes (Grey et al., 2015).

Application of the Revised Self and Family Management Framework

According to the Revised Self and Family Management Framework (Grey et al., 2015), there are barriers and facilitators which affect self-management. Comorbid depression, a highly prevalent condition in patients with diabetes acts as a barrier and negatively affects patients' motivation, emotions and lifestyle patterns. Comorbid depression leads to poor self-management of diabetes such as adjusting to psychosocial needs, dealing with self-monitoring, managing medications, maintaining diet and physical activity, navigating through the healthcare system and having meaningful engagement with the health care team (Grady & Gough, 2014). Poor self-management leads to complications of diabetes (Shah et al., 2015; Waitzfelder et al., 2010). Higher incidence of diabetes symptoms and utilization of healthcare services may affect the patients' quality of life which may increase their depression symptomatology and in turn worsen their motivation and emotions (Egede & Hernández-Tejada, 2013; Katerndahl, et al., 2012). This

vicious cycle potentially affects the overall quality of life, disease outcomes and health care costs. Identification of depression is the initial step in eliminating this potential barrier.

According to the Revised Self and Family Management Framework (Grey et al., 2015), there are three types of processes guiding self-management. Processes include those focusing on illness needs such as learning, taking ownership and health promotion activities, processes for activating resources such as health care, spiritual, psychological and community resources and processes involved in living with diabetes such as processing emotions, finding meaning, and adjusting to the disease. Depression negatively influences an individual's desire to assume ownership of self-management and motivation to learn self-management activities (Adam & Folds, 2014; Egede & Ellis, 2010). The presence of depression may impair a person's ability to problem solve, approach and avail assistance and to advocate for self. Control of depression will facilitate these processes of self-management and may lead to better outcomes.

The Revised Self and Family Management Framework (Grey et al., 2015) conceptualizes self-management behaviors as proximal outcomes and improvement in health status and quality of life as distal outcomes. Proximal outcomes correspond to an improvement in behaviors such as motivation and adherence to self-management, control of symptoms such as stress, pain, fatigue, sleep, physical activity and activities of daily living. Proximal outcomes lead to distal outcomes. Distal outcomes for individuals include control of disease complications, reduction in morbidity and mortality, and improvement in individual's psychological well-being and quality of life. For the healthcare system, the distal outcomes are improved access to health care, appropriate utilization of health care services and cost effectiveness. Outcomes measured in this scholarly practice study are the severity of depressive symptoms, health-related quality of life (HRQoL), and re-admissions.

CHAPTER 4: METHODOLOGY

Management of Comorbid Depression in Veterans with Diabetes was a demonstration study conducted from July 28, 2016, through December 31, 2016, in the medical-surgical units of Durham Veterans Administration Medical Center (DVAMC).

Study Design

The goal of this clinical demonstration study was to examine the feasibility and effect of depression screening and management in patients with diabetes during their hospitalization for medical illness. This study included screening for depression, health-related quality of life (HRQoL) and diabetes self-management. Providers were involved in initiating interventions to manage depression. At the completion of the study, participants were rescreened for depression, health-related quality of life (HRQoL) and diabetes self-management.

The specific goals of the study were:

- To evaluate the feasibility of depression screening and initiation of depression management for patients with diabetes admitted to the DVAMC with medical illness.
- Evaluate the effect of depression management on depressive symptoms, diabetes self-management, HRQoL, and health care utilization.

Setting

This Doctor of Nursing practice (DNP) scholarly study setting was located within the inpatient medical-surgical units at the local Veteran Affairs Medical Center (VAMC). The VAMC shares the mission of the Veterans Health Administration which is honoring America's

veterans with exceptional care delivered by collaborative teams which support continuous improvement (Mission, Vision, Values, 2012). The core values of the VAMC include Integrity, Commitment, Advocacy, Respect, and Excellence (I CARE) and reflects its efforts to keep Lincoln's promise to all "who shall have borne the battle." The philosophy and mission statement of the VAMC aligns with the practice change this study addresses. The stakeholders of this study included veterans, their families, health care providers in the hospitalist team, clinical psychologists, mental health providers, and primary care providers.

The DVAMC is a 274-bed tertiary care referral, teaching and research facility affiliated with major universities in North Carolina. The medical center provides medical, surgical, mental health inpatient and outpatient services. DVAMC is a major referral center for veterans residing in nearby states. In the fiscal year 2015, the DVAMC had 61,704 veterans in primary care which include 12,900 veterans with diabetes. In addition to outpatient services, veterans use DVAMC for their inpatient needs. There are ninety-six beds assigned to four medical-surgical units which are utilized by patients admitted to medicine or surgery services. Various medical teams are involved in the management of these patients as primary teams. This study included patients admitted to the hospitalist teams. Hospitalist teams consist of five advanced practice providers (nurse practitioners and physician assistants) and eight attending medical doctors including the two session chiefs. The hospitalist service has an average of 18.9 admissions per week. Patients are admitted with acute medical concerns or for acute exacerbations or complications of chronic medical illnesses. Diabetes is a common medical condition in this population. The average length of stay for these patients is 5.6 days.

Sample

Participants of this study included a convenience sample of seven veterans aged 18 and above, admitted to hospitalist medical teams during the study period with a primary diagnosis of type 2 diabetes and a HbA1c of 7.0% or higher. However, two participants were lost to follow-up due to death and the data collected from five participants who completed the study is reported here. Patients admitted to other teams, patients who did not have a known diagnosis of type 2diabetes or who had type 2 diabetes with HbA1c of less than 7.0%, patients who were currently receiving treatment for depression and cognitively impaired patients were excluded from the study.

Screening Tools

There are several instruments available for screening for depressive symptoms and for evaluating diabetes self-management and HRQoL. The instruments used in this study included the Patient Health Questionnaire – 2 (PHQ-2) (Kroenke, Spitzer, Williams, 2003), the Patient Health Questionnaire – 9 (PHQ-9) (Kroenke, Spitzer, & Williams, 2001), the Veterans RAND (Research and Development) 12-item Health Survey (VR-12) (Kazis et al., 2006), and the Stanford Diabetes Questionnaire (English Diabetes Research Instruments, 2016). These instruments (see Appendices A, B, C, and D) are widely used in clinical practice and research. The PHQ and VR-12 are used at the Veterans health care system by various specialties and are built into its electronic health record.

Patient Health Questionnaire (PHQ). Both the PHQ-2 (see Appendix A) and the PHQ-9 (see Appendix B) are used widely to screen for depression (Arroll et al., 2010). The PHQ- 2, a two-item questionnaire uses the first two questions from the PHQ-9. These two questions inquire about anhedonia and depressed mood and are helpful as a quick screen for depressive symptoms. Patients who scored three or higher on PHQ-2 screening were given the PHQ-9

evaluation to assess the severity of depressive symptoms (Jin, Wu, & Di Capua, 2015; Kroenke, Spitzer, Williams, 2003).

The PHQ-9 is a self-reported questionnaire consisting of nine questions which inquire about depressive symptoms such as anhedonia, depressed mood, suicidality and physical symptoms caused by depression (Kroenke, Spitzer, & Williams, 2001). These nine questions fulfill the criteria used for diagnosis of depression by *Diagnostic and Statistical Manual of Mental Disorders*, *Fifth Edition* (*DSM-5*) criteria (Trangle et al., 2016). The questionnaire asks about symptoms such as lack of interest or pleasure in doing things, feeling down or depressed, or hopeless, problems with sleep, feeling tired or having lack of energy, problems with appetite, feeling bad about themselves, trouble concentrating on things, moving or speaking slowly that concerned others or feeling restless, and thoughts that they were better off dead and thought of self-harm. Patients reported the degree at which they were bothered by these symptoms for the past two weeks. They rated the frequency of these symptoms using a scale ranging from 0-3 where 0= not at all, 1= several days, 2= more than half the days, and 3= nearly every day. The sum of the scores of the responses to the nine questions gave the PHQ-9 score. Participants were also asked how difficult had these problems made it for them to do their work, take care of things at home, or get along with other people and they rated the difficulty as not difficult at all, somewhat difficult, very difficult, or extremely difficult.

The possible PHQ-9 total score ranges from 0-27, and the severity is classified as follows: PHQ-9 scores up to 4 represent minimal depression, 5-9 mild depression, 10-14 moderate depression, 15-19 moderately severe depression and 20-27 severe depression (Kroenke, Spitzer, & Williams, 2001). Trangle and colleagues (2016) reported that PHQ-9 scores of 10-14 correspond to mild major depression, 15-19 corresponds to moderate major

depression and ≥ 20 corresponds to severe major depression. Kroenke and colleagues (2001) examined the validity of PHQ-9 by comparing the results with mental health professional interview outcomes and reported an 88% sensitivity and specificity for major depression with PHQ-9 scores of 10 or higher. Wittkampf et al. (2009) evaluated the accuracy of the PHQ-9 in primary care settings and reported a sensitivity of 0.93 and specificity of 0.85 for screening depressive symptoms. Eun Jin, Hall, & Moser (2014) evaluated the reliability and validity of PHQ-9 in patients with medical co-morbidities and supported the reliability (Cronbach's alpha 0.87) and excellent concurrent validity with the Beck Depression Inventory ($r = .78$, $p < .01$).

Veterans RAND 12-Item Health Survey (VR-12). The VR-12 is a health survey questionnaire (see Appendix C) used to evaluate health-related quality of life (Kazis et al., 2006). It has been used in several large studies conducted by veterans' health administration and in Medicare Outcome Surveys (Dobscha et al., 2009; Hsiao et al., 2012; Kazis et al., 2012; Kent et al., 2015). The VR-12 was developed from the VR-36, the 36-item survey which was used in main studies in the Veterans Health Administration (Iqbal et al., 2007). This 12-item self-reported survey addresses eight domains of physical and mental health such as general health perceptions, physical functioning, and activity limitations due to physical and emotional problems, pain, fatigue, social functioning and mental health. These components are weighed by the scoring computer program which provides a physical health summary measure called the Physical Component Summary (PCS) and a mental health summary measure called the Mental Component Summary (MCS) (Iqbal et al., 2007). The PCS and MCS scores are standardized using a t-score transformation. Higher physical component summary and mental component summary reflects better health-related quality of life (Kazis, et al., 2012; Selim, et al., 2009). A recent Medicare outcome study reported average PCS and MCS scores of 39.82 (SD$\pm$12.2) and

50.08 (SD±11.4) respectively (Selim et al., 2009). These scores represent the current normal PCS and MCS for clinical applications. Kazis and colleagues (2006) proposed that change by 1-2 or more points in MCS or PCS may be considered a clinically relevant change. In the Veterans Health Administration, the difference in the PCS and MCS scores in VR-12 is used to evaluate the clinical impact of intervention on outcomes (Iqbal et al., 2007). The Medicare Outcome Survey (Health Services Advisory Group, 2006), the Managed Care Community Healthcare Access Program (CHAPS) Enrollee Survey and the Medicare Current Beneficiary Survey (MCBS) Cost and Use Data (Kazis et al., 2012) consider a one point improvement in the PCS to be associated with a 6% decrease in total health care expenditures whereas one point improvement in the MCS is associated with a 7% decrease in total health care expenditures (Health Services Advisory Group, 2006).

Stanford Diabetes Questionnaire. This questionnaire (see Appendix D) consists of diabetes-specific questions to evaluate patient's health behaviors, health status, health care utilization and self-efficacy. It was developed by the Stanford Patient Education Research Center and is available on the Stanford University website (English Diabetes Research Instruments, 2016)**.** This self- reported survey includes questions about patient's perception of general health, physical and emotional symptoms, influence of physical and emotional health on daily activities, diabetes self-management activities such as diet, glucose monitoring, management of low and high blood glucose, medications, follow-up visits and patient's confidence in managing various dimensions of diabetes care (English Diabetes Research Instruments, 2016). Though this survey is widely used, no studies were identified which reported the validity of this tool.

Survey to evaluate the feasibility of depression screening. At the completion of the study, five participants answered the survey that explored their experience with depression screening (See Appendix E). Participants were asked about what they liked about the study; whether they felt that they needed help with their depressive symptoms; whether they received any treatment for their depression; whether they talked to a psychologist for follow-up of their depressive symptoms; how they felt about knowing that they had depressive symptoms; whether they liked receiving telephone calls for follow-up interviews; whether they had any concerns about discussing depressive symptoms with the provider who managed their diabetes; their willingness to consult a mental health provider for their depressive symptoms; and their suggestions to better serve them in terms of managing their diabetes and depression.

At the conclusion of the participant enrollment, an anonymous survey (See Appendix F) was distributed among the hospitalist providers. The survey was distributed among the hospitalist team providers irrespective of being involved in the study as a provider who initiated management for participants with depressive symptoms. Of the thirteen providers, nine providers answered this voluntary survey. The survey asked about what they liked or did not like about the study; whether they considered patients with diabetes have an increased risk for developing depression as compared to patients who do not have diabetes; whether they believed that screening and management of co-morbid depression needs to be integrated to management of patients with diabetes; whether they experienced any difficulty in managing patients with depressive symptoms; their confidence in managing depressive symptoms; and any suggestions for screening and managing co-morbid depression in hospitalized patients with diabetes.

Regulatory Approval and Ethical Concerns

The Institutional Review Board (IRB) at the DVAMC granted approval after a full review and the University of North Carolina at Chapel Hill IRB gave approval after an expedited review. Participants signed an informed consent (see Appendix G) and the authorization for the use and release of individually identifiable health information by the Health Insurance Portability and Accountability Act (HIPAA) (see Appendix H) before enrolling in the study. Procedures were in place to ensure participants' privacy. All electronic data was coded and saved in the H drive at the DVAMC, and paper data was kept in a locked cabinet behind a locked door.

Provider Engagement

Before the study, the DNP student discussed the study protocol with the hospitalist team providers in a group education session during their team meeting held on July 4, 2016. Of the thirteen providers, ten providers attended this information session. The DNP student discussed the increased risk for comorbid depression in patients with diabetes and the effect of comorbid depression in their health-related quality of life, diabetes self-management, and diabetes outcomes. The information session highlighted the study protocol and the expectations from the providers. Site mentor, Brian Schneider, MD, chief of the hospitalist team explained the procedure for the providers to consult the primary care mental health integration service at the time of discharge to ensure outpatient follow-up of depressive symptoms. The DNP student distributed laminated pocket cards (See Appendix I) with sections from Veterans Affairs/ Department of Defense (VA/ DoD) Clinical Practice Guidelines on the management of major depressive disorder. These pocket cards included prescribing and monitoring information of common antidepressants. The DNP student communicated positive depression screens to the providers via electronic health record. As the participant enrollment in the study ended, the DNP

student distributed a survey questionnaire to the hospitalist team providers which inquired about their perception on managing depression and any barriers they encountered in the process.

