THE ASSOCIATION BETWEEN HEALTH LITERACY AND DIABETES OUTCOMES AND SELF-MANAGEMENT BEHAVIORS AMONG OLDER ADULTS IN THE U.S

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ABSTRACT

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Background: In the United States an estimated 10.9 million people aged 65 and older are living with diabetes mellitus. Previous research has found that demographic and socioeconomic factors, health status, health behaviors, and interventions are potential determinants of diabetes outcomes. Recent studies have found that limited health literacy may be a potential new determinant of diabetes outcomes. Limited health literacy is common in underrepresented and marginalized groups such as people with low economic status, low educational attainment, new immigrants, the elderly, racial and ethnic minorities, and patients with chronic conditions. Older adults are at higher risk of developing chronic complications from improper diabetes self-management and self-care.

Purpose: In this dissertation, we explore the association between health literacy and diabetes outcomes and self-management behaviors among older persons with an imputed health literacy score derived from demographic information.

Methods: This study is a secondary analysis of existing cross-sectional data from the National Health & Nutrition Examination Surveys (2009-2010), in the United States. The final sample consisted of 779 participants who were ≥55 years and older and diagnosed with DM by self-report or through bio-marker laboratory testing. The predictor and outcome variables were DAHL proxy health literacy score, categorized as adequate (HL>76), marginal (HL 63-75), and inadequate (HL<62); biomarker test (HbA1c, FBG, OGTT); and known indicators of proper diabetes management. The proxy HL score used in the present study was derived from four demographic variables (gender, age, education, and marital status). Hierarchical multiple regression, hierarchical logistic regressions, and linear regressions were performed to test the hypotheses and to determine the strength of the relationship between the proxy HL scores diabetes outcomes and self-management behaviors.

Results: 1 in 3 participants were not aware of their DM positive status. Hierarchical regression analysis revealed that after controlling for the effect of covariates, health literacy score was not a significant predictor of glycohemoglobin score, (β=−.003; Sig F change; p = 0.66). Proxy health literacy score contributed to the prediction of fasting blood glucose in Block 2, and made a unique contribution (β=−.392; Sig F. change: p = .028) to the full model. The fully adjusted hierarchical regression models for HbA1c showed that HL did not add any variability to the model. The fully adjusted FBG model was not statistically significant. After controlling for covariates, we found that in separate hierarchical logistic regression, health literacy level, was not associated with predicting the odds of the eight indicators of proper diabetes management. Furthermore, the R^2 change attributed solely to the addition of health literacy level did not exceed 2.7% for any of the logistic regression models.

Conclusion: The present study supports previous findings that found no association between HbA1c, diabetes self-management behaviors and health literacy. This study found that the characteristics of individuals who were not aware of their diabetes status was higher among subjects that were younger, more educated, higher socioeconomic status and not married. More studies are needed to examine factors associated with diabetes self-management behaviors that take into account individual health literacy, diabetes knowledge, and create targeted initiatives that decrease the risk factors associated with diabetes among the aging population.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ACRONYMS

AA ……………………….	African American
AADE…………………….	American Association of Diabetes Educators
ADA……………..............	American Diabetes Association
ADL………………………	Activities of Daily Living
AHA……………..............	American Heart Association
AHRQ…………………….	Agency for Healthcare Research and Quality
BP……………….............	Blood Pressure
BMI ……………..............	Body Mass Index
CAD………………………	Coronary Artery Disease
CDC………………………	Centers for Disease Control and Prevention
CHD………………………	Coronary Heart Disease
CHIRr…………………….	Consumer Health Informatics Research Resource
CSLR……………………..	Complex Samples Logistic Regression Procedure
CVD ……………………...	Cardiovascular Disease
DAHL…………………….	Demographic Assessment for Health Literacy
DKQ ……………………..	Diabetes Knowledge Questionnaire
DM………………………...	Diabetes Mellitus
eAG………………………..	Estimated Average Glucose
GDM………………………	Gestational Diabetes Mellitus
GED……………………….	General Education Diploma
HbA1c …………………….	Glycated Hemoglobin or glycosylated hemoglobin
HHS……………………….	U.S. Department of Health and Human Service
HL…………………………	Health Literacy
HRS……………………….	Health and Retirement Study
HS ………………………...	High School
IDF………………………...	International Diabetes Federation
IPDSM…………………….	Indicators of proper diabetes management
IOM……………………….	Institute of Medicine

LDL……………………….	Low-density lipoprotein
MEC………………………	Mobile Examination Center
MeSH……………………...	Medical Subject Heading
Mg/dL……………………...	Milligrams per Deciliter
Mm/Hg…………………….	Millimeter of Mercury
MVU………………………	Masked Variance Unit
mmol/L…………………….	Millimoles per Liter
NAAL……………………...	National Assessment of Adult Literacy
NCES……………………...	National Center for Education Statistics
NCHS ……………………..	National Center for Health Statistics
NDIC………………………	National Diabetes Information Clearinghouse
NGSP……………………...	National HbA1c Standardization Program
NIH………………………...	National Institutes of Health
NHANES …………………	National Health and Nutrition Examination Surveys
NHIS………………………	National Health Interview Survey
NIDDK……………………	National Institute of Diabetes, Digestive, and Kidney Disea
NLM……………………….	National Library of Medicine
NVS………………………..	New Vital Statistics
OGTT……………………...	Two-Hour Glucose Tolerance Test
PIR…………………………	Poverty Income Ratio
PSU………………………...	Primary Sampling Unit
PVT………………………..	Poverty Ratio
REALM…………………….	Rapid Estimate of Adult Literacy in Medicine
ROC………………………..	Receiver Operating Characteristic
SDSCA…………………….	Summary of Diabetes Self-Care Activities
STD………………………..	Sexually Transmitted Diseases
S-TOFHLA………………..	Spanish Test of Functional Health Literacy in Adults
T2D………………………...	Type 2 Diabetes
TOFHLA…………………..	Test of Functional Health Literacy in Adults
WHO………………………	World Health Organization

DEDICATION

To my dear son Benjamin; you are my greatest blessing. You show me the beauty of life every single day and I am so incredibly fortunate to be your mother. You are, my everything. Te Amo.

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Preface

The conceptual model of diabetes management suggests that demographic and socioeconomic factors, health status, health behaviors, and interventions are potential determinants of diabetes outcomes (Brown et al., 2004). In recent years, a number of studies have suggested that limited health literacy may be a potential new determinant of diabetes outcomes. Limited health literacy is common in patients with diabetes, and has been associated with worse diabetes outcomes since the late 1990's (Schillinger et al., 2002). Poor health literacy disproportionately affects people from low economic status, people who have low educational attainment, recent immigrants, the elderly, racial and ethnic minorities, and patients with chronic conditions (Cowie et al., 1995; Schillinger et al., 2002). Inadequate literacy pervades our society, especially among the elderly population, and must be considered in patient education because they are at a higher risk of developing chronic complications (Kirsch et al., 1993; Mayeaux, 1996). Insights into the complex determinant of diabetes outcomes may be useful for tailoring intervention programs to help reduce diabetes-related health disparities (Yamashita et al., 2011).

Diabetes among older adults is a complex chronic disease that affects multiple domains: emotional, psychological, physical, social, and financial (Jack, 2004). Response to this health burden requires more than focusing solely on patient's bio-markers e.g., (HbA1c, BP, cholesterol, blood glucose) and pharmaceutical interventions to control them. Consideration must be given to patient's external environment (social and physical). Recognizing the importance of these factors is at the heart of public health, which acknowledges that health behavior is shaped by psychological, social, and anthropological factors which impact the individual at multiple levels. On a community level, health education programs should be tailored to meet the special demands of particular groups in order to enhance quality of life, prevent disease progression, and reinforce self-care recommendations. On a systems level, providers should engage in proper and continuous health literacy screenings in order to identify at risk groups along with providing pharmaceutical interventions. On an individual level, patients must have the necessary tools to engage in proper daily diabetes self-management.

