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Glycemic Control in Elderly Diabetics: A Function of Informal Caregivers' Health Literacy

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By

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Glycemic Control in Elderly Diabetics: A Function of Informal Caregivers' Health Literacy

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About 27% Americans ≥ 65 years have Diabetes Mellitus (DM). The complexities of DM care often prompt family members to provide DM care to elderly persons. However, low health literacy of informal caregivers may be a barrier to effective DM care. Unfortunately, about 90 million American adults have low health literacy, and some may be caring for an elderly diabetic. The aim of this study was to examine the relationship between caregiver health literacy and DM control in elders with type 2 DM.

Using a correlational design, the sample consisted of 88 dyads (veterans and their caregivers) recruited from a health care facility located in the Eastern U.S. Measurements included the REALM instrument for assessment of health literacy, the Katz Basic Activities of Daily Living (ADL) scale to assess the care recipients' level of dependency, a socio-demographic questionnaire, and the Bayer DCA 2000 point of care A1c instrument to obtain care recipients' A1c, if the A1c was not documented in the medical records. The data was analyzed with descriptive statistics and logistic regression.

Thirty-two percent of caregivers of care recipients with a mean A1c of 7.82 (*SD* 1.65), aged 78 (*SD* 8.38), and duration of disease 14.03 years (*SD* 8.34), were found to have low health literacy. Caregivers' health literacy significantly influenced care recipients' A1c. Higher caregivers' health literacy was associated with lower care recipients' A1c $X(1, N=88) = 3.86, p < .05$.

Caregivers' health literacy was significantly associated with educational attainment, $\chi^2 [5] = 28.90, p <.000$, annual income, $\chi^2 [5] = 12.92, p <.05$ and race, $\chi^2 [2] = 15.40, p <.000$.

Findings substantiated the importance of assessment of a caregiver's level of health literacy. Patient care instructions should be provided at the level of the caregiver's health literacy to facilitate understanding and compliance with instructions. Further research should include studies to elucidate how caregivers with low health literacy process and understand health instructions and longitudinal studies to examine the effect of caregivers' health literacy on diabetic outcomes of care recipients over time.

This dissertation by Dora E. Ifon fulfills the dissertation requirements for the doctoral degree in Nursing approved by Petra Goodman, Ph.D., WHNP-BC, FAANP, as Director, and by Nalini Jairath, Ph.D., RN, and Marin Allen, Ph.D. as Readers.

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Dedication

This work is dedicated to the Lord God Almighty for the great things that He has done!

Without His wisdom and guidance, this day would not have come to fruition.

To God be the glory!

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CHAPTER 1

Informal caregivers' low health literacy may be a barrier to effective diabetes mellitus (henceforth, referred to as diabetes) care for elderly diabetics who are recipients of informal care. Selden, Zorn, Ratzan and Parker (2000, Introduction section, para. 7), defined health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." Caregivers with low health literacy may be unable to make appropriate health care decisions or navigate the U. S. health care system to improve the outcomes of elderly diabetics who are recipients of informal care. For example, the caregiver with low health literacy may find it difficult to follow recommended diet instructions or plan a meal with a low glycemic index to improve the care recipient's glycemic control. An estimated 80 to 90 million Americans do not possess the qualities that define health literacy and are categorized as having low health literacy (Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011). Among American adults with low health literacy, are persons in the caregiving role who may be caring for an elderly relative with diabetes.

Low health literacy is associated with underutilization of preventive health services, frequent emergency room visits, higher rates of hospitalization, and poor health outcomes, including poor glycemic control (Baker et al., 2002, 2004; Berkman et al., 2011; Osborn, Bains & Egede, 2010; Stiles, 2011). Moreover, the burden of low health literacy on the U. S. economy is placed between \$106 and \$236 billion annually (Somers & Mahadevan, 2010).

Informal caregivers care for about 14 million elderly Americans, including an estimated 27% Americans 65 years of age and older, who are diabetic (Centers for Disease Control, [CDC] 2011a; Health Services Research Information Center [HSRIC], 2003). The number of elderly Americans receiving informal care is expected to reach 28 million by 2050 (HSRIC, 2003).

Diabetes is a common illness among elderly Americans and it is associated with significant health complications, higher mortality rate, functional decline, and higher rates of institutionalization in this age group (Kirkman et al., 2012). Diabetes self-care is complex and often challenging for the elderly diabetic who may have significant barriers, such as, cognitive or visual impairments or debilitating physical conditions. The complexities surrounding elderly diabetics and diabetes management often prompt family members (informal caregivers) to step up and provide care to elderly relatives with diabetes, in order to prevent health complications. However, how the three components of health literacy (obtaining, processing, and understanding) impact the informal caregivers' abilities to make appropriate diabetes care decisions affecting the elderly diabetic care recipients is not entirely understood. To date, there are no known studies which have examined the relationships between the informal caregivers' levels of health literacy and glycemic control in elderly diabetics who are recipients of informal care. Therefore, the purpose of this study is to examine the relationships between informal caregivers' levels of health literacy and glycemic control in elderly diabetics who are recipients of informal care.

Background

Fourteen million elderly Americans, including an estimated 11 million with diabetes, are recipients of informal care. The number of elderly Americans receiving such care is expected to reach 28 million by 2050 (HSRIC, 2003).

In addition to the 11 million elderly Americans with diabetes, 79 million adults have prediabetes (CDC, 2011a). With the projected increase in older Americans, 65 years and older, to over 88.5 million in 2050 (U.S. Census Bureau, 2008), there might even be a higher number of elderly diabetics who are recipients of informal care. Diabetes management is complex and requires the use of multi-faceted skills, which could be challenging for a caregiver with low health literacy. Low health literacy of caregivers of young children and adolescents with diabetes, has been implicated in poor glycemic control in the care recipients (Hassan & Heptulla, 2010). Persons with low health literacy tend to underutilize preventive health services, use many hospital emergency rooms visits, lack the ability to adhere to medication regimen, and may misinterpret medication labels and/or medical instructions (Berkman et al., 2011).

Diabetes is a serious illness with significant complications. Diabetes may cause kidney failure, lower leg amputations, blindness, heart disease, and stroke (CDC, 2011a, 2011b). In 2012, the estimated direct medical cost for diabetes care in the U. S., not including the cost for associated complications, was \$176 billion (CDC, 2011a). Caregiver low health literacy is a potentially modifiable barrier to improving diabetes outcomes, but the evidence is scant. In a recent study, investigators measured the health literacy levels of caregivers of elderly Hispanic care recipients.

The researchers suggested that to improve the quality of care that older patients receive, policymakers should be cognizant of low health literacy among caregivers (Garcia, Espinosa, Lichtenstein, & Hazuda, 2013). Therefore, it is necessary to carry out studies to determine the relationships between caregivers' health literacy and diabetic outcomes for older adults.

Statement of the Problem

There is a paucity of literature on the impact of caregivers' health literacy on diabetes outcome for elderly diabetic care recipients. This lack of knowledge of the influence of caregivers' health literacy on diabetes outcome may adversely affect communication between health care providers and caregivers, which may produce an adverse result for the care recipient. Therefore, the present study is timely and relevant, especially with the implementation of the Affordable Care Act, to assess the impact of caregivers' health literacy on the clinical outcomes of elderly diabetics who are recipients of informal care. This study examined the relationships between informal caregivers' level of health literacy and glycemic control in a sample of older veterans with type 2 diabetes, who were recipients of informal care.

Research objective. The purpose of this study was to establish if there were any relationships between caregivers' health literacy and glycemic control in elderly care recipients with type 2 diabetes.

Research question. What effects does informal caregivers' levels of health literacy have on A1c of elderly veterans with type 2 diabetes who are recipients of informal care?

Hypothesis

The hypotheses for this study was derived from the review of the literature.

Null hypothesis. Caregivers' levels of health literacy, as measured by the Rapid Estimate of Adult Literacy in Medicine (REALM), will have no influence on glycemic control as measured by the A1c levels in elderly diabetic veterans with type 2 diabetes, for whom the caregivers provide care.

Alternative hypothesis. Higher levels of caregivers' health literacy, as measured by the Rapid Estimate of Adult Literacy in Medicine (REALM), will influence glycemic control as measured by the A1c levels in elderly veterans with type 2 diabetes, for whom the caregivers provide care.

Conceptual Framework

The theoretical underpinning for this study was based on the theoretical model proposed by Paasche-Orlow and Wolf (2007) to describe the association between limited health literacy and health outcomes. This model explains how the interplay of patient characteristics, systems characteristics, and provider characteristics affect clinical outcomes. The primary reason for choosing the Paasche-Orlow and Wolf model hereafter referred to as P-O-W Model is that the model focuses on the link between health literacy and health outcomes. In this direction, the model implicates health literacy as an important determinant of clinical outcomes based on its role as a factor in system access and utilization, and patient-provider interaction. Therefore, the P-O-W model lends itself as a suitable guide in the present study because the focus of this study is to examine how the health literacy of caregivers affects clinical outcomes of care recipients.

Caregivers often have to access and use the health system and interact with providers, in the process of providing care for their care recipients. Figure 1 is a graphic display of the caregiver health literacy and care recipient's health outcomes framework.

The P-O-W model demonstrates how specific characteristics affect an individual's level of health literacy. More explicitly, specific characteristics affect "the degree to which the individual has the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Nielsen-Bohlman, Panzer, Hamlin, & Kindig, 2004, p.4). Health literacy, in turn, influences how an individual accesses and uses health care services, affects interactions with healthcare providers and determines how an individual chooses to administer self-care (Paasche-Orlow & Wolf, 2007). In figure 1, the caregiver and care recipient are in a reciprocal relationship in which the interplay of each group's characteristics influences health literacy of the caregiver. Health literacy, on the other hand, affects how the caregiver accesses and uses the health care system and interacts with providers. The interplay of all of these factors ultimately determines the health outcome of the care recipient.

The P-O-W model indicates that socioeconomic factors (e.g., employment status, and income), demographic characteristics (e.g., race/ethnicity, education, and age), and physical characteristics (e.g., vision and hearing) impact health literacy. Earlier reports have also confirmed that education, age, and ethnicity, are common determinants of health literacy (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005).

Figure 1. Caregiver Health Literacy Framework

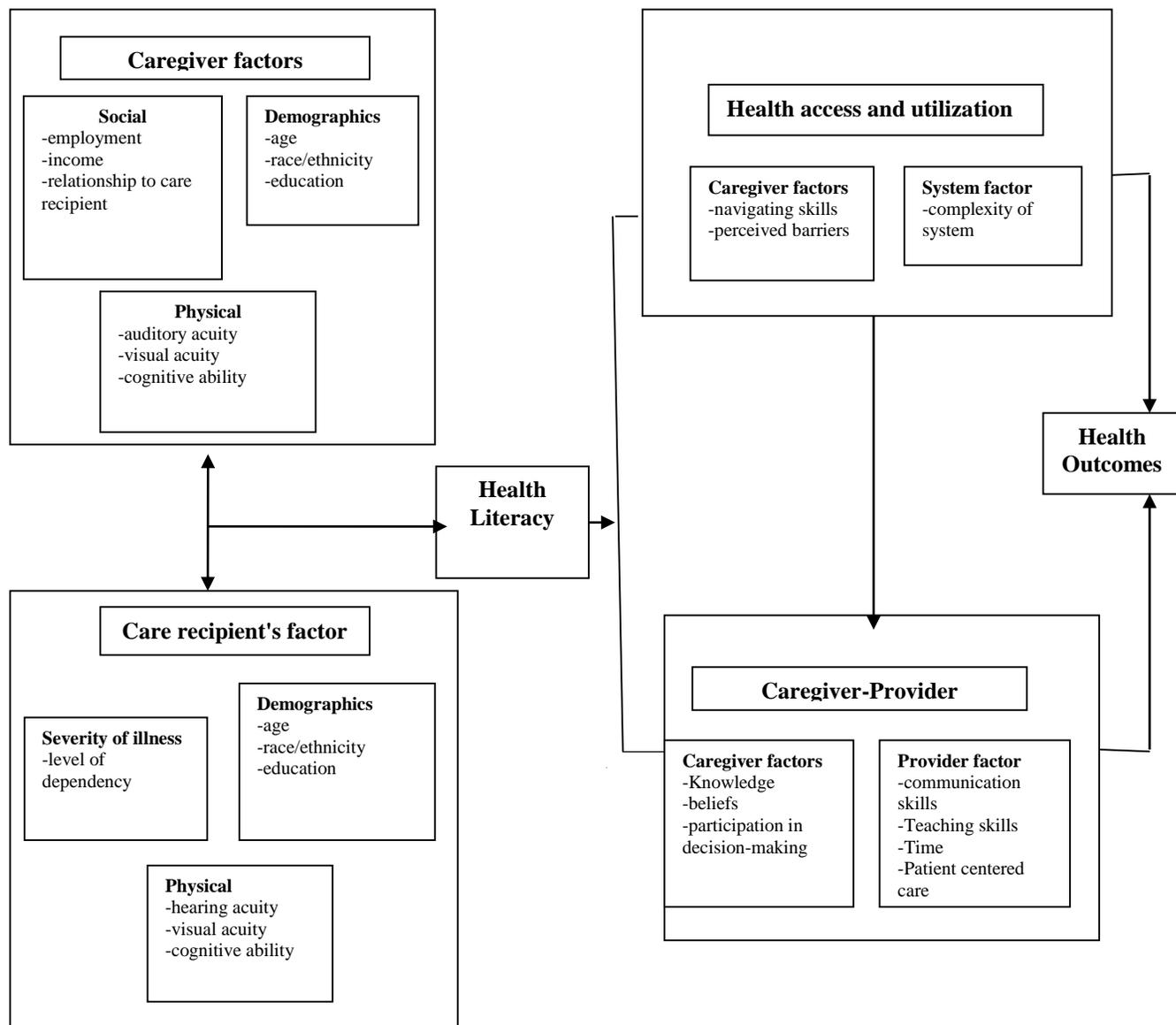


Figure 1. Adapted from conceptual model of causal pathways between limited health literacy and health outcomes by Paasche-Orlow, M. & Wolf, M. (2007). *American Journal of Health Behavior*, 31, S19-S26.

Thus, socioeconomic status and demographic characteristic are factors to consider when addressing a caregiver's level of health literacy. However, Paasche-Orlow and Wolf (2007) argue that it is hard to discern the independent effect of the socioeconomic status, and demographic characteristics on health literacy. Therefore, in the present model (figure 1), we recognize that factors such as the care recipient's severity of illness (level of dependency), demographic characteristics, and physical characteristics influence a caregiver's ability to obtain, process, and understand basic health information in order to make appropriate decisions about the care recipient.

A person, who is very ill, old or has memory impairment, by natural disposition, requires relatively more complex health-related skills for provision of care. The more complex the requisite health-related skills, the more challenging it is for the caregiver to process and understand the needed skills or navigate the health care system. Thus, it is important to recognize that there are other factors, such as patient-related factors, that may indirectly affect the caregiver's level of health literacy. In the present model, care recipient factors are in a reciprocal relationship with the caregiver factors, the one influencing the other, either negatively or positively.

As previously alluded to, the P-O-W model postulates that limited health literacy affects clinical outcomes from the following three perspectives: (1) access to and utilization of health systems, (2) patient-provider interaction and (3) patient self-care efforts. The model was modified to suit the present study by replacing patient-provider interaction with caregiver-provider interaction, and excluding patient self-care because the focus of the survey is on caregivers.

At each level of impact (health system access and utilization and caregiver-provider interaction), there may be related factors that are capable of modulating the relationship between caregiver health literacy and health outcomes (see figure 1).

At the system level, the factors that are likely to affect access and utilization include the complexity of the system, whether it is an acute care setting, or a multi-level care delivery system. In this regard, Paasche-Orlow and Wolf (2007) contended that people with limited health literacy have difficulties navigating such health care systems, either by the lack of ability to understand verbal directions or read signs.

In the context of caregivers, successful navigation of the health care system is substantially dependent on the caregiver's ability to understand or follow health-related instructions provided by clinicians, to manage the care recipient's illness and enhance caregiving. In this regard, the caregiver specific factors, such as prior navigation skills, self-efficacy (belief in one's ability), and perceived barriers, come into play. These factors may enhance or impede access and utilization of the health system, depending on the complexity of the organization. Certainly, prior navigation skills and self-efficacy (belief in one's ability) are factors that would enhance access and utilization. Conversely, low health literacy is one barrier that might impede access to and use of the health care system from the inability of the caregiver to communicate effectively. This view is consistent with an earlier observation by Weld, Padden, Ramsey, Garmon, and Bibb (2008) that limited health literacy is associated with poor access to preventive health care services.

People with limited or low health literacy do not usually disclose their deficiencies due to shame (Paasche-Orlow & Wolf, 2007).

Shame was an observation in early health literacy research. In 1996, Parikh, Parker, Nurss, Baker, and Williams carried out a study to determine the relationship between shame and low functional literacy in the health care setting and found that almost 40% of those with low functional literacy admitted shame. All of these are capable of influencing the clinical outcomes of the care recipients. This finding supports the need to screen patients, particularly caregivers, for the level of health literacy, to personalize health-related instructions/teaching.

At the level of caregiver-provider interaction, the present model predicts that a caregiver's level of knowledge, beliefs, and decision-making capacity are distinct factors that can alter the health outcome of the care recipient. Paasche-Orlow and Wolf (2007) argue that a patient's poor knowledge about a disease may determine how a patient with low health literacy interacts with the provider. For example, the patient may avoid asking questions and have the tendency to be passive (Paasche-Orlow and Wolf, 2007). In support of this assertion, Osborn, Paasche-Orlow, Bailey and Wolf (2011) posit that low health literacy could infringe upon the patient's knowledge, beliefs, and the ability to participate in decision-making. Additionally, low health literacy could negatively influence a patient's motivation, self-efficacy, knowledge, and capacity to solve problems, about self-care (Osborn et al., 2011). Similarly, a caregiver with inadequate knowledge of a care recipient's illness status may not know what questions to ask or may avoid asking questions altogether. The caregiver may become less motivated, unable to validate his or her beliefs and shy away from participating in decision-making involving the care of a loved one. Poor caregiver participation may have an adverse consequence on the health outcome of the care recipient. Sometimes, the caregiver factors and provider factors work in concert with each other.