Procedures

The participants of this study included a convenience sample of five veterans admitted to hospitalist medical team care from July 2016 to December 2016 with a primary diagnosis of type 2 diabetes who screened positive for depression. Patients admitted to other medical teams and those without type 2 diabetes were excluded from this study. Cognitively impaired patients, patients who were suffering from delirium or those patients who could not provide a reliable response to the questionnaires were also excluded from the study. Participation was voluntary. Patients who screened negative for depression were also excluded from the study.

The DNP student identified potential participants from the electronic health records using the above inclusion criteria. The DNP student described the study in detail to the potential participant in a face-to-face, individual encounter and answered all questions before asking the participant if they wanted to sign the informed consent (See Appendix G). Participants signed the authorization also for the use and release of individually identifiable health information collected for the research (See Appendix H).

The DNP student then administered the PHQ-2. If the patient screened negative for depression using the PHQ-2 (Kroenke, Spitzer, & Williams, 2001), they were excluded from the study. Those patients who scored ≥ 3 on the PHQ-2 (Kroenke, Spitzer, & Williams, 2001) were enrolled in the study. These participants received additional screening using the PHQ-9 (Kroenke, Spitzer, & Williams, 2001) to quantify the severity of depressive symptoms. The DNP student discussed the results of the screening with the participant and provided information materials on depression and depression management. The patient information materials distributed were ‘What is Major Depression? A VA Fact Sheet providing information on basic

facts, symptoms, treatments, and information for families (2011)' and 'Depression: An easy-to-read booklet that explains what depression is, how long it lasts and how to get help, National Institute of Mental Health (2013)'. The DNP student then administered the PHQ-9 (Kroenke, Spitzer, & Williams, 2001), the VR-12 (Iqbal et al., 2007) and the Stanford Diabetes Questionnaire (English Diabetes Research Instruments, 2016). The DNP student then updated the inpatient provider about presence and severity of depression symptoms using the computerized patient record system (CPRS), the electronic health records used in the facility.

The inpatient provider then discussed depression management options with the participant and made depression management plans honoring the participant's choice. Depending on the severity of depressive symptoms and participant's acceptance, the hospitalist provider made referrals to the mental health provider or prescribed antidepressants or both. Upon discharge from the inpatient unit, the participant received a schedule for a follow-up appointment with their primary care provider in 30 days. The primary care provider continued to follow the participant's severity of depressive symptoms and continued management during routine outpatient visits.

Approximately eight weeks and twelve weeks following their discharge from the hospital, the DNP student contacted the participants via telephone. During this telephone follow-up, each participant was administered the PHQ-9 (Kroenke, Spitzer, & Williams, 2001), the VR-12 (Iqbal et al., 2007) and the Stanford Diabetes Questionnaire (English Diabetes Research Instruments, 2016) over the telephone. The PHQ-2, PHQ-9 (Kroenke, Spitzer, & Williams, 2001) and the VR-12 (Iqbal et al., 2007) are part of the Computerized Patient Record System, so the scores of PHQ-2, PHQ-9 and VR-12 became part of their permanent health record. During the post-discharge follow-up calls, the participants were asked about any life events or stressors,

participant's experience of depression screening and readiness to receive depression treatment and details of adherence to antidepressant medications.

Data Analysis

Descriptive statistics (means, standard deviations, range, and percentages) were used to describe the demographics, PHQ-9, VR-12 and the Stanford Diabetes Questionnaire scores. A paired t-test was conducted to assess any change in mean PHQ-9, VR-12 and Stanford Diabetes Questionnaire scores.

CHAPTER 5: RESULTS

Participant Enrollment

Participant selection and enrollment in this study took place from July 2016 to December 2016 in the inpatient medical units. Computerized health records of (n=193) patients admitted to the hospitalist medicine team service were screened for eligibility. Among the 193 charts screened, 35.8% of the patients (n=69) had a documented diagnosis of type 2 diabetes in their health records. Medical records of these 69 patients were screened for recent HbA1c values. All of these 69 patients (100%) had their HbA1c value recorded within the past three months of hospitalization, and 60.9% of these patients (n=42) had a HbA1c of 7.0% or higher and qualified for further review. Seventeen patients (n=17) were excluded for various reasons (see Figure 1). Nine patients (n=9) declined to enroll in the study. Twenty-one patients (n=21) signed the informed consent, and the DNP student administered the PHQ-2 questionnaire (See Appendix A). Seven patients (n=7) who had PHQ-2 scores ≥ 3 qualified for the study and enrolled in the study. However, two of the participants were lost to follow-up due to death. In the Electronic Health Record, the causes of their death were noted as natural causes and sepsis respectively.

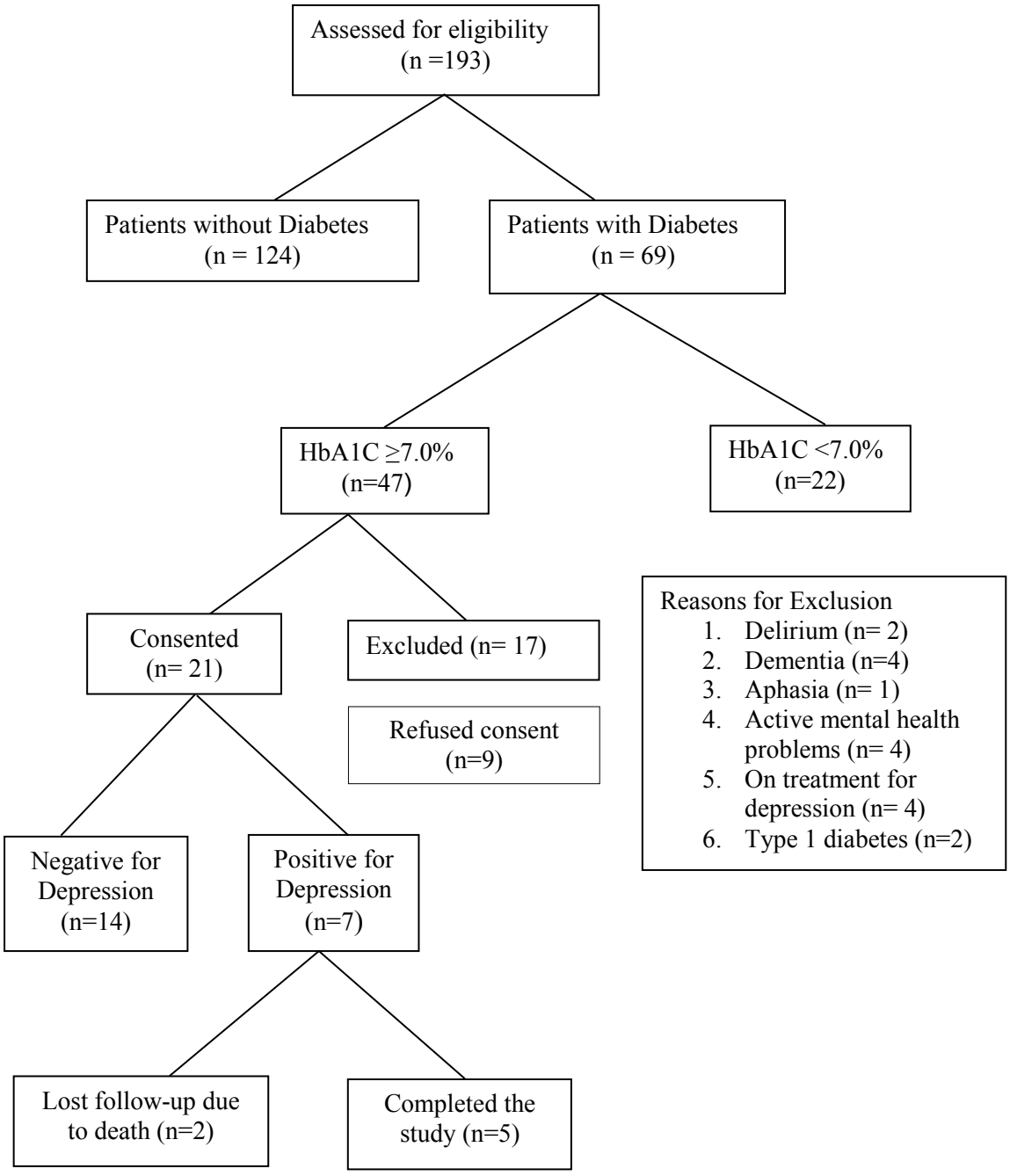

Figure 1. Participant enrollment and completion of the study

Of the 21 patients screened and consented for the study, seven patients qualified and enrolled in the study, and five participants completed the study

Demographic Data

Twenty-one male participants were screened using the PHQ-2 questionnaire. Participants' age ranged from 51 to 85 years (Mean= 67.2, SD $\pm$ 7.5). Of these 21 participants, 61.9% were Caucasian (n=13), 28.5% were African American (n=6), 4.8% were Latino (n=1) and 4.8% were American Indian (n=1). The HbA1c ranged from 7% to 13.2% (Mean = 8.2, SD $\pm$1.6). Of the 21 participants screened for depression, 33.3% (n=7) had positive screens with a score $\geq$ 3. These seven patients were enrolled in the study (See Table 1). Participants' age ranged from 56 to 72 (Mean = 65.3, SD $\pm$ 5.7). Of these seven patients, 57.1% were Caucasian (n=4), 14.3% were African American (n=1), 14.3% were Latino (n=1) and 14.3% were American Indian (n=1). Of the seven participants, 57.2% were high school graduates (n=4), 28.5% reported some college education (n=2) and 14.3% had a bachelor's degree (n=1). HbA1c of these seven participants ranged from 7.0 to 13.2 (Mean = 8.8, SD $\pm$ 2.3).

Table 1. Demographic Characteristics

Total consented (n=21)			Total who met inclusion criteria (n=7)		
Age			Age		
Mean	SD	Range	Mean	SD	Range
67.2	7.5	51-85	65.3	5.7	56-72
Race/ Ethnicity			Race/ Ethnicity		
	Number	Percent		Number	Percent
Caucasian	13	61.9	Caucasian	4	57.1
African American	6	28.5	African American	1	14.3
American Indian	1	4.8	American Indian	1	14.3
Latino	1	4.8	Latino	1	14.3
HbA1c			HbA1c		
Mean	SD	Range	Mean	SD	Range
8.2	1.6	7-13.2	8.8	2.3	7-13.2
PHQ-2					
	Number	Percent			
<3	14	66.7			
≥3	7	33.3			

Abbreviations: HbA1c (Hemoglobin A1c); PHQ-2 (Patient Health Questionnaire-2 items); SD (Standard Deviation)

Depression Scores

Participants (n=5) answered the Patient Health Questionnaire (PHQ-9) nine-item depression screening tool (Kroenke, Spitzer, & Williams, 2001). For the five participants who completed the study, initial PHQ-9 scores ranged from 12 to 17 (Mean = 16, SD $\pm$ 2.2). Of the five participants, one participant (20%) scored in the range of 10-14 (moderate depression), four participants (80%) scored in the range of 15-19 (moderately severe depression). All five participants received some intervention initiated by their provider and had post-discharge follow-up plans arranged by the inpatient provider. Four of these participants received antidepressants while inpatient and a prescription to continue the antidepressant after discharge. One participant received an antidepressant and a few sessions of psychotherapy from a clinical Psychologist while receiving inpatient rehabilitation. At the eight weeks follow-up, the PHQ-9 scores ranged from 1 to 16 (Mean = 8, SD $\pm$ 7). At eight weeks, three participants received a PHQ-9 score that ranged from 0-4 (minimal depression), one participant received a PHQ-9 score in the range of 5-9 (mild depression), and one participant received PHQ-9 scores in the range of 15-19 (moderately severe depression). At 12 weeks, the participants' PHQ-9 scores ranged from 1 to12 (Mean = 4, SD $\pm$ 4.6). Of the five participants, three participants received PHQ-9 scores in the range of 0-4 (minimal depression), one participant received a PHQ-9 score in the range of 5-9 (mild depression), and the other participant received a PHQ-9 score in the range of 10-14 (moderate depression). From Time 1 to Time 3, there was a significant improvement in PHQ-9 scores ($p = 0.017$).

At Time 1, depressive symptoms made it somewhat difficult for two participants (40%), very difficult for another two participants (40%) and extremely difficult for one participant (20%) to do their work or to take care of things at home, and to get along with other people. At Time 2 and Time 3, two of the participants (40%) reported that these symptoms were not at all

making it difficult for them to do their work or take care of things at home or to get along with other people. However, depressive symptoms continued to affect the other three participants (60%) and made it somewhat difficult for the participants to do their work or take care of things at home or to get along with other people. None of the participants felt that depressive symptoms made it very difficult or extremely difficult for them to do their work or take care of things at home or to get along with other people due to depressive symptoms.

Table 2. Depression and Quality of Life Outcomes (n=5)

	Time 1	Time 2 (8 weeks)			Time 3 (12 weeks)		
	Mean±SD	Mean±SD	t	p	Mean±SD	t	p
PHQ-9	16.0±2.2	8.0±7.0	2.10	0.128	4.0±4.6	4.87	**0.017**
PCS	31.3±7.5	32.5±10.2	-1.28	0.291	39.86 ±10.0	-7.01	**0.006**
MCS	26.18±3.4	44.72±9.6	-4.10	**0.026**	48.18±9.1	-4.60	**0.019**

A lower PHQ-9 score indicates better mental health. Higher PCS and MCS scores indicate better health-related quality of life. Bold *p* values indicate significance
Abbreviation: Mental Component Summary (MCS); Physical Component Summary (PCS); Patient Health Questionnaire-9 items (PHQ-9)

Health-Related Quality of Life

Participants (n=5) answered the Veteran's RAND-12-item questionnaire (Iqbal et al., 2007). They rated their general health as either poor, fair, good, very good or excellent; degree of activity limitations as not at all limited, limited a little or limited a lot; extent that their physical health and mental health affected their daily activities for the previous four months and resulted in lesser accomplishments and limitation in type of activities they wanted to do as none of the time, little of the time, some of the time, most of the time or all of the time; interference of pain with normal work both inside and outside home as not at all, little bit, moderately, quite a bit or extremely; extent of feeling calm and peaceful over the previous four weeks as all of the time, most of the time, good bit of the time, some of the time, a little of the time or none of the

time; extent of experiencing lot of energy as all of the time, most of the time, good bit of the time, some of the time, a little of the time or none of the time; occasions when they felt downhearted or blue as all of the time, most of the time, good bit of the time, some of the time, a little of the time or none of the time; interference of physical health or emotional problems in their social activities as all of the time, most of the time, some of the time, a little of the time or none of the time. The last two questions asked the participants to compare their present physical health and mental health to those at a year ago as much better, slightly better, about the same, slightly worse or much worse. The Computerized Patient Record System, the electronic health record used in the facility calculated the Physical Component Summary (PCS) and Mental Component Summary (MCS) from the VR-12 questionnaire responses. From Time 1 to Time 3, there were significant improvements in PCS (p=0.006) and MCS (p=0.019) scores.