CHAPTER I

INTRODUCTION

Overview

Diabetes Mellitus (DM) is a significant problem in the United States that affects an estimated 10.9 million people, or 26.9 % of the population aged 65 and older. An estimated 1.9 million people aged 20 years or older were newly diagnosed with diabetes in 2010 alone (Centers for Disease Control, 2011), and another 54 million were determined to be at risk for developing the chronic condition (Chaudhry, 2005). The prevalence of diabetes in the U.S. is expected to increase exponentially in the future given the continued increase in the prevalence of associated risk factors such as older age, obesity (Boyle et al., 2001), sedentary life-styles, and family history. Projections have indicated that the prevalence of diabetes will increase to an estimated 366 million cases worldwide by the year 2030 (Wild et al., 2004), with 39 million cases in the U.S. by the year 2050 (Honeycutt et al., 2003).

Statement of the Problem

In the U.S., the death rate for diabetes increased by 45% from the years 1970 to 2002 (Jemal et al., 2005), and in 2011, diabetes became the seventh leading cause of death in the U.S. (CDC, 2011)**.** Diabetes is likely to be underreported as a cause of death because diabetes complications are often an underlying cause of death (NIDDK, 2011). Chronic complications of diabetes tend to be more severe among older adults (Morley, 2008). Such complications included blindness, amputations, nephropathy, retinopathy, higher rates of hospitalizations, and increased mortality risk among others. Diabetes is a chronic disease that often requires patients to alter their lifelong behaviors, engage in routine self-monitoring, and adhere to other recommended self-care behaviors (Funnell et al., 2010). The intricacies of the diabetic diet, insulin injection, exercise, home glucose level monitoring, and other self-management behaviors, place an even greater educational requirements on patients to adhere to the recommended diabetes management regimen (AADE, 1995; ADA, 1996). Poorly controlled diabetes can cause individuals to experience overall poorer health status, reduce their quality of life, and early mortality.

The complexities of diabetes care require an informed individual to seek, obtain, and comprehend information to actively engage in proper self-care. Health outcomes for adults with diabetes are better for those who can optimally incorporate self-management of their diabetes into their daily lives (Sigurdardottir, 2005). Adequate self-management requires that patients collect, process, and comprehend diabetes specific information in a manner that allows them to appropriately implement recommended treatment solutions related to diet and nutrition, exercise, weight management, stress management, feet, eye self-check, and compliance with glucose monitoring and medications (Yamashita, 2011). Decreasing elevated blood pressure (BP), low-density lipoprotein (LDL), and glycated hemoglobin (HbA1C) in patients with Type 2 diabetes (T2D) reduces the risk of cardiovascular events by 50% (Gaede et al., 2003). However, people with diabetes are more likely to experience a heart attack or stroke and have worse prognosis (World Heart Federation, 2012). Compared to the general population, diabetics are more likely to have elevated depression symptoms and higher rates of clinical depression (Golden et al., 2008). Recent research findings indicate that fewer than one- half of all T2D U.S. adults adequately control their disease (Yamashita, 2011).

The health disparities research model recognizes the importance of identifying vulnerable populations as a necessary first step in addressing a wide array of public health problems (Kilbourne, 2006). Limited health literacy is potentially a barrier to improving healthcare quality and outcomes and is a concern to patient safety. Patients with diabetes and low literacy have poorer knowledge of their disease (Gazmararian, 1999; William et al., 1998; Hawthorne et al., 1999; Nurss et al., 1997; Schillinger et al., 2002; Kicklighter et al., 1993), and may have difficulties learning the advanced self-care skills needed to improve glycemic control, particularly in a fast-paced and multifaceted health care system. Patients with poor health literacy levels have difficulties that range from reading labels on pill bottles and interpreting blood sugar values or dosing schedules, to comprehending appointment slips, educational brochures, or informed consent documents (Williams, 1995). Patients with poor health literacy also have greater difficulties naming their medications and describing their indications (Baker, 1997), more frequently hold health beliefs that interfere with adherence (Kalichman, 1999), and are more likely to have poor understanding of their conditions and its management (Kalichman, 2000; Williams et al., 1998). Consequently, they experience a greater number of hospitalizations and emergency room visits and have higher medical expenditures (Baker et al., 2002; Howard et al., 2005). In the context of health care systems in which scientific advances and market forces place greater technical and self-management demands on patients, poor health literacy may be a particularly important barrier to chronic disease care (Schillinger, 2002) and a significant component in health disparities research among the aging population.

To date, there have been a limited number of studies that have evaluated the relationship between health literacy and diabetes (self-management skills and outcomes), and these studies have produced mixed results. Some studies have suggested that no association exists between the health literacy (HL) and DM outcomes (Morris et al., 2006; Mancuso et al., 2010). The lack of positive results may be due to over adjustment i.e., the researchers may have controlled for too many potential confounders (Berkman, 2011). It has been recommended that the linkage between patient's literacy skills and health outcomes be studied in larger samples to better understand the relationships (Williams, 1998). The vast majority of published reports have measured health literacy exclusively with one of the three most frequently used health literacy measures (TOFHLA, REALMS & NVS). This common practice has limited the use of national population surveys because they do not incorporate one of these health literacy measures into their questionnaires. To date, existing health literacy studies have been conducted in clinical and hospital settings, administered directly to each participant, or with the use of medical records.

Among diabetes patients, previous studies have found a disproportionate number of people with low health literacy. Even among those who attend formal diabetes education programs, many do not master basic concepts needed to manage their disease (William et al., 1998). Despite the availability of extensive health education materials with relatively consistent content, many are written at too high a reading level for low-literate patients to comprehend essential points (Leichter et al., 1981; Boyd et al., 1983; Meade et al., 1989; Davis et al., 1990; Dixon et al., 1990). Many reports have emphasized that patients' literacy skills must be considered in the care and education of patients with chronic disease such as diabetes (Francis et al., 1991; Bronner et al., 1995; Overland et al., 1993; Hinnen et al., 1993; Doak et al., 1993). Other studies have demonstrated that literacy is independently associated with self-rated health (Baker et al., 1997; Wolf et al., 2005), risk of hospitalization (Baker et al., 2002), knowledge of self-management practices (William et al., 1998), and metabolic control in adult-onset T2D (Schillinger et al., 2002). It is estimated that between one-third to one-half of individuals with T2D, have inadequate or marginal literacy skills (Schillinger et al., 2002; Cowie et al., 1995). Given the significant association with other co-morbidities and complications it is particularly important to achieve adherence to lessen the progression of complications from diabetes.

There are several possible explanations for why previous research has been equivocal as to whether health literacy is a barrier to proper diabetes management and control among older adults. First, although there are reasons to believe that poor health literacy may directly contribute to poor outcomes, there is uncertainty as to whether health literacy is merely associated with or causally related to diabetes outcomes (Schillinger, 2002). Second, clinicians could be neglecting to provide ongoing screening for health literacy among older patients because they dismiss their ability to comprehend important management information. This increases the risk for poor patient-provider communication. Third, patients may feel shame or embarrassment acknowledging that they do not understand, hence misleading health professions to believe they evidently understand the health message being conveyed to them. Fourth, the health care community has not been quick to adapt to this potential barrier. Lastly, the public health and scientific community may have mistakenly assumed that receiving a diabetes diagnosis instills a sense of urgency which prompts patients to follow through with a recommended treatment regimen. Unfortunately, this may not be the case for many patients because they fail to recognize the severity of their disease. Thus, from the public health perspective, health literacy may represent an important variable explaining the prevalence of poor health outcomes among elderly patients with type 2 diabetes (Harris, 2000), as well as some of the socioeconomic, racial and ethnic disparities in diabetes outcomes in the United States (Healthy People, 2001; Harris, 1995).