Provider factors that may have broad implication on the care recipient's health outcomes include the method of communication, the time allotted to communicate pertinent information, and patient-centered attitude. Good provider-patient relationships often result in good health outcomes. In a cross-sectional study, Rosenthal, Socolar, Dewalt, Pignone, Garrett, and Margolis (2007) found that parents of low literacy reported a better quality of parent-provider relationships with resident doctors than with attending physicians.

The authors contended that the residents were more efficient at relationship building (Rosenthal et al., 2007), perhaps as compared to the attending physicians. In like manner, providers with effective communication skills, well-developed teaching skills, and patient-centered attitude would probably gain the trust and acceptance of the caregiver, thereby making information sharing a concerted effort towards better patient outcomes.

Drawing from the framework proposed by Paasche-Orlow and Wolf (2007), the present study assumed that a care recipient's health outcome is the result of the interplay between selected caregiver factors, patient factors, the ability of the caregiver to navigate the health system, and level of interaction with the health provider. The patients' factors and caregivers' factors are in a reciprocal relationship, and they influence the caregiver's level of health literacy. For example, if both are hearing impaired, the impairments will impede communication between the two and consequently caregiver function in health-related decision making and navigation of the health care system. The level of health literacy, in turn, determines the ability of the caregiver to access and use the healthcare system, interact with providers, which ultimately determine the care recipient's clinical outcomes. Any impediment in this pathway may have broad implications on the care recipient's clinical outcomes.

Definition of Terms

REALM. REALM refers to the Rapid Estimate of Adult Literacy in Medicine questionnaire. It is a medical word recognition and pronunciation tool consisting of 66 items arranged in order of increasing complexity that is used to identify adults at risk of low health literacy (Davis, Crouch & Long, 1993).

Permission to use this tool, for this study, was obtained from Terry C. Davis, Ph.D., Professor, Department of Medicine and Pediatrics, Louisiana State University Health Sciences Center, Shreveport. LA.

Informal caregiver. In the present study, the informal caregiver was conceptually defined as a spouse, an adult child (18 years or older), other relatives or significant other, who provided unpaid care to an elderly veteran with diabetes. The care that they provide included but not limited to managing medications, diet, arranging and transporting or accompanying the veteran to medical appointments. Operationally, the informal caregiver was defined as a spouse, adult child, other relatives or significant other in a caregiving role for an elderly diabetic veteran for at least six months.

Glycated hemoglobin. (A1c): Mosby's Medical Dictionary (2013) defines A1c as the amount of hemoglobin bound to glucose and determined by the measure of the amount of glucose in the blood in the preceding 2 to 4 months. A1c "is the preferred test for monitoring glucose control" (Selvin et al. 2010, p. 801). A1c values range from 4.6% to 5% for those without diabetes, 5.7% to 6.4% for those at risk of developing diabetes, and 6.5% and higher for those with diabetes (Osborn et al., 2010). Operationally, for the purpose of this study, the A1c

value was based on a measure obtained in veterans no more than three months preceding enrollment in the study.

Diabetes mellitus (diabetes). Diabetes is a group of metabolic diseases, which causes an increase in blood sugar because of defects in insulin production, insulin action, or both (American Diabetes Association [ADA], 2004). Operationally, diabetes was defined as A1c assay levels of 6.5% or higher (ADA, 2010).

Diabetic. For the purpose of this study, the term diabetic referred to a study participant with a medical diagnosis of diabetes mellitus or diabetes in his/her medical record. Operationally, for the purpose of this study, a diabetic was defined as a study participant with an ICD -9 diagnosis code 250.00 - 250.93.

Glycemic control. Conceptually, glycemic control is how well the patient was maintaining his/her blood sugar. Operationally, glycemic control was defined as mean A1c of 7% or less (Clement, 2004). However, in the present study, glycemic control for study participants was the achievement of A1c of 7.5% or less. The target A1c was based on the U.S. Department of Veteran Affairs and the Department of Defense diabetes guidelines (2010), which recommends target A1c of less than 7% for elders with mild or no microvascular complications and life expectancy greater than ten years. While the recommendation for elders with a life expectancy of 5 and ten years, and moderate microvascular complications, was A1c of 8% or less.

Functional status. Conceptually, functional status was defined as a function of patient's level of independence versus dependence in six domains of daily living, namely: bathing, dressing, toileting, transfer, continence, and feeding. Operationally, functional status was

defined by the score earned by an individual as measured by the Katz Activities of Daily Living (ADL) Scale (Periyakoil, 2010). A score of one was assigned to each task accomplished independently and zero if needing assistance or entirely dependent on others to complete. For the purpose of this study, a care recipient with a total score of 6 on the Katz ADL scale was classified as independent, while a care recipient with a total score less than six was classified as dependent.

Assumptions

The following assumptions underpinned this study:

Informal caregivers (family members/significant others) wanted to give proper care to elderly relatives/significant other with diabetes.

Diabetes care is complex.

Diabetes care is challenging.

Care provided by an informal caregiver/significant other was different from care provided by a paid caregiver.

Participants would answer survey questions truthfully.

Limitations

A major limitation of this study was related to the population sampled and method of sampling. A non-probability sampling of caregiver/elderly dyad from one health care facility, which is gender-biased (mostly males) and non-rationally diverse (mostly African Americans) in the Eastern United States (U. S.), was a major limitation. The observed limitation would restrict generalization of findings to the general population. The design does not allow for follow-up of

subjects over time to capture changes that might further explain the relationship between caregivers' health literacy and care recipients' clinical outcomes.

Older caregivers may be reluctant to participate as assessing health literacy may evoke shame and embarrassment as people do not want to be seen or labeled as illiterate or stupid. Other factors, such as diet, exercise, alcohol use, and use of certain antidepressants, antihypertensive, and diuretics, may influence glycemic control. However, the study did not collect these additional information regarding care recipient factors.

Obtaining consent from patients and their caregivers by the Principal Investigator (PI), who was also an employee at the study site, may have introduced some biases as participants may have felt obligated to participate. However, there was a clause in the consent document assuring participants that failure to participate or withdrawal after consenting would not affect the usual care the veteran was currently receiving from the study site or any other VA in the nation.

Significance

Low health literacy of caregivers may be a potential barrier to good diabetes care for elderly diabetic recipients of informal care. The ability of an informal caregiver to obtain process, understand, and make basic diabetes care decisions, may be significant in the health outcome of an elderly diabetic recipient of informal care. Understanding the impact of caregivers' level of health literacy on glycemic control in elderly diabetics who are recipients of informal care would help health care practitioners to improve caregiver knowledge and support towards better clinical outcomes. Additionally, improved caregivers' knowledge might reduce or delay diabetes complications.

Summary

With the projected growth of older Americans (65 years and older) to over 88.5 million in 2050 (U. S Census Bureau, 2008), more non-institutionalized elderly Americans may be recipients of informal care. Informal caregivers who do not have adequate health literacy may have difficulties navigating the health care system or the ability to provide appropriate care for elderly relatives or significant other with diabetes.

While informal caregivers play important roles in the care of elderly diabetics, low health literacy may be a barrier to the care these caregivers provide. To date, only a few studies have examined caregivers' health literacy in association with older adults as the recipients of care. This study aimed at examining the relationship between informal caregivers' levels of health literacy and glycemic control in elderly veterans with type 2 diabetes who were recipients of informal care.

CHAPTER 2

Review of the Literature

Introduction

This section presents the analysis of works supporting the need for the current study. An extensive literature search was conducted using multiple databases for articles published in peer-reviewed journals for the period 2000 to present. The databases searched included: Academic Search Complete, Academic Search Premier, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Dissertation Abstracts International, Educational Resources Information Center (ERIC), Google Scholar, Health and Psychosocial Instruments, PsycINFO, MEDLINE and Web of Science.

The following keywords and phrases were used to search for relevant articles: health literacy, functional health literacy, informal caregiver, family caregiver, diabetes mellitus, diabetes, and elderly diabetics; diabetes in old age, diabetes care and the phrase elderly diabetics and informal care. However, the searches did not accurately identify informal caregiver health literacy-related articles. Thus, the reference list of retrieved articles was searched for relevant articles. Government and related organizational websites, such as the National Alliance for Caregiving (NAC), American Association of Retired Persons (AARP), National Council on Aging, Center for Disease Control (CDC), and National Caregivers Association, were searched for additional information. The searches included articles published in the English-language; however, the search was not restricted to studies conducted in the U.S. so as to gain knowledge of the global influence of health literacy on health outcomes in diverse health care environments.

There is a significant body of literature on family caregiving for elderly persons with a focus on the economic and financial burden and the physical and emotional health of the caregiver. Only one study examined the impact of paid caregivers' levels of health literacy on the health of older adults (Lindquist, Jain, Tam, Martin, & Baker, 2010). Health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (Selden et al., 2000, Introduction section, para. 7). The only national health literacy survey conducted in 2003, suggested that about 80 million American adults have low health literacy (as cited in Kutner, Greenberg, Yin, & Paulsen, 2006), implying that many in the caregiving role probably have low health literacy. The economic burden of low health literacy on the U. S. economy is between \$106 billion and \$236 billion annually (Somers & Mahadevan, 2010).

Low health literacy potentially increases emergency room visits, frequent hospitalizations, poor clinical outcomes, health care costs and decreased use of preventive health services (Baker et al., 2004; Cavanaugh et al., 2010; Cho, Lee, Arozullah, & Crittenden, 2008; Herndon, Chaney, & Carden, 2011; Howard, Gazmararian, & Parker, 2005; Murray et al., 2009). In a study of adults 30 years and older, low health literacy was an independent contributor to poor glycemic control (Schillinger et al., 2002). In another study, which examined the impact of paid caregivers' level of health literacy on health-related tasks, such as filling pill boxes, more than 60% of the caregivers were shown to make errors in filling pill boxes. In fact, 35% of the caregivers reportedly had low health literacy (Lindquist et al., 2010). Similarly, studies that examined parents and legal guardians of children and adolescents also found that caregivers' health literacy played important roles in glycemic control.

For example, one study found that parent's low health literacy accounted for 7.6% of the variance in glycated hemoglobin (A1c) of children with type 1 diabetes (Ross, Frier, Kelnar, & Deary, 2001). Another study found that parents with low health literacy were likely to struggle in helping "high-risk" adolescents with insulin dependent diabetes adhere to diabetes regimen (Janisse, Naar-King, & Ellis, 2010).

Diabetes care is complex and requires a good understanding of the plan of care. However, there is a paucity of literature on the influence of informal caregivers' level of health literacy on the glycemic control of elderly diabetics.

Health Literacy

The concept of health literacy emerged in the health care arena in 1974 when Scott Simonds (1974) used the term to discuss how health education policies affected the healthcare system and general communication in the U.S. Since then many researchers have studied health literacy in children, adolescents, adults, and the elderly. However, the last ten years has seen a shift in health literacy research. In recent years, many studies have focused on how health literacy impacts health care delivery in the U.S. (Zarcadoolas, Pleasant, & Greer, 2005). In keeping with the change in focus, this study will concentrate on a third party association of health literacy and the health of elderly Americans with diabetes.

Health literacy is depicted as "the currency for improving the quality of health and health care in America" (Paasche-Orlow et al., 2005, p. 175). Therefore, it is necessary to understand how health literacy influences the health of individuals in today's health care environment. In seeking to understand the association between health literacy level and use of health care services, clinical outcomes, costs and disparities in health outcomes, Berkman et al. (2011)

conducted a systematic review of the literature in an attempt to find a possible association.

Berkman and colleagues examined one hundred and eleven relevant articles and concluded that the researchers consistently reported low health literacy as being associated with higher rates of hospitalizations, frequent visits to emergency rooms, and less use of preventive health services; poor medication adherence, and improper interpretation of medical instructions. Berkman and others (2011) also found that multiple studies reported a high prevalence of low health literacy in the elderly population, poorer clinical outcomes, and higher mortality rate. Racial disparities in some outcomes were partially explained by some of the studies reviewed (Baker et al., 2004; Berkman et al., 2011; Donelan et al., 2002; Gazmararian, Williams, Peel, & Baker, 2003; Howard et al., 2005; Murray et al., 2009).

The concept of measuring health literacy in clinical settings was first proposed in the early 1990s by Davis and others to help clinicians identify patients at risk of low health literacy skills (Davis et al., 1993). Davis and colleagues developed the Rapid Estimate of Adult Literacy in Medicine (REALM) questionnaire for this purpose. The first REALM tool comprised of 125 words taken from typical patient education and directions materials and was later shortened to the current 66-word version (Davis et al. 1993). The development of other health literacy measurement tools soon followed; the test of functional health literacy in adults (TOFHLA) by Parker, Baker, Williams, and Nurss (1995) and the medical terminology achievement reading test (MART) by Hanson-Divers (1997). In addition, earlier literacy tools such as, the Wide Range Achievement Test (WRAT) (McNaughton, Wallston, Rothman, Marcovitz, & Storrow, 2011), the Slosson Oral Reading Test (SORT) (Davis et al., 2006), Peabody Individual

Achievement Test (PIAT) (Paasche-Orlow et al., 2005), were revised and used to measure health literacy skills in clinical settings.

Most of the studies conducted on health literacy categorized health literacy into three distinctive levels, namely, inadequate, marginal, and adequate (Berkman, et al, 2011). Some scholars have combined inadequate and marginal levels of health literacy to represent limited, low, or inadequate health literacy because empirical evidence to delineate between marginal and adequate health literacy is sparse (Berkman et al., 2011). Berkman's et al. (2011) findings that higher rates of hospitalizations, many emergency rooms visits, and lower use of preventive health services are common in patients with low health literacy, is consistent with evidence in the literature. In a prospective cohort study of 3260 Medicare enrollees, Baker et al. (2002) reported that of the 29.5% of participants who were hospitalized, hospitalization was higher among those with inadequate and marginal health literacy. Further analysis of data from this study by Baker et al. (2002) also revealed that participants with low (30.4%) and marginal (27.7%) health literacy were more likely to visit the emergency room compared to those with adequate (21.8%) health literacy.

Other studies have produced evidence associating inadequate health literacy with inappropriate medication use. One of such studies was conducted by Lindquist et al. (2012). Lindquist and colleagues (2012) followed up 254 community-dwelling elders, 48 hours after discharge by phone interview and found that those with low and marginal health literacy were more likely to skip their medications unintentionally because they did not understand the medication instructions. Another study by Gazmararian et al. (2003), which examined the relationship between health literacy and knowledge of disease among 653 Medicare enrollees

with chronic illnesses, including diabetes, asthma, congestive heart failure, and hypertension, revealed that less than 50% of those with low health literacy associated lowering their blood sugar with taking insulin or oral hypoglycemic agents. Similarly, caregivers of elders with diabetes may not associate insulin administration or oral hypoglycemic agents to lowering blood glucose in those they care for; they may think that it is all right to skip medications.

Eighty to 90 million Americans lack basic reading and computation skills that are necessary for successful navigation of the U. S. healthcare system (Berkman et al., 2011; IOM, 2004). This finding suggests that a significant proportion of Americans have inadequate or low health literacy. Low health literacy is an obstacle to patients' understanding of necessary health information, which enhances high-quality health care (Parikh, Parker, Nurss, Baker, & Williams, 1996). Patients are routinely given verbal or written information, from health care providers, about their health and are expected to read, understand, and make an informed decision concerning their medical treatments or procedures. In like manner, caregivers are often provided with care recipients' health-related instructions that they are expected to implement. Given the staggering number of Americans with low health literacy, an impressive number of caregivers must constitute this statistic. Therefore, it is pertinent to understand how the health literacy of caregivers will influence the clinical outcomes of elderly care recipients with diabetes. Despite the prevalence of low health literacy among Americans and the role of caregivers in the health care environment, caregivers of older persons have not been the focus of many health literacy research, particularly, caregivers of elders with diabetes. The current study examined the relationships between caregivers' levels of health literacy and glycemic control in elderly veterans with type 2 diabetes who were recipients of informal care.

The study focused on elderly diabetics because diabetes is not only prevalent in the elderly population, its care is complex and requires a command of adequate health literacy.

Caregiver and Health Literacy

Family caregivers play important roles in providing care for elders living with diabetes. An estimated 43 million Americans care for family members who are 50 years of age and older (National Alliance for Caregiving and American Association of Retired Persons, 2009). In 2011, the economic contributions of caregivers to the nation's health system was estimated at \$450 billion (Feinberg, Reinhard, Houser, & Choula, 2011). Caregivers of the elderly with diabetes may be the spouse, an adult child, or other close kin (Donelan et al., 2002; Haas, 2006). These caregivers often feel the need to help their elderly relatives but are frequently overwhelmed due to the complexities of diabetes care, such as, administration of insulin injections or diabetic pills, checking and recording blood glucose levels, planning and preparing diabetic meals, and managing symptoms of hypoglycemia (Stallwood, 2006). Caregivers' services are invaluable. However, it is important to establish the health literacy of the caregiver, using a standardized and valid instrument, and assess how the level of health literacy might impact the diabetes outcomes of the elderly care recipient.

In a cross-sectional survey of 200 families of children with type 1 diabetes, Hassan and Heptulla (2010) found a significant relationship between caregivers' level of literacy and A1c of the children cared for, and concluded that literacy of the caregivers significantly influenced the glycemic control of children with diabetes. In another cross-sectional survey, in which Stallwood (2006) examined 73 caregivers of children under the age of 9 years, higher caregiver

knowledge was associated with lower A1c of the children. Arguably, these studies have significant limitations in that the care recipients were children, and the care recipients all had Type 1 diabetes, which will limit the generalizability of the findings to caregivers of elders with adult onset diabetes. The present study will add new knowledge by reporting results on the influence of informal caregivers' levels of health literacy on A1c of elderly veterans with type 2 diabetes who are recipients of informal care.