Diabetes Self-Management

The Stanford Diabetes Questionnaire collected information on participants' general health, symptoms, daily activities, blood glucose testing, physical activity, confidence about doing things, diet and medications, and utilization of medical care (Stanford Patient Education Research Center, 2016).

General health. Participants (n=5) rated their general health on a scale 1 to 5 where 1=excellent, 2=very good, 3=good, 4=fair and 5=poor. At the beginning of the study (See Table 3), participants rated their general health as fair or poor (Mean=4.2, SD$\pm$0.5). By Time 3, there was a significant improvement in their general health (p=0.041), and participants rated their general health as either good or very good (Mean=2.6, SD$\pm$1.7).

Symptoms. Participants (n=5) rated their symptom burden using different scales (See Table 3). The first four questions inquired whether in the past month they were discouraged by their health problems, fearful about their future health, their health caused worries in their life, or

they were frustrated by their health problems. Participants answered these questions on a scale of 0 to 5 where 0=none of the time, 1=little of the time, 2=some of the time, 3=good bit of the time, 4=most of the time, and 5=all of the time. At the beginning of the study, participants reported that a good bit of the time they were discouraged by their health problems, some of the time they were fearful about their future health and a good bit of the time they worried about their health and were frustrated by their health problems. At Time 2, the participants were worried about their health or were discouraged by their health problems a little of the time. At Time 3, participants reported that none of the times they worried about their health or were frustrated by their health problems.

Questions 5 to 7 asked the participants to rate the severity of their symptoms such as fatigue, pain, and shortness of breath for the past two weeks using a scale 0-10 where 0=the absence of symptoms and 10=severe symptoms. At Time 3, participants reported a significant decrease in the severity of their fatigue (p=0.028); however, pain (p=0.105) and shortness of breath (p=0.060) did not decrease significantly.

Questions 8 to 21 inquired about the presence of symptoms such as increased thirst, dry mouth, decreased appetite, nausea or vomiting, abdominal pain, frequent nocturia, blood glucose > 300, morning headaches, nightmares, night sweats, lightheadedness, shakiness or weakness, intense hunger or occasions when they passed out or fainted. Participants reported the presence of these symptoms for the past two weeks period as 0-2 where 0=no, 1=yes, 2=don't know. At Time 1, participants reported experiencing all these symptoms except intense hunger. By Time 3, participants reported to significant improvement in previously reported symptoms such as increased thirst (p=0.182), dry mouth (p=0.058), decreased appetite (p=0.182), nausea or vomiting (p=0.391), abdominal pain (p=0.182) frequent nocturia (p=0.182), blood glucose > 300,

morning headaches (p=0.391), nightmares (p=0.182), night sweats (--), lightheadedness (p=0.058), shakiness or weakness (p=0.391), and passing out or fainting (p=0.182).

Daily activities. Participants (n=5) rated the interference of their health (See Table 3) in their normal social activities with family or friends, hobbies or recreational activities, household chores and errands for the past four weeks using 0-4 scale where 0=not at all, 1=slightly, 2=moderately, 3=quite a bit, and 4=almost totally. At Time 1, participants reported moderate interference of health in these activities. By Time 3, participants reported a significant reduction of interference of their health in their normal social activities with family or friends (p=0.016), hobbies or recreational activities (p=0.010), household chores (p=0.030); however, there was no significant change in running errands (p=0.078).

Blood glucose testing. Participants (n=5) were asked (See Table 3) whether they had a blood glucose machine, how many days in the past week they tested their blood glucose and how many times they tested their blood glucose on an average day if they tested their blood glucose. All participants reported that they had a blood glucose machine and test strips at home. By Time 3, there was no significant increase in the number of days they checked their blood glucose (p=0.215) and no significant increase in number of times they checked their blood glucose in a typical day (p=0.1).

Physical activity. Participants (n=5) answered five questions (See Table 3) about the total time spend on different forms of exercises such as stretching or strengthening exercises, walking, swimming or aquatic exercise, bicycling and other aerobic exercises during a typical week using 0-4 scale where 0=none, 1=< 30 minutes/ week, 2=30-60 minutes/week, 3=1-3 hours/week, and 4=> 3 hours/week. Participants reported some stretching and walking as the

types of physical activities they did. By Time 3, participants reported a significant increase of their time spent on walking as part of their regular exercise regime (p=0.003).

Confidence about doing things. Participants (n=5) answered eight questions (See Table 3) about their confidence in doing things and rated their present confidence level using a 1-10 scale where 1=not at all confident and 10=very confident. By Time 3, there was a significant improvement in the participants' confidence that they could eat their meals every 4 to 5 hours including breakfast every day (p=0.003), follow their diet when they had to prepare and share food with other people who did not have diabetes (p=0.019), choose healthy snacks when hungry (p=0.019), exercise 15-20 minutes, 4 to 5 times per week (p=0.001), doing something to prevent their blood sugar from dropping when they exercised (p=0.031), judge changes in their health and make decisions to visit their health care providers (p=0.003), and control their diabetes so that diabetes wouldn't interfere with the things they wanted to do (p=0.001). However, there was no significant different in their ability to institute measures when their blood sugar went higher or lower than it should be (p=0.099).

Diet and medications. Participants (n=5) were asked about the number of days they ate breakfast in the previous week (See Table 3). At the initial screening, participants reported having breakfast 2-3 days per week, and by Time 3, they reported having breakfast on a daily basis. Four questions (See Table 3) were asked about the usage of oral hypoglycemic agents, insulin, anti-hypertensives and lipid-lowering drugs in the previous week. Across the study, there were no differences in medication use.

Medical care. Participants (n=5) answered eight questions about their utilization of medical care (See Table 3). The first three questions inquired about their preparation and involvement in their medical visits and participants answered them using a 0-5 scale, where

0=never, 1=almost never, 2=sometimes, 3=fairly often, 4=very often, and 5=always. At the beginning of the study, participants reported that they almost never prepared questions for their medical providers prior to the clinic visits. At Time 3, participants did not report any significant difference in preparing questions for their medical providers prior to clinic visits or in discussing those personal problems which potentially affected their health with the providers. Also, there were no significant improvements in the frequency of asking questions about their treatment and things which they did not understand about their treatment (p=0.098).

The next five questions inquired about their utilization of health care services in the previous six months. The questions asked for information on visits with health care providers, emergency department visits, hospitalizations, the length of stay in the hospital if they were hospitalized, and any stay in a skilled nursing facility or a convalescent center. At Time 2 these questions focused on health care utilization during the period between Time 1 and Time 2. Similarly, at Time 3, these questions were focused on health care utilization during the period between Time 2 and Time 3. At Time 1, the participants' average emergency department visit was 2.6 (SD $\pm$ 1.5). At Time 2 follow-up, one of the participants was admitted to an inpatient unit for a planned lower extremity amputation. Another participant was admitted for a planned adrenalectomy during the interval between Time 2 and Time 3. No participants reported any unplanned hospitalizations. Participants were asked about their preventive care such as foot examinations and eye examinations. Participants did not report any differences in preventive care practices during the study period.

Table 3. Diabetes Self-Management Results (N=5)

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
General health (scale 1-5)	4.2±0.5	3.4±0.9	1.6	0.215	2.6±1.7	3.5	**0.041**
		Symptoms					
1. Were you discouraged by your health problems (past month)? (0-5)	3.4±0.9	1.6±0.9	3.6	0.037	1.4±0.6	5	**0.015**
2. Were you fearful about your future health (past month)? (0-5)	1.8±1.5	1.2±1.1	1.6	0.215	0.4±0.6	1.7	0.181
3. Was your health a worry in your life (past month)? (0-5)	3.6±1.1	2±1.4	7	**0.005**	1.2±1.1	8.7	**0.003**
4. Were you frustrated by your health problems (past month)? (0-5)	3.2±0.8	1.8±1.1	4.9	**0.016**	0.8±0.8	7.35	**0.005**
5. Describe your fatigue (past 2 weeks) (0-10)	7.6±2.3	4.2±2.6	1.9	0.141	3.2±1.8	3.99	**0.028**
6. Describe your pain (past 2 weeks) (0-10)	6.2± 4.5	3.6±3.3	2.6	0.078	0	2.3	0.105
7. Describe your shortness of breath (past 2 weeks) (0-10)	5.6±5.1	3.4±3.1	2.7	0.076	2.8±2.6	2.9	0.060
8. Increased thirst (past week)? (yes/no)	0.4±0.6	0	1.7	0.181	0	1.7	0.182
9. Dry mouth (past week)? (yes/no)	0.8±0.5	0	3	0.058	0.2±0.5	3	0.058
10. Decreased appetite (past week)? (yes/no)	0.6±0.6	0.2±0.5	1.7	0.182	0	1.7	0.182

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
11. Nausea or vomiting (past week)? (yes/no)	0.4±0.6	0	1	0.391	0	1	0.391
12. Abdominal pain (past week)? (yes/no)	0.4±0.6	0	1.7	0.182	0	1.7	0.182
13. Frequent urination at night at least three times (past week)? (yes/no)	0.4±0.6	0	1.7	0.182	0	1.7	0.182
14. Severely high (>300) blood glucose (past week)? (yes/no)	0.8±0.5	0.4±0.6	1.7	0.182	0	-	-
15. Morning headaches (past week)? (yes/no)	0.2±0.5	0	1	0.391	0	1	0.391
16. Nightmares (past week)? (yes/no)	0.4±0.6	0.2±0.5	1	0.391	0	1.7	0.182
17. Night sweats (past week)? (yes/no)	0.2±0.5	0	-	-	0.2±0.5	-	-
18. Lightheadedness (past week)? (yes/no)	0.8±0.5	0	3	0.058	0	3	0.058
19. Shakiness or weakness (past week)? (yes/no)	0.2±0.5	0	1	0.391	0	1	0.391
20. Intense hunger (past week)? (yes/no)	0.2±0.5	0	1	0.391	0	1	0.391
21. Times when you passed out or fainted (past week)? (yes/no)	0.4±0.5	0	1.7	0.182	0	1.7	0.182

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
		Daily activities					
1. Has your health interfered with your normal social activities with family, friends, neighbors or groups (past 4 weeks)? (0-4)	2.4±0.9	1.2±1.3	3.66	**0.035**	0.8±0.8	4.9	**0.016**
2. Has your health interfered with your hobbies or recreational activities (past 4 weeks)? (0-4)	3±1	1.6±1.1	2.5	0.091	0.8±0.8	5.7	**0.010**
3. Has your health interfered with your household chores (past 4 weeks)? (0-4)	2.6±1.1	1.2±1.3	2.8	0.66	0.6±0.9	3.9	**0.030**
4. Has your health interfered with your errands and shopping (past 4 weeks)? (0-4)	2.4±1.5	1±1.2	2	0.133	0.4±0.9	2.6	0.078
		Glucose testing					
1. Do you have a machine to measure your blood glucose? (yes/no)	1±0	1±0	-	-	1±0	0	0
2. How many days last week did you check your blood glucose?	4.2±3.8	5.4±2.3	-1.6	0.215	4.8±3	-1.6	0.215
3. On the days that you check your blood glucose how many days do you check on average?	2.2±2.2	2.4±1.3	-.522	0.638	2.2±1.1	0	1

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
Physical activity (during the past week)							
1. Did you do stretching and strengthening exercises? (0-4)	0	0.2±0.4	-1	0.391	1.2±-.8	-2.5	0.091
2. Walk for exercise? (0-4)	0	1.2±0.4	-5	**0.015**	2±1.2	-8.7	**0.003**
3. Swimming or aquatic exercise? (0-4)	0	0	-	-	0	-	-
4. Bicycling (including stationary exercise bikes)? (0-4)	0	0	-	-	0	-	-
5. Other aerobic exercise (Stairmaster, rowing, skiing machine)? (0-4)	0	0	-	-	0	-	-
Confidence about doing things (at the present time)							
1. How confident are you that you can eat your meals every 4 to 5 hours every day, including breakfast every day? (1-10)	3.8±1.9	6.4±1.5	-6	**0.009**	7.6±2.3	-19.1	**0.0003**
2. How confident do you feel that you can follow your diet when you have to prepare and share food with other people who do not have diabetes? (1-10)	3.4±2.3	6.8±1.8	-3	0.058	7.8±1.5	-4.6	**0.019**

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
3. How confident do you feel that you can chose appropriate foods to eat when you are hungry (for example, snacks)? (1-10)	3.6±2.3	6.8±1.8	-3	0.058	7.8±1.5	-4.6	**0.019**
4. How confident do you feel that you can exercise 15 to 20 minutes, 4 to 5 times a week? (1-10)	1.6±0.9	3.2±1.6	-2.8	0.066	6.2±1.1	-12.3	**0.001**
5. How confident do you feel that you can do something to prevent your blood sugar from dropping when you exercise? (1-10)	4.6±2.9	7.6±2.1	-3.2	**0.050**	9.2±1.3	-3.9	**0.031**
6. How confident do you feel you know what to do when your blood sugar goes higher or lower than it should be? (1-10)	6±4.3	7.8±2.2	-2	0.141	9±1.7	-2.4	0.099
7. How confident do you feel you can judge when the changes in your illness mean you should visit your doctor? (1-10)	61.9±	8±2.4	-1.7	0.186	9.4±0.9	-9	**0.003**
8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do? (1-10)	3.6±1.7	7.4±2.3	-5.4	**0.012**	9.2±0.8	-12	**0.001**

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
			Diet				
1. How many times last week did you eat breakfast when you got up?	1.8±1.1	5±2.1	-5.4	**0.012**	6.6±0.9	-8.3	**0.004**
			Medications				
1. In the past week did you take pills for diabetes? (yes/no)	0.6±0.5	0.6±0.5	-	-	0.6±0.5	-	-
2. In the past week did you take insulin injections? (yes/no)	0.6±0.5	0.6±0.5	-	-	0.6±0.5	-	-
3. In the past week did you take pills for high blood pressure? (yes/no)	1±0	1±0	-	-	1±0	-	-
4. In the past week did you take pills for cholesterol? (yes/no)	0.8±0.4	1±1	-1	0.391	0.8± 0.4	0	1
			Medical care				
1a. How often do you prepare a list of questions for your health care provider? (0-5)	1.4±1.7	1.2±1.8	-	-	1.4±1.9	-1	0.391
1b. Ask questions about the things you want to know and things you don't understand about your treatment? (0-5)	2.8±1.6	3.2±1.3	-0.6	0.604	4.8±0.4	-2.4	0.098

	Time 1 (0 weeks)	Time 2 (8 weeks)			Time 3 (12 weeks)		
	M±SD	M±SD	t	p	M±SD	t	p
1c. Discuss any personal problems that may be related to your illness? (0-5)	2.2±1.6	1.8±0.4	0.2	0.840	3.8±1.8	-1.9	0.155
2. In the past 6 months, how many times did you visit a health care provider?	2.8±2.2	1.4±0.9	1.1	0.367	1.6±0.9	1	0.406
3. In the past 6 months, how many times did you go to the hospital emergency department?	2.6±1.5	0	3.2	**0.048**	0	3.2	**0.048**
4. In the past 6 months how many times were you hospitalized for one night or longer?	2.4±1.7	0.2±0.4	3.2	**0.049**	0.2±0.4	2.6	0.080
5. How many total nights did you spend in the hospital in the past 6 months?	13.8±12.7	0.4±0.9	2.7	0.761	6.2±12.3	2.5	0.090
6. Were any of these hospitalizations at a skilled nursing facility, convalescent hospital, or other minimum care facility? (yes/no)	0.2±0.4	0	1	0.390	0.2±0.4	1	0.390

Bold *p* values indicate significance.