The objectives of this study were to:

(1) To test the relationship between diabetes biomarkers (hemoglobin A1c, two-hour glucose tolerance test, and fasting glucose) and health literacy using an imputed measure known as the Demographic Assessment for Health Literacy or DAHL; (respondents are classified into three groups: adequate, marginal, and inadequate health literacy.

(2) Determine whether DAHL level is associated with eight known indicators of proper diabetes self-management behaviors (physical activity, diabetes specialist, primary doctor visits, medication use, controlled BP, glucose check, foot exam, and eyes checked.

This study used the 2009-2010 National Health and Nutrition Examination Survey (NHANES) to assess the relationship between DAHL status and three diabetes biomarker measures: HbA1c, two-hour glucose tolerance test, and fasting glucose serum. All of the variables selected for use in this study were selected because they have been found to be important in previous studies.

Research Question 1: Among older U.S adults with diabetes, is adequate, marginal, and inadequate health literacy status (DAHL level) associated with higher diabetes biomarker levels (HbA1c levels, fasting glucose levels, and 2-hour tolerance glucose test scores)?

Research Question 2: Among U.S adults with diabetes, is DAHL status associated with indicators of proper diabetes self-management (IPDSM) (i) physical activity, (ii)time since last diabetes specialist visit, (iii) oral hypoglycemic medication use (iv) insulin use (v) target BP, and (vi) blood glucose check.. We conducted secondary analysis on two variables: (vii) foot exam and (viii) eyes exam; these variables are also indicators of proper diabetes self-management behaviors according to the ADA but have been shown in previous literature to be of small association to health literacy.

CHAPTER II

REVIEW OF THE LITERATURE

Overview

To date, there are few published research studies on the association between health literacy and diabetes self-management behaviors. The literature used for this review includes a comprehensive analysis of research finding from various electronic searches including key terms in the title, abstract, or MeSH (Medical Subject Heading): diabetes management, aging, older adults, health literacy, diabetes barriers, HbA1c levels, diabetes outcomes, among others. The search was limited to peer-reviewed articles using Medline databases published from January 1995 to April 2012 consisting of studies conducted in the United States using older adults as the sample population. Reference lists from included articles were reviewed to identify additional studies. For the purpose of this literature review, health literacy studies were separated from those that only measure numeracy, oral literacy, only diabetes literacy/numeracy, or literacy alone.

Defining Health Literacy

In 1999, health literacy was defined by the National Academy of Sciences, National Library of Medicine (NLM), Healthy People 2010 and the Institute of Medicine (IOM). By definition, health literacy is the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions (Ratzan and Parker, 2000). The concept of health literacy represents a constellation of skills necessary to function effectively in the health care environment and is more than simply the ability to read. Health literacy requires an ability to listen, to analyze, and to act appropriately on health care information (Berkman, 2011). Some authors include in this definition a working knowledge of disease processes, an ability to use technology, ability to network and interact with others socially, motivation for policy change, and self-efficacy (Berkman, 2011). Expanded definitions of health literacy include, understanding the social determinants of health as an important component of health literacy (Wang, 2000; Nutbeam, 2000). According to the World Health Organization (WHO, 2008) literacy report, "the scope of health literacy should be expanded to include the ability to access, understand, evaluate, and communicate information on the social determinants of health".

In 2003, the National Centre for Education Statistics of the U.S. Department of Education developed a survey entitled "National Assessment of Adult Literacy" (NAAL). The broadest examination of adult literacy to date -the NAAL surveyed more than 19,000 adults age 16 and older and included items intended to directly measure health literacy (AHRQ, 2011). The NAAL report found that approximately 75 million adults aged 16 years and older, were projected to have literacy skills in the *Basic* and *Below Basic* range on the literacy scale. Some of the key findings suggest that the most over represented group is the *below basic level*; in this group, adults 65 and older, scored lower than their youngest counterparts. Whites scored highest, followed by Pacific Islanders/Asians, Blacks, and Hispanics (Kutner et al., 2003). Other important findings were that adults who received government sponsored insurance coverage (Medicaid or Medicare) and adults who had no health insurance, had lower average health literacy than those who were covered by other types of insurance (Kutner et al., 2003). The

NAAL found a higher prevalence of poor health literacy among the elderly U.S. population (Baker et al., 2002). Compared with the 36% of all adults who scored in the bottom two categories on the NAAL survey, 59% of adults age 65 and older scored in the "below basic" and "basic" range (Berkman, 2011). Taken together, these findings identify ethnic minority older adults with low educational attainment and lacking health insurance or receiving Medicaid or Medicare benefits as the group most at risk for low literacy.

For the purpose of the current study, limited health literacy, low health literacy, inadequate health literacy, and below basic health literacy, are used interchangeably to define health literacy levels below intermediate/marginal skills. This is due to the previous definitions set forth by preceding research and resulting in various names to define poor health literacy. The National Assessment of Adult Literacy identified the following four levels of health literacy (Kutner et al., 2003). Below Basic: indicates no more than the most simple and concrete literacy skills- 14% of the population was in this level (NAAL Results Report, 2006, p.5). Example: Being able to identify and correctly circle the date of a medical appointment on a hospital slip.

Basic: indicates skills necessary to perform simple and everyday literacy activities- 21% of the population was in this level (NAAL Results Report, 2006, p.5). Example: Can give two reasons a person with no symptoms of a specific disease should be tested for that disease based on information contained in a clearly written pamphlet.

Intermediate: indicates skills necessary to perform moderately challenging literacy activities- 53% of the population was in this level (NAAL Results Report, 2006, p.5). Example: Ability to accurately interpret and understand a prescription drug label.

Proficient: indicates skills necessary to perform more complex and challenging literacy activities- 12% of the population was in this level (NAAL Result Report, 2006, p.5). Example: Can calculate an employee's share of health insurance costs for a year using a table that shows how the employee's monthly cost varies depending in income and family size.

Measuring Health Literacy

To date, instruments for measuring health literacy skill levels have focused primarily on the ability to read and pronounce words, use numbers, or interpreting food labels and pill bottle instructions. Two of the most common literacy measures are the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA). They are generally, the commonly used measures of health literacy in a health setting and have generated the most validity and reliability data (CHIRr, 2012). The Rapid Estimate of Adult Literacy in Medicine (REALM) is a screening instrument to assess an adult patient's ability to read common medical words and lay terms for body parts and illnesses. It helps health professionals estimate a patient's literacy level and potentially adjust to the appropriate level of patient education materials or oral instructions. The test takes two to three minutes to administer and score. The REALM has been correlated to other standardized tests (Davis, 1993)**.** The Test of Functional Health Literacy Assessment (TOFHLA) assesses a patient's level of comprehension of health-related material. It is available in a *full-format*, a *shortened version,* and a *Spanish version*. The passages on the TOFHLA use a modified Cloze procedure where every fifth to seventh word is omitted and subjects select the correct word from among a set of four options (Parker, 1995). Another commonly used tool is the Newest Vital Sign (NVS), a 6-question screening tool based on nutrition label questions. It takes approximately 3 minutes to administer, and serves as swift assessment of patients' literacy, which can then allow practitioners an opportunity to adapt communication to achieve better outcomes. One of the most significant limitations to these tools is the lack of consistency in the abilities being measured by the instrument. A complete list of the existing health literacy measures and screeners is available in Appendix A.