The one study that examined the relationship between caregivers' level of health literacy and health-related tasks (Lindquist et al., 2010) found that almost 36% of 98 paid caregivers who provided care to older adults had low health literacy. About 60% of all the caregivers made errors filling pill boxes for older adults under their care. The study participants were paid caregivers; hence, it will be interesting to establish any differences between paid and unpaid (informal) caregivers' levels of health literacy and to delineate any modifiable or contributing factors.

Diabetes Mellitus and Health Literacy

Diabetes mellitus is a group of metabolic diseases which causes an increase in blood sugar because of defects in insulin production, insulin action, or both (ADA, 2004). Diabetes is generally classified into two broad categories: type 1 and type 2. Type 1 diabetes, previously identified as juvenile or insulin-dependent diabetes, is usually due to an autoimmune disorder of the pancreas or the individual's genetic disposition (ADA, 2004). Whereas, type 2 diabetes, previously identified as adult-onset or non-insulin dependent diabetes, is often due to the body's resistance to the action of insulin or the body's inability to produce enough insulin to maintain a

normal blood glucose. Caspersen and colleagues contend that between 90% and 95% of all diabetic cases are type 2 category (Caspersen, Thomas, Boseman, Beckle, & Albright, 2012).

The incidence of diabetes in the elderly population is on the rise. Even though the rate of new diabetes cases among adults between the ages of 18 and 79 years dropped significantly by about 1.4 million in 2014 (CDC, 2015b), the incidence of diabetes in those 65 to 79 years, increased by about 75% per 1,000, compared to 1980 (CDC, 2015a). The prevalence of diabetes in those 65 years of age and older is of a concern given the associated health risk and economic implications of diabetes care in this population group.

Most recent data suggests that diabetes affects an estimated 11 million (approximately 27%) Americans over the age of 64 years in 2010, and this number is predicted to rise in the next 40 years (CDC, 2011b; Fravel, McDaniel, Ross, Moores, & Starry, 2011). Another 11% of elderly Americans between the ages of 60 and 70 are undiagnosed (McKoy, 2003). Due to the significant role that caregivers play in caring for seniors, the focus of this study was on the caregivers. The goal was to improve the care that seniors with diabetes receive, given that diabetes is associated with an increased risk of untimely death, functional decline, high blood pressure, heart disease, stroke, and kidney disease (McKoy, 2003; CDC, 2011a). Diabetes ranks highest in the cause of kidney failure, heart attack, stroke, and lower leg amputation (CDC, 2011a). Moreover, the high prevalence of diabetes in older adults makes management of the disease a public health priority of national interest.

The goal of diabetes care in older adults, as well as, for younger individuals, is to achieve glycemic control, control related symptoms, and minimize vascular complications (McKoy, 2003).

To achieve this goal, the older adult with diabetes has to be judicious in diabetic self-care.

However, because the elderly with diabetes are at higher risk of developing common geriatric syndromes, like depression, cognitive impairment, and polypharmacy, which are capable of significantly influencing the older persons' diabetic self-care, they often turn to family members for help in managing their diabetes. Unfortunately, these family members are among the 90 million Americans with low health literacy, which could be a potential barrier to good diabetes care (Berkman et al., 2011; Parikh et al., 1996).

Summary

Several studies suggest that a vast number of health information resources are incomprehensible by most Americans (Paasche-Orlow et al., 2005). These Americans include those who provide care to others. Therefore, low health literacy has significant implications for health care providers, consumers, and policymakers. Understanding how caregiver health literacy impacts the health of the care recipients will help clinicians, researchers, and decision makers in finding solutions to mitigate low health literacy among Americans, hence, the purpose of this study. The next chapter describes the methods engaged in this research.

CHAPTER 3

Methodology

Introduction

This section describes the study design, variables, the inclusion and exclusion criteria, the setting, sample, ethical considerations, procedure, and data analysis. The study aimed at examining the relationship between informal caregivers' levels of health literacy and A1c in a sample of elderly veterans with type 2 diabetes, who were recipients of informal care.

Design

This research was a quantitative descriptive correlational study of a convenience sample of 90 veterans, 65 years of age and older and their caregivers. The variables of interest were derived from the review of the literature.

Variables

Independent variables. The primary independent variable was the caregiver raw REALM score; a continuous variable with three levels (low, marginal, and adequate), which measured the caregiver level of health literacy. The REALM test, is a word recognition test comprised of 66 health-related words listed in three columns in increasing order of difficulty to test correct pronunciation of medical words and lay terms for body parts and illnesses (Davis et al., 1993; Hoffman & McKenna, 2006; Ibrahim et al., 2008; Rosenthal et al., 2007). The examiner's copy of the REALM test contains a description of the test, standardized directions for administering and scoring and a chart converting the raw scores to grade range estimates (Davis et al., 1993). It takes about 2-3 minutes to administer the REALM test.

The REALM test is one of the most commonly used instruments for assessing health literacy. Studies with the REALM test have shown significant correlation with other literacy assessment tools. For example, when 300 patients admitted into the hospital, in a United Kingdom (UK) study were given the REALM test and the UK Basic Skills Agency Initial Assessment Test (BSAIT) to complete, the two instruments were highly correlated ($r = 0.70$, $p < 0.001$) (Ibrahim et al., 2008). The REALM test also has a good consistent reliability coefficient. Shea et al. (2004) used 19 different strategies to shorten the 66-items on the REALM test, and the reliability coefficient remained above 0.80. However, a noteworthy weakness of the REALM instrument is that it is only available in the English language (Cornett, 2009). To accommodate this weakness, recruitment of study participants was limited to only English speaking volunteers. Permission to use this tool was obtained from Dr. Terry C. Davis, Professor, Departments of Medicine and Pediatric, Louisiana State University Health Sciences Center, Shreveport, LA.

The Katz Basic Activities of Daily Living (ADL) Scale is another independent variable examined in this study. The Katz provides an objective measure of an individual's level of dependency. Katz, Ford, Moskowitz, Jackson and Jaffe (1963) developed the ADL instrument for use as an objective measure of functional capacity in the elderly and the chronically ill. The Katz is a widely used tool. It has been found to be very sensitive in predicting the functional capacity of older adults. It measures the ability to perform common daily tasks in six domains namely bathing, dressing, use of the toilet, transferring, managing continence, and feeding (Katz et al., 1963). Individuals are ranked from 0 to 6 depending on the level of independence or dependence. The higher the ranking, the higher the level of independence. Conversely, the lower

the ranking, the higher the level of dependence. The Katz instrument is currently in the public domain and does not require permission for its use. However, the Katz instrument employed in this study was derived online, provided by the courtesy of the Hartford Institute for Geriatric Nursing, New York University, College of Nursing (Shelkey, Mason, & Wallace, 2012). In a review article Shrivastava, Shrivastava, and Ramasamy (2013) assert that being physically active correlates with good glycemic control. Therefore, in this study, the functional status of the care recipient was examined to determine how much of it impacted the recipient's level of glycemic control.

For the caregiver, other variables included age, gender, race/ethnicity, educational attainment, annual household income, period in a caregiving role, relationship with the care recipient, marital status, diabetic care activities and whether or not the caregiver lives with the care recipient. For the care recipient, other variables included age, gender, years with diabetes diagnosis and type of diabetes treatment.

Dependent variable. The dependent variable, also a continuous variable, was the measure of A1c of the elderly veteran recipient of informal care. A1c is a widely acceptable and reliable test used to determine patients' glycemic control in the preceding 2-3 months (Delmater, 2006). The A1c is the product of the glycosylation of glucose with the alpha or beta chain of hemoglobin. The hemoglobin A1c level is proportional to both the blood glucose level and the life span of hemoglobin. Hence, the A1c test is a reliable clinical indication of glycemic control in 2-3 months. The A1c is measured with High-Performance Liquid Chromatography (HPLC) instrument (WeyKamp, John, & Mosca, 2009).

Validity

Internal validity. Potential threats to internal validity posed by instrumentation, were eliminated by the use of reliable and valid instruments for data collection. Furthermore, in a view to improving consistency, only the PI administered all measurements to the caregivers and care recipients who participated in the study. Additionally, data collection was completed in approximately nine months, which reduced the threat to mortality and attrition.

External validity. The threat to external validity was addressed by ensuring representativeness of study participants. All eligible elderly veterans, 65 years and older, with type 2 diabetes (and their informal caregivers) who use a large integrated health care system located in the Eastern U. S. were approached to solicit voluntary participation. Also, study flyers were widely distributed throughout the medical facility and affiliated Community-Based Outpatient Clinics (CBOC), to access a wider spectrum of potential participants.

Setting

The study was conducted at a large health care facility located in the Eastern U.S. The facility boasts of more than 500,000 patient visits per year (Veterans Affairs Medical Center, 2013).

Study Population. A convenience sample of veterans with type 2 diabetes and their informal caregivers were enrolled and surveyed, before or after their clinic appointments. Veterans in Home-Based Primary Care (HBPC) and their informal caregivers were enrolled and interviewed in their homes.

Two hundred and fifty veterans, 65 years of age and older, and their informal caregivers were screened. One hundred and seventy dyads (veterans and their caregivers) were eligible to

participate, but 80 dyads declined participation and the number enrolled was 90 dyads. However, two dyads were dis-enrolled due to consenting errors. The final participants count for data analysis was 88 dyads. The number of participants was a sufficient count to achieve a statistical power of 0.8, medium effect size (0.25), and probability level set at 0.05, using the statistical calculator developed by Daniel Soper (2006). Daniel Soper's statistical calculator is used widely by researchers for statistical calculations and it is in the public domain.

The inclusion and exclusion criteria for enrollment in this study were:

Inclusion criteria. Caregivers who satisfied the following criteria were enrolled in the study:

- a) caregiver understood the written consent and signed the consent form.
- b) caregiver was in the caregiving role for at least six months.
- c) caregiver was 18 years of age or older.
- d) caregiver was fluent in the English language.
- e) caregiver was cognitively intact and exhibited no visual or hearing impairment.

2. Veterans who satisfied the following criteria were enrolled in the study:

- a) veteran was at least 65 years of age.
- b) veteran had documented diagnosis of diabetes in the medical record.
- c) veteran had no hospital admission in the preceding three months.
- d) veteran was not acutely ill.
- e) veteran had no diagnosis of end-stage renal disease in the medical record.
- f) veteran was on diabetes treatment (oral or injectable).

All study participants were surveyed only after they voluntarily consented to participate.

Exclusion criteria. Participants (veterans and their caregivers) were excluded if:

- a) either was unable to recall three unrelated words after 3 minutes.
- b) the caregiver had uncorrected vision or hearing.
- c) the caregiver exhibited poor hand dexterity.
- d) the veteran had type 1 diabetes
- e) the veteran was hospitalized in the three months preceding recruitment.
- f) the veteran had a terminal stage of illness or was in hospice level of care.

Study Tools. The following tools were used for screening to determine eligibility to participate in the study and for data collection:

1. A chart abstraction instrument (Appendix A), developed for this research was used to abstract veterans' (care recipients) information from their electronic medical records.
2. Questionnaire to obtain caregivers' socio-demographic information, which was by self-report (Appendix B).
3. The REALM instrument by Davis et al. (1993), a health literacy screening tool to assess caregivers' level of health literacy (Appendix C).
4. The Katz basic activities of daily living (ADL) scale was used to evaluate the care recipients' level of dependency (Appendix D).
5. The Bayer DCA, 2000 point of care A1c instrument, was used to obtain care recipients' A1c at the point of care, if there was no measure of A1c in the veteran's electronic medical record in the preceding three months. The Bayer DCA, 2000 point of care instrument, uses an immunoassay technology to determine A1c at the point of care. It is widely used in many

health care settings to facilitate diabetes care. According to Tamborlane et al., (2005), A1c by the Bayer DCA 2000 is comparable to laboratory values with very minimal variations.

Ethical Considerations

The study was conducted by the protocol and applicable regulatory requirements. The Institutional Review Boards (IRB) at the Veterans Affairs Medical Center IRB (Appendix F) and the Catholic University of America Institutional Review Board for the Protection of Human Subjects (Appendix G), approved the use of human subjects for this study, before data collection. The IRB was informed of subsequent protocol amendment to include caregivers of veterans in the HBPC program. The IRBs received notifications on the progress of the study at intervals stipulated by the guidelines.

Confidentiality of participants was ensured by the anonymity of the completed questionnaires and no collection of personal information for future contact. Study data was stored in a locked cabinet and a secured folder in the VA network that was only accessible by the PI and the institution designated co-investigator. Participants were offered the freedom to withdraw at any point during data collection. Each participant completed, signed, and received a copy of the signed consent documents (Appendices H and I).

Procedure

Recruitment of participants. The PI presented the study proposal to primary care providers, nursing staff, and social workers for referral of potential participants. The outpatient clinic rosters were scrutinized daily to identify potential study participants. A few of the participants with a medical diagnosis of diabetes in their medical records were directly approached at the time of their clinic appointments to solicit participation. The majority of study

participants were recruited by a direct approach by the PI and others were by self-referral or other medical staff.

Participants were eligible veterans (and caregivers) who were enrolled in a large health care facility, within the Veterans Integrated Network (VISN), in the Eastern U.S., from October 2014 through July 2015. Participants were recruited before or immediately after their medical appointments at the medical center or CBOCs and their homes for those in the HBPC program. Caregivers recruited were with the veterans at the time of recruitment and either identified self as the veteran's caregiver or by the veteran as their caregiver. Those enrolled were older than 18 years of age and were able to read and write the English language; had intact cognition and were visually and physically able to fill out the survey questionnaires.

Before study enrollment, the study objectives, procedures, potential risks were explained to potential study participants. Potential participants were given the affirmation that participation was entirely voluntary and that refusal to participate would not affect the care the veteran was receiving from the medical center, the CBOCs or any other health care facility within the VISN or in the nation. Each willing participant signed a VA approved consent form and kept a copy. The original consent forms signed by the veterans (care recipients) were scanned into the veterans' electronic medical records, and a research participation note was added to each veteran's electronic medical record, using the VA Computerized Patient Record System (CPRS). The original copy of the consent form signed by each caregiver was kept in a locked cabinet only accessible by the PI.

Upon consenting, each caregiver completed a questionnaire and a Katz survey, both of which took approximately 3-5 minutes to complete. The questionnaire was designed to provide

socio-demographic information about the caregiver while the Katz survey provided information about the functional capacity of the veteran (the care recipient) with regards to activities of daily living (ADL). The socio-demographic information included: gender, age, educational attainment, race/ethnicity, marital status, and annual household income. Other information on the questionnaire were: a) the caregiver's relationship to the care recipient, b) period in caregiving role, c) diabetic care activities, such as: checking recipient's blood sugar by finger stick, helping recipient take oral medications, helping recipient take insulin injection. Also, helping recipient fill/refill medication(s), helping recipient schedule medical appointments, accompanying recipient to medical appointments, helping recipient with grocery shopping and helping recipient with meals preparations. Information on the care recipient's ADLs included the level of independence versus dependence with bathing, dressing, toileting, transferring, continence, and feeding. A score of "yes" denoted independence and a score of "no" as needing assistance. The PI reviewed all responses to the study questionnaires for accuracy and completeness before dismissing the participants from the data collection session. The anonymity of participants was ensured during and after the study ended.

Additional information obtained on care recipients came from the care recipients' medical records. These included the care recipients' gender, age, years of diabetes diagnosis, type of diabetes, current diabetes treatment (oral medication only, insulin injection only, or the combination of both), and current levels of A1c. Care recipients without current A1c received finger sticks for point of care (POC) A1c if they consented to do so, otherwise, they were not enrolled. Before the finger stick for POC A1c, verbal consent was obtained. An oral explanation of the purpose of the procedure including the risk of minimal discomfort and

insignificant blood loss was explained to the participants and they had the option to decline.

After consenting, a clinic nurse would perform a finger stick to obtain a small drop of blood for estimation of A1c using the Bayer DCA 2000 POC instrument. It often took approximately 6 minutes to produce the A1c results.

For perceived caregiver health literacy, caregivers' level of health literacy were assessed with the REALM test, administered by the PI. The test took approximately 3-5 minutes to complete and slightly longer for those who had difficulties with recognition of word items on the test. The REALM test is a 66 item word instrument that tests an individual's ability "to read common medical words and lay terms for body parts and illnesses" (Davis, 1993, p. 5). The words are listed in three columns (list 1, list 2, and list 3) in order of difficulty. Each participant received a laminated copy of the REALM word list, with a verbal explanation of the REALM test. Beginning with list 1 on the REALM word list, participants were instructed to say the words they knew out loud and go down the list; proceed to list 2 and to list 3 until they had looked at or attempted all the words on all three columns. They could skip any word they did not know or were unable to pronounce and just move on to the next word that they knew or were able to pronounce. The examiner (PI) scored each participant on the examiner's record form by placing a check mark (✓) next to each word pronounced correctly and an (X) next to any word mispronounced or not attempted. Dr. T. C. Davis of the Department of Medicine and Pediatrics, Louisiana State University, Health Sciences Center, Shreveport, LA, provided components of the REALM tool and the permission to use the tool. The Katz's functional assessment instrument is in the public domain, and no permission was required to use this tool.

Data handling and patient privacy. Collecting and processing personal information from participants were limited to those necessary to support the study protocol. Extreme precautions were used to collect and process data to ensure confidentiality and compliance with applicable data privacy protection laws and regulations. All study dyads were assigned numeric codes beginning from the number 1 followed by the first letter of the alphabet (e.g. 1a for the veteran and 1b for the caregiver) until enrollment was completed for all 90 dyads. Access to veteran participants' identifiers was restricted to the PI or co-investigator unless requested by the VAMC Research and Development Committee for internal protocol review purposes. No participants' identifiers were collected. De-identified data was stored in a locked cabinet, accessible only to the PI and co-investigator, at the VAMC. Also, data was stored in an encrypted file on a VA computer network folder. VA policy was followed about consenting and participants without proper consents were disenrolled in the study. All study related data that were no longer needed were shredded at VAMC using VA provided shredding resources.