Feasibility of Depression Screening

At the completion of the study, participants (n=5) answered the survey that explored their experience with depression screening (See Appendix E). All five participants reported feeling that they needed help regarding their depression and all five participants received medications for their depressive symptoms. Of the five, one participant received a few individual face to face

psychotherapy sessions with a clinical Psychologist. Three out of five participants reported that they knew about their depressive symptoms and did not report them to their providers. None of the participants reported having any concerns about the medical provider discussing their depressive symptoms or prescribing treatment for their depression. Of the five participants, four participants preferred that their medical provider was managing their depression where as one participant had equal preference for medical and mental health provider. One of the participants who preferred the medical provider reflected "I am not crazy. I don't want to see mental health." None of the participants had any suggestions for improving the care of their diabetes or depression. Two of them felt they were receiving the "best medical care possible."

At the conclusion of the study, an anonymous survey (See Appendix F) was distributed among the hospitalist providers. Of the thirteen providers, nine providers answered this voluntary survey. All nine providers (100%) reported that they consider patients with diabetes as having a higher risk for developing depression. One provider did not consider this increased risk in the past; however, with this study and the provider learning session associated with the study, the provider now agrees with the increased risk for patients with diabetes to develop depression. Of the nine providers who responded to the survey, 100% believed that depression screening and management needed to be integrated into the management of patients with diabetes. Providers rated themselves regarding their confidence in initiating depression management as "confident" (33.3%), "fairly confident" (33.3%), "somewhat confident" (11.1%), "moderately confident" (11.1%) and "7/10" (11.1%). Of the nine providers, three (33.3%) suggested that involving of mental health specialist through an electronic consult may improve the process of depression screening and management for hospitalized patients. For improving the process of depression screening and management, four of the nine providers (44.4%) suggested adding PHQ-2 in the

standard admission screening, another four providers (44.4%) suggested routine depression screening in the outpatient setting and one provider (11.1%) did not offer any suggestions. Providers reported that they liked the information received in the provider education session conducted before the study, handouts/ pocket cards distributed to the providers (See Appendix G) and the alerts received about positive depression screens. Two providers mentioned that the depression screen notes by the DNP student in the electronic health record were "easy to see" and "clear" whereas one provider considered these notes as "lengthy." One provider noted that the researcher was "very clear in approach and delivery and involved the team."

CHAPTER 6: DISCUSSION

The incidence of depression in patients with diabetes is higher than in patients without diabetes (Hasan, Mamun, Clavarino, Kairuz, 2015). Patients with diabetes and comorbid depression report increased physical symptoms and higher utilization of emergency departments and preventable hospitalizations (Davydow et al., 2013; Smith, Gariepy, & Schmitz, 2014). The purpose of this study was to explore the feasibility of depression screening and initiation of management for depressive symptoms in patients with diabetes while they are hospitalized with a medical illness and to evaluate the effect of depression management in their depressive symptoms, health-related quality of life, and diabetes self-management. The results of this study support the feasibility of screening for depressive symptoms in hospitalized patients with diabetes. The findings from this study suggest that depression screening and initiation of management for depressive symptoms in patients with diabetes during their hospitalization may improve their depressive symptoms, health-related quality of life, and diabetes self-management. Also, the management of comorbid depression in patients with diabetes may decrease their emergency department use for non-emergent conditions and re-hospitalizations for ambulatory care sensitive conditions.

Effect on Depressive Symptoms

Over the study period, participants reported improvement in their depressive symptoms. The improvement in depressive symptoms in this study was similar to the improvement reported by Nicolau and colleagues (2013) in patients with diabetes who received medication management for their depressive symptoms. Similarly, a Cochran review of psychological and

pharmacological interventions for depression in patients with diabetes reported clinically significant improvement in depressive symptoms (Baumeister, Hutter, & Bengel, 2014). In the current study, the improvement in depressive symptoms showed a noticeable trend over the 12 week study period. By the completion of the study, the improvement was statistically significant. At baseline and at Time 2, participants' depressive symptoms made it either extremely difficult or very difficult for them to do their work or to take care of things at home or to get along with other people. Antidepressants require time and sometimes dosage adjustments to reach their full therapeutic effect, and during this period, patients may continue to experience depressive symptoms. These findings endorse the importance of enhanced support from the clinician and health care team to ensure treatment adherence in patients with diabetes and comorbid depression. However, at 12 months follow-up, Jani and colleagues (2015) did not identify a difference in depressive symptoms in participants who received antidepressants as compared to those participants who did not receive antidepressants. Future studies need to examine the long-term outcomes of depression management on depressive symptoms.

Effect on Health-Related Quality of Life

Health-related quality of life refers to individuals' perception of their physical, psychological, and social health and well-being (Speight, Reaney, & Barnard, 2009). In the current study, data from Veteran's RAND12 reports the health-related quality of life as Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. At baseline, the participants' PCS and MCS scores were less than the population average. The lower PCS and MCS scores might reflect the poor physical health of the participants, especially when they were hospitalized for a medical illness. However, the poor quality of life could also be due to depressive symptoms as there is a reciprocal relationship between severity of depression and health-related quality of life in patients with diabetes as reported by Timar and colleagues

(2016). Over the study period, there were improvements in participants' PCS and MCS scores. The improvement in MCS scores was beyond the improvement in PCS scores. This improvement in scores was very similar to the results from the Medical Expenditure Panel Survey analysis (Alenzi, Sambamoorthi, & Alenzi, 2016) where patients with diabetes and comorbid depression showed improvement in MCS scores, but not in PCS scores when their depressive symptoms were managed by antidepressants alone. However, at the conclusion of the current study, there was a statistically significant improvement in PCS and MCS scores and thereby significant improvement in health-related quality of life. Similar statistically significant improvements in health-related quality of life-related to the management of depressive symptoms in patients with diabetes and comorbid depression were reported by Nicolau and colleagues (2013) and Filipcić, Margetić, Simunović, & Jakovljević (2010). Since the PCS and MCS scores showed improvement over the twelve week period, not at Time 2, the improvement may not be attributed entirely to participant not being in the hospital at the time of data collection. Also, at Time 2, one of the five participants who completed the study and one participant who later lost follow-up were admitted to the hospital. Of these two participants who were in the hospital at Time 2, the participant who later lost follow-up due to death had not received management for depression. This participant had a higher PHQ-9 score, lower PCS and MCS scores as compared to this participant's baseline scores. However, the other participant who was hospitalized at Time 2, received treatment for depressive symptoms had a higher MCS score compared to baseline, and the PCS score remained the same as the baseline score, which was similar to what Alenzi and colleagues (2016) reported.

Effect on General Health

At the completion of the study, participants reported improvement in their general health. One can argue that when participants were hospitalized with a medical illness, they perceived their general health as poor, and once they were discharged from the hospital, they perceived better health. In the current study, the perceived improvement in general health was not significant until Time 3 which indicates that not being hospitalized alone did not improve the participants' perception of their general health. Research supports individual's self-rated poor health as a predictor for exacerbations and hospitalizations in patients with chronic diseases such as chronic obstructive pulmonary disease (Farkas, Kosnik, Flezar, Suskovic, & Lainscak, 2010) and heart failure (Creber, Allison, & Riegel, 2013). It is possible that patients with diabetes also have the increased risk for developing acute symptoms which require hospitalizations when they perceive poor general health. Future studies examining the relationship between self-rated general health and hospitalizations in patients with diabetes may provide supporting data specifically for patients with diabetes.

Effect on Symptoms

At the completion of the study, participants reported statistically significant improvement in fatigue. There was also an improvement in symptoms such as pain, polydipsia, hyperglycemia and symptoms of hypoglycemia. However, participants continued to report physical symptoms such as shortness of breath, decreased appetite, nausea, vomiting, nocturia, and morning headache. However, the health-related quality of life substudy of Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial analyzed the factors affecting diabetes symptoms and reported a significant association of current depressive symptoms (PHQ-9 score > 10) with the severity of diabetes symptoms (Sullivan et al., 2012). In the current study, it is unsure whether the short follow-up period of 12 weeks was inadequate to influence the diabetes

symptoms. Even though these symptoms persisted, participants reported less severity of these symptoms as compared to baseline. At Time 3, though the participants continued to report certain symptoms, they were neither worried about their future health nor frustrated by their current health problems. Participants' positive approach to health and health problems may have resulted from their improved confidence in managing their diabetes.

Effect on Confidence in Doing Things

The study reported statistically significant improvement in participants' confidence in performing several functions related to diabetes self- management. A similar outcome was reported by Egede & Ellis (2008) and Ludman and colleagues (2013). In the current study, participants lacked confidence in managing symptoms related to hypoglycemia and hyperglycemia though they reported confidence in preventing their blood sugars from dropping down. Also, the improvement in confidence in choosing appropriate diet was not significant. Diet is an important aspect of diabetes self-management. It is likely that several barriers such as personal preference, culture, social practices, access, and availability exist in following a therapeutic diet with modifications to keep optimum glycemic control. Knowledge deficit may also affect the individual's confidence in following the appropriate diet. But, Egede & Ellis (2008) found that diabetes knowledge was not the determining factor in confidence related to diabetes self-management. Gharaibeh, Gajewski, Al-smadi, & Boyle (2016) examined the relationships between depression, diabetes knowledge, self-care agency, self-efficacy and diabetes self- management. In this study, self-care agency was defined as the individual's capability to perform self-care activities whereas self- efficacy referred to cognitive, social and skills capability that a person has to perform a course of action (Gharaibeh et al., 2016). This study identified a direct negative relationship of depression with self-care agency and self-efficacy. However, the effect of depression on diabetes self-management was not direct but

mediated by self-care agency and self-efficacy. Also depression did not affect diabetes knowledge. So, improvement in self-efficacy and self-care agency is vital to improving self-management. Along with depression screening and management of depressive symptoms, activities to enhance patient self-care agency and self-efficacy may improve diabetes self-management.

Effect on Physical Activity

Over the study period, participants did not report much physical activity. At baseline, participants reported some walking as the main physical activity. By Time 3, there was a significant improvement in time spent for walking for exercise. Participants' age, comorbidities, and symptoms such as shortness of breath might explain their reluctance to exercise. Physical activity is an important aspect of diabetes management. Clinicians may improve patients' physical activity by helping them identify potential activity modifications based on individual limitations and potentials. As Gharaibeh and colleagues (2016) supported, the management of depressive symptoms alone may not improve patients' diabetes self-management. Innovative approaches such as involvement of a health coach (Wayne, Perez, Kaplan, & Ritvo, 2015), walking groups (Hanson, Guell, & Jones, 2015), psycho-social group interventions (Sabourin, Vallis, & Currie, 2011), and Whole Person Model of Disease-Self Management (Clarke, Baird, Perera, Hagger, & Teede, 2014) may improve physical activity in patients with diabetes and depressive symptoms. Also, a patient-centered approach may improve patient's adherence to physical activity recommendations.

Effect on Daily Activities

Manderson & Kokanovic (2009) reported the effect of diabetes on patients' activities of daily living. In the current study, at baseline, participants reported their health interfered with household activities, running errands, social and recreational activities. Health-related

disengagement in social activities may be an early predictor of disability and death in older adults with diabetes (Kuo et al., 2004). Over the study period, participants considered that health caused less interference in their activities. This significant improvement might be an effect of improvement in their general health. Also, the improvement in daily activities might have improved their health-related quality of life. The improvement in functional ability related to the improvement in depressive symptoms may be sustainable if the participants continue to have improvement in their depressive symptoms as reported by Huang and colleagues (2012).

Effect on Glucose Monitoring and Medication Adherence

At baseline and throughout the study, the participants reported adequate blood glucose monitoring practices and appropriate medication adherence. However, the literature supports the association between medication non-adherence and depression in patients with type 2 diabetes (Axon et al., 2016; Dirmaier et al., 2010; Gonzalez, Kane, Binko, Shapira, & Hoogendoorn, 2016). Medication non-adherence may apply to oral hypoglycemic agents, insulin, antidepressants and medications prescribed for other co-morbidities. Shared decision making may improve patients trust in health care providers leading to improved medication adherence especially the adherence to antidepressants (Bauer et al., 2014). Interventions to enhance social support may improve medication adherence in patients with diabetes and comorbid depression (Chew, Hassan, & Sherina, 2015; Kim et al., 2015; Osborn & Egede, 2012).

Effect on Preventive Health Care

Patients with diabetes and comorbid depression have a higher risk for missed preventive self-care practices (Egede, Grubaugh, & Ellis, 2010). In the current study, at baseline, participants did not report appropriate preventive health care practices regarding annual ophthalmic or podiatry follow-up. Over the study period, participants did not report attending or scheduling any ophthalmic or podiatry follow-up. A short follow-up period of 12 weeks seems

to be inadequate for evaluating changes in preventive care practices with improvement in depressive symptoms.

Health Care Utilization

During the study period, there was no significant change in participants' preparation for medical care visits such as preparing a list of questions or concerns about their health to discuss with their provider. However, there was an improvement in participants' interaction with providers regarding seeking an explanation of treatment or asking questions about their illness.