Diabetes: A Significant Public Health Problem

Type 1 diabetes is an autoimmune disease in which the immune system destroys the insulin-producing beta cells of the pancreas that help regulate blood glucose levels (NIDDK, 2011). It requires the person to administer insulin (either by injection or insulin pump) and to adhere to self-management activities. It is believed that Type 1 diabetes is triggered by certain viral infections and sometimes by environmental toxins (NIDDK, 2011). Type 2 diabetes occurs when the body does not respond to the insulin that it produces (NIDDK, 2011). Type 2 diabetes can be triggered by a variety of interrelated factors (e.g. weight, food intake, lack of exercise) and some non-modifiable factors (e.g. increasing age, ethnicity and a family history of diabetes). Gestational diabetes (GD) first appears during pregnancy. Women diagnosed with gestational diabetes have a 35% to 60% chance of developing diabetes in the next 10 to 20 years (NDIC, 2011). Diabetes is attributable to a variety of genetic, epigenetic, environmental and biological factors, many of which are outside the control of people with the condition (Colagiuri, 2010; IDF, 2010). (see Appendix B for expanded descriptions of diabetes)

Cost of Diabetes on the Health Care System

Population growth, aging, and obesity increase the likelihood of developing diabetes, and potentially a public health crisis, due to its consequences of premature death, health complications, and economic cost to the health care system (Samuel-Hodge et al., 2006). Diabetes is the seventh leading cause of death in the U.S. with the estimated total direct and indirect health care cost at $174 billion dollars in 2007 ($116 billion in excess medical expenditures and $58 billion in reduced national productivity), with experts predicting a total of $3.4 trillion by the year 2020 (CDC, 2011). In 2007, cost of inpatient hospital care was $58.3 billion and $9.9 billion on physician office visits directly attributed to diabetes (ADA, 2008). On average, medical expenditures among diagnosed diabetes patients is approximately 2.3 times higher than those without diabetes. Approximately $1 in $10 health care dollars is attributable to diabetes and $1 in $5 health care dollar is spent caring for someone with diagnosed diabetes (ADA, 2008). The 2007 per capita annual costs of health care for people with diabetes in the U.S was $11,744 a year, of which $6,649 (57%) was attributed to diabetes. Examples of indirect costs are: absenteeism, reduced productivity, and lost productive capacity due to early mortality (ADA, 2008). Poorly controlled Type 2 Diabetes can lead to life-altering complications including blindness, kidney failure, heart disease and amputations, among others, and in turn, greater health disparities among diabetic patients (IDF, 2011). Overall, the risk for death among people with diabetes is about twice that of people of similar age but without diabetes (NDIC, 2011).

Review of Literature from 1998-2012 by variable

Factors Affecting Proper Glycemic Control

Several studies on aging populations have identified factors that contribute to poor diabetes management and control, such as (i) race/ethnicity (Cowie et al., 1995), (ii) existing comorbidities (Kerr, 2007; Feil et al., 2009), (iii) duration of disease (Fox, 2004), (iv) insurance type (NAAL, 2003), and (v) education level (Baker, 2007). These studies suggest that multiple factors interact in a manner that facilitates a person's ability to follow through with proper diabetes management or alternately become barriers to self-management. It is possible that other factors such as health literacy may affect those same variables in ways that present research has yet to study in depth. To date, there have been no studies that have looked at the association between health literacy and diabetes management and control using data gathered from a population-based national survey such as the NHANES, mainly because NHANES does not include measures of health literacy. Notably, there has been no national health survey in the U.S. that has attempted to measure health literacy among the participants. A complete list of U.S.-based studies on the relationship between health literacy and diabetes self-management and outcomes (1998-2012) can be found in Appendix C.

Early Findings

In nearly two decades, a small body of research has explored health literacy and diabetes outcomes. To date, it is unclear as to whether health literacy causes or is merely associated with diabetes outcomes and diabetes management. Several studies have found significant associations between poor health literacy and poor diabetes outcomes (e.g., Schillinger et al., 2002). Williams et al. (1995) documented low rates of health literacy among patients. For example, 35.1% of English-speaking patients and 61.7% of Spanish-speaking patients seeking care at public hospitals lacked literacy skills sufficiently adequate to function in the health care settings.

Subsequently, Williams et al. (1998) examined the relationship between health literacy and knowledge of disease and treatment among patients with hypertension or diabetes. With a sample of 114 diabetes patients and 352 hypertension patients taken from 2 urban public hospitals, they measured health literacy using the TOFHLA and classified the participants into one of three categories: inadequate HL (0-59), marginal HL (60-75), or adequate HL (76-100). They also developed a questionnaire based on questions from traditional ADA, AHA, and the Joint National Committee 5th Report on Hypertension, to assess patient's knowledge of their disease. They concluded that health literacy was highly correlated with knowledge of disease.

Williams et al. (1998) found that participants with inadequate HL had less knowledge of their disease, despite having attended a diabetes education class. Participants with lower literacy levels had fewer years of schooling and were less likely to answer correctly knowledge questions about their illness. For example, 50% of diabetes participants with inadequate literacy were unable to identify physical symptoms of low blood glucose levels. However, despite the association of less knowledge of disease with lower functional HL levels, biomarkers (BP and HbA1c) were not significantly associated with literacy. They found no association between literacy level and diastolic BP; among patients with HbA1c results, the differences between patients with adequate and inadequate HL was also not significant. The most significant limitation to these findings were the number of disease outcomes studied (BP and HbA1c) and the relatively small sample size (diabetes patients); also, the study did not capture a complete measure of disease outcome or proper self-management.

Other research suggests that diabetic patients with limited health literacy have worse diabetes knowledge (Gazmararian et al., 1999; Schillinger et al., 2002; William et al., 1998; Gazmararian et al., 2003). A notable study found that higher health literacy levels were independently associated with good glycemic control and that patients with inadequate health literacy were less likely to achieve strict glycemic control (< 7%) (Schillinger et al., 2002). In this study the association between health literacy and diabetes outcomes was examined in a sample of 408 English or Spanish speaking patients from 2 primary care clinics. Health literacy was measured by the s-TOFHLA and HbA1c levels. The cross-sectional observational study asked survey questions on demographics, health related habits (alcohol use, tobacco use, illicit drug use), social support, depression symptoms, current diabetes treatment (diet, oral agents, insulin use), prior diabetes education, time since diabetes diagnosis, and diabetes complications (retinopathy, nephropathy, amputations, ischemic heart disease, cerebrovascular disease). Diabetes related social support was measured by using the Diabetes Care Profile Scale, depression was assessed with the Center for Epidemiologic Studies Depression Scale, and diabetes related conditions were assessed by asking participants if a physician had notified them as suffering from the above mentioned complications.

(Schillinger et al., 2002) found that among participants with inadequate health literacy, they had twice the likelihood of having retinopathy (adjusted OR = 2.33, $p = 0.01$) or cerebrovascular disease (adjusted OR = 2.71, $p = 0.04$). In bivariate analysis, the relationship between predictors of glycemic control and HbA1c values reveal that only health literacy, insurance status (uninsured or Medicare), and treatment regimen (diet or oral hypoglycemic agent) were independently associated with HbA1c after adjustment. Among participants with inadequate health literacy, 30% reported poor glycemic control in contrast to participants with adequate literacy where only 20% reported poor glycemic control (unadjusted OR=1.70, *p*=0.02). This means that among participants with inadequate versus adequate health literacy, the former group had 1.7 times the odds of having poor glycemic control. Nearly, 38% had inadequate health literacy and 13% had marginal health literacy. They found that patients with inadequate health literacy were: (1) older, (2) female, (3) non-white, (4) Spanish speaking, (5) on Medicare, (6) have less than high school education, (7) and have had diabetes diagnosis longer. This study was the first to explore the association between health literacy and HbA1c levels and was the first to reveal that these factors were independently associated.

Diabetes Education

Kim et al. (2004) conducted a prospective observational study of participants enrolled in a diabetes education class that followed ADA recommendations. They examined the association of health literacy with self-management behaviors among patients with diabetes and also sought to determine whether diabetes education courses improved self management behaviors among those with limited health literacy. Using the S-TOFHLA to measure health literacy, participants scoring below 22 (on a scale of 0-36) were classified as “inadequate” or “marginal health literacy” self management behaviors were assessed using the Summery of Diabetes Self-Care Activities Measure (SDSCA). This is a validated measure consisting of diet, exercise, self-glucose monitoring, foot exam, and medication adherence. They also measured diabetes knowledge using the Diabetes Knowledge Questionnaire (DKQ). In a sample of 95, they found that 23% of the participants had limited health literacy.