Privacy of participants, as well as, their rights, interests, access to personal information, were protected as stipulated in the VAMC HIPAA authorization and consent documents. No direct clinical benefits to participants were anticipated. However, each dyad (veteran and caregiver) was compensated for their time with a \$20 gift card.

Regulatory compliance. Compliance with the VA Human Subjects and Good Clinical Practices recommendations were ensured with regards to ethical principles, assessing participants' risk, informed consent, privacy and confidentiality, data management, and basic IRB regulations and review process. Additionally, all participants' data received a level of protection equivalent to that accorded to protected health information. Annual training on good

clinical practice, human subject protection, cybersecurity, and privacy policy were maintained. Participants' data were password-protected and only accessible by the PI using a username and a password that is secured. Furthermore, study data were encrypted to prevent unauthorized access and data were stored in a VA protected network folder. Participants' identifying information were not shared with individuals or organizations outside the VA. Participants' privacy were protected by restricting data access to the PI only and ensuring data storage on a password-protected folder on the VA network.

Data management. This was a quantitative correlational study designed to examine the effect of informal caregivers' level of health literacy on glycemic control of elderly veterans (65 years and older) who were recipients of informal care. The protocol for data entry and management was established prior to recruitment of participants. Quantitative data were cleaned and inspected for missing data. Each dyad was assigned a numeric identification (ID) number starting from the number 1.

For caregiver data, the raw REALM score, ranging from 3 to 66 was coded as a continuous variable. Caregiver socio-demographic variables were coded as categorical variables and included: Age (1= male, 2 = female), race/ethnicity (1 = African American/Black, 2 = White/Caucasian, 3 = Asian, 4 = Hispanic/Latino, 5 = American Indian/Alaska native, 6 = Native Hawaiian/Pacific Islander, 7 = other), marital status (1 = married to care recipient, 2 = married to someone else, 3 = separated, 4 = divorced, 5 = never married, 6 = widowed, 7 = live-in partner), education (9 = finished 9th grade, 10 = some high school, 12 = finished high school, 14 = some college, 16 = finished college, 18 = graduate), income (1 = 20,000 or less, 2 = 21,000 to 40, 000, 3 = 41,000 to 60,000, 4 = 61,000 to 80,000, 5 = 81,000 to 100,000, 6 = above

100,000). Other categorical variables included: care recipient's relationship to caregiver, (1 = husband, 2 = wife, 3 = father, 4 = mother, 5 = brother, 6 = sister, 7 = grandmother, 8 = grandfather, 9 = father in-law, 10 = mother in-law, 11 = uncle, 12 = aunt, 13 = cousin, 14 = significant other/partner), caregiver period in caregiving role (1 = 6 months to 1 year, 2 = more than a year), caregiver lives with care recipient (0 = no, 1 = yes), caregiver activities (helps with checking blood sugar with finger sticks, helps care recipient take oral medications, helps care recipient take insulin injection, helps fill and refill medications, help with scheduling medical appointments, helps with going to medical appointments, helps with grocery shopping, prepares meals (0 = no, 1 = yes).

For care recipients', socio-demographic variables included age, coded as continuous variable; gender, coded 1= male and 2 = female; years with diabetes coded as continuous variable; current diabetes medication coded as 1 = oral medication only, 2 = insulin only, and 3 = combination of oral medication and insulin; functional capacity (bathing, dressing, toileting, transferring, continence, feeding) coded, yes = performs activity independently and no = needs assistance. The A1c level for the care recipients was coded as a categorical variable.

The Statistical Package for Social Sciences (SPSS) versions 23 software package for data analysis was used to compute data. Descriptive statistics was computed to describe the characteristics of the sample and to test for any violation of assumptions. Due to skewness of the data, a non-parametric statistics (Kruskal – Wallis) was computed to determine if there were statistically significant differences between selected groups of variables. A cross tabulation test was used to determine if there were any significant relationships between the A1c score and selected caregiver demographic characteristics (age, educational attainment, marital status,

income). Logistic regression was computed to determine predictors of glycemic control, using the model: $\hat{Y} = \frac{e^{(a+B_1X_1+B_2X_2\dots)}}{1+e^{(a+B_1X_1+B_2X_2\dots)}}$. The dependent variable (glycemic control) was recoded (0 = A1c > 7.5 (no control); 1 = A1c ≤ 7.5 (controlled)).

Summary

Chapter three presented a comprehensive description of the study approach to include the study design, the hypothesis, the variables, the internal validity, and the external validity. It also included a description of the study setting and population. Recruitment of participants based on inclusion/exclusion criteria were presented in detail, and the tools used for data collection were also described in length. A description of ethical considerations, data handling, the privacy of participants, and regulatory compliance observed from the inception to the closing of the study were presented in detail. Finally, data management and procedure for data analysis were presented. The next chapter presents data analysis and the results.

CHAPTER 4

Data Analysis and Results

Introduction

The purpose of this study was to examine the relationship between caregivers' health literacy and glycemic control in elderly care recipients with type 2 diabetes. A convenience sample of caregivers and their veteran care recipients, enrolled in a Veterans' health care system located in the Eastern U.S., were recruited for the study. The purpose of the survey was to test the following hypothesis:

1. **Null hypothesis.** Caregivers' levels of health literacy, as measured by the Rapid Estimate of Adult Literacy in Medicine (REALM), will have no influence on glycemic control as measured by the A1c level of elderly diabetic veterans, for whom the caregivers provide care.
2. **Alternative hypothesis.** Caregivers' health literacy, as measured by the Rapid Estimate of Adult Literacy in Medicine (REALM), will influence glycemic control as measured by the A1c level of elderly diabetic veterans, for whom the caregivers provide care.

This chapter presents a description of the dyads, assessment of assumptions, bivariate analysis, and results of hypotheses testing.

Participants were recruited by self-referral from flyers posted in the healthcare facility and affiliated community-based clinics and by the direct approach by the investigator.

Participants were enrolled at the time of their primary care or subspecialty clinic appointments.

Veterans receiving care through Home-Based Primary Care (HBPC) were enrolled in their homes. Data collection started on October 27, 2014, and ended July 23, 2015.

Each study participant signed a written consent, the Health Insurance Portability and Accountability Act (HIPAA) authorization, and the written Permission for Release of Protected Health Information for Research Purposes and Notice of Privacy Practices document, before data collection. Each participant received copies of all signed documents and a copy of the Veterans' Participation in Research brochure.

Two hundred and fifty veterans and their caregivers (250 dyads) were screened for eligibility. One hundred and seventy veterans and their caregivers (170 dyads) met the inclusion criteria. Of the 170 dyads, 80 dyads declined participation. The final number of participants enrolled was 90 dyads; however, two dyads had to be disenrolled due to consenting errors. Each dyad was compensated with \$20 for their time.

Characteristics of Dyads

Care recipients. All of the care recipients were veterans ($N = 88$). They ranged in age from 65 to 94 years ($M = 78$, $SD = 8.38$) with the majority being 70 years of age ($n = 34$). Most of the care recipients were males ($n = 87$) with only one female in the group. All of the care recipients had type 2 diabetes, duration ranging from 1 to 38 years ($M = 14.03$, $SD = 8.38$). Slightly over 50% had been diagnosed with diabetes for more than 13 years. Older care recipients were more likely to have been diagnosed with diabetes for a longer length of time ($r = .29$, $p = 0.12$). The method of diabetes treatment varied for each care recipient. Forty-two percent ($n = 37$) of the care recipients took only oral medication(s) to treat their diabetes, while

47% ($n = 41$) used only insulin and slightly over 11% ($n = 10$) used a combination of oral medication(s) and insulin.

Diabetes control for the care recipients, as measured by the level of A1c was diverse, ranging from 5.3% to 13.8%. Slightly over 53% of the care recipients had an A1c level of 7.5% or lower ($n = 47$), followed by individuals with an A1c level between 8% to 12% ($n = 27$). A very small number of the care recipients had an A1c level that was higher than 12% ($n = 4$). Care recipients' A1c levels were significantly associated with the method of diabetes treatment, ($\chi^2 [2, N = 88] = 13.9, p = .001$). Care recipients who received only insulin injections, had a higher A1c level (mean rank = 53.78) than individuals who received only oral medication(s) (mean rank = 32.65) and individuals with combination therapy (mean rank = 50.30).

The majority of the care recipients ($n = 51$) were independent in activities of daily living (ADL), such as bathing, dressing, toileting, transferring, managing own continence, and feeding self. However, about 42% ($n = 37$) of the care recipients needed assistance in executing one or more ADLs. Table 1 is an illustration of the areas of ADLs that the care recipients frequently needed assistance.

Caregivers. The caregivers ($N = 88$), ranged in age from 37 to 87 years ($M = 65.90, SD = 12.07$). Approximately, 93% ($n = 82$) of the caregivers were female and 77% ($n = 68$) were African Americans. In reference to race, the other caregivers were Caucasian 17%, ($n = 15$), Hispanic/Latino 4.5% ($n = 4$), and American Indian/Alaska native 1%, ($n = 1$). Slightly over 62% ($n = 55$) of the caregivers were married. Fifty-one percent ($n = 45$) were married to the care recipients and 11.4% ($n = 10$) were married to someone else.

Table 1. ADLs for which Care Recipients Frequently Needed Assistance (*n* =37)

<i>ADL</i>	<i>Frequency</i>	<i>Percentage</i>
<i>Bathing</i>	20	22.7
<i>Dressing</i>	19	21.6
<i>Toileting</i>	10	11.4
<i>Getting in and out of bed</i>	6	6.8
<i>Continence of bowel and bladder</i>	27	30.7
<i>Feeding</i>	1	1.1

For the other caregivers, about 18% were divorced ($n=16$), 12.5% were live-in partners ($n = 11$), slightly over 2% were widowed ($n =2$) and 4.5% never married ($n = 4$).

The types of relationship between the caregivers and the care recipients were also diverse. Fifty-one percent were spouses, followed by 24% who reported their relationships as children and another 16% self-identified as significant other. The rest of the individuals fell into other categories of family members who had volunteered to take on the role of caregiving for their relatives. Most of the caregivers had been providing care for the care recipient for more than a year ($n = 82$). A majority of the caregivers lived in the same household as the care recipients ($n = 71$) and were providing diabetic related care activities full-time. The diabetic related care activities were: (a) checking blood sugar, (b) administering or reminding care recipient to take oral medication(s), (c) administering insulin injection, (d) filling and refilling medications (e) scheduling medical appointments, (f) accompanying care recipient to medical appointments, (g) grocery shopping, and (h) meal preparation. The most common activities provided by the caregivers were accompanying the care recipients to medical appointments (96.6%), followed by helping the care recipients with grocery shopping (95.3%), and meal preparation (92%). The least performed activity was the administration of insulin (40.9%), explained by the fact that only 46.6% of the participants were on insulin.

Annual earnings for the caregivers ranged from less than \$20,000 to over \$100,000. The majority reported annual household incomes between \$41,000 and \$60,000 ($n = 29$) followed by caregivers with incomes between \$21,000 and \$40,000 ($n =24$). Approximately, 16% ($n =14$) reported incomes between \$61,000 and \$100,000, while 4.5% ($n = 4$) reported incomes of over \$100,000. Nineteen percent ($n = 17$) reported incomes less than \$20,000.

Thirty-three percent of the caregivers were high school graduates, whereas, almost 57% had attained more than a high school level of education. Only 10% reported a level of education less than a high school graduation. All of the caregivers (N = 88) were assessed on medical words recognition, as measured by the REALM, to determine their level of health literacy. A substantial proportion of participants (68%) scored high (61 – 66), equivalent to a high school reading level. Close to 22% scored 45 to 60 (equivalent to a 7th to 8th-grade reading level), and only 10% scored between 3 and 42, which is below the 6th-grade reading level. Those who scored high (61- 66) are considered able to read most patient education materials and would not find low literacy material intimidating (Davis et al. 1993).

The caregivers' REALM scores were significantly associated with educational attainment, $\chi^2 [5], = 28.90, p <.000$, annual household income, $\chi^2 [5] = 12.92, p <.05$ and race, $\chi^2 [2], = 15.40, p <.000$. Caregivers who reported a graduate level of education scored higher on the REALM (mean rank = 68.05), than those who reported that they had finished college (mean rank = 58.25). These caregivers with graduate level of education also scored higher on the REALM than those who had some college education (mean rank =50.27), and those who reported having graduated from high school (mean rank = 30.66). The lowest REALM scores were earned by those with a 9th-grade level of education (mean rank = 21.75), followed by those who reported having received a few years of high school education (mean rank = 25.79).

With regards to how the caregivers' household income affected the caregivers' REALM scores, caregivers whose household annual income was greater than \$100,000 had a higher score on the REALM (mean rank = 55.5), than caregivers in the rest of the income brackets.

Interestingly, those who reported household incomes between \$41,000 and \$60,000, scored higher on the REALM (mean rank = 54.12) than those who reported an income between \$61,000 and \$80,000 (mean rank = 50.33), and those with an annual household income between \$81,000 and \$100,000 (mean rank = 52.70). The caregivers with household incomes less than \$20,000, scored the lowest on the REALM (mean rank = 33.03) and were closely followed by those who earned between \$21,000 and \$40,000 (mean rank = 35.27).

Finally, regarding race, caregivers who self-identified as White/Caucasian ($n = 15$), scored higher on the REALM (mean rank = 66.07), followed by Hispanic/Latino caregivers ($n = 4$, mean rank = 51.25). African American caregivers ($n = 68$) scored the lowest on the REALM (mean rank = 38.71).

Assessment of Assumptions

Normality was assessed by analyzing the interaction between each predictor and its logit transformation within the logistic regression analysis. Results indicated that the significance values for all of the interactions were less than 0.05. Therefore, the assumption of linearity has been met for all predictors. The independence of errors assumption was also met, for all of the participants were measured at just one time.

Regarding multicollinearity, collinearity diagnostics were evaluated. All of the tolerance values were > 0.31 , and no VIF values were > 3.15 . These values indicate no collinearity. However, the eigenvalue of the first dimension (REALM score) was 15.08, which was much larger than the next highest value, 0.782, and the condition index of the last dimension (K score) was 151, which was large compared to the other dimensions. Further bivariate analysis results indicated no multicollinearity.

Testing the Hypothesis

Logistic regression (LR) was performed to examine if caregivers' level of health literacy was influential in predicting the care recipients' level of A1c. Also, based on bivariate analysis, variables identified as significantly related to the dependent variable were also included in the logistic regression. Such variables included caregiver age, care recipient age, duration of type 2 diabetes diagnosis, and type of medication. Variables were entered in the LR model using a backward method. This approach was selected to prevent exclusion of predictors that may be suppressed. Forward selection is more likely to exclude predictors secondary to suppressor effects potentially facilitating a Type II error (Field, 2009). Care recipients' A1c was recoded 0 and 1 for A1c greater than 7.5% and A1c less than or equal to 7.5%, respectively, and entered into the model as the dependent variable. The independent variables entered in the model were the caregivers' REALM score (major variable), the caregivers' age, care recipients' age, care recipients' years with diabetes, and care recipient type of medications.

The full model (step 1) containing all predictors was statistically significant, $\chi^2(6, N= 88) = 17.79, p < .01$ and when one predictor was removed in step 2, the model was still statistically significant, $\chi^2(4, N= 88) = 17.77, p = .001$. The model was equally significant when 2 predictors were removed from the model (step 3), $\chi^2(3, N= 88) = 17.19, p = .001$. The model as a whole explained between 18.3% (Cox & Snell R square), and 24.4% (Nagelkerke R square) of the variance in care recipients' A1c, and correctly classified 64.8% of cases. In the final model, only three of the independent variables significantly influenced A1c levels (Table 2).

Table 2. Logistic Regression Predicting Likelihood of Care Recipients' A1c level $\leq 7.5\%$

	B	S.E.	Wald	df	p	Odds Ratio	95% CI for Odds Ratio	
							Lower	Upper
REALM (Caregiver)	.055	.028	3.861	1	.049	1.057	1.000	1.117
Caregiver age	.045	.021	4.553	1	.033	1.046	1.004	1.089
Care recipient age	-.004	.033	.018	1	.892	.996	.934	1.062
Recipients' years with DM	-.021	.031	.482	1	.488	.979	.922	1.039
Type of medication by recipient (oral)	-1.410	.518	7.402	1	.007	.244	.088	.674
Type of medication (injectable or combination of oral and injectable)	-.795	.794	1.002	1	.317	.451	.095	2.141
Constant	-5.349	2.354	5.162	1	.023	.005		

Variable removed on step 2: Care recipients' age

Variable removed on step 3: Care recipients' years with DM diagnosis

Regarding predictors, findings indicated that a higher level of caregiver health literacy was associated with a lower care recipient A1c level, $X(1, N = 88) = 3.86, p = 0.049$. Results indicated that as the rate of the caregiver's health literacy increased, care recipients were 1.06 times more likely to have an A1c level of $< 7.5\%$. Another significant predictor of the A1c level was oral medication ($p < .01$). Care recipients that took only oral medications were 24 percent more likely to have an A1c $\leq 7.5\%$, $X(1, N = 88) = 7.40, p = 0.007$. Finally, results indicated that a higher level of caregiver age was associated with a lower care recipient A1c level, $X(1, N = 88) = 4.55, p = 0.033$. As the caregiver's age increased, the care recipients were 1.05 times more likely to have an A1c level $\leq 7.5\%$.