One of the significant outcomes of this study is the decrease in participants' emergency department use for non-emergent conditions and re-hospitalizations for ambulatory care sensitive conditions. At baseline, all the participants reported minimum one emergency department visit in the previous month. During the study period, none of the participants received care in emergency departments. Two of the participants were hospitalized over the 12 week study period. Both these participants were admitted for elective surgical procedures. A significant reduction in re-hospitalizations for ambulatory care conditions in the participants could be due to improvement in their depressive symptoms. Davydow and colleagues (2013) reported higher re-hospitalization rates in patients with diabetes and depression. Increased risk for re-hospitalization for medical illness has been reported for patients with other chronic diseases when they also have comorbid depression as compared to patients with same chronic diseases who did not have depressive symptoms (Iyer et al., 2016; Kartha et al., 2007; Mitchell et al., 2010; Cancino et al., 2014). Pederson and colleagues (2016) claim that presence of depressive symptoms at discharge from medical units predicts the possibility of readmission or death. The two participants who enrolled in the study and were lost to follow-up due to death had PHQ-9 scores in the range of 20-27 (severe depression) at initial screening.

Feasibility of Depression Screening

Li et al. (2009) reported that nearly 45% of patients with diabetes suffer from undiagnosed depression. However, in the current study, 33.3% of population presented positive symptoms for depression. Considering the number of patients excluded for reasons such as dementia and delirium and patients who declined to participate in the study, patients screened for depressive symptoms may not represent the actual population. Also, the facility performs routine annual depression screening as part of primary care services. Routine screening might be instrumental in reducing the number of patients with unidentified depressive symptoms. However, Shankman, Nadelson, McGowan, Sovari, and Vidovich (2012) reported the low sensitivity for annual screening in identifying depression among patients with Coronary Artery Disease. This observation might be pertinent for patients with diabetes also. After reviewing the negative outcomes in patients with medical illness and comorbid depression, IsHak and colleagues (2017) recommended screening for depressive symptoms in hospitalized patients with medical illnesses.

In the current study, though participants were aware of their depressive symptoms, they did not report their symptoms to the providers. However, when the participants received positive screens for depressive symptoms as part of the study, participants accepted treatment for their depressive symptoms. The majority of the participants preferred management of depression from their medical provider and one of the participants reflected that he was not "crazy" to consult a mental health provider. This comment may be an expression of the stigma associated with mental illness. It is possible that patients who are reluctant to approach mental health providers for their depressive symptoms may receive management for their depressive symptoms if medical providers recognize these symptoms and offer management.

According to the current study, health care providers recognized the increased risk for comorbid depression in patients with diabetes and agreed with the benefits of depression screening during hospitalization. Providers were confident in initiating the management for comorbid depression. However, the providers acknowledged the benefits of collaboration with a mental health provider. One of the providers who responded to the survey contemplated the possibility of "false positive screens" among hospitalized patients due to physical symptoms which may not indicate true depression. However, evidence supports the feasibility and acceptability of depression screening in hospitalized patients using different screening tools including PHQ-9, the screening tool used in this study. Sowden, Mastromauro, Januzzi, Fricchione, and Huffman, (2010) reported feasibility and acceptability of depression screening among hospitalized patients with cardiac conditions. Wagner et al. (2017) supported the feasibility of screening for depressive symptoms in patients with cancer who were admitted to radiation oncology units. Karamchandani et al. (2015) also favored the feasibility of the screening in patients who were hospitalized following a stroke.

Limitations

Outcomes of the current study concur with the existing evidence of unidentified depression in patients with diabetes and the effect of comorbid depression on patients' health-related quality of life and diabetes self-management. However, the current study has several limitations, which include a very small sample size, a short duration of the study, and the absence of a control group. Of the seven participants enrolled in the study, two participants died during the study period and lost follow-up. Secondary to the short duration of the study, the effect of management of depressive symptoms on glycemic control was not measured. The three screening tools used in the study are widely used and are capable of providing valuable data on depressive symptoms, quality of life and diabetes self-management. Some of the questions in the

three questionnaires asked for same information though questions were worded differently. It was noted that the participants provided slightly different responses to these questions within a single encounter. It is likely that when these three surveys were administered in one session, the participants felt overwhelmed and answered some of the questions in haste. Despite the limitations, this study addresses the effect of depression treatment on depressive symptoms, health-related quality of life, diabetes self-management, and health care utilization of adults with diabetes and comorbid depression.

Implications for Practice

The study confirms the presence of comorbid depression in patients with diabetes and initiates discussion on the feasibility of routine screening for depressive symptoms in patients with diabetes hospitalized with a medical illness. The study offers opportunities for improvement in health care delivery by implementing routine screening and initiation of management for depressive symptoms in patients with diabetes during their hospitalization. The three dimensions of the Triple Aim Framework proposed by Institute of Healthcare Improvement (IHI) for improved health care delivery are population focus, patient experience of care, and health care costs (Berwick, Nolan, & Whittington, 2013). Comorbid depression act as a barrier in diabetes self-management leading to poor health-related quality of life and self-management outcomes. Patients with diabetes and unmanaged depression report increased physical symptoms, have a higher risk of developing microvascular and macrovascular complications, poor quality of life, and increased utilization of emergency departments and inpatient services for ambulatory care sensitive conditions. Identification of depressive symptoms in patients with diabetes and the initiation of management for the depressive symptoms satisfy the three dimensions of the Triple Aim Framework for improvement in health care quality.

According to the American Diabetes Association (2016), 25.9% of the older adults suffer from diabetes. In the current study, the prevalence of diabetes was 35.8%. Management of depressive symptoms in patients with diabetes benefits a large population. As Knowles et al. (2015) described, collaborative management initiated by a medical provider is an opportunity for patients to overcome the stigma associated with depression and seek professional support for their depressive symptoms. Improvement in health-related quality of life, self-management, and ability to manage their disease will improve patients' experience and enhance patient's satisfaction with health care services. In addition to improvement in patient experience with care delivery, management of depressive symptoms may be cost effective. According to the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project, patients with diabetes and related complications have 20.3% re-admission rate within 30 days of discharge from a hospital (Elixhauser & Steiner, 2013). In the Veterans Health Administration, healthcare spending for managing diabetes with comorbid depression accounts for the highest healthcare expenditure (Egede et al., 2015). A decrease in healthcare spending evidenced in the study regarding reduction in preventable emergency department visits and hospitalizations supports the economic benefits of the routine screening and management of depressive symptoms.

Outcomes of this study uphold the role of healthcare professionals in recognizing depressive symptoms in hospitalized patients with diabetes. Any team members can administer a screening questionnaire for depressive symptoms with minimum training. Nurses, healthcare providers, clinical social workers, case managers and professionals from those disciplines directly involved in patient care need ongoing education on the increased risk of depressive symptoms in patients with diabetes and the warning signs of depression. The providers in this study appreciated the pocket cards with information from the Veterans Affairs/ Department of

Defense Clinical Practice Guidelines for Management of Depression. Healthcare providers will benefit from ongoing education on depression management and opportunities for collaboration with inpatient mental health providers. Improved communication between inpatient providers and outpatient providers may ensure appropriate post discharge follow-up.

Plan to Sustain

The design of this program and utilizing the electronic medical record to communicate with healthcare providers was well received. Plans to expand the program and working with the health care providers to make depression screening a part of every admission may take time, however, a worthwhile endeavor to continue to expand the program. If this program becomes part of the entire Durham site, then it may be expanded to other sites in the state and the country. This feasibility study revealed barriers and achievements that will help in transitioning to other sites to potentially benefit a wider range of patients being served by the Veterans Administration.

Conclusion

Patients with diabetes have an increased risk of developing depressive symptoms. Depression management in patients with diabetes seems to improve their general health, daily activities and health-related quality of life and tends to reduce preventable emergency department visits and hospitalizations. The current study supports the feasibility of screening for depressive symptoms in hospitalized patients with diabetes. This study was conducted in a small group of participants over a short period. Further research on long-term effects of depression management in patients with diabetes may provide future directions for care. Also, future studies need to examine the effect of depression management in glycemic control of patients with diabetes and comorbid depression.

APPENDIX A: PATIENT HEALTH QUESTIONNAIRE-2 (PHQ-2)

Name: Date:

Over the past two weeks, how often have you been bothered by any of the following problems?

Little interest or pleasure in doing things.
0 = Not at all
1 = Several days
2 = More than half the days
3 = Nearly every day

Feeling down, depressed, or hopeless.
0 = Not at all
1 = Several days
2 = More than half the days
3 = Nearly every day

Total point score: _____

APPENDIX B: PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems (Use "✔" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3.Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4.Feeling tired or having little energy	0	1	2	3
5.Poor appetite or overeating	0	1	2	3
6.Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9.Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Total	0 +	____ +	____ +	____
Total Score				

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

APPENDIX C: THE VETERANS RAND 12-ITEM HEALTH SURVEY (VR-12)

The following questions ask for your views about your health—how you feel and how well you are able to do your usual activities. All kinds of people across the country are being asked these same questions. Their answers and yours will help to improve health care for everyone. There are no right or wrong answers; please choose the answer that best fits your life right now. Answer each question by marking an 'X' next to the best response.

Q1. In general, would you say your health is:

□ Excellent □ Very good □ Good □ Fair □ Poor

Q2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf?

□ Yes, limited a lot □ Yes, limited a little □ No, not limited at all

b. Climbing several flights of stairs?

□ Yes, limited a lot □ Yes, limited a little □ No, not limited at all

Q3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

a. Accomplished less than you would like.

□ No, none of the time □ Yes, a little of the time □ Yes, some of the time

□ Yes, most of the time □ Yes, all of the time

b. Were limited in the kind of work or other activities.

□ No, none of the time □ Yes, a little of the time □ Yes, some of the time

□ Yes, most of the time □ Yes, all of the time

Q4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

a. Accomplished less than you would like.

□ No, none of the time □ Yes, a little of the time □ Yes, some of the time

□ Yes, most of the time □ Yes, all of the time

b. Didn't do work or other activities as carefully as usual.

□ No, none of the time □ Yes, a little of the time □ Yes, some of the time

□ Yes, most of the time □ Yes, all of the time

Q5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

□ Not at all □ A little bit □ Moderately □ Quite a bit □ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

Q6a. How much of the time during the past 4 weeks: Have you felt calm and peaceful?

□ All of the time □ Most of the time □ A good bit of the time

□ Some of the time □ A little of the time □ None of the time

Q6b. How much of the time during the past 4 weeks: Did you have a lot of energy?

□ All of the time □ Most of the time □ A good bit of the time

□ Some of the time □ A little of the time □ None of the time

Q6c. How much of the time during the past 4 weeks: Have you felt downhearted and blue?

□ All of the time □ Most of the time □ A good bit of the time

□ Some of the time □ A little of the time □ None of the time

Q7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

□ All of the time □ Most of the time □ Some of the time

□ A little of the time □ None of the time

Now, we'd like to ask you some questions about how your health may have changed.

Q8. Compared to one year ago, how would you rate your physical health in general now?

□ Much better □ Slightly better □ About the same

□ Slightly worse □ Much worse

Q9. Compared to one year ago, how would you rate your emotional problems (such as feeling anxious, depressed or irritable) now?

□ Much better □ Slightly better □ About the same

□ Slightly worse □ Much worse

The Veterans RAND 12-item Health Survey was developed from the Veterans RAND 36 Item Health Survey which was developed and modified from the original RAND version of the 36-item Health Survey version 1.0 (also known as the "MOS SF-36")

APPENDIX D: STANFORD DIABETES QUESTIONNAIRE

Stanford Patient Education Research Center

Stanford University School of Medicine

SAMPLE QUESTIONNAIRE

DIABETES

You may use all or parts of the questionnaire at no charge without permission

Stanford Patient Education Research Center
1000 Welch Road, Suite 204
Palo Alto CA 94304
(650) 723-7935 voice • (650) 725-9422 fax
http://patienteducation.stanford.edu
self-management@stanford.edu

Name:_____ Today's date: _____

Address: _____

City, state, zip: _____

Telephone: home ( ) - _____Date of birth: _____

Work ( ) – _____

Sex: ☐ Female ☐ Male

Background

1. Ethnic origin (check ☐**only one**):

☐ White not Hispanic
☐ Black not Hispanic
☐ Hispanic
☐ Other: _____
☐ Asian or Pacific Islander
☐ Filipino
☐ American Indian/Alaskan Native

2. Please circle the **highest** year of school completed:

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23+

(primary) (high school) (college/university) (graduate school)

3. Are you currently (check ☐**only one**):

☐ married ☐ separated ☐ widowed ☐ single ☐ divorced

4. Please indicate below which chronic condition(s) you have:

☐ Diabetes type 2 ☐ Diabetes type 1 ☐ High cholesterol ☐ High blood pressure

☐ Heart disease Type of heart disease:

☐ Lung disease Type of lung disease:

☐ Other chronic condition Specify:

General Health

1. In general, would you say your health is: (Circle one)

Excellent.....1

Very good.....2

Good.....3

Fair.....4

Poor.....5

Symptoms

How much time during the **past month**...

	None of the time	**A little of the time**	**Some of the time**	**A good bit of the time**	**Most of the time**	**All of the time**
1. Were you discouraged by your health problems?.....	0	1	2	3	4	5
2. Were you fearful about your future health?.....	0	1	2	3	4	5
3. Was your health a worry in your life?....	0	1	2	3	4	5
4. Were you frustrated by your health problems?.....	0	1	2	3	4	5

5. We are interested in learning whether or not you are affected by fatigue. Please circle the number below that describes your **fatigue** in the **past 2 weeks:**

0 1 2 3 4 5 6 7 8 9 10

No Fatigue — Severe Fatigue

6. We are interested in learning whether or not you are affected by pain. Please circle the number below that describes your **pain** in the **past 2 weeks.**

0	1	2	3	4	5	6	7	8	9	10
No Pain										Severe Pain

7. We are interested in learning whether or not you are affected by shortness of breath. Please circle the number below that describes your **shortness of breath** in the **past 2 weeks:**

0	1	2	3	4	5	6	7	8	9	10
No Shortness of Breath										Severe Shortness of Breath

In the PAST WEEK, did you ever have any of the following symptoms?