Kim et al. (2004) used bivariate tests to compare baseline differences, and DKQ and SDSCA scores between the health literacy groups. At baseline, lower literacy was associated with being older, having less education, having lower income, and reporting more diabetes complications. At 3-month follow-up, there was an increase in diabetes knowledge and self-management behaviors (diet, foot care, and self-glucose monitoring) among all participants but the adequate literacy group performed worse than the inadequate health literacy group in certain self-management behaviors. These findings indicate that diabetes education is beneficial to all diabetic patients regardless of health literacy level. Both groups equally benefit from educational material possibly because most had indicated receiving prior diabetes education, thereby reinforcing the information increased their knowledge and reinforced self-care behaviors. One critical finding revealed that there was no statistically significant improvement in HbA1c levels, which is a central outcome in diabetes management. This underscores the need to more effectively educate diabetes patients on the importance of achieving optimal glucose levels daily.

Race/Ethnicity and Poor Diabetes Management:

Type 2 Diabetes disproportionately affects ethnic minorities and individuals from disadvantaged backgrounds (Cowie et al., 1995). Therefore, understanding the association between health literacy and diabetes outcomes may have implications for the reduction of health disparities (Schillinger et al., 2002). African-Americans are less adherent to their diabetes medication than Whites (Trinacty et al., 2009), and as a result, have worse glycemic control than Whites (Heisler, 2007). Osborn et al. (2011) hypothesized that patient's health literacy scores would be associated with medication adherence and would explain the association between racial status and adherence. They performed path analytic models to test whether health literacy was associated with diabetes medication adherence, and whether those variables explained the relationship between African American race and less medication adherence (Osborn et al., 2011). They concluded that African-American racial status was associated with poor medication adherence ($r = -0.10$, $p < 0.05$) and that health literacy had a direct effect on medication adherence ($r = 0.12$, $p < 0.02$) (Osborn et al., 2011). Additionally, they report that African American racial status had an indirect effect on diabetes medication adherence through health literacy ($r = -0.03$, $p < 0.01$), suggesting that health literacy explained the relationship between racial status and adherence (Osborn et al., 2011).

One limitation of the Osborn et al. (2011) study was the reliance on a self-report measure of medication adherence and no assessment of other potentially important factors such as length of diagnosis, income, and advanced age. Also, the correlations between African-American racial status and poor medication adherence and health literacy and medication adherence were of low magnitude. Finally, it can be argued that other factors explain the relationships and account for the associations such as the distrust that the African American community experiences towards medicine and research.

Existing Comorbidities and Poor Diabetes Management:

The Health and Retirement Study (HRS) 2003 Diabetes Study (funded by the National Institute on Aging) found that those with a greater number of comorbidities had worse HbA1c, higher weight, higher blood pressure, longer history of diabetes, higher cognitive impairment, receiving insulin therapy, and experienced depression (Feil et al., 2009). In a nationally representative sample of 1,901 diabetes patients, Kerr et al. (2007) assessed the association between presence of comorbidities and diabetes prioritization and self-management ability, controlling for patient demographics (Kerr, 2007). Chronic conditions were classified as either concordant or discordant: diabetes concordant conditions (hypertension, neuropathy, nephropathy, retinopathy, and heart disease) may be either *microvascular* complications (e.g., retinopathy) or *macrovascular* complications (e.g., cardiovascular and cerebrovascular disease, or hypertension) (Kerr, 2007). Discordant conditions are not directly related in either their pathogenesis or management to diabetes and do not share an underlying predisposing factor (e.g., lung disease, cancer, arthritis). They hypothesized that the presence of concordant conditions would increase diabetes prioritization and self-management scores, but instead found that the presence of *microvascular*-concordant conditions was associated with lower self-management, but not lower prioritization scores (Kerr, 2007). Two or more comorbid conditions were reported by 70% of the study participants. They also found that a higher burden of *macrovascular* conditions was associated with both lower prioritization and self-management ability (Kerr, 2007). Literature shows that diabetic patients have higher morbidity and mortality rates due to *macrovascular* conditions. Evidence shows that both diabetes-related and non diabetes-related comorbidity can increase the use of medical care substantially in patients with diabetes (Struijs et al., 2006).

Role of Duration of Diabetes and Coronary Heart Disease

The mean duration of diabetes is 7.4 years for whites, 7.1 years for African-Americans, and 6.7 years for Hispanics (CDC, 2011). The mean diabetes duration is 8 years for women and 6.7 for men (CDC, 2011). The mean duration is 6.4 years among those aged 45-64 years old and 9.7 years for those aged 65-79 years (CDC, 2011). As these individuals age, they face potential increased risk of coronary heart disease death due to the duration of diabetes (Fox et al., 2004). Coronary artery disease (CAD) and cerebral vascular disease is more common in people with diabetes (CDC, 2011). Duration of diabetes increases the risk of CHD death independent of coexisting risk factors (Fox etal., 2004). In addition, poor glycemic control may contribute to neuronal damage, brain atrophy, and cognitive impairment, which is associated to CVD (Roberts et al., 2008).

Role of Education Level and Diabetes Outcomes

Nearly all health literacy studies among diabetes patients have shown a significant association between inadequate or marginal health literacy and lower levels of education regardless of age, gender, duration of disease, or insurance type especially among ethnic minorities and low social-economic status (Schillenger, 2002; Rothman, 2004; Kim., 2004). Inadequate literacy has been found to be associated with demographic characteristics and markers of socioeconomic status, such as older age, non-white, immigrant status, lower educational attainment and income (Sum et al., 2004; Kirsh et al., 1993; Nielson-Bohlman et al., 2004). The first study to explore whether health literacy mediates the effect of education on diabetes health outcome (glycemic control) was conducted by Schillenger et al. (2006). Similar to previous findings (e.g., Chaturvedi et al., 1996), they found that educational attainment was associated with better glycemic control, especially among those who were high school graduates versus those with less than high school education. Individuals with low literacy common have problems with reading and writing in a health care environment and are at greater risk for education-related health disparities. Numerous studies demonstrate that mortality rates from chronic diseases, communicable diseases, and injuries are all inversely related to education

(Pamuk et al., 1998). Education has the potential to serve as a protective barrier against disease by influencing lifestyle behaviors, developing problem-solving abilities, and better communication skills (Winkleby et al., 1992).

Indicators of Proper Diabetes Management

The best indicator of proper diabetes management is adequate glycemic monitoring and achieving the target glycemic levels daily, as well as practicing routine self-care. The following are recommendations from the American Diabetes Association for proper diabetes management (ADA, 2003). First, identifying the target blood glucose level and maintaining the recommended estimated average glucose (eAG) of 140 mg/dL. Second, reducing blood pressure reduces the risk of CVD by 33-50%, reduces the risk of microvascular complications by 33% and reduced risk of developing kidney disease by 35%. Maintaining a blood pressure below 140/90 (mm Hg) is recommended to reduce diabetes related complications. Third, controlling blood lipid below 100 mg/dL (reduction in LDL levels) reduces cardiovascular complications by 20% to 50%. Fourth, checking eyes helps detect and reduce diabetic eyes disorders and reduces severe vision loss by nearly 50% to 60%. Fifth, maintaining continuous foot care and prevention can reduce amputations by 45% to 85%. Sixth, detecting and treating diabetic kidney disease by lowering BP, since it can reduce the decline in kidney function by 30% to 70%. Seventh, maintaining a healthy diet, learning to regulate meals, making healthy eating choices, portion control, and learning to read a nutrition label. Eighth, adhering to medications and following the recommended instructions, because it helps patients feel better and helps prevent diabetes complication. Finally, attending diabetes education because it enables patients to learn coping skills, learn about the risk of diabetes complications, and reinforce daily diabetes management and self-care routines. These recommendations show that diabetes treatment regimens are complex and require making significant lifestyle changes that are difficult even for educated patients (Powell et al., 2007). A patient's health literacy status is critical to adherence and it helps clinicians and researchers anticipate a patient's ability to understand complex health regimens and to deliver better patient-centered information and instruction (Kirk et al., 2011).