Summary

This chapter presented a description of the dyads, assessment of assumptions, bivariate analysis, and results of hypothesis testing. Descriptive statistics were computed to determine the sociodemographic characteristics of study participants. Participants were mostly of African American descent. More than one-half of the participants were more than 60 years of age among the caregivers and 70 years among the care recipients. Most of the caregivers who were married were married to the care recipients and lived in the same household as the care recipients and were providing diabetes-related care for the care recipients for at least six months. A large number of the caregivers had attained more than high school level of education and were able to read common medical words and lay terms for body parts.

A logistic regression analysis was computed to determine whether the caregiver's level of health literacy was predictive of diabetes control in the care recipient. The care recipient's A1c was the outcome variable recoded 0 and 1 for A1c $> 7.5\%$ and A1c $\leq 7.5\%$, respectively,

controlling for all other factors. The logistic model was a good fit. The full model containing all predictors was statistically significant and equally significant when 2 predictors were removed from the model, indicating that the model was able to distinguish the care recipients with A1c that were not $\leq 7.5\%$. The final model was good at predicting that for every unit increase in caregiver's REALM score, the care recipient's A1c was likely to decrease more than 1 percentage point, controlling for other factors, supporting rejection of the null hypothesis.

The next chapter will give a detailed discussion of the study findings and the limitations as well as the practice and policy implications; and recommendations for future research.

CHAPTER 5

Discussion

Introduction

This chapter will provide a summary of the pertinent findings and sample characteristics as compared to previous studies. The limitations of the study is addressed. The study implication for practice and policy is also discussed. Finally, the directions for future research is discussed.

The purpose of this study was to examine the relationships between informal caregivers' level of health literacy and glycemic control in elderly veterans with type 2 diabetes for whom the caregivers provided care. Also, through bivariate analysis, the study examined if demographic variables, caregivers' activities for the care recipient, and the care recipient's level of independence in performing activities of daily living were related to care recipient's glycemic control.

Health Literacy

Findings indicated that the caregivers' level of health literacy was predictive of the care recipients' A1c level. Higher caregiver health literacy was associated with lower care recipient's A1c level based on target A1c of $\leq 7.5\%$. This finding was similar to findings in prior studies conducted with caregivers of children. In a previous study that examined the role of parental health literacy in young children (ages of 3 to 9.9 years) with type 1 diabetes, findings indicated that parental numeracy skills and not their reading skills were inversely related to the children's A1c (Pulgarón et al., 2014). Similar to the present study, caregivers were the focus of the survey, but these caregivers were younger with a mean age of 40 years and were providing care

to young children with type 1 diabetes. It is interesting to note that the impact of caregiver health literacy on diabetic outcomes in the present study is in agreement with the findings of Pulgarón et al. (2014), even though there were differences in caregiver/care recipients' ages and disease characteristics. The present study comprised of older caregivers who provided care for elderly individuals with type 2 diabetes. These studies highlight the fact that the effect of caregiver health literacy on diabetic outcome transcends the factor of age.

In another study by Hassan and Heptulla (2010), in which the literacy of family caregivers of young children with type 1 diabetes was also assessed, they found a significant relationship between health literacy and glycemic control. The A1c of children whose caregivers had inadequate (low) health literacy was significantly higher than those whose caregivers had adequate (high) health literacy. Again, the findings were similar to those in the present study, which demonstrated that higher levels of caregiver health literacy was associated with lower care recipients' A1c levels.

The present study also showed a strong correlation between educational attainment and health literacy. Caregivers with a higher number of years of schooling demonstrated higher health literacy compared to those with fewer years of education. Similar findings were reported by Shea et al. (2004) who examined health disparities among African American and Caucasian adults attending the Philadelphia VA Medical Center Primary Care clinics and three other Primary Care clinics within the University of Pennsylvania Health System. Findings indicated that health literacy increased with level of education among participants.

Although Dr. Shea and colleagues (2004) focused on veterans who were self-care, their conclusions are of particular interest because the present study examined caregivers of veterans.

Thirty-two percent (32%) of participants in the current study scored 60 or less on the REALM instrument, the measure for health literacy. In an earlier study, Gordon, Hampson, Capell, and Madhok (2002), classified a score of 60 or less on the REALM instrument, as signifying functional illiteracy (equivalent to low health literacy). The observed 32% of caregivers, in the present study, with low health literacy is slightly higher than the overall estimated 26% of adults with low health literacy in the general population (Paasche-Orlow et al., 2005). However, the low health literacy status among the caregivers in this sample compares favorably with the findings by Lindquist et al. (2010), who found that 35.7% of paid caregivers, who provided a variety of health-related responsibilities to seniors, had inadequate (low) health literacy. In a different study examining the health literacy of caregivers for children, Lee and colleagues (2014), reported that 15% of the caregivers had low health literacy.

Findings indicated that there was no significant relationship between total caregiver activities measured and caregiver level of health literacy. The activities measured included: (a) checking blood sugar, (b) administering or reminding care recipient to take oral medication(s), (c) administering insulin injection, (d) filling and refilling medications (e) scheduling medical appointments, (f) accompanying care recipient to medical appointments, (g) grocery shopping, and (h) meal preparation. Conversely, Lindquist et al. (2010) and Lee et al. (2014) reported inverse relationships between inadequate (low) health literacy and health-related activities performed by caregivers for care recipients. These activities included picking up medications

from the pharmacy, reminding or handing medications to elderly care recipients, scheduling medical appointments, accompanying the care recipients to medical visits (Lindquist et al., 2010) and Medicaid enrollment (Lee et al., 2014). The lack of significant correlation between caregivers' activities and health literacy, as observed in this study may be due to the measurement of caregiver activities. Care activities were only measured as being performed, and a total score was calculated based on the number of activities performed. Other aspects of such activities such as the caregivers' ability to efficiently carry out the activity or if the caregiver failed to perform an activity were not captured. These aspects may have been critical to assess the relationship between caregiver health literacy and caregiver activities.

Higher levels of education, higher household income, and being of the white race were also associated with higher health literacy. Study participants who had attained more than a high school level of education had higher levels of health literacy, compared to those with only a high school level of education or lower than high school level of education. Similar findings were noted by Shea et al. (2004), in a study examining health literacy in a cohort of 1, 610 adults. They reported that adults with a college degree had higher health literacy than those with only some college and technical school training.

With regards to household income in relation to caregivers' health literacy, caregivers whose household annual income was greater than \$100,000 had higher REALM scores than those with household incomes below \$100,000. These findings are corroborated by previous research which annotated that low levels of health literacy were associated with low income. Macy, Davis, Clark, and Stanley (2011) reported that parental caregivers earning an income of

\$20,000 or less had low health literacy. DeWalt et al. (2007) also indicated that those with an annual income less than \$15,000 were in the low literacy group.

About race, Caucasians scored higher for health literacy. The mean REALM score observed for African Americans was significantly lower than the average score found for participants who were white. This finding is supported by a study by Shea et al. (2004), who also reported lower mean health literacy scores for African Americans than Caucasians.

Results indicated no correlation between health literacy and income. However, in some previous studies, relationships between caregivers' income and level of health literacy were reported, (Adams et al., 2013; Baker et al., 2004; Berkman et al., 2011; Donelan et al., 2002; Gazmararian et al., 2003; Hassan & Heptulla, 2010; Howard et al., 2005; Murray et al., 2009; Ross, Frier, Kelnar, & Dreary, 2001; Stallwood, 2006). The differences observed in the present study are inconclusive; however, one possible explanation may be related to the measurement of income and education. In this study, although only the caregivers' educational level was attained, the caregivers income may have reflected the income for both the caregiver and the care recipient or, if the caregiver was married to someone else, the income for the caregiver and her respective spouse. Therefore, the income did not represent only the income of the caregiver, and this may have confounded the results.

Demographic characteristics

The demographic characteristics of caregivers who participated in this study included: age, gender, marital status, educational attainment, and income.

These characteristics were found to compare favorably with those reported in previous studies of informal caregivers of elderly persons. The caregivers age in this study ranged from 37 years to 87 years ($M = 65.90$, $SD = 12.07$). The mean age of caregivers in this study was similar to informal caregivers' mean age of 65.4 ($SD = 12.6$) reported in a cross-sectional survey of informal caregivers ($N = 124$) of elderly persons with dementia by Wang, Robinson, and Carter-Harris (2014). In another study by Travis, Bethea, and Winn (2000), the age range of 23 informal caregivers of adult day care participants surveyed, was 33 to 77 years ($M = 60$), comparable to the age range in the present study. However, the research report of caregiving by The National Alliance for Caregiving (NAC)/AARP Public Policy Institute (2015), observed a mean age of 50.3 years for caregivers of those 50 years of age and older in the U.S. In comparison to the present study and the studies reported by Wang et al. (2014) and Travis et al. (2000), there appears to be a wide variation in caregiver age.

The dominant gender in this study was female, and this was consistent with findings in previous studies. For example, the 2015 NAC/AARP research report on caregiving in the U.S. stated that 60% of caregivers for individuals 50 years and older were females. Similarly, in the study by Wang et al. (2014), they observed in their survey of informal caregivers of elderly persons that 69.4% were female. Females are overwhelmingly in the caregiving role in many studies, regardless of the size of the study or age composition of participants (Avila, Pereira, & Bocchi, 2015; Kim and Schulz 2008; Sinclair, Armes, Randhawa, & Bayer, 2010; Travis et al., 2000).

Regarding marital status, most of the caregivers in the present study were either married or were in a committed relationship with the care recipients. About 51% of the caregivers were married to the care recipients, and approximately 13% were live-in partners. Another 11% were married children or other relatives of the care recipients. The role of caregiving seems to be prevalent among married individuals in that caregivers are married to the care recipients (Kim, Carver, Shaffer, Gansler, & Cannady, 2015; Kim & Carver, 2007; King-Marshall et al., 2015).

Regarding educational attainment of participants, 57% of the participants had achieved more than high school level of education. This finding was similar to a study of caregivers of adults who were undergoing colonoscopy procedures. The study results indicated that 63% of the caregivers also reported an educational level of high school or greater (King-Marshall et al., 2015). In a study by Pulgarón et al. (2014), 73% of the caregivers had completed more than a high school level of schooling. On the other hand, Lee et al. (2014) found that only 37% of the caregivers had attained more than a high school level of education.

Limitations

Limitations included a single setting, the failure to assess other factors that may impact the relationship between caregiver health literacy and the A1c level in care recipients, and the use of a measure of glycemic control that is influenced by numerous other factors. The setting was a single medical center in a metropolitan area in the Eastern U.S. Therefore, findings may not be generalized to all populations of caregivers for elderly diabetic patients.

Caregiver health literacy is an indirect measure of a care recipient's A1c level. Several additional factors are critical to understanding how the health literacy of the caregiver impacts

the care recipient's A1c level. Factors such as the relationship between health literacy and the performance of caregiver activities, and, in turn, the relationship between these activities and care recipients' outcomes need to be considered.

Glycemic control for the care recipient was measured by the care recipient's A1c level. The A1c level is affected by many factors such as diet, exercise, other comorbidities, and adherence to a recommended diabetic care plan. In this study, data regarding these factors were not collected. Therefore, it is not known, how these factors would have interacted with the relationship between health literacy and the A1c level.

Another significant limitation was the demographic information which was by self-report. Participants may have overstated or understated some socio-demographic information. Furthermore, the population studied lacked racial diversity as the majority of the study participants were African Americans. All of the limitations in this study preclude generalization of findings to the general population.

Practice Implications

The findings in this study contribute to practice by highlighting the gaps in literature regarding health literacy of caregivers. Caregivers play important roles in the care of elderly diabetics; however, low health literacy of caregivers may be a potential barrier to good diabetes care. The ability of an informal caregiver to obtain, process, understand, and make basic diabetes care decisions, may be significant in the health outcome of an elderly diabetic.

Data from this study demonstrated a significant relationship between caregiver level of health literacy and care recipient's level of diabetes control.

The study finding indicated that a higher level of caregiver health literacy was associated with a lower care recipient's A1c. This study is the first known study that has investigated the influence of caregivers' level of health literacy on diabetes control in elderly diabetics who are recipients of informal care. Therefore, this new knowledge of the impact of caregivers' level of health literacy on elderly diabetic outcome substantiates the importance of assessment of a caregiver's level of health literacy before providing diabetic-related care instructions. Patient care instructions should be made available at the level of the caregiver health literacy to facilitate understanding and compliance of instructions. Furthermore, colleges and universities that educate health care practitioners should include in their curriculum health literacy education in order to equip future health care practitioners on how to successfully address the problem of low health literacy in the general population.

Often, patients and caregivers are given verbal or written health-related instructions by health-care practitioners. In view of the complexities of diabetes care, which often include, checking blood sugars, taking insulin, and/or oral medications at certain times of the day, following a prescribed diet plan, checking the feet for sores, following an exercise regimen, and keeping multiple medical appointments, diabetic care instructions for caregivers with low health literacy should be short and simple. It should be written in a simple prose that the caregiver can easily read and understand and the health-care practitioner should request the caregiver to repeat the instructions in the caregivers' own words to validate accurate transfer of information. Sometimes, the use of visual aids may be necessary to convey intended information.

Moreover, for certain procedures, caregivers should be required to demonstrate accurate performance of procedures such as insulin injections. Additionally, follow-up phone calls a few days later and at intervals before the next scheduled visit may empower the caregiver with low health literacy to articulate any related concerns and obtain solutions that would enhance good diabetes care.

Policy Implications

From a policy perspective, regulations are necessary to address low health literacy. Health literacy has been defined as the ability for one to obtain, process, and understand basic health information that is needed to navigate the health care system and make appropriate health-related decisions. Currently, 26% of Americans have basic or below basic health literacy (Paasche-Orlow et al., 2005), implying that these 26% of Americans do not have the ability to navigate our health care system successfully or make important decisions affecting their health. It is even more worrisome when one envisions that many more elders would become recipients of informal care.

The economic burden of low health literacy is enormous. Between \$106 billion and \$236 billion (USD) annual expenditure in the U.S. is attributed to low health literacy (Somers & Mahadevan, 2010). Low health literacy has been associated with frequent emergency room visit, frequent hospitalization, decreased preventive health services, and poor clinical outcomes (Baker et al., 2002, Baker, Wolf, Feinglass, Thompson, Gazmararian, & Huang, 2007; Cavanaugh et al., 2010, Cho et al., 2008, Herndon, Chaney, & Carden, 2011, Howard et al., 2005, Murray et al., 2009).

This is probably due to interplay of many factors, one of which might have been the lack of affordable health insurance and health services. The other being due to low health literacy in itself posing as a barrier to access and utilization of needed health care information and services. Therefore, it is pertinent to implement policies and programs that can help reduce the effect of low health literacy, particularly for caregivers, and improve health outcomes and access. Such programs could be effective at the outpatient and inpatient settings, if properly implemented.

Policies related to the health literacy of caregivers are also needed within hospitals to address how not only nursing but all disciplines assess health literacy and ensure that caregivers understand the healthcare information. For example, pharmacy personnel need to not only instruct caregivers on prescriptions but verify that they understand the information that has been provided. The actual medication being picked up should serve as the teaching tool, to include dosing and side effects to watch out for, and not just a lengthy script accompanying the prescription bottle as it is often the case. In this way, caregivers with low health literacy will stand to gain because they can seek necessary clarification at that time. In support of the above recommendation, a randomized clinical trial using a plain language, pictogram-based intervention to counsel caregivers of children, resulted in few medication errors in the intervention group compared to the control group (Yin et al., 2008).

Similar policies could also be beneficial to caregivers at the inpatient level, as patients for whom the caregivers provide care for are being discharged home to their care. One of the contributing factors for the readmission of patients who are provided care by a caregiver may be attributed, in part, to low health literacy of the caregivers.

Patients and caregivers are often provided information based on the assumption that the information furnished are taken in and are understood. A study by Dickens et al. (2013) reported that nurses overestimated their patients' level of health literacy when they surveyed nurses' knowledge of their patients' level of health literacy. It is not surprising then that the same patients often return for readmission. However, if individuals, particularly caregivers, are screened to identify those that are at risk of low health literacy, these caregivers can then receive targeted intervention to improve health literacy. Improved health care communication between health care practitioners and caregivers will improve health outcomes for the care recipients and might decrease frequent hospitalization.

Future Research

The present study underscores the need for further investigations on the influence of caregivers' health literacy on disease outcome for those whom they provide care. In order to advance caregivers' health literacy research, it is necessary that future research be focused on finding causal pathways of low health literacy, which would help develop appropriate interventional programs to mitigate low health literacy. Furthermore, the proliferation of various forms of information technology and social media and the use of these media to gather health-related information by many healthcare consumers, including caregivers, warrants interventional studies, which may suggest causal inferences of low health literacy.

Longitudinal studies are needed for a better understanding of the level of impact of caregiver low health literacy on elderly diabetic outcome. It would be important to figure out whether the diabetic outcomes of elderly care recipients whose caregivers have low health

literacy, slowly or rapidly deteriorate over time. Longitudinal studies may also offer the opportunity to delineate other factors, over time, which might contribute to caregivers' level of health literacy.

The present study was conducted in one setting; thus limiting the generalizability of the results. It is necessary to expand the current study to a larger veteran population health care setting, with a focus on those who are recipient of informal care, so as to determine if the findings are reproducible. The Veterans Administration has the largest integrated health care system. Therefore, it would be quite suited to repeat this study in multiple VA medical facilities in different locations within the U.S. and its territories. It would also be important to extend the study to a non-veteran population of caregiver/elderly dyads to elucidate any similarities and differences.

In addition, a mix-method study approach would shed more light on the impact of caregivers' health literacy as the qualitative data may elucidate how caregivers with low health literacy obtain, process, understand, and retain basic health instructions. It is possible that those with low health literacy have natural ways of managing information, which may be better illuminated through focus groups. In summary, research on informal caregivers of elderly care recipients is emerging and calls for much investigation for the purpose of improving and supporting caregivers with low health literacy.