8. Increased thirst? .....□ No □ Yes □ Don't know

9. Dry mouth?..... □ No □ Yes □ Don't know

10. Decreased appetite? .....□ No □ Yes □ Don't know

11. Nausea or vomiting? .....□ No □ Yes □ Don't know

12. Abdominal pain?.....□ No □ Yes □ Don't know

13. Frequent urination at night? Do you have to get up to urinate 3 or more times a night?……..... □ No □ Yes □ Don't know

14. Severely high blood sugar (blood glucose readings of 300 mg or higher?) ……..... □ No □ Yes □ Don't know

15. Morning headaches?..... □ No □ Yes □ Don't know

16. Nightmares?.....□ No □ Yes □ Don't know

17. Night sweats?.....□ No □ Yes □ Don't know

18. Lightheadedness?.....□ No □ Yes □ Don't know

19. Shakiness or weakness?.....□ No □ Yes □ Don't know

20. Intense hunger?.....□ No □ Yes □ Don't know

21. Times when you passed out fainted or lost consciousness, even for a short time? ..... □ No □ Yes □ Don't know

Daily Activities

During the **past 4 weeks**, how much... (Circle **one**)

	Not at all	Slightly	Moderately	Quite a bit	Almost totally
1. Has your health interfered with your normal social activities with family, friends, neighbors or groups?	0	1	2	3	4
2. Has your health interfered with your hobbies or recreational activities?	0	1	2	3	4
3. Has your health interfered with your household chores?	0	1	2	3	4
4. Has your health interfered with your errands and shopping?	0	1	2	3	4

Your Glucose Testing

1. Do you have a machine to measure your blood sugar (glucose) level? □ Yes □ No

2. On how many days in the **last week** did you test your blood sugar level? (If you were sick in the last week, think of the most recent 7 days when you were NOT sick) _____ Days

3. On **days** that you test your blood sugar, how many **times** do you test on **average**? _____ Times

Physical Activities

During the past week, even if it was not a typical week for you, how much **total** time (for the **entire week**) did you spend on each of the following? (Please circle **one** number for each question.)

	None	Less than 30 min/wk	30-60 min/wk	1-3 hrs per week	More than 3 hrs/wk
1. Stretching or strengthening exercises (range of motion, using weights, etc.)	0	1	2	3	4
2. Walk for exercise	0	1	2	3	4
3. Swimming or aquatic exercise	0	1	2	3	4
4. Bicycling (including stationary exercise bikes)	0	1	2	3	4

5. Other aerobic exercise equipment
(Stairmaster, rowing, skiing machine, etc.)..... 0 1 2 3 4

6. Other aerobic exercise

Specify_____.....0 1 2 3 4

Confidence About Doing Things

For each of the following questions, please **circle** the number that corresponds with your **confidence** that you can do the tasks regularly at the present time.

1. **How confident** do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

2. **How confident** do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

3. **How confident** do you feel that you can chose the appropriate foods to eat when you are hungry (for example, snacks)?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

4. **How confident** do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

5. **How confident** do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

6.**How confident** do you feel that you know what do when your blood sugar level goes higher or lower than it should be?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

7. **How confident** do you feel that you can judge when the changes in your illness mean you should visit the doctor?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

8. **How confident** do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

Not at all confident | | | | | | | | | | Very confident
1 2 3 4 5 6 7 8 9 10

Your Diet

1. How many **times last week** did you eat breakfast when you got up? __ times last week

2. **This morning**, did you eat any of the following foods for breakfast? (Please check all that apply)

□ milk (½ cup) □ cheese □ yogurt □ eggs □ meat, poultry, or fish □ beans

If you ate anything else, please write here:

Medications

1. In the past week did you take pills for diabetes?.....□ No □ Yes □ Don't know

Please specify the name(s) of the diabetes pills you took:

2. In the past week did you get insulin injections?.....□ No □ Yes □ Don't know

3. In the past week did you take pills for high blood pressure? □ No □ Yes □ Don't know

Please specify the name(s) of the blood pressure pills you took:

4. In the past week did you take pills for cholesterol?.....□ No □ Yes □ Don't know

Please specify the name(s) of the cholesterol pills you took:

Medical Care

1. When you **visit your doctor**, how often you do the following (please circle **one** number for each question):

	Never	Almost never	Some times	Fairly often	Very often	Always
a. Prepare a list of questions for your doctor	0	1	2	3	4	5
b. Ask questions about the things you want to know and things you don't understand about your treatment	0	1	2	3	4	5
c. Discuss any personal problems that may be related to your illness	0	1	2	3	4	5

2. **In the past 6 months**, how many times did you visit a physician? Do **not** include visits while in the hospital or the hospital emergency department..... _____ visits

3. **In the past 6 months**, how many times did you go to a **hospital** emergency department?....._____ times

4. **In the past 6 months**, how many TIMES were you hospitalized for one night or longer?....._____ times

   a. How many total NIGHTS did you spend in the hospital **in the past 6 months**?....._____ nights

   b. Were any of these hospitalizations at a skilled nursing facility, convalescent hospital, or other minimum care facility?..... Yes No

5. When was the last time you had your eyes examined? (example: for glaucoma or any other problem)..... Month /Year

6. How many **times** did the doctor or nurse examine your feet in the last 6 months?....._____ times

Thank you for your help!

APPENDIX E: SURVEY QUESTIONS FOR PARTICIPANTS AT THE END OF THE STUDY

Thank you for your participation in this project. This is a voluntary survey to evaluate the feasibility of depression screening and management for patients when they are admitted to medical wards.

1. What did you like about the study?

2. Did you feel that you needed help regarding your depression?

3. Did you receive medicine for your depression?

4. Did you see a Psychologist for your depression?

5. How do you feel since knowing that you have symptoms of depression?

   Choose one - better/ worse/ same

6. Did you like receiving telephone calls at 8 weeks and 12 weeks after discharge asking you the questions about your symptoms, self- care, overall health, and hospital visits?

7. Did you have any concerns for discussing depression symptoms with your provider who helps you manage diabetes?

8. What is your willingness to consult a mental health provider for depression symptoms?

   a. Same as consulting the medical provider

   b. I prefer medical provider helping me with my depression

   c. I prefer a mental health specialist – Psychiatrist managing my depression symptoms.

9. In regards to your diabetes and depression management, how can we serve you better?

APPENDIX F: SURVEY QUESTIONS FOR PROVIDERS AT THE END OF THE STUDY

Thank you for your participation in this project. This is a voluntary and anonymous survey to evaluate the feasibility of depression screening and management for comorbid depression in the medical setting.

1. What did you like about the study process?

2. What did you dislike about the study process?

3. Do you consider patients with diabetes having higher risk for developing depression?

4. Do you believe screening and management of co-morbid depression need to be integrated into diabetes care?

5. Did you like receiving an alert about your patients' need for follow-up of depressive symptoms?

6. Did you identify any difficulty in initiating depression management? If yes, mention it here?

7. How confident are you in initiating management of co-morbid depression in patients with diabetes?

8. What would you suggest to improve the process of screening and starting management for co-morbid depression during their hospitalization?

APPENDIX G: CONSENT FORM

Department of Veterans Affairs	Research Informed Consent Form	
	Version Date: 5/3/16	Page 1 of 6
	IRB Template: 20150904	VA Form 10-1086

Participant Name:	**Date:**
Study Title: Depression in Veterans with Diabetes	
Principal Investigator: Letha M Joseph	**VAMC:** Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE? The purpose of this project is:

1. To study the feasibility of checking for depression in diabetic patients who are admitted to the Durham Veterans Affairs Medical Center (DVAMC) with medical problems.
2. To find out if the diabetic patients who also have depression will be able to manage their diabetes better if they receive treatment for their depression.
3. To find out if the diabetic patients who also have depression will have better quality of life if they receive treatment for their depression

You are being asked to participate in this research study because you are eligible for VA services and diagnosed with diabetes. Only veterans admitted in DVAMC are invited to participate in this project. The project plans to enroll 50 veterans with diabetes. If you agree to participate, your individual participation will last approximately 12 weeks from your discharge from the hospital or until 28th February 2017 whichever comes first.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

This study plans to look at the effect of treating depression in veterans with diabetes who are admitted to the DVAMC, and how the treatment in impacts depressive symptoms, quality of life, and self-care.

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this project:

- You will be checked for symptoms depression or sadness using the first two questions of the Patient Health Questionnaire 9 (PHQ- 9). If these questions show that you may have symptoms of depression, the rest of the PHQ-9 questions will be administered along with the Veterans RAND-12 Health Survey (VR-12) and a diabetes self-management questionnaire will be administered.
- The investigator will inform your medical team about the presence or absence of depression symptoms. If you have symptoms of depression and you chose to receive treatment for depression, your medical team will start the management of depression.
- Approximately 8 weeks and 12 weeks of your discharge from hospital, the study team member will contact you over telephone and ask the above screening questions

IRB Approved
DVAMC
Date 10/24/16

- By participating in this project, you will not incur any increases in time, complexity, additional payment, discomfort, and/or prolongation of hospitalization or hospitalization entirely for research purposes.
- All questionnaires together may take 15-20 minutes of your time.
- Both men and women will be enrolled in this project.

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. You do not have to join this or any other research study. If you do join and later change your mind, you may quit at any time. If you withdraw from the study, no new data about you will be collected for study purposes. If you refuse to join or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You may choose to not participate in this study. If this is your choice, you may speak with your VA clinical provider(s) about receiving treatment without being in the study. Or, you may choose to not receive treatment.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

The study period is from July, 2016 to February, 2017. If you choose to participate, your enrollment will begin while you are admitted at the DVAMC. You will continue to be enrolled in the study for 12 weeks after discharge from the hospital, or on February28th 2017, whichever comes first.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

During the research visits, a research staff member will ask you about your symptoms of depression. Discussing these symptoms may cause you to become upset. The research staff member will work with you to make this experience less distressing. In order to lessen the risk of distress, the study team will always maintain a pleasant and professional demeanor, and allow you to discuss these reactions and feelings if they occur. You may take breaks during the interviews and assessments if needed. You may choose to skip any interview questions that cause you discomfort or end the interview at any time if you become uncomfortable. Taking part in this study will involve collecting private information about you. The risk of breach of confidentiality has been minimized in the following ways: the information collected will be kept in locked files, and on computers protected with passwords. If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

We cannot promise that you will get any benefits from taking part in this research study. A possible benefit may be that your symptoms of depression lessen through treatment with a provider, although this is not guaranteed. Also, your participation may give us information to help develop better depression screening programs for Veterans with diabetes in the future. Even if you do not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study. Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

No, you will not be paid for participating in this study.

ARE THERE REASONS THAT MY RESEARCH PARTICIPATION MAY END EARLY?

You are not required to take part in this study: your participation is entirely voluntary. You can refuse to participate now or you can withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide to withdraw from this study, you should contact Letha Joseph (investigator). The investigator may also withdraw you without your consent for one or more of the following reasons: 1) project is cancelled, 2) investigator decides that continuing your participation is difficult due to inability to reach you after three unanswered telephone calls, or 4) failure to follow instructions of investigator and/or study staff.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you, your condition, or your willingness to participate in this study.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

Results of this study will not be shared with you.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

No. There is no financial support from any sponsors. The investigator does not financial interests related to this study.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

Original research files will be maintained at DVAMC per VA guidelines. Study data will be stored in secure VA computer with access only for approved research staff. The paper data will be stored in locked cabinet which is accessible only to approved research staff. Inadvertent disclosure will be avoided by coding the data and removing any sensitive identifiers. No individual data will be reported while communicating the results of the study.

There are VA rules (called records control requirements) about how long your research records are kept. Your research records will be maintained and destroyed according to VHA records retention requirements

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). No investigational drug, device, or procedure is involved. The Food and Drug Administration (FDA) may choose to inspect research records that include your medical records. Your data will be shared with UNC Chapel Hill faculty for analysis purpose. We will not share any information with anyone outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

ARE THERE ANY LIMITS TO THE PRIVACY AND CONFIDENTIALITY OF MY RESEARCH INFORMATION?

During the initial screening while you are in the hospital, if you reveal current intent to harm yourself or someone else, it will be immediately reported to your treating team. The treating team determines the severity of the screen and whether safety precautions or interventions are required, including: mental health consultation or one to one sitter. In addition, if during the study any information reveals suicidal intent, depression, or other major clinical findings, your primary physician will be notified. In addition, if you reveal current intent to harm yourself or someone else, we may be required to escort you or have you escorted to this hospital's emergency room to be seen by staff in the Psychiatric Emergency Clinic (PEC). During follow up screening after discharge from the hospital, if you reveal intent to harm yourself, you will be asked to identify and contact a potential personal, family or social contact who may offer support. You may be asked to contact the suicide hotline or come to PEC or visit an emergency department. If during the course of the study you discuss or mention anything that gives us cause to suspect abuse or neglect of any child, elderly adult, or person with a disability, we are required by federal law to report the suspected abuse to your local Department of Social Services

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact the Investigator, Letha Joseph, at (919) 286-0411, Extension 7702, during the day.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Letha Joseph at (919) 286-0411 Extension 7702 during the day. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 7632.

Participant Name:	**Date:**
Study Title: Depression in Veterans with Diabetes	
Principal Investigator: Letha M Joseph	**VAMC:** Durham

AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature **Date**

Signature of Person Obtaining Consent **Date**

APPENDIX H: AUTHORIZATION FOR THE USE AND RELEASE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

Department of Veterans Affairs	Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research	
Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**
VA Facility (Name and Address): VA Medical Center Durham North Carolina 27705		
VA Principal Investigator (PI): Letha M Joseph	**PI Contact Information:** 919 286 0411 Extn 7702	
Study Title: Depression in Veterans with Diabetes		

Purpose of Study:

The purpose of this project is

1. To study the possibility of checking for depression in diabetic patients who are admitted with medical problems
2. To find out if the diabetic patients who also have depression will be able to manage their diabetes better if they receive treatment for their depression
3. To find out if the diabetic patients who also have depression will have better quality of life if they receive treatment for their depression

USE OF YOUR INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION (IIHI):

Your individually identifiable health information is information about you that contains your health information and information that would identify you such as your name, date of birth, or other individual identifiers. VHA is asking you to allow the VA Principal Investigator (PI) and/or the VA research team members to access and use your past or present health information in addition to new health information they may collect for the study named above. The investigators of this study are committed to protecting your privacy and the confidentiality of information related to your health care.

Signing this authorization is completely voluntary. However, your authorization (permission) is necessary to participate in this study. Your treatment, payment, enrollment, or eligibility for VA benefits will not be affected, whether or not you sign this authorization.

Your individually identifiable health information used for this VA study includes the information marked below:

- ☒ Information from your VA Health Records such as diagnoses, progress notes, medications, lab or radiology findings
- ☐ Specific information concerning:
  - ☐ alcohol abuse ☐ drug abuse ☐ sickle cell anemia ☐ HIV
- ☒ Demographic Information such as name, age, race
- ☐ Billing or Financial Records
- ☐ Photographs, Digital Images, Video, or Audio Recordings
- ☒ Questionnaire, Survey, and/or Subject Diary
- ☒ Other as described: Participant will receive a unique ID related to this project

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research

Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (Instruction: When banking or further analysis is an **optional** research activity, complete page 5 and leave this section blank. If banking is a required research activity to store "Data" and/or "Specimen" for future use or if "Not Applicable" is selected, remove page 5 in its entirety.)