Diabetes Self-Management

Diabetes self-care activities are behaviors undertaken by people with or at risk of diabetes in order to successfully manage the disease on their own self-care in diabetes has been defined as an evolutionary process of development of knowledge or awareness by learning to survive with the complex nature of the diabetes in a social context (Cooper et al., 2003). The seven essential self-care behaviors to achieve optimal diabetes outcomes include: daily glucose monitoring, exercise, healthy balance diets, medication adherence, physician check-ups every 3 months, annual eye exam, daily feet check and continuous glycemic control (ADA, 2003).

Patients are able to live long healthy lives without major complications when their diabetes is well controlled and monitored. Self-management plays an essential role to people living with this chronic disease and consequences for poorly managed diabetes are severe. For this reason, self-management is critical to individuals with diabetes. Proper self-management prevents further complication and increases quality of life. Maintaining adequate HbA1c levels is associated with decreased mortality (Tkac, 2009; Siddiqui et al., 2008; Jacobsen et al., 2008; Tesfaye et al., 2005; Schellhase et al., 2005) and fewer complications; most importantly it is recognized as an essential part of effective glycemic control and self-management (Lorig et al., 1999).

Diabetes and Quality of Life among Older Adults

Diabetes is the leading cause of kidney failure, non-traumatic lower-limb amputations, and new cases of blindness among adults in the United States (CDC, 2011). A great deal of concern for the rapidly growing aging population in the U.S. will be its ability to maintain a high level of engagement with health care professionals who can help them navigate the ever expanding scope of health information to better manage their health conditions. As the baby boomer generation enters into retirement, those at age 65 have a life expectancy of 13.8 years (Freedman et al., 2004). By 2030, the 65 and older population is projected to be close to 71 million, and the 75 and older population is projected to be nearly 33 million (CDC, 2005). Since chronic diseases prevalence increases with age, increased longevity is a major contributor to the high and steadily rising prevalence of chronic diseases and the aggregate costs of care for people with them (Thrall., 2005).

Understanding the experience of adults living with long-term diabetes provides practical patient-centered clinical recommendations and reduces the risk of diabetes complications (Chiu et al., 2011). Some of the long term experiences that diabetes patients face are amputation, blindness which in turn causes reduced activities of daily living, nerve problems, weakness, less mobility, worsening cognitive functioning, and decreased social activities. Many complications of diabetes are associated with physical disability, which is one of the most relevant predictors of quality of life. For example, amputation and blindness may limit activities of daily living (Katz et al., 1963). Nerve problems may put limitations on strengths and mobility activities (e.g., reach above the head), and the worsening cognitive function may impose limitations on instrumental activities of daily living (e.g., managing money, preparing meals, using maps) (Lawton & Brody, 1969). Among older adults, diabetes accelerates cognitive decline, physical disability, and other limitations (Hassing et al., 2004). Diabetes causes premature death, health complications, increased economic cost, and is expected to worsen over the next several decades (Mancuso, 2010).

Mortality Risk

In 2007, diabetes was found to be the underlying cause of death in 71,382 cases and was a contributing cause of death in 160,022 additional cases (CDC, Diabetes Fact Sheet, 2011). Macrovascular complications are attributed to overall morbidity and mortality in diabetes patients. Type 2 diabetes patients have two to four-fold increased risk of cardiovascular disease (CVD) compared to non-diabetics. CVD mortality rates are nearly 1.5 to 4.5 times higher compared to non-diabetics (Haffner, 2002). Among persons who suffer a myocardial event, 50% of those who are diabetic will die within one year, typically from sudden death (Miettinen et al., 1998). Diabetes is responsible for premature CVD related death among all age groups (Roper et al., 2002).Generally, individuals with low health literacy have less health knowledge, worse self-management of chronic disease, and lower use of preventative services (Baker et al., 2007).

Baker et al. (2007) conducted a prospective study of 3,260 Medicare enrollees age 65 and older from 4 U.S. cities. They analyzed differences in mortality during a 6-year period (1997-2003).They used the s-TOFHLA to assess health literacy and the mini-mental state examination to measure cognitive functioning. Using the National Death Index, they matched name, social security number, and date of birth to the participants and found a total of 815 matches. Cause of death was determined by the International Classification of Disease, 9th revision. Among the 3,260 participants, 35.7% had marginal or inadequate health literacy. Consistent with other health literacy studies, they were more likely to be older, non-white, low income, low education level, worse physical health, and worse mental health to their counterparts.

During the follow-up period, 25% of the participants died (Baker, 2007). Those with marginal health literacy (Hazard Ratio = 1.28) and inadequate health literacy (Hazard Ratio = 1.70) were more likely to die during the follow-up period. Possible explanations for the association of health literacy and mortality are health behaviors, but when they were added to the model to explain excess mortality, the results remained fairly consistent (Hazard Ratio = 1.48) among participants with inadequate health literacy (Baker, 2007). Diabetes patients who maintain the recommended glucose levels, on average gain 5 years extra of life, 8 years of sight, and 6 years free of kidney disease (Marchand, 1996). Every 1% drop in HbA1c, reduces the risk of eye, kidney, and nerve disease by 40% (CDC, 2011), decreases myocardial infarction and all-cause mortality by 14%, decreases diabetes related death by 21%, and reduces amputations or death from peripheral vascular disease by 43% (Stratton et al., 2000)

Age, Gender, and Race/Ethnicity

Findings from (Chiu, 2011) used data from the HRS 1998-2006 study of 20,433 participants to examine the changes in physical disability from midlife to older adulthood among people with and without diabetes. The results reveled that among those with diabetes and low educational levels; participants experienced faster rates of deterioration in functioning and had higher levels of physical disability over time. Being a woman, member of a minority group (both African-American and Hispanic or other), or reporting less education were associated with higher levels of physical disability (Chiu, 2011). Since diabetes is a disease that typically begins at midlife, it is important for clinicians to promote early diabetes education to help reduce short-term and long term physical disability and increase overall well-being. During aging, declining cognitive ability can impact health literacy and the trajectory of chronic disease complication such as diabetes. The association between age and health literacy has proven consistent in other studies of literacy in health care settings (Berkman, 2004). However, the majority of these studies are cross-sectional, making it difficult to determine whether the higher prevalence of poor health literacy in the elderly population results from a cohort effect (e.g., fewer educational opportunities; higher prevalence of a native language other than English) or whether literacy declines with age or cognitive function (Berkman, 2011). It is well documented that minorities are disproportionally afflicted by diabetes, partly because they have higher rates of obesity, high blood pressure, etc (ADA, 2012).

Is One Health Literacy Measure Better Than The Other?

Among the variety of health literacy measure, it is difficult to determine which health literacy measure is most appropriate for the various populations e.g., older adults, children, non-English speakers. No consensus exists on criteria to use for selecting an appropriate measure (Kirk et al., 2011). This is a special concern among the aging population given the normal decline in cognitive ability and mental acuity. Neither the REALM nor the TOFHLA capture a complete assessment of health literacy. These two measures, are indicators of reading skills (word recognition or reading comprehension and numeracy), rather than measures of the full range of skills needed for adequate health literacy (cultural and conceptual knowledge, listening, speaking, numeracy, writing and reading) (Nielsen-Bohlman et al., 2004).

Among the available health literacy measures and screeners, none are able to distinguish between (a) reading ability, (b) lack of background knowledge in health-related domains, (c) lack of familiarity with language and types of materials, or (d) cultural differences in approaches to health and health care (Nielsen-Bohlman et al., 2004). In addition, no existing measure of health literacy assesses oral communication or writing skills (Nielsen-Bohlman et al., 2004). For this reason, a proxy score for health literacy (i.e., the DAHL) will function as a screening tool because capturing the entire scope of health literacy is simply impractical since NHANES does not collect data on literacy level. Health literacy changes with time and is influenced by life course and everyday experiences. However, the instruments included in the reviewed studies capture only static measures of health literacy (Berkman et al., 2011). Participants may also face difficulty completing these screening exams given the length and complexity of most standard health literacy tools.