Conclusion

This study makes a contribution to the limited body of knowledge on the impact of informal caregivers' level of health literacy on diabetic outcomes for elderly care recipients of

informal care. The study is significant because of the role that informal caregivers play in the care of elderly diabetics. The study is also notable because of its ability to predict diabetes outcomes for elderly diabetic care recipients based on the level of health literacy of the caregiver. Low health literacy of caregivers appears to be a potential barrier to good diabetes care for elderly diabetic recipients of informal care.

Overall, the findings support the hypothesis that the caregiver level of health literacy would influence the care recipient's diabetes outcome as measured by the care recipient's A1c level. Even though the majority of caregivers scored high for health literacy, 32% of the caregivers still had low health literacy; slightly higher than the estimated national average of 26% of adults with low health literacy.

As observed in previous studies, the caregivers' level of education had a strong correlation with caregivers' level of health literacy. Caregivers with higher educational attainment were more likely to have higher levels of health literacy compared to those who had limited years of schooling. The correlation between health literacy and race was also consistent with findings reported in earlier works. Health literacy, for African Americans was significantly lower compared to their white counterparts, despite the fact that a significant number had attained more than a high school level of education. Health care practitioners should be cognizant of the disproportionate disparity of low health literacy among ethnic/racial minority, and take this knowledge into consideration when encountering caregivers belonging to ethnic/racial minority groups.

Also significant was the relationship between income and health literacy. Those that were financially deprived, demonstrated low health literacy, supporting growing evidence that being poor is associated with low health literacy.

Caregivers play a very pivotal role in the lives of elderly persons. With the aging of America, understanding the impact of caregivers' level of health literacy on health outcomes for elders is an important factor for advancing health and closing the health literacy gap. Hence, it is important that health practitioners should approach caregivers with low health literacy by communicating with these caregivers in the simplest form, using feedback, visual aids, and when necessary, follow-up with phone calls to respond to any issues or concerns. There is also a need to implement policies that facilitate ease of communication and empower caregivers with low health literacy. Low health literacy of caregivers is a predictor of poor diabetes control for elderly diabetics who are recipients of informal care.

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Appendix A
Chart Abstraction Instrument

Medical Record Abstraction Form

Reviewer _____

Date _____

Case Number _____

Identifying Characteristics

Patient's gender

Male

Female

Patient's Age _____

Diabetes Diagnosis

Yes

No

Year diagnosed _____

Diabetes Type

Type II

Type I

Current Diabetes Medications

Oral agent

Specify name/dose _____

Insulin

Specify brand/dose _____

Both

A1c Level _____

Date obtained _____

Appendix B

Questionnaire for Caregivers' Socio-Demographic Information

CAREGIVER DEMOGRAPHIC QUESTIONNAIRE

Please answer the following questions:

1. Gender (check one)

Male

Female

2. The person under my care is my (check one)

Husband

Wife

Father

Mother

Brother

Sister

Grandmother

Grandfather

Father In-law

Mother in-law

Uncle

Aunt

Cousin

Other (Please specify _____)

3. I have been caring for my relative (check one)

6 months to 1 year > 1 year

4. I help my relative with (check all that applies)

checking blood sugar

taking oral medications

taking insulin injections

filling and refilling medications

scheduling medical appointments

going to medical appointments

grocery shopping

meals preparations

5. I live in the same house with my loved one

Yes No

If no, approximate miles away _____

6. Years of schooling (check one)

- finished 6th
- finished 9th
- some high school
- finished high school
- some college
- finished college
- graduate degree
- other _____

7. Please indicate the race that best describes you (circle one)

- Black/African American
- White
- Hispanic
- American Indian/Alaskan Native
- Native Hawaiian/Pacific Islander
- Other _____

8. Age (please specify)

9. Marital status (check one)

- married
- separated
- divorced
- never married
- Other----- (please specify)

10. Estimated family combined income (check one)

- under \$20,000
- between \$21,000 and \$40,000
- between \$41,000 and \$60,000
- between \$61,000 and \$80,000
- between \$81,000 and \$100,000
- greater than \$100,000

Appendix C
Sample Size Calculator

model, not
 including the
 regression
 constant.
 0.05
 Also known as
 the p-value,
 alpha level, or
 type I error rate.
Probability level: By convention,
 this value
 should be less
 than or equal to
 0.05 to claim
 statistical
 significance.

Minimum required sample size: 84

The minimum required sample size of 84 (dyad), is based on a priori sample size value for multiple regression by Cohen as illustrated below:

Cohen's f^2 effect size for an F-test:

$$f^2 = \frac{R^2}{1 - R^2}$$

where R^2 is the squared multiple correlation.

Reference

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Appendix D

Rapid Estimate of Adult Literacy in Medicine (REALM) Test

Word List and Scoring Sheet (Examiner's Copy)

List 1	List 2	List 3
fat	fatigue	allergic
flu	pelvic	menstrual
pill	jaundice	testicle
dose	infection	colitis
eye	exercise	emergency
stress	behavior	medication
smear	prescription	occupation
nerves	notify	sexually
germs	gallbladder	alcoholism
meals	calories	irritation
disease	depression	constipation
cancer	miscarriage	gonorrhea
caffeine	pregnancy	inflammatory
attack	arthritis	diabetes
kidney	nutrition	hepatitis
hormones	menopause	antibiotics
herpes	appendix	diagnosis
seizure	abnormal	potassium
bowel	syphilis	anemia
asthma	hemorrhoids	obesity
rectal	nausea	osteoporosis
incest	directed	impetigo

**RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE
(REALM)**

Terry Davis, PhD, Michael Crouch, MD, Sandy Long, PhD

Chart # _____

Examine date: _____

Name: _____

Birth date: _____

REALM generated reading level: _____

Grade completed: _____

List 1	List 2	List 3
Fat _____	Fatigue _____	Allergic _____
Flu _____	Pelvic _____	Menstrual _____
Pill _____	Jaundice _____	Testicle _____
Dose _____	Infection _____	Colitis _____
Eye _____	Exercise _____	Emergency _____
Stress _____	Behavior _____	Medication _____
Smear _____	Prescription _____	Occupation _____
Nerves _____	Notify _____	Sexually _____
Germs _____	Gallbladder _____	Alcoholism _____
Meals _____	Calories _____	Irritation _____
Disease _____	Depression _____	Constipation _____
Cancer _____	Miscarriage _____	Gonorrhea _____
Caffeine _____	Pregnancy _____	Inflammatory _____
Attack _____	Arthritis _____	Diabetes _____
Kidney _____	Nutrition _____	Hepatitis _____
Hormones _____	Menopause _____	Antibiotics _____
Herpes _____	Appendix _____	Diagnosis _____
Seizure _____	Abnormal _____	Potassium _____
Bowel _____	Syphilis _____	Anemia _____
Asthma _____	Hemorrhoids _____	Obesity _____
Rectal _____	Nausea _____	Osteoporosis _____
Incest _____	Directed _____	Impetigo _____
# of (+) Responses in List 1: _____	# of (+) Responses in List 2: _____	# of (+) Responses in List 3: _____

LEGEND: (+)=Correct (-)=Word not attempted (/)=Mispronounced word

Raw Score: _____

Red Lake Hospital, Red Lake MN 56671
4/98/JMcD

Appendix E

The Katz Basic Activities of Daily Living (ADL) Scale



KATZ BASIC ACTIVITIES OF DAILY LIVING (ADL) SCALE

ACTIVITY	PERFORMS ACTIVITY INDEPENDENTLY	
	YES	NO
1. Bathing (sponge bath, tub bath, or shower)— Receives either no assistance or assistance in bathing only one part of body		
2. Dressing— Gets clothes and dresses without any assistance except for tying shoes.		
3. Toileting— Goes to toilet room, uses toilet, arranges clothes, and returns without any assistance (may use cane or walker for support and may use bedpan/urinal at night).		
4. Transferring— Moves in and out of bed and chair without assistance (may use can or walker).		
5. Continence— Controls bowel and bladder completely by self (without occasional "accidents").		
6. Feeding— Feeds self without assistance (except for help with cutting meat or buttering bread).		

Appendix F

Study Flyer

Appendix G
Research & Development Committee
Washington DC VA Medical Center
Study Approval

Research & Development Committee
Washington DC VA Medical Center
Washington, DC

APPROVAL - Previously Tabled Protocol

Date: June 24, 2014
From: Joao L. Ascensao, MD, PhD, FACP, Chairperson
Marc R. Blackman, M.D., ACOS/R&D
Investigator: Dora Ifon, Ph.D.(c), NP
Protocol: Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy
ID: 01658 Prom#: N/A Protocol#: N/A

The following items were reviewed and approved at the 06/13/2014 meeting:

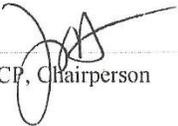
- Advertisement - flyer (06/11/2014)
- Revised
 - Advertisement - Study Flyer (06/04/2014; Revised: 4-19-2014)
 - Advertisement - Study Flyer- Tracked Copy (04/22/2014)
 - Advertisement - Study Flyer-Clean Copy (04/22/2014)
 - Advertisement - Study Flyer (01/13/2014)
 - Consent Form - Tracked Changes (06/11/2014; Version #5: 06/10/2014)
- Care Recipient Consent
 - Consent Form - Tracked Changes (06/11/2014; Version #5: 06/20/2014)
- Caregiver Consent
 - Consent Form - Clean Copy (06/10/2014; Version #5: 06/10/2014)
- Caregiver Consent- Revised to include Ms. Ifon financial support
 - Consent Form - Clean Copy (06/10/2014; Version #5: 06/10/2014)
- Care Recipient Consent- Revised to include Ms. Ifon support
 - Consent Form - Clean Copy- Care Recipient (04/28/2014; Version 4: 04/25/2014)
 - Consent Form - Clean Copy- Caregiver (04/28/2014; Version 4: 04/25/2014)
 - Consent Form - Clean Copy- Care Recipient (04/22/2014; Version 3: 04/17/2014)
 - Consent Form - Clean Copy- Caregiver (04/22/2014; Version 3: 04/17/2014)
 - Consent Form - Tracked Copy- Care Recipient (04/22/2014; Version 3: 04/17/2014)
 - Consent Form - Tracked Copy- Caregiver (04/22/2014; Version 3: 04/17/2014)
 - Consent Form - Care Recipient (03/14/2014; Version 2: 03/14/2014)
 - Consent Form - Caregiver (03/14/2014; Version 2: 03/14/2014)
 - Consent Form (01/13/2014; Version 01/04/2014)
 - Financial Disclosure Form - Suzanne McNicholas (02/27/2014)
 - Financial Disclosure Form - Ifon, Dora E. (01/13/2014)
 - HIPAA Worksheet (01/13/2014)
 - Initial Review Submission Form (01/13/2014)
 - Memo - Addressing Issues raised from R&D (06/04/2014; Letter Dated: June 2, 2014)
 - Memo - Checklist for Reviewing (ISO/PO) (01/13/2014)

- Demographic Questionnaire (06/04/2014)
 - Katz ADL Tool (06/04/2014)
 - REALM- Participant Copy (06/04/2014)
 - REALM-Examiner WordList (06/04/2014)
 - Study Proposal Chart Abstraction (06/04/2014; May 2014)
 - Proposal VA IRB Protocol (06/04/2014; Revised: June 2014)
 - Protocol (03/14/2014)
 - PI Certification of Researcher's Eligibility (02/27/2014; Suzanne McNicholas)
 - Protocol (01/24/2014)
 - HIPAA Authorization (01/21/2014)
 - Request for Waiver of HIPAA Authorization (01/13/2014)
 - Study Assessments (01/13/2014)
 - Personnel Roster - Investigator Roster (02/27/2014)
- Addition of Suzanne McNicholas to the study.
- Personnel Roster - Investigator Roster (01/13/2014)
 - Project Data Sheet - with Abstract (03/14/2014)
 - Project Data Sheet - with Abstract (01/13/2014)
 - Protocol Face Sheet (01/13/2014)
 - Scientific Review - Response to Scientific Review #1 (01/24/2014)
- Updated Protocol Version 1/24/14
- Scientific Review - Response to Scientific Review #2 (01/24/2014)
- Updated Protocol Version 1/24/14
- Scientific Review - Scientific Review #2 (01/23/2014)
 - Scientific Review - Scientific Review #1 (01/22/2014)

The committee recommends including additional variables in the analysis to strengthen the study. Some options include: a) medication compliance by reviewing medication refills, b) attendance for scheduled medical/primary care appointments.

YOU MAY NOW INITIATE RESEARCH.

Approval by each of the following is required prior to study initiation:
 Human Studies Subcommittee (IRB) [Approval Granted 04/07/2014]
 Research & Development Committee


Joao L. Ascensao, MD, PhD, FACP, Chairperson

24 June, 2014
Date


Marc R. Blackman, M.D., ACOS/R&D

6.25.14
Date

Research & Development Committee
Washington DC VA Medical Center
Washington, DC

APPROVAL - Continuing Review

Date: April 17, 2015

From: Joao L. Ascensao, MD, PhD, FACP, Chairperson
Marc R. Blackman, M.D., ACOS/R&D

Investigator: Suzanne McNicholas, Ph.D RN CIP

Protocol: Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy

ID: 01658 Prom#: 0001 Protocol#: N/A

The following items were reviewed and approved at the 04/17/2015 meeting:

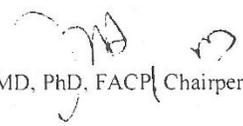
- Consent Form - IRB Stamped Approved January 26, 2015 (03/06/2015; Version 6: 01//23/2015)
- Continuing Review (03/06/2015)
- Financial Disclosure Form - Ifon, Dora (03/06/2015)
- Financial Disclosure Form - McNicholas, Suzanne (03/06/2015)
- HIPAA Worksheet (03/06/2015)
- HIPAA Authorization (03/06/2015)
- Protocol (03/06/2015)
- PI Certification of Researcher's Eligibility (03/06/2015; Ifon, Dora)
- Personnel Roster - Investigator Roster (03/06/2015)
- Project Data Sheet - w/Abstract (03/06/2015)

The following other committee reviews are scheduled:

Human Studies Subcommittee (IRB) [03/14/2016]

Approval by each of the following is required prior to study continuation:

Human Studies Subcommittee (IRB) [Approval Granted 03/16/2015]
Research & Development Committee


Joao L. Ascensao, MD, PhD, FACP, Chairperson


Marc R. Blackman, M.D., ACOS/R&D

APR 17 2015
Date

4-20-15
Date

Human Studies Subcommittee (IRB)
Washington DC VA Medical Center
Washington, DC

IRB APPROVAL - Continuing Review

Date: April 5, 2016
From: Cynthia L. Gibert, M.D., Chairperson
Investigator: Suzanne McNicholas, Ph.D RN CIP
Protocol: Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy
ID: 01658 Prom#: 0005 Protocol#: N/A

The following items were reviewed and approved through Expedited Review:

- Continuing Review (03/14/2016)
- Financial Disclosure Form - Ifon, Dora (03/14/2016)
- Financial Disclosure Form - McNicholas, Suzanne (03/14/2016)
- HIPAA Worksheet (03/14/2016)
- Personnel Roster - Investigator Roster (03/14/2016)
- Project Data Sheet - w/Abstract (03/14/2016)
- Privacy and Data Security Plan (03/14/2016)
- Protocol (03/14/2016)

Expedited Approval was granted on 03/24/2016 for a period of 12 months and will expire on 04/06/2017. Your Continuing Review is scheduled for 04/03/2017. This Expedited review will be reported to the fully convened Human Studies Subcommittee (IRB) on 04/04/2016.

In accordance with 38. CFR16.110 (b) (8c), the remaining research activities are limited to data analysis, the submission was granted expedited approval.

"REMINDERS"

"The most current IRB-approved stamp version of Informed Consent Form for each study must be used as the informed consent form."

Records will be maintained until the end of the study and until disposition instructions are approved by the National Archives and Records Administration.

The following other committee reviews are scheduled:
Research & Development Committee [04/22/2016]

Approval by each of the following is required prior to study continuation:
Human Studies Subcommittee (IRB)

Research & Development Committee [Approval Granted 04/17/2015]

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

Appendix H

The Catholic University of America

Office of Sponsored Programs and Research Services

Washington, DC

IRB Approval



THE CATHOLIC UNIVERSITY OF AMERICA
Office of Sponsored Programs and Research Services
Washington, DC 20064
202- 319-5218

September 19, 2014

Ms. Dora Ifon
7819 Aylesford Lane
Laurel, MD 20707

Subject: Project title **“Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy”**
Protocol No. **14-050**

Dear Ms. Ifon:

Your research for the subject project was certified by the Committee for the Protection of Human Subjects (CPHS) as meeting the requirements of the Federal regulations governing protection of human subjects.

CPHS will maintain a copy of your submission on file. You are obligated to follow the research protocol and procedures for obtaining informed consent as you have specified. If you wish to initiate any changes in the research protocol or the informed consent procedure, you should submit this request to CPHS in writing.

The reviewer finds that the protocol does not involve undue risk for the subjects. The protocol is approved and expires **06/10/15**. The protocol is currently approved by the IRB at the research site (Washington DC VA Medical Center, IRB ID# 01658). This protocol is approved by the CUA IRB, contingent upon continued approval by WDC VAMC. Should WDC VAMC approval lapse or expire, CUA approval is revoked.

Sincerely,

Ralph Albano
Secretary
Committee for the Protection of Human Subjects

cc: [] Dr. Paterson
School of Nursing

14-050 ARP 08-30-14
[170]



THE CATHOLIC UNIVERSITY OF AMERICA
Office of Sponsored Programs and Research Services
Washington, DC 20064
202- 319-5218

June 15, 2015

Ms. Dora Ifon
7819 Aylesford Lane
Laurel, MD 20707

Subject: Project title **“Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy”**
Protocol No. **14-050**

Dear Ms. Ifon:

Your request to renew the subject project as described in the IRB Decisions 06/11/15 was subject to continuing review, and it has been approved by the Committee for the Protection of Human Subjects. Approval for this protocol now expires **04/06/16**. The primary IRB is at Washington DC VA Medical Center. CUA approval is contingent upon continued approval by the DCVAMC.