☒ Not Applicable - No Data or Specimen Banking for Other Research

An important part of this research is to save your

☐ Data

☐ Specimen

in a secure repository/bank for other research studies in the future. If you do not agree to allow this use of your data and/or specimen for future studies approved by the required committees, such as the Institutional Review Board, you will not be able to participate in this study.

DISCLOSURE: The VA research team may need to disclose the information listed above to other people or institutions that are not part of VA. VA/VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy Act of 1974 and all other applicable federal laws and regulations that protect your privacy. The VHA Notice of Privacy Practices (a separate document) provides more information on how we protect your information. If you do not have a copy of the Notice, the research team will provide one to you.

Giving your permission by signing this authorization allows us to disclose your information to other institutions or persons as noted below. Once your information has been disclosed outside VA/VHA, it may no longer be protected by federal laws and regulations and might be re-disclosed by the persons or institutions receiving the information.

☐ Non-VA Institutional Review Board (IRB) at _____
who will monitor the study

☐ Study Sponsor/Funding Source: _____
VA or non-VA person or entity who takes responsibility for; initiates, or funds this study

☒ Academic Affiliate (institution/name/employee/department): Dr. Dianne Berry of UNC CH, who is the faculty support for the
A relationship with VA in the performance of this study DNP student will receive the coded data for analysis purposes.

☐ Compliance and Safety Monitors: _____
Advises the Sponsor or PI regarding the continuing safety of this study

☐ Other Federal agencies required to monitor or oversee research (such as FDA, OHRP, GAO):

☐ A Non-Profit Corporation (name and specific purpose):

☐ Other (e.g. name of contractor and specific purpose):

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research		
Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

Note: *Offices within VA/VHA that are responsible for oversight of VA research such as the Office of Research Oversight (ORO), the Office of Research and Development (ORD), the VA Office of Inspector General, the VA Office of General Counsel, the VA IRB and Research and Development Committee may also have access to your information in the performance of their VA/VHA job duties.*

Access to your Individually Identifiable Health Information created or obtained in the course of this research: While this study is being conducted, you

☒ will have access to your research related health records

☐ will not have access to your research related health records

This will not affect your VA healthcare including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

REVOCATION: If you sign this authorization you may change your mind and revoke or take back your permission at any time. You must do this in writing and must send your written request to the Principal Investigator for this study at the following address:

Letha M Joseph
Nurse Practitioner, CLC
Durham VA Medical Center
508nFulton Street, Durham, NC 27705

If you revoke (take back) your permission, you will no longer be able to participate in this study but the benefits to which you are entitled will NOT be affected. If you revoke (take back) your permission, the research team may continue to use or disclose the information that it has already collected before you revoked (took back) your permission which the research team has relied upon for the research. Your written revocation is effective as soon as it is received by the study's Principal Investigator.

EXPIRATION: Unless you revoke (take back) your permission, your authorization to allow us to use and/or disclose your information will:

☒ Expire at the end of this research study

☐ Data use and collection will expire at the end of this research study. Any study information that has been placed into a repository to be used for future research will not expire.

☐ Expire on the following date or event:

☐ Not expire

Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research		
Subject Name (Last, First, Middle Initial):	**Subject SSN** (last 4 only):	**Date of Birth:**

TO BE FILLED OUT BY THE SUBJECT

Research Subject Signature. This permission (authorization) has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the VHA facility Privacy Officer to file a verbal or written complaint.

I give my authorization (permission) for the use and disclosure of my individually identifiable health information as described in this form. I will be given a signed copy of this form for my records.

Signature of Research Subject _____ Date _____

Signature of Legal Representative (if applicable) _____ Date _____

To Sign for Research Subject (Attach authority to sign: Health Care Power of Attorney, Legal Guardian appointment, or Next of Kin if authorized by State Law)

Name of Legal Representative (please print) _____

APPENDIX I: PROVIDER POCKET CARD

VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder

Nine Symptom Checklist (PHQ-9)

Over the last 2 weeks, how often have you been every		**Not at**	**Several**	**More than half**	**Nearly**
a	Little interest or pleasure in doing things?	0	1	2	3
b	Feeling down, depressed, or hopeless?	0	1	2	3
c	Trouble falling or staying asleep, or sleeping too much?	0	1	2	3
d	Feeling tired or having little energy?	0	1	2	3
e	Poor appetite or overeating?	0	1	2	3
f	Feeling bad about yourself—or that you are a failure or have let yourself or your family down?	0	1	2	3
g	Trouble concentrating on things, such as reading the newspaper or watching television?	0	1	2	3
h	Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual?	0	1	2	3
i	Thoughts that you would be better off dead or of hurting yourself in some way?	0	1	2	3
For office coding: Total Score = + + +					

Antidepressant Dosing and Monitoring

Class	Agent	Initial Dose	Titration	Max dose/day	Initial dose/ Guidance Specific populations			
					Geriatrics	Renal	Hepatic	Pregnancy FDA Category
SSRIs	Citalopram	20 mg once a day	20 mg weekly	40 mg; 20 mg geriatric	10-20 mg once a day	Avoid: CrCl <20 ml/min	↓ dose	C
	Escitalopram	10 mg once a day	10 mg weekly	20 mg	5-10 mg once a day	Avoid: CrCl <20 ml/min	10 mg once a day	C
	Fluoxetine	20 mg once a day	20 mg every 2 weeks	80 mg	10 mg once a day	↓ dose and/or ↓ frequency	↓ dose 50%	C
	Fluoxetine weekly	90 mg once a week	N/A	90 mg	90 mg once a week	No change	Avoid	C
	Paroxetine	20 mg once a day	20 mg weekly	50 mg	10 mg once a day	10 mg once a day	10 mg once a day	D
	Paroxetine CR	25 mg once a day	12.5 mg weekly	62.5 mg; 50 mg geriatric	12.5 mg; once a day	12.5 mg once a day	12.5 mg once a day	D
	Sertraline	50 mg once a day	50 mg weekly	200 mg	25 mg once a day	25 mg once a day	↓ dose	C
	Vilazodone	10 mg once a day	10 mg weekly	20-40 mg	5 mg	No change	No change	C

Antidepressant Dosing and Monitoring

Class	Agent	Initial Dose	Titration	Max dose/day	Initial dose/ Guidance Specific populations			
					Geriatric	Renal	Hepatic	Pregnancy
SNRIs	Duloxetine	20-30 mg twice a day	20-30 mg weekly	60 mg	20 mg once or twice a day	Avoid if CrCl <30 ml/min	Avoid	C
	Venlafaxine IR	37.5 mg twice a day	75 mg weekly	225-375 mg	25mg once or twice a day	↓dose based on CrCl	↓ dose 50%	C
	Venlafaxine XR	75 mg once a day	75 mg weekly	225 mg	37.5-75 mg once a day	↓dose based on CrCl	↓ dose 50%	C
	Levomilnacipran	20 mg once a day	20-40 mg every 2 days	120 mg	Refer to adult dosing	Max doses less if CrCl<60 ml/min	No change	C
	Desvenlafaxine	50 mg once a day	Unnecessary	100 mg;	Consider CrCl	CrCl <30, 25mg daily	No change	C
5-HT3 receptor antagonist	Vortioxetine	10 mg once a day	10 mg once daily	5-20mg	5-20 mg once a day	No change	Severe: not recommended	
NDRIs	Bupropion IR	100 mg twice a day	100 mg weekly	450 mg	37.5mg twice a day	Has not been studied	Severe: 75 mg/day	
	Bupropion SR	150 mg once a day	150 mg weekly	200 mg twice daily	100 mg once a day		100 mg once a day or 150 mg every other day;	C
	Bupropion XR	150 mg once a day	150 mg weekly	450 mg	150 mg once a day			C
5-HT2 receptor antagonist	Trazodone	50 mg three times a day	50 mg weekly	600 mg	25-50 mg bedtime		Unknown	C
	Nefazodone	100 mg twice a day	100 mg weekly	600 mg	50 mg twice a day	No change	Avoid	C
Noradrenergic antagonist	Mirtazapine	15 mg daily at bedtime	15 mg weekly	45 mg	7.5 mg at bedtime	Caution in renal impairment	Cl ↓ 30%	C

Antidepressant Dosing and Monitoring

Class	Agent	Initial Dose	Titration	Max dose/day	Initial dose/ Guidance Specific populations			
					Geriatric	Renal	Hepatic	Pregnancy risk
TCAs	Amitriptyline	25-50 mg daily	Weekly	300 mg	10–25 mg	No change	Lower dose and slower titration recommended	C
	Imipramine	25 mg 1- 4 times/day	Weekly	300 mg	10-25 mg at			Un classified
	Nortriptyline	25 mg 3-4 times/day	Weekly	150 mg	30-50 mg/day			
	Desipramine	25-50 mg once daily or in divided doses	Weekly	300 mg; 150 mg geriatric	10-25 mg once a day			
	Doxepin	25-50 mg daily at bedtime or twice a day	Weekly	300 mg	Low dose, once daily			
MAOIs	Isocarboxazid	10 mg twice a day	10 mg/day every 2-4 days to 40 mg/day. After first week, may increase by up to 20 mg/week to a Max 60 mg/day.	60 mg	10 mg twice a day	Avoid in any renal impairment.	Contraindicated in history of liver disease or abnormal LFTs	C
	Phenelzine	15 mg 3 times a day	Increase rapidly, based on patient tolerance, to 60-90 mg/day	90 mg; 60 mg geriatric	7.5 mg once a day	Avoid if severe	Avoid	Undetermined
	Selegiline patch	6 mg/24 hours	3 mg/24 hours every 2 weeks	12 mg/24 hours	6 g/24 hours	Use in CrCl <15 ml/min - not studied	Mild to mod: no adjustment Severe: - not studied not studied	C
	Tranylcypromine	10 mg twice/day	10 mg weekly	60 mg	10 mg twice a day	No change	Avoid	C

Abbreviations: 5-HT = serotonin, BID = twice a day, CrCl = creatinine clearance, CR = controlled release, IR = immediate release, LFT = liver function test, MAOI = monoamine oxidase inhibitor, mg = milligram, min = minute, ml = milliliter, N/A= not applicable, NDRI= norepinephrine and dopamine reuptake inhibitor, QD = once a day, QHS = once before bedtime, QID = four times a day, QOD = every other day, SNRI = serotonin norepinephrine reuptake inhibitor, SR = sustained-release, SSRI = selective serotonin reuptake inhibitor, TCA = tricyclic antidepressant, TDM = therapeutic drug monitoring, XR = extended-release

Antidepressant Adverse Event Profiles

Drug class/ drug	Amine Update		Antic - holine rgic activit	Seda tion (H1 Acti vity	Orthos tatic Hypote -nsion (alpha	Car diac Con duc tion	GI effec ts	Weight gain	Comments
	5HT	NE							
SSRIs	+++	0/+	0/++	0/ +	0	0/+	+++	0/+	Sexual dysfunction common; Citalopram and escitalopram dose-related conduction effects Paroxetine most anticholinergic; avoid in elderly ; Paroxetine and fluoxetine CYP2D6 and CYP2B6 inhibitors ; Vilazodone CYP2C8 2C1 and 2D6 inhibitor
SNRIs	++/+ ++	++/+ ++	0/+	0/+	0/++	0/+	++/+ ++	0/+	Sexual dysfunction common Venlafaxine NE activity dose-related; Desvenlafaxine active metabolite of venlafaxine
Bupropion	0/+	0/+	0	0	0	0	++	0	Risk of seizures is dose- related; avoid if seizure history, bulimia or eating disorder; CYP2D6 inhibitor
Trazodone Nefazodone	+++	0/+	0	+++	0	0/+	++	0/+	Very sedating; Nefazodone associated with a higher risk of hepatotoxicity ; Nefazodone CYP3A4 inhibitor
Mirtazapine	0/+	0/+	0	+++	0/+	0	0/+	+++	Doses >15 mg less sedating. May stimulate appetite
Vortoxetine	+++	++	0	0	0	0	+++	0	
TCAs	+/++ +	+/++ +	+/+++	0/++ +	+/+++	++/ +++	0/+	0/++	Desipramine and nortriptyline more tolerable; least sedating, anticholinergic and orthostatic hypotension Therapeutic blood concentrations established for desipramine, imipramine, and nortriptyline
MAOI s	0	0	0	0/+	0/+	0	0/+	0/+	Requires a low tyramine diet except selegiline patch Contraindicated with other antidepressants sympathomimetics and

Key: +++ = strong effect, ++ = moderate effect, + = minimal effect, 0 = no effect
Abbreviations: MAOI = monoamine oxidase inhibitor, SNRI = serotonin norepinephrine reuptake inhibitor, SSRI = Selective serotonin reuptake inhibitor, TCA = tricyclic antidepressant

APPENDIX J: INSTITUTIONAL REVIEW BOARD APPROVAL FROM VETERAN'S AFFAIRS MEDICAL CENTER DURHAM

Institutional Review Board
Durham VAMC Research (151)
508 Fulton St. • Durham, NC 27705 • 919-286-6926 • Fax: 919-286-6824

IRB APPROVAL - Initial Review

Date: June 10, 2016
From: David Edelman, M.D., Chairperson
Investigator: Letha M. Joseph, MSN, RN, AGPCNP-BC
Protocol: Depression in Veterans with Diabetes
ID: 01987 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 05/19/2016 meeting, contingent upon stipulations in each item marked with an asterisk (*):

- IRB Submission Checklist (03/23/2016)
- Abstract (05/09/2016; v 5.3.16)
- Conflict of Interest (05/09/2016; for LJ)
- (05/09/2016; Initial Submission Checklist)
- Questionnaire / Survey (05/09/2016; PHQ9)
- Questionnaire / Survey (05/09/2016; Stanford Patient Educ Research Center) ✓
- Questionnaire / Survey (05/09/2016; Survey Question for Patients)
- Questionnaire / Survey (05/09/2016; Veterans rand 12 Item Heatlh Survey) ✓
- Request to Review (05/09/2016; Initial Request to Review 5.9.16)
- Protocol (05/09/2016; v 5.9.16) ✓
- * Waiver or Alteration of Informed Consent (05/09/2016; v 5.8.16 Patient)
- * Waiver or Alteration of Informed Consent (05/09/2016; v 5.8.16 Provider)
- HIPAA Authorization (05/09/2016; v 5.3.16) ✓
- Memorandum (05/09/2016; From PI to IRB)
- LETTER (05/09/2016; from Hospitalist Dir to IRB)
- Support Letter (03/25/2016; Medicine Service)
- Staff Listing (05/09/2016)
- Privacy/Information Security Checklist (05/09/2016; signed by ISO/PO)
- Informed Consent (05/09/2016; v 5.3.16 Patient)
- Appendix F-Data Management Plan for Public Access (05/09/2016)

Waiver or Alteration of Informed Consent (05/09/2016; v 5.8.16 Patient) was returned to you with stipulations. The following revised items incorporate the stipulations and are now approved:

- Waiver or Alteration of Informed Consent (05/27/2016; Revised Patient IRB - 5/19/16)
- Waiver or Alteration of Informed Consent (05/27/2016; Revised Provider IRB - 5/19/16)

Waiver or Alteration of Informed Consent (05/09/2016; v 5.8.16 Provider) was returned to you with stipulations. The following revised items incorporate the stipulations and are now approved:

- Waiver or Alteration of Informed Consent (05/27/2016; Revised Patient IRB - 5/19/16)

The Durham VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews, continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

- Waiver or Alteration of Informed Consent (05/27/2016; Revised Provider IRB - 5/19/16)

The following additional items were received to address stipulations and are now approved:
- Response to Recommendations - IRB - 5/19/16 (05/27/2016; From Dr Joseph to IRB)
- HIPAA Waiver or Alteration (05/27/2016; Revised Patient IRB - 5/19/16)
- HIPAA Waiver or Alteration (05/27/2016; Revised Provider IRB - 5/19/16)
- Memorandum - IRB - 5/19/16 (05/27/2016; From Dr Joseph to IRB)

Conditions of Approval are attached. These conditions are further detailed in the HHS, FDA, and VA regulations, which are available in the Research Office.