Kirk et al. (2011) explored this topic further by conducting a cross-sectional study utilizing in-person interviews with diabetic patients. Participants were age 60 and older. They completed 2 of 3 health literacy assessments (s-TOFHLA and REALM-SF or NVS). The goal of the study was to determine how the latter two assessments performed relative to the s-TOFHLA among an ethnically diverse sample. The sample population consisted of 563 participants of which 490 completed the s-TOFHLA health literacy assessment. Next, those same participants were administered one of two assessments: either the REALM-SF or the NVS. Among those who took the REALMS-SF, 243 successfully completed the assessment and among those who took the NVS, 205 successfully completed the assessment.

Kirk et al. (2011) found that nearly 23% of the study participants were unable to complete at least one of the literacy assessments. Among non-completers, the majority were Native American, had low educational attainment, and low income. Approximately 28.8% of the entire sample population was found to have marginal or inadequate health literacy. Among those who took the S-TOFHLA and the REALM-SF, 37.5% scored marginal or inadequate literacy. Among those who took the S-TOFHLA and the NVS, 49.8% scored marginal or inadequate literacy. Some of the reason for non-completion given by the participants included: self-admitted illiteracy, poor sight, sensory problems, and not having enough time to complete the assessment. These results led researchers to conclude that these instruments may not be useful for assessing health literacy in older adults.

Upon closer analysis, it was determined that the S-TOFHLA with the REALM-SF and the NVS had weak correlations contrasting with previous literature that report a correlation of (0.81 between the S-TOHFLA and the REALM-SF) and (0.61 between the S-TOFLHA and the NVS) (Nurss et al., 2001; Osborn et al., 2007). Others have also reported that the TOFHLA and the NVS were not comparable and are not suitable for older adults (Patel et al., 2011). However, it is cautioned that there are differences in content that could possibly explain the lack of stronger correlation among the S-TOFHLA and the REALM-SF and/or NVS (Kirk et al., 2011) and all three tools measure distinct domains (health literacy, comprehension literacy, and health literacy using a nutrition label) (Weiss et al., 2005).

The Demographic Assessment for Health Literacy (DAHL)

As few population surveys provide comprehensive assessment of health literacy, the Demographic Assessment for Health Literacy (DAHL), a readily calculated health literacy proxy measure has been found useful for expanding the scope of health literacy research in national survey data. The DAHL approach to be used in this study relies on a different method for assessing health literacy. Instead of assessing literacy abilities or skills, the DAHL estimates health literacy based on respondents socio-demographic indicators. Miller et al. (2007) proposed a similar measure based on social demographic variables. The main difference between Miller's measure and the DAHL is that the latter has been tested for external validity in population-representative samples (Hanchate et al., 2008). In this study, DAHL estimates will be based on the results from Hanchate et al. 2008 (see Table 1).

The first step in creating the DAHL scores was to use Prudential Medicare Study data to derive scoring weights that predicted S-TOFHLA scores from various predictors (Hanchate et al., 2008). Next, weights were applied to the values of the predictors in the NHIS data, to produce the imputed health literacy score for both groups of study participants. With the Prudential Medicare Study data and cutoffs scores for inadequate literacy, they performed tests of sensitivity, specificity and c-statistics [the area under the receiver operating characteristic (ROC) curve] to describe the model's ability to predict S-TOFLA-like health literacy scores. The model with the best balance of simplicity and predictive value was deemed the DAHL. The score weights for the DAHL are a sum of the score for the reference group minus adjustments for other demographic cohorts. The reference group was non-Hispanic White, Female, aged 65-69, with more than a high school education with a mean score of (91.3), the highest imputed health literacy score possible. The lowest possible score was (15.6) for non-Hispanic African American, male, less than 9th grade education, and 85 years old or greater.

Table 1.
Demographic Assessment of Health Literacy (DAHL), N=2,824

	Health Literacy Score	95% Confidence Intervals
Reference Group		
White, Female, Age 65-69, >12 years of schooling	91.3	[89.3, 93.2]
	Adjustments for other Groups	
Gender		
Male	-1.8	[-3.5, -0.27]
Age Group		
70–74	-5.5	[-7.5, -3.5]
75–79	-10.9	[-13.1, -8.65]
80–84	-16.2	[-18.9, -13.4]
85+	-27.8	[-31.8, -23.9]
Race/Ethnicity		
Black	-15.9	[-18.5, -13.4]
Hispanic	-6.7	[-9.4, –3.9]
Other	-8.7	[-15.8, -1.7]
Education Level		
0–8	-30.2	[-32.7, -27.6]
9–11	-15.9	[-18.3, -13.6]
12 or GED	-6.2	[-8.1,-4.2]

Note: From "The Demographic Assessment for Health Literacy (DAHL): A New Tool for Estimating Associations between Health Literacy and Outcomes in National Surveys" by A. Hanchete et. al., 2008, *Journal of General Internal Medicine*, p.1561-1566.

The DAHL weights (Table 1.) used in the National Health Interview Survey (NHIS) are suitable for use in analyzing NHANES data because they are comparable surveys. Both surveys are representative samples from U.S civilian non-institutionalized populations and are sponsored by the NCHS. The NHANES uses some of the same PSUs as the NHIS and some of the NHANES's household interview questions are the same as or similar to those of the NHIS (Gentleman & Pleis, 2002). However, these surveys cannot be linked because it is probable that none of the same people could be in both surveys (Gentleman & Pleis, 2002).

DAHL Development

The DAHL was developed using data from the 1997 Prudential Medicare Study (Hanchate et al., 2008). This study assessed the performance of the imputed score as a covariate in predictive models of health status in both the Prudential Medicare Study and the 1997 National Health Interview Survey. The 1997 Prudential Medicare Study assessed (n=3,260) community-dwelling adults aged 65 and older in Ohio, Florida, and Texas from 1996 to 1997 (Hanchate et al., 2008). The in-person baseline survey collected demographic information, socioeconomic information, health characteristics, and measured health literacy with the use of the S-TOFHLA. The possible range of scores on the S-TOFHLA was 0 to 100. Scores of 53 and lower were classified as inadequate health literacy, with scores equal to or greater than 54 were deemed marginal or adequate health literacy. The marginal and adequate literacy groups were merged because the marginal group was deemed as too small and shared many similarities with the adequate literacy group.

The 1997 National Health Interview Survey is an in-person, national survey which collects data from a probability sample of Americans. In 1997, it included 6,819 participants ages 65 and older. Both the NHIS and the Prudential Study share almost identical outcome measures and were considered comparable for the study of within cohort associations between health literacy measures and outcomes. The NHIS did not include any measures of health literacy and does not have measures of Activities of Daily Living (ADL).

In the Prudential Medicare Study, the S-TOFHLA, and the DAHL had a correlation of 0.58, meaning a strong positive correlation. In this study, "inadequate health literacy" was defined as those in the lowest quartile (scores ≤53) whereas the "inadequate imputed health literacy score" was defined as scores equal to or less than 62. Based on these cutting scores, the DAHL had an overall, correct classification rate of 79%, with a sensitivity rate of 59% and a specificity rate of 84% for correctly predicting adequate health literacy. When the DAHL threshold was increased to a cutting score equal to or less than 69, sensitivity increased to 72% but specificity declined to 77%, meaning that overall the DAHL is somewhat more effective at correctly identifying true negatives results classifying those with adequate health literacy than correctly classifying those with inadequate health literacy. The C-statistic was 0.81, indicating that the DAHL discriminates well among people with higher and lower S-TOFHLA scores. It was found that the DAHL captured a large percentage of those who would be classified as having "inadequate health literacy" in the S-TOFHLA.