Attached is a signed copy of the request for renewal form.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Ralph Albano'.

Ralph Albano
Secretary
Committee for the Protection of Human Subjects

Enclosure

cc: [] Dr. Paterson
School of Nursing

14-050 RNC 06-11-15
[171]

Appendix I
Consent Forms

Subject Name: Care Recipient's Name: _____**Last 4 SSN** _____ **Date:** _____

Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy

Title: _____**Principal Investigator:** Dr. Suzanne McNicholas **VAMC:** Wash., DC**PURPOSE**

You are being asked to take part in this study because you have diabetes mellitus, otherwise known as diabetes or sugar diabetes and a caregiver (family member or friend) is helping you manage your diabetes. The purpose of this study is to see whether the information doctors, nurses, pharmacists, social workers, and anyone else you or your caregiver meet with during medical appointments, discussed with you, is understood well enough to help manage your diabetes well. This study will include only 90 veterans who use this VA Medical Center or the Community Outpatient Clinics serviced by this VA and 90 caregivers caring for these veterans. The study will last for 6 months to 1 year but you and your caregiver will only be required to spend about 30 to 45 minutes to answer a few questions. Dr. Suzanne McNicholas is a full time member of the VAMC staff and the Principal Investigator for this study and Ms. Ifon, a Nurse Practitioner, also a full time staff of this VAMC, is the Co-investigator.

PROCEDURES

If you agree to participate in this research study, you will be asked to give permission to look at your medical record to gather information about you. These will include, your age, when you were first diagnosed, with diabetes, the number of medications you take for your diabetes, and the level of your A1c, which is the number that tells how well your diabetes is controlled. If you do not have a recent A1c, I will ask permission to prick your finger for a small drop of blood to check your A1c level. The finger pricking and testing for your A1c will take about 3 minutes to complete.

In addition, I will ask your permission to have your caregiver answer a few questions about how much of the common activities we do day- to -day that you do for yourself, using an instrument developed by Dr. Katz for that purpose. Information gathered about you will not be shared with anyone unless the information requires an intervention; in that case, it will be shared with your Primary Care Provider.

RISKS

Your participation in this study puts you at minimal risk. You may lose more than a drop of blood with the finger pricking. You may also experience some discomfort, local bruising, or minor infection to your finger. If your experience requires any treatment, the VA will provide the treatment to you at no additional cost.

Taking part in this study may not personally benefit you, but your participation may lead to knowledge that will help others. For example, health care personnel may change the ways health care instructions are given to caregivers, which may improve the level of care they provide to care recipients with diabetes or other chronic illnesses.

OTHER TREATMENT AVAILABLE

This is not a treatment study. Your participation does not affect the veteran's usual care.

PRIVACY & CONFIDENTIALITY

Confidentiality. Any information provided by you for this study will be kept in a locked cabinet and/or a password-protected computer and not shared with any other person(s). However, the Institutional Review Board of this medical center may ask to review the information gathered from this study, in which case, your information would be made available but your name would not be attached to the information provided.

RESEARCH RESULTS

1. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.
2. We will maintain your privacy and the confidentiality of the research record and no information by which you can be identified, will be released or published without your authorization unless required by law. The PI will have possession of all data including questionnaires. All research data will be kept secured in accordance with the record control schedule.

SPECIAL INFORMATION

1. You are not required to take part in this study: your participation is voluntary.
2. You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with the veteran's regular medical treatment.
3. There will be no costs to you or the veteran for any of the testing done as part of this research study. You will receive a \$10 gift card, from my personal funds, in appreciation for your time.
4. Eligibility for medical care for a veteran is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
5. The VAMC will provide necessary medical treatment if you are injured as a result of your participation in this study unless you were injured because you did not follow the instructions that you were given.
6. Additional compensation may or may not be payable in the event of physical injury arising from this study under applicable federal law. Further information about compensation may be obtained from the Patient Advocate Office at this VA Medical Center.
7. If you would like to talk to someone unaffiliated with the research, to discuss problems, concerns, and questions, including questions about your rights, you may do so. If you have problems,

concerns or complaints, or think you have been injured you can contact the Associate Chief of Staff for Research & Development, Dr. Marc Blackman, at 202-745-8133 or the Chairman of the Institutional Review Board, Dr. Cynthia Gibert, at 202-745-2238. You may also call them if you want more information, want to offer a suggestion, or want to provide input.

8. A copy of this consent form will be given to you to keep for yourself.

AFFIRMATION FROM SUBJECT

Ms. Ifon has explained the study to me and answered all of my questions. I have been told of risks or discomforts and possible benefits of the study. I have been told that this is not a treatment study and my participation does not affect the veteran's usual care.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which the veteran is entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which the veteran is entitled.

The results of this study may be published, but my identity will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Ms. Ifon at 202-412-8342 during the day.

I understand the explanation of my rights as a research subject, and I voluntarily agree to participate in this study. I understand the explanation of what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

Participant's Signature

Date

I have informed the participant of the intent, nature benefits and risks of the research project. I judge that he/she understood my explanation and that his consent was given freely.

Consent Informant Signature

Print Name

Date

Subject Name: Caregiver's Name: _____**Last 4 SSN** _____ **Date:** _____
Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy**Title:** _____**Principal Investigator:** Dr. Suzanne McNicholas VAMC:Wash., DC**PURPOSE**

You are being asked to take part in this study because you are providing care for a veteran with diabetes mellitus, otherwise known as diabetes or sugar diabetes. The purpose of this study is to see whether the information doctors, nurses, pharmacists, social workers, and anyone else you meet with during a medical appointment with a veteran, discussed with you, is understood well enough to help you manage the veteran's diabetes. This study will include only 90 veterans with diabetes who use this VA Medical Center or the Community Outpatient Clinics serviced by this VA and 90 caregivers who help these veterans manage their diabetes. The study will last for 6 months to 1 year but you and the veteran will only be required to spend about 30 to 45 minutes to answer a few questions. Dr. Suzanne McNicholas is a full time member of the VAMC staff and the Principal Investigator for this study and Ms. Ifon, a Nurse Practitioner, also a full time staff of this VAMC, is the Co-investigator.

PROCEDURES

If you agree to participate in this research study, you will be asked to give information about your age, your level of education, your income, and how long you have been helping the veteran manage his/her diabetes. In addition, you will be given the REALM test, which is a list of commonly used medical words, to read aloud. If you are unable to pronounce any word, you will simply move on to the next word unless you are asked to stop. You will be given simple tests for your hearing and vision before you are given the list of medical words to read. You will also be asked to answer about six questions on the Katz instrument, which addresses the level of function of the veteran under your care. All of these will take place in a room with only you and the Principal Investigator or Co-investigator present. It will take approximately 30 to 45 minutes to complete the questionnaires, words pronunciations, the hearing and vision tests.

RISKS

Your participation in this study may put you at minimal risk. You may feel uneasiness reading unfamiliar medical words. If that is the case, you should not feel compelled to finish reading all the words within the 30 to 45 minutes period. If you wish to stop reading at any time, you will be free to do so and your stopping will not affect the care the veteran is receiving from VAMC.

BENEFITS

BENEFITS

Taking part in this study may not personally benefit you, but your participation may lead to knowledge that will help others. For example, health care personnel may change the ways health care instructions are given to caregivers, which may improve the level of care they are able to provide to people with diabetes or other chronic illnesses.

OTHER TREATMENT AVAILABLE

This is not a treatment study. Your participation does not affect your usual care.

PRIVACY & CONFIDENTIALITY

Confidentiality. Any information provided by you or retrieved from your medical records for this study will be kept in a locked cabinet and a password-protected computer and not shared with any other person(s). However, the Human Studies Committee of this medical center may ask to review the information gathered from this study, in which case, your information would be made available but your name would not be attached to the information provided.

RESEARCH RESULTS

1. I will let you and your health care provider know of any abnormal level of A1c obtained during this study, which may affect you, your condition, or your willingness to participate in this study.
2. If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.
3. We will maintain your privacy and the confidentiality of the research record and no information by which you may be identified, will be released or published without your authorization unless required by law. The PI, will have possession of all data including questionnaires. All research data will be kept secured in accordance with the record control schedule.

SPECIAL INFORMATION

1. You are not required to take part in this study: your participation is voluntary.
2. You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment.
3. There will be no costs to you for any of the testing done as part of this research study. You will receive a \$10 gift card, from my personal funds, in appreciation for your time.
4. Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.
5. The VAMC will provide necessary medical treatment if you are injured as a result of your participation in this study unless you were injured because you did not follow the instructions that you were given.

Version 6: 01/23/2015

Washington DC VAMC
IRB APPROVED
January 26, 2015Updated: by IRB office 3/13
VA FORM 10-1086

6. Additional compensation may or may not be payable in the event of physical injury arising from this study under applicable federal law. Further information about compensation may be obtained from the Patient Advocate Office at this VA Medical Center.
7. If you would like to talk to someone unaffiliated with the research, to discuss problems, concerns, and questions, including questions about your rights, you may do so. If you have problems, concerns or complaints, or think you have been injured you may contact the Associate Chief of Staff for Research & Development, Dr. Marc Blackman, at 202-745-8133 or the Chairman of the Institutional Review Board, Dr. Cynthia Gibert, at 202-745-2238. You may also call them if you want more information, want to offer a suggestion, or want to provide input about the conduct of the study.
8. A copy of this consent form will be given to you to keep and another copy placed in your medical record.

AFFIRMATION FROM SUBJECT

Ms. Ifon has explained the study to me and answered all of my questions. I have been told of risks or discomforts and possible benefits of the study. I have been told that this is not a treatment study and my participating will not affect my usual care.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my identity will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Ms. Ifon at 202-412-8342 during the day.

I understand the explanation of my rights as a research subject, and I voluntarily agree to participate in this study. I understand the explanation of what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

Participant's Signature _____
Date

I have informed the participant of the intent, nature benefits and risks of the research project. I judge that he/she understood my explanation and that his consent was given freely.

Consent Informant's Signature _____
Print Name _____
Date

Appendix J
Training Certificates

Certificate of Completion

This certifies that

DORA E IFON

Has successfully completed

VA Privacy and Information Security Awareness and Rules of Behavior

Completed on Jun 27, 2013 6:14 PM

Instructor

Certificate of Completion

This certifies that

DORA E IFON

Has successfully completed

Privacy and HIPAA Focused Training

Completed on Dec 20, 2013 3:23 PM

Instructor

Certificate of Completion

This certifies that

DORA E IFON

Has successfully completed

Annual Government Ethics Training

Completed on Aug 27, 2013 8:00 PM

Instructor

Appendix K

Authorization for Use and Release of Individual Identifiable Health Information



Subject Name (Last, First, Middle Initial):

Subject Social Security Number (last 4 numbers only):

VA Facility (Name and Address):

Washington DC VA Medical Center
50 Irving Street, NW
Washington, DC 20422

VA Principal Investigator (PI):

Suzanne McNicholas, Ph.D.

PI Contact Information:

202-745-2238

Study Title:

Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy

Purpose of Study:

The purpose of this study is to see whether the information that caregivers received from doctors, nurses, pharmacists, social workers, and anyone else, during medical appointments, are understood well enough to help with providing care for elderly veterans with diabetes under their care.

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, etc.

Specific information concerning:

alcohol abuse

drug abuse

sickle cell anemia

HIV

Demographic Information such as name, age, race, etc.

Billing or Financial Records

Photographs, Videotapes, and/or Audiotapes of you

Questionnaire, Survey, and/or Subject Diary

Other, as immediately described below:

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

USE OF YOUR DATA OR SPECIMENS FOR OTHER RESEARCH: (This section must only be completed when banking is a required component of this study. When banking is an optional component of this study complete page 5 of this form in lieu of this section.)

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 outside the VA/VHA 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. These non-VA/VHA institutions or persons include the entities marked below:

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

Study Sponsor (name): _____
Person who takes responsibility for and initiates a clinical investigation

Academic Affiliate (institution/name/employee/department): _____
A relationship with VA in the performance of this study

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**

Note: Offices within VAVHA 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 VAVHA 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:

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
 Not expire for _____
(For example: the creation of a research database or research data repository)
 Expire on the following date or event: _____

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

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 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)

Date

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

Subject Name (Last, First, Middle Initial):

Subject Social Security Number (last 4 numbers only):

VA Facility (Name and Address):

Washington DC VA Medical Center, 50 Irving Street, NW Washington, DC 20422

VA Principal Investigator (PI):

Suzanne McNicholas, Ph. D.

PI Contact Information:

Study Title:

Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy

**Optional Authorization Supplement for Placing My Data or My Biological Specimens in a Repository or for
Conducting Optional Analysis of My Specimens For Use by Veterans Health Administration (VHA) Research**

Purpose. This supplement to the authorization is for either banking of data and/or biological specimens (for example blood, urine, tissue) collected during the study for future research or for conducting optional analysis for this study. You are not required to provide this permission and not providing this permission will have no impact on your participation in this study, i.e., granting this permission is not a condition of participating in this study.

Research Subject Signature. This additional permission (authorization) has been explained to me and I have been given the opportunity to ask questions about this activity. By signing below, I am giving my permission for VHA to:

- Store my health information in a research data repository,
- Store my biological specimens (blood, tissue, urine, etc.) in a research data repository, or
- Further optional analysis of my specimens occurring below:

Future research of data maintained within a research data repository will only occur after further Institutional Review Board and/or other applicable approvals to ensure the protection of your individual privacy.

Signature of Research Subject

Date

Signature of Legal Representative (if applicable)

Date

Name of Legal Representative (please print)

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)

Appendix L

VA Notice of Privacy Practices



Department of Veterans Affairs
Veterans Health Administration
NOTICE OF PRIVACY PRACTICES
Effective Date September 23, 2013

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED OR DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.

PLEASE REVIEW IT CAREFULLY.

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) is required by law to maintain the privacy of your protected health information and to provide you with notice of its legal duties and privacy practices. VHA is also required to abide by the terms of this Notice and its privacy policies.

How VHA May Use or Disclose Your Health Information without Your Authorization (See below for more information about these categories)

- Treatment (e.g., giving information to VHA and other doctors and nurses caring for you)
- Payment (e.g., giving information to non-VHA facilities that provide care or services)
- Health Care Operations (e.g., giving information to individuals conducting Quality of Care reviews)
- Eligibility and Enrollment for VA Benefits (e.g., giving information to officials who decide benefits)
- Abuse Reporting (e.g., giving information about suspected abuse of elders or children to government agencies)
- Health or Safety Activities
- Public Health Activities (e.g., giving information about certain diseases to government agencies)
- Judicial or Administrative Proceedings (e.g., responding to court orders)
- Law Enforcement
- Health Care Oversight (e.g., giving information to the Office of Inspector General or a Congressional Committee)
- Cadaveric Organ, Eye, or Tissue Donation
- Coroner or Funeral Activities
- Services (e.g., giving information to contractors or business associates performing services for VHA)
- National Security Matters
- Workers' Compensation Cases (e.g., giving information to officials who decide payments for workplace injuries)
- Payment (e.g., giving information to non-VHA facilities that provide care or services)
- Correctional Facilities and/or Parole Officers
- When Required by Law
- Activities Related to Research (e.g., certain activities with only minimal or limited privacy or confidentiality risks)
- Planning VA research projects (e.g., investigator accesses, but does not disclose or record, individual health information to determine feasibility of opening a study)
- Military Activities (e.g., giving information to the Department of Defense (DoD))
- Academic Affiliates (e.g., giving information to assist in training medical students)
- State Prescription Drug Monitoring Program (SPDMP) reporting and query
- General Information Disclosures (e.g., giving out general information about you to your family and friends)
- Verbal disclosures to others while you are present
- Verbal Disclosures when you are not present (e.g., assisting Family Members or Designated Individuals Involved in your Care)

Other Uses and Disclosures with Your Authorization. We may use or disclose your health information for any purpose based on a signed, written authorization you provide us. Your signed written authorization is always required to disclose your psychotherapy notes if they exist. If we were to use or disclose your health information for marketing purposes we would require your signed written authorization. In all other cases, we will not use or make a disclosure of your health information without your signed, written authorization, unless the use or disclosure falls under one of the exceptions described in this Notice. When we receive your signed written authorization we will review the authorization to determine if it is valid, and then disclose your health information as requested by you in the authorization.

Revocation of Authorization. If you provide us a written authorization or permission to use or disclose your health information, you may revoke that permission, in writing, at any time. If you revoke your authorization, we will no longer use or disclose your health information except to the extent that VHA has relied on your written authorization. Please understand that we are unable to take back any uses or disclosures we have already made based on your authorization.

Your Privacy Rights

Right to Request Restriction.

You may request that we not use or disclose all or part of your health information to carry out treatment, payment or health care operations, or that we not use or disclose all or part of your health information with individuals such as your relatives or friends involved in your care, including use or disclosure for a particular purpose or to a particular person.

Please be aware, we are not required to agree to such restriction, except in the case of a disclosure restricted under 45 CFR § 164.522(a)(1)(vi). This provision applies only if the disclosure of your health information is to a health plan for the purpose of payment or health care operations and your health information pertains solely to a health care service or visit which you paid in full. However, VHA is not legally able to accept an out of pocket payment from a Veteran for the full cost of a health care service or visit. We are only able to accept payment from a Veteran for co-payments. Therefore, this provision does not apply to VHA and VHA is not required or able to agree to a restriction on the disclosure of your health information to a health plan for the purpose of receiving payment for health care services provided to you.

To request a restriction, you must submit a written request that identifies the information you want restricted, when you want it to be restricted, and the extent of the restrictions. All requests to restrict use or disclosure should be submitted to the facility Privacy Officer at the VHA health care facility that provided or paid for your care. If we agree to your request, we will honor the restriction until you no longer make the restriction request valid or you revoke it.