Approval is granted for a period of 12 months and will expire on 05/18/2017. Your Continuing Review is scheduled for 04/13/2017, and the requirements are attached.

The protocol was determined to have the following level of risk:
Minimal

The purpose of this non-funded minimal risk study is to examine the possibility of checking for depression in diabetic patients who are admitted with medical problems, find if the diabetic patients who also have depression will able to manage their diabetes if they receive treatment for depression and to find out if the diabetic patients who also have depression will have better quality of life if they receive treatment for their depression. A survey will be distributed to all 18 Providers in the hospitalist medicine team. Fifty Veterans admitted at the Durham VA Medical Center (DVAMC) will be invited to participate in this project by completing questionnaires. Study data will be stored on a secure VA computer and data will be shared with University of North Carolina, Chapel Hill (UNC CH) faculty for analysis purposes and will be sent via FIPS 140-2 encrypted CD or FIPS 140-2 encrypted hard drive/flash drive using VA approved carrier with tracking. A conflict of interest is submitted with no financial conflicts to report. This study was reviewed and Tabled at the IRB April 2016 meeting. Items have been revised and resubmitted. The IRB contingently approved this study pending response to their recommendations. Conflict of Interest forms were submitted with no financial conflicts to report. A HIPAA Waiver of Authorization to screen/recruit for the study Participants met the approval criteria at 45 CFR 164.512 (i) (2) (ii), and the Waiver or Alteration of Informed Consent met the approval criteria at 45 CFR 46.116(d). A HIPAA Waiver of Authorization to conduct the study for Providers met the approval criteria at 45 CFR 164.512 (i) (2) (ii), and the Waiver or Alteration of Informed Consent met the approval criteria at 45 CFR 46.116(d).The response to recommendations was received 5/27/16 and final approval was granted 6/10/16.
NOTE: Providers do not require consent.

If you are a new Investigator, you are required to meet with the Human Research Protection Program (HRPP) Coordinator prior to initiating this study.

"If this is a multi-site study, note that the attached ICF is valid for Durham VAMC site only. Each engaged participating site in a multi-site trial must use the informed consent document that was approved by the IRB at the individual study site."

The Durham VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews, continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

If this study has a HIPAA Authorization, it has been reviewed and approved by the VA Privacy Officer.

"Only stamped, unexpired informed consent forms (ICF) are to be used in this study."

Approval by each of the following is required prior to study initiation (unless Exempt):
Institutional Review Board
Research & Development Committee

Approval for study initiation is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects.

This initial review has been reviewed and approved for ethical use of human subjects.

6/22/16

Miriam Morey, Ph.D.
Research and Development Committee, Chairperson Date

This initial review has reviewed and approved by all relevant committees and subcommittees and is now approved to be initiated.

6/22/16

John D. Whited, M.D., MHS
ACOS for R&D Date

The Durham VAMC IRB is not connected with, has no authority over, and is not responsible for human research conducted at any other institution, except where a Memorandum of Understanding specifies otherwise. Separate consent forms, initial reviews, continuing reviews, amendments, and reporting of serious adverse events are required if the same study is conducted at multiple institutions.

APPENDIX K: INSTITUTIONAL REVIEW BOARD AMENDMENT APPROVAL FROM VETERANS AFFAIRS MEDICAL CENTER DURHAM

E.1

Institutional Review Board
Durham VAMC Research (151)
508 Fulton Street · Durham, NC 27705 · Phone: (919) 286-6926 · Fax: (919) 286-6824

PROTOCOL AMENDMENT IRB SUBMISSION FORM

[rev 06/21/2001]

Date: 10/11/16 MIRB #: 01987 Promise #: ~~N/A~~ 001 TW 10/11/16

Principal Investigator: Letha Joseph, MSN, RN,AGPCNP-BC

Protocol Title: Depression in Veterans with Diabetes

Research Coordinator: Letha Joseph Phone: 919 610 4217 Pager: 0013

Amendment Date: 10/11/16 Amendment Number/Version: 1

In order for the IRB to fully evaluate an amendment request, please provide a summary of the modifications from the sponsor/investigator.

Check all protocol amendments that apply:

☒ **Consent Form Changes**
(Provide copy of original consent form and new consent form with highlighted changes)

One or more subjects have already provided written or verbal consent to enroll in this study:
☒ **Yes** ☐ **No**

OCT 11 '16 PM2:58

☐ **Inclusion / Exclusion Change**

☐ **Editorial / Administrative Changes**

☐ **New Information Provided to Subjects**

☐ **Therapy Changes**

☐ **Scientific Changes**

☒ **Other** (e.g., closure, suspension, substudy): Extension of study period from 31st December 2016 to 28th February 2017. Patient enrolment will extend December 31st and participants will be enrolled in the study till 28th February 2017 or until 12 weeks of discharge from the hospital, whichever comes first. Amendment is requested to reflect these changes in the protocol (pages 12, 15, 23) and in the consent form (pages 1 and 2).

OCT 11 '16 PM2:58

Signature of PI: Letha M Joseph Date: 10/11/16

Reviewer: Approved: ☒ Yes ☐ No Date: 10.21.16

Comments: ____

The Durham VAMC IRB is not connected with, and has no authority over, and is not responsible for human research conducted at any other institution. Separate consent forms, initial reviews, continuing reviews, amendment, and reporting of

Web Form | December 18, 2015

MIRB TW

APPENDIX L: INSTITUTIONAL REVIEW BOARD APPROVAL FROM UNIVERSITY OF NORTH CAROLINA CHAPEL HILL

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Letha Joseph

School of Nursing

From: Non-Biomedical IRB

Approval Date: 7/26/2016

Expiration Date of Approval: 7/25/2017
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Initial
Expedited Category: 7.Surveys/interviews/focus groups
Study #: 16-0886

Study Title: Depression in Veterans with Diabetes

This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this research is no more than minimal.

Study Description:

Purpose: The purpose of this Doctorate in Nursing Practice scholarly project is to explore the feasibility of depression screening and follow-up for veterans admitted to Durham VA Medical Center with diabetes and to evaluate the effect of depression management in depressive symptoms, health related quality of life, self- reported diabetes self- management and all-cause 30-day readmission rates of veterans with diabetes.

Participants: Participants of this project will be a convenience sample of 50 veterans admitted to hospitalist medical team during the study period with a primary diagnosis of diabetes and has glycated hemoglobin of seven or higher

Procedures (methods): After identification of potential participants using the above inclusion criteria, the DNP student will secure informed consent from the participants and administer Patient Health Questionnaire – 2 (PHQ-2). Patients screen negative using the PHQ-2 will be excluded from the project. Those patients scoring ≥ 3 for the PHQ-2 will receive additional screening using the nine item questionnaire PHQ-9 to quantify the severity of depressive symptoms. DNP student will discuss the results of the screening with the patient. Additionally their Health Related Quality of Life (HRQoL) will be evaluated using the Veterans RAND 12-item health survey (VR-12) diabetes self-management using Stanford Diabetes Questionnaire. The DNP student will update the inpatient provider about presence and severity of depression symptoms using the computerized patient record system (CPRS), the electronic health records used in the facility.

The inpatient provider will discuss depression management options with the participant and will make depression management plans honoring the patient's choice. Depending on the severity of depression symptoms and patient's acceptance, the hospitalist provider will make referrals to a clinical psychologist, prescribe antidepressants or refer to an inpatient psychiatrist. Upon discharge from the inpatient unit, patient will receive a schedule for a follow-up appointment with their primary care provider in 30 days. The primary care provider will continue to follow the patients' severity of depression and continued management during routine outpatient visits.

At eight weeks and twelve weeks following discharge from the hospital, the DNP student will contact the participant via telephone. During this telephone follow-up, the participant will be screened for depression symptoms, diabetes self- management and HRQoL using PHQ-9, VR-12 and Stanford Diabetes Questionnaires.

Regulatory and other findings:

This approval includes a limited waiver of HIPAA authorization to identify potential subjects for recruitment into this research study, as allowed under 45 CFR 164.512. This temporary waiver provides access to protected health information (PHI) to confirm eligibility and facilitate initial contact, after which consent and HIPAA authorization will be sought when applicable. Access and use is limited to the minimum amount of PHI necessary to review eligibility criteria and to contact potential subjects.

Investigator's Responsibilities:

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

Your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=16-0886.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Any unanticipated problem involving risks to subjects or others

(including adverse events reportable under UNC-Chapel Hill policy) should be reported to the IRB using the web portal at http://irbis.unc.edu.

Please be aware that additional approvals may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:

Diane Berry, School of Nursing

APPENDIX M: INSTITUTIONAL REVIEW BOARD AMENDMENT APPROVAL FROM UNIVERSITY OF NORTH CAROLINA CHAPEL HILL

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS
720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: Letha Joseph
School of Nursing
From: Non-Biomedical IRB

Approval Date: 11/28/2016
Expiration Date of Approval: 7/25/2017
RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)
Submission Type: Modification
Expedited Category: 7.Surveys/interviews/focus groups, Minor Change to Previously Approved Research
Study #: 16-0886

Study Title: Depression in Veterans with Diabetes
This submission has been approved by the IRB for the period indicated. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.
Submission Description:
Extension of study period from 31st December 2016 to 28th February 2017. Patient enrollment will extend until December 31st and newly enrolled participants will be enrolled in the study till 28th February 2017 or until 12 weeks of discharge from the hospital, whichever comes first. Amendment is requested to reflect these changes in the consent form (pages 1 and 2).
Investigator's Responsibilities:
If applicable, your approved consent forms and other documents are available online at http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=16-0886.
The current data security level determination is Level III. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.
This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:
Diane Berry, School of Nursing

APPENDIX N: PERMISSION TO USE VR-12 QUESTIONNAIRE

B O S T O N U N I V E R S I T Y M E D I C A L C E N T E R

SCHOOL OF MEDICINE • SCHOOL OF PUBLIC HEALTH • GOLDMAN SCHOOL OF DENTAL MEDICINE • BOSTON MEDICAL CENTER

Boston University School of Public Health

Department of Health Policy & Management

715 Albany Street, T3W

Boston, Massachusetts

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Tel: 617 638-5042

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June 29 2016

Letha M Joseph, MSN, RN, AGPCNP-BC

DNP Student, UNC Chapel Hill, NC

Letha.joseph@va.gov

Dear Letha,

I am in receipt of your letter and description of the project. This letter will serve to give you permission to use the Veterans RAND 12-item Health Survey (VR-12) and/or the Veterans RAND 36 Item Health Survey (VR-36) subject to the conditions as specified in the memorandum attached to this e-mail. This includes the appropriate attribution given for the VR-12/VR-36 as noted below.

The VR-36 and VR-12 are in the public domain and there is no cost for their use. The VA Office of Quality and Performance have previously used the RAND 12-item Health Survey (VR-12) as part of the SHEP National Survey in the VA and earlier the VR-36 in the 1999 Large Health Survey of Veterans. CMS has also endorsed the use

of the VR-12 in their Health Outcome Survey to assess the outcomes of the Medicare Advantage Program on a national basis. The VR-36 and VR-12 were developed with the use of federal funds and were modifications from the MOS SF-36 version. You are free to use the VR-12/VR-36 assessment tool, for the specific purpose/study described in your request. Any other use of the VR-36 or VR-12 will require a separate request for approval.

In any use of the VR-12 the user needs to provide the correct and complete attribution with references as follows, "the Veterans RAND 12-item Health Survey was developed from the Veterans RAND 36 Item Health Survey which was developed and modified from the original RAND version of the 36-item Health Survey version 1.0 (also known as the "MOS SF-36"). For the VR-36 the attribution needs to read that this was developed from the MOS SF-36. In addition to note that the user will comply with the uses of the Rand 36-Item Health Survey given at the Web Site: http://www.rand.org/health/surveys/sf36item/permission.html.

We have also attached the package of documentation, including the questionnaire, 'scoring guide' and 'algorithms for scoring' including imputation of missing values. If the imputation approaches reflected in these algorithms are used proper credit needs to be given by citing the document on scoring and imputation contained in this package *(Spiro A, Rogers W, Qian S and Kazis L. Imputing Physical and Mental Summary Scores (PCS and MCS) for the Veterans SF-12 Health Survey in the Context of Missing Data, Sept. 2004, Report submitted to CMS.)* A reference list of publications is also included.

Good luck with your work and we will keep you posted of any further updates and releases related to the VR-36 or the VR-12.

Sincerely,

Lewis E. Kazis, Sc.D.

Professor and Director

Center for the Assessment of Pharmaceutical Practices

Department of Health Policy and Management

Boston University School of Public Health

And

Chief, Pharmaco-Outcomes and Epidemiology Section

Center for Health Quality, Outcomes and Economic Research (CHQOER)

Veterans Administration Medical Center, Bedford, MA.

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