CHAPTER III

METHODOLOGY

Purpose and Description of Study

The purpose of the present study was to examine the relationship between health literacy and self-management behaviors in older adults. To date, the research is inconclusive, though none has analyzed data obtained from a national probability sample which may provide results that have greater external validity. The purpose of this study is to expand the knowledge base about diabetes in the aging American population. The use of proxy health literacy score based on demographic data from a national health surveys was calculated. A proxy measure was used to test the relation of health literacy to HbA1c levels and indicators of proper diabetes management. This study has potential to contribute to more effective patient education and more tailored diabetes interventions for this population. This research also has the potential to contribute to the limited body of knowledge and reaffirm findings from previous studies.

This study analyzed cross-sectional data from the NHANES 2009-2010 database. The NHANES 2009-2010 data was obtained from a nationally representative sample of Americans. The DAHL was used to calculate proxy health literacy scores based on four demographic variables, including age, race/ethnicity, gender, and education level.

Research Question 1: Among older U.S adults with diabetes, does proxy health literacy predict diabetes biomarker test scores (HbA1c, FBG, and OGTT)? This leads to the following hypotheses.

Hypothesis 1a: There will be a positive association between higher HbA1 blood glucose (HbA1c) levels and health literacy score, adjusting for poverty ratio, BMI, Insurance status, marital status, number of years since diagnosis, and family history of diabetes.

Hypothesis 1b: There will be a positive association between higher fasting glucose (FBG) level and health literacy scores, adjusting for poverty ratio, BMI, Insurance status, marital status, number of years since diagnosis, and family history of diabetes.

Hypothesis 1c: There will be a positive association between higher 2-hour glucose tolerance test (OGTT) scores and health literacy sores, adjusting for poverty ratio, BMI, Insurance status, marital status, number of years since diagnosis, and family history of diabetes.

<u>Research Question 2</u>: Among U.S adults with diabetes, is DAHL status associated with indicators of proper diabetes self-management (IPDSM), adjusting for poverty ratio, BMI, Insurance status, marital status, number of years since diagnosis, and family history of diabetes.

Hypothesis 2a: There will be a positive association between taking insulin and DAHL status, after adjusting for potential confounders.

Hypothesis 2b: There will be a positive association between taking blood sugar lowering oral hypoglycemic medication and DAHL status, after adjusting for potential confounders.

Hypothesis 2c: There will be a positive association between physical activity and DAHL status, after adjusting for potential confounders.

Hypothesis 2d: There will be no association between DAHL status and target blood pressure, after adjusting for potential confounders.

Hypothesis 2e. There will be a positive association between performing daily glucose check and DAHL status, adjusting for potential confounders.

Hypothesis 2f: There will be a positive association between visit a DM specialist with the last year and DAHL status, after adjusting for potential confounders.

The following sub-hypothesis were derived from ADA self-management recommendations; based on the literature review, these variables were found to be non-significant. This study explore associations in order to validate previous results.

Sub-hypothesis 2h: There will be no association between daily foot exam and DAHL status, after adjusting for potential confounders.

Sub-hypothesis 2i: There will be no association between eye exam and DAHL status, after adjusting for potential confounders.

<u>Population and Sample</u>

Description of NHANES data and sample design:

The 2009-2010 National Health and Nutrition Examination Survey (NHANES) is a continuous, annual survey that collects data from a nationally representative sample of non-institutionalized, civilian U.S. population aged 2 and older (NHANES Tutorials, 2012). The

NHANES is conducted by the National Center for Health Statistics, Center for Disease Control and Prevention, to assess the status of adults and children in the U.S. It provides national estimates and examines trends overtime. Initially, NHANES was conducted in cycles: NHANES I: 1971-1974, NHANES II: 1976-1980, NHANES III: 1988-1994. In 1999, NHANES became a continuous survey without breaks between cycles. The continuous NHANES survey data is released to the public in two-year increments (NHANES Tutorials, 2012). Data collected in NHANES comes from interviews, examinations, and laboratory tests from blood and urine samples.

The NHANES relies on a complex, four-stage, probability sampling procedure. Stage one, selects a primary sampling unit (PSU), mostly consisting of single counties or smaller counties combined to meet minimum sample size requirements. Stage two, divides PSUs into segments, the equivalent of a city or suburban block. Stage three, randomly selects clusters of households within areas. Stage four, identifies individuals for participation within households (NHANES Tutorials, 2012).

Sample Weights

Each sample person (SP) is assigned a sample weight which allows analysts to produce estimates that would have been obtained if the entire population had been surveyed. Sample weights can be considered a measure of the number of people in the population represented by that specific sample person. Sample weights for NHANES participants incorporate adjustments for unequal selection probabilities, non-response and differences between the sample and the total population (NCHS/NHANES, 2010). Sample weights must be incorporated into the analysis to obtain proper estimates and standard errors of estimates (NHANES Tutorials, 2012). In this study, the sample is limited to respondents from one year. The data were adjusted by three types of weights; sample weights, interview weights, and laboratory sub-sample weights.

Data Collection Methods and Instrumentation

NHANES data was collected by trained professionals through in-home personal interviews, physical examinations in mobile examination centers (MECs), and mailed follow-up food frequency questionnaires (NHANES Tutorials, 2012). For the 1999-2002 and 2003-2006 survey periods, sub-groups were oversampled including, adolescents, older adults, ethnic minorities, low-income, and pregnant women. The sample design of NHANES 2007-2010 differs from previous cycles of the continuous NHANES ; adolescents are no longer oversampled and all Hispanics were oversampled (CDC, 2011). NHANES data are publicly available files provided by NCHS without possible identifiers. A detailed description of the NHANES sampling method is described in the NHANES analytic guide (CDC, 2011).

Missing Data

The present study used the Little's Missing Value Analysis, to determine the percentage of missing data for all the variables used for the analysis. Since this study merged several sub-sample population it was found that some variables had large percentages of missing data. For example, OGTT had 79.2% missing data and a very small sub-sample size of (n = 108). In the 2009-2010 cycle, the OGTT variable was collected on a smaller sub-sample, as were the diabetes questionnaire, and fasting blood glucose. Logistic regression relies on maximum likelihood estimation (MLE) and the reliability of estimates declines significantly for combinations of cases where there are too few cases for each observed combination of independent variables (Antonogeorgos et.al.,2011). For the stated reason, OGTT and triglycerides were the only variables omitted from analysis. For variables with less than 10% missing data, the study included that variable as recommended by the NCHS analytical guide. For variable with more than 20% missing data, we did not use imputation method because it could lead to reporting incorrect results.

Inclusion and Exclusion Criteria

For the purpose of this study, data was analyzed from the NHANES sub-sample of older adults aged 55 and older with self-reported type 1 or type 2 diabetes and/or those participants who by definition are classified as diabetic by one of three bio-markers: HbA1c, fasting plasma glucose, or 2-hr glucose tolerance test. The study excluded participants who were defined as non-diabetic by laboratory examination. To facilitate the analysis of research question two, the data was selected to include only those participants who stated prior acknowledgement of having diabetes mellitus. The NHANES diabetes questionnaire used a sub-sample and therefore, the sample size is smaller (n=542).

Independent Variables, DAHL Variables, and Covariates:

Health Literacy Score: is a numeric score on a scale from 15.6 to 91.3 derived from four demographic measures based on scoring weights: (a) age, (b) gender, (c) education level, and (d) race/ethnicity (Hanchate et al., 2008). The study recoded scores to categories (DAHL_LEVEL): (1) "Inadequate" if score was ≤ 62, (2) "Marginal" if score was 63-75, and (3) "Adequate" if score was ≥ 76. This study derive the imputed scores based on the results from Hanchate et al.

(2008) (see Table 1).The score weights for the DAHL are a sum of the score for the reference group minus adjustments for other demographic cohorts. The reference group was non-Hispanic White, Female, aged 65-69, with more than a high school education with a mean score