NOTE: We are not able to honor requests to remove all or part of your health information from the electronic database of health information that is shared between VHA and DoD, or to restrict access to your health information by DoD providers with whom you have a treatment relationship.

Right to Review and Obtain a Copy of Health Information. You have the right to review and obtain a copy of your health information in our records. You must submit a written request to the facility Privacy Officer at the VHA health care facility that provided or paid for your care.

NOTE: Please send a written request, to your VHA health care facility Privacy Officer. The VHA Privacy Office at Central Office in Washington, D.C. does not maintain VHA health records, nor past military service health records. For a copy of your military service health records, please contact the National Personnel Records Center at (314)801-0800. The Web site is <http://www.archives.gov/veterans/military-service-records/medical-records.html>.

Right to Request Amendment of Health Information. You have the right to request an amendment (correction) to your health information in our records if you believe it is incomplete, inaccurate, untimely, or unrelated to your care. You must submit your request in writing, specify the information that you want corrected, and provide a reason to support your request for amendment. All amendment requests should be submitted to the facility Privacy Officer at the VHA health care facility that maintains your information.

If your request for amendment is denied, you will be notified of this decision in writing and provided appeal rights. In response, you may do any of the following:

- File an appeal
- File a "Statement of Disagreement"
- Ask that your initial request for amendment accompany all future disclosures of the disputed health information

Right to Request Receipt of Communications in a Confidential Manner. You have the right to request that we provide your health information to you by alternative means or at an alternative location. We will accommodate

reasonable requests, as determined by VA/VHA policy, from you to receive communications containing your health information:

- At a mailing address (e.g., confidential communications address) other than your permanent address
- In person, under certain circumstances

Right to Receive an Accounting of Disclosures. You have the right to know and request a copy of what disclosures of your health information have been made to you and to other individuals outside of VHA. To exercise this right, you must submit a written request to the facility Privacy Officer at the VHA health care facility that provides your care.

Right to a Printed Copy of the Privacy Notice. You have the right to obtain an additional paper copy of this Notice from your VHA health care facility. You can obtain this Notice from the facility Privacy Officer at your local VHA health care facility. You may also obtain a copy of this Notice at the following website, http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1089

Notification of a Breach of your Health Information. If a breach of any of your protected health information occurs, we will notify you and provide instruction for further actions you should take, if any.

Complaints. If you are concerned that your privacy rights have been violated, you may file a complaint with:

- The VHA health care facility's Privacy Officer, where you are receiving care. Visit this Web site for VHA facilities and telephone numbers http://www1.va.gov/directory/guide/division_flash.asp?dnum=1.
- VA via the Internet through "Contact the VA" at <http://www.va.gov>; by dialing 1-800-983-0936 or by writing the VHA Privacy Office (10P2C1) at 810 Vermont Avenue NW, Washington, DC 20420.
- The U.S. Department of Health and Human Services, Office for Civil Rights at <http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html>
- The Office of the Inspector General. <http://www.va.gov/oig/contact/default.asp>
- Complaints do not have to be in writing, though it is recommended.
- An individual filing a complaint will not face retaliation by any VA/VHA organization or VA/VHA employee.

Changes. We reserve the right to change this Notice. The revised privacy practices will pertain to all existing health information, as well as health information we receive in the future. Should there be any changes we will make available to you a copy of the revised Notice within 60 days of any change.

When We May Use or Disclose Your Health Information Without Your Authorization

Treatment. We may use and disclose your health information for treatment or to provide health care services. Treatment may include:

- Emergency and routine health care or services, including but not limited to labs and x-rays; clinic visits; inpatient admissions
- Contacting you to provide appointment reminders or information about treatment alternatives
- Prescriptions for medications, supplies, and equipment
- Coordination of care, including care from non-VHA providers
- Coordination of care with DoD, including electronic information exchange

NOTE: *If you are an active duty service member, Reservist or National Guard member, your health information is available to DoD providers with whom you have a treatment relationship. Your protected health information is on an electronic database that is shared between VHA and DoD. VHA does not have the ability to restrict DoD's access to your information in this database, even if you ask us to do so.*

Examples:

1) A Veteran sees a VHA doctor who prescribes medication based on the Veteran's health information. The VHA pharmacy uses this information to fill the prescription.

- 2) A Veteran is taken to a community hospital emergency room. Upon request from the emergency room, VHA discloses health information to the non-VHA hospital that needs the information to treat this Veteran.
- 3) A National Guard member seeks mental health care from VHA. VHA discloses this information to DoD by entering the information into a database that may be accessed by DoD providers at some future date.

Payment. We may use and disclose your health information for payment purposes or to receive reimbursement for care provided, including:

- Determining eligibility for health care services
- Paying for non-VHA care and services, including but not limited to, CHAMPVA and fee basis
- Coordinating benefits with other insurance payers
- Finding or verifying coverage under a health insurance plan or policy
- Allowing you to pay for your health care out of pocket so that your insurance is not billed
- Pre-certifying benefits
- Billing and collecting for health care services provided
- Providing personal information to consumer reporting agencies regarding delinquent debt owed to VHA

Examples:

- 1) A Veteran is seeking care at a VHA health care facility. VA uses the Veteran's health information to determine eligibility for health care services.
- 2) The VHA health care facility discloses a Veteran's health information to a private health insurance company to seek and receive payment for the care and services provided to the Veteran.

Health Care Operations. We may use or disclose your health information without your authorization to support the activities related to health care, including:

- Improving quality of care or services
- Conducting Veteran and beneficiary satisfaction surveys
- Reviewing competence or qualifications of health care professionals
- Providing information about treatment alternatives or other health-related benefits and services
- Conducting health care training programs
- Managing, budgeting and planning activities and reports
- Improving health care processes, reducing health care costs and assessing organizational performance
- Developing, maintaining and supporting computer systems
- Legal services
- Conducting accreditation activities
- Certifying, licensing, or credentialing of health care professionals
- Conducting audits and compliance programs, including fraud, waste and abuse investigations

Examples:

- 1) Medical Service, within a VHA health care facility, uses the health information of diabetic Veterans as part of a quality of care review process to determine if the care was provided in accordance with the established best clinical practices.
- 2) A VHA health care facility discloses a Veteran's health information to the Department of Justice (DOJ) attorneys assigned to VA for defense of VHA in litigation.

Eligibility and Enrollment for Federal Benefits. We may use or disclose your health information to other programs within VA or other Federal agencies, such as the Veterans Benefits Administration, Internal Revenue Service or Social Security Administration, to determine your eligibility for Federal benefits.

Abuse Reporting. We may use or disclose your health information without your authorization to report suspected child abuse, including child pornography; elder abuse or neglect; or domestic violence to appropriate Federal, State, local, or tribal authorities. This reporting is for the health and safety of the suspected victim.

Health and Safety Activities. We may use or disclose your health information without your authorization when necessary to prevent or lessen a serious threat to the health and safety of the public, yourself, or another person. Any disclosure would only be to someone able to help prevent or lessen the harm, such as a law enforcement agency or the person threatened. You will be notified in writing if any such disclosure has been made by a VHA health care facility.

Public Health Activities. We may disclose your health information without your authorization to public health and regulatory authorities, including the Food and Drug Administration (FDA) and Centers for Disease Control (CDC), for public health activities. Public health activities may include:

- Controlling and preventing disease, injury, or disability
- Reporting vital events such as births and deaths
- Reporting communicable diseases such as hepatitis, tuberculosis, sexually transmitted diseases & HIV
- Tracking FDA-regulated products
- Reporting adverse events and product defects or problems
- Enabling product recalls, repairs or replacements

Judicial or Administrative Proceedings. We may disclose your health information without your authorization for judicial or administrative proceedings, including:

- We receive an order of a court, such as a subpoena signed by a judge, or administrative tribunal, requiring the disclosure
- To defend VA in judicial and administrative proceedings

Law Enforcement. We may disclose your health information to law enforcement agencies for law enforcement purposes when applicable legal requirements are met. These law enforcement purposes may include:

- Responding to a court order
- Responding to a specific request when in pursuit of a focused civil or criminal law enforcement investigation
- Reporting crimes occurring at a VHA site
- Identifying or apprehending an individual who has admitted to participating in a violent crime
- Reporting a death where there is a suspicion that death has occurred as a result of a crime
- Reporting Fugitive Felons
- Routine reporting to law enforcement agencies, such as gunshot wounds
- Providing certain information to identify or locate a suspect, fugitive, material witness, or missing person

Health Care Oversight. We may disclose your health information to a governmental health care oversight agency (e.g., Inspector General; House Veterans Affairs Committee) for activities authorized by law, such as audits, investigations, and inspections. Health care oversight agencies include government agencies that oversee the health care system, government benefit programs, other government regulatory programs, and agencies that enforce civil rights laws.

Cadaveric Organ, Eye, or Tissue Donation. When you are an organ donor and death is imminent, we may use or disclose your relevant health information to an Organ Procurement Organization (OPO), or other entity designated by the OPO, for the purpose of determining suitability of your organs or tissues for organ donation. If you have not specified your donation preferences and can no longer do so, your family may make the determination regarding organ donation on your behalf.

Coroner or Funeral Services. Upon your death, we may disclose your health information to a funeral director for burial purposes, as authorized by law. We may also disclose your health information to a coroner or medical examiner for identification purposes, determining cause of death, or performing other duties authorized by law.

Services. We may provide your health information to individuals, companies and others who need to see your information to perform a function or service for or on behalf of VHA. An appropriately executed contract and business associate agreement must be in place securing your information.

National Security Matters. We may use and disclose your health information without your authorization to authorized Federal officials for the purpose of conducting national security and intelligence activities. These activities may include protective services for the President and others.

Workers' Compensation. We may use or disclose your health information without your authorization to comply with workers' compensation laws and other similar programs.

Correctional Facilities. We may disclose your health information without your authorization to a correctional facility if you are an inmate and disclosure is necessary to provide you with health care; to protect the health and safety of you or others; or for the safety of the facility.

Required by Law. We may use or disclose your health information for other purposes to the extent required or mandated by Federal law (e.g., to comply with the Americans with Disabilities Act; to comply with the Freedom of Information Act (FOIA); to comply with a Health Insurance Portability and Accountability Act (HIPAA) privacy or security rule complaint investigation or review by the Department of Health and Human Services).

Activities Related to Research. Before we may use health information for research, all research projects must go through a special VHA approval process. This process requires an Institutional Review Board (IRB) to evaluate the project and its use of health information based on, among other things, the level of risk to you and to your privacy. For many research projects, including any in which you are physically examined or provided care as part of the research, you will be asked to sign a consent form to participate in the project and a separate authorization form for use and possibly disclosure of your information. However, there are times when we may use your health information without an authorization, such as, when:

- A researcher is preparing a plan for a research project. For example, a researcher needs to examine patient medical records to identify patients with specific medical needs. The researcher must agree to use this information only to prepare a plan for a research study; the researcher may not use it to contact you or actually conduct the study. The researcher also must agree not to remove that information from the VHA health care facility. These activities are considered preparatory to research.
- The IRB approves a waiver of informed consent and a waiver of authorization to use or disclose health information for the research because privacy and confidentiality risks are minimal and other regulatory criteria are satisfied.
- A Limited Data Set containing only *indirectly* identifiable health information (such as dates, unique characteristics, unique numbers or zip codes) is used or disclosed, with a data use agreement (DUA) in place.

Military Activities. We may use or disclose your health information without your authorization if you are a member of the Armed Forces, for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, when applicable legal requirements are met. Members of the Armed Forces include Active Duty Service members and in some cases Reservist and National Guard members. An example of a military activity includes the disclosure of your health information to determine fitness for duty or deployment to your Base Commander.

Academic Affiliates. We may use or disclose your health information, without your authorization, to support our education and training program for students and residents to enhance the quality of care provided to you.

State Prescription Drug Reporting Program (SPDMP). We may use or disclose your health information, without your authorization, to a SPDMP in an effort to promote the sharing of prescription information to ensure appropriate medical care.

General Information Disclosures. We may disclose general information about you to your family and friends. These disclosures will be made only as necessary and on a need-to-know basis consistent with good medical and ethical practices, unless otherwise directed by you or your personal representative. General information is limited to:

- Verification of identity
- Your condition described in general terms (e.g., critical, stable, good, prognosis poor)
- Your location in a VHA health care facility (e.g., building, floor, or room number)

Verbal Disclosures to Others While You Are Present. When you are present, or otherwise available, we may disclose your health information to your next-of-kin, family or to other individuals that you identify. For example, your doctor may talk to your spouse about your condition while at your bedside. Before we make such a disclosure, we will ask you if you object. We will not make the disclosure if you object.

Verbal Disclosures to Others When You Are Not Present. When you are not present, or are unavailable, VHA health care providers may discuss your health care or payment for your health care with your next-of-kin, family, or others with a significant relationship to you without your authorization. This will only be done if it is determined that it is in your best interests. We will limit the disclosure to information that is directly relevant to the other person's involvement with your health care or payment for your health care.

Examples of this type of disclosure may include questions or discussions concerning your in-patient medical care, home-based care, medical supplies such as a wheelchair, and filled prescriptions.

IMPORTANT NOTE: *A copy of your medical records can be provided to family, next-of-kin, or other individuals involved in your care only if we have your signed, written authorization or if the individual is your authorized surrogate (the individual who is authorized to make health care decisions on your behalf if you can no longer do so) and the practitioner determines that the information is needed for the individual to make an informed decision regarding your treatment.*

When We Offer You the Opportunity to Decline to the Use or Disclosure of Your Health Information

Patient Directories. Unless you opt-out of the VHA medical center patient directory when being admitted to a VHA health care facility, we may list your general condition, religious affiliation and the location where you are receiving care. This information may be disclosed to people who ask for you by name. Your religious affiliation will only be disclosed to members of the clergy who ask for you by name. **If you do object to being listed in the Patient Directory, no information will be given out about you unless there is other legal authority. This means your family and friends will not be able to find what room you are in while you are in the hospital. It also means you will not be able to receive flowers or mail, including Federal benefits checks, while you are an inpatient in the hospital or nursing home. All flowers and mail will be returned to the sender.**

When We Will Not Use or Disclose Your Health Information

Sale of Health Information. We will not sell your health information. Receipt of a fee expressly permitted by law, such as Privacy Act copying fees or FOIA fees is not a sale of health information.

Genetic Information Nondiscrimination Act (GINA). We will not use genetic information to discriminate against you either through employment or to determine your eligibility for VA benefits.

Contact Information.

You may contact your VHA health care facility's Privacy Officer if you have questions regarding the privacy of your health information or if you would like further explanation of this Notice. The VHA Privacy Office may be reached by mail at VHA Privacy Office, Office of Informatics and Analytics (10P2C1), 810 Vermont Avenue NW, Washington, DC 20420 or by telephone at 1-877-461-5038.

NOTE: *A large print version of this Notice is available upon request from the facility where you are receiving care.*

Appendix M

Letters



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
50 Irving Street, N.W.
Washington, DC 20422

November 5, 2013

Ms. Dora Ifon, MS, RN, AGPCNP-BC
Washington DC VAMC
50 Irving St NW
Washington, DC 20422

Dear Ms. Ifon:

This is a letter of support for Ms. Ifon to collect data from the DC VAMC for the research proposal, "Glycemic Control in Elderly Diabetics: A Function of Informal Caregiver Health Literacy Dissertation Proposal." The dissertation proposal must be approved by the DC VAMC IRB and R&D Committees with the signature of the ACOS for Research and Development Dr. Blackman.

You have been in contact with me regarding the development of the research proposal. We are interested to see the start of the dissertation research. Please feel free to contact me regarding any questions related to the IRB.

Sincerely,

Suzanne McNicholas, PhD, RN, CIP
Suzanne McNicholas, PhD, RN, CIP

c. James D. Finkelstein, MD IRB Chair

From: TDavis1@lsuhsc.edu
To: difon05@hotmail.com
CC: creyn1@lsuhsc.edu
Subject: Re: REALM
Date: Tue, 27 Aug 2013 13:45:34 +0000

Dora

I a, delighted you want to use the REALM you do not need my permission.
Do you need copy of manual Or the test

Terry

Sent from my iPad

From: creyn1@lsuhsc.edu
To: difon05@hotmail.com
Subject: Info about REALM
Date: Tue, 15 Oct 2013 20:03:30 +0000

Hi Dora;

We are excited to learn of your interest in literacy and in the REALM. I'm Cristalyn Reynolds, Terry Davis's research assistant. She asked me to respond to your request about the REALM.

The REALM is available in kit form or as individual pieces, the kit includes the manual, one tablet of examiner's sheets, and 4 laminated patient word lists. Information about test development, administration and scoring can be found in the *REALM Administration Manual*. The tablet contains 50 examiner record forms that may be photocopied. The laminated purple page is the word list that is given to the patient. Dr. Davis asks that for actual patient testing, staff use this specially formatted laminated patient word list. Additional materials are available upon request.

The REALM is not available in Spanish. Reading recognition tests like the REALM are a standard method of screening for reading ability in English but not in other languages. A great Spanish speaking literacy test is the SAHLSA (Short Assessment of Health Literacy for Spanish-speaking Adults), which is designed after the REALM. You can contact Dr. Shoou-Yih D. Lee at sylee@email.unc.edu for a copy of the test.

The REALM has been copyrighted; however, it is in the public domain. You do not need permission to use the REALM.

The most up to date review of literacy testing in health care research is a chapter that Dr. Davis wrote with colleagues who developed the TOHFLA (Test Of Functional Health Literacy In Adults). The chapter is found in a recent AMA book, Understanding Health Literacy. Joanne G, Schwartzberg, M.D. is the editor, which is attached to this email.

you have any questions, do not hesitate to call (318) 675-4585 or e-mail me at creyn1@lsuhsc.edu.

Thank you for your interest.

Cristalyn Reynolds // Research Associate

Department of Medicine

LSUHSC-Shreveport

1501 Kings Highway

Shreveport, LA 71130

P (318) 675-4585 F (318) 675-4319

creyn1@lsuhsc.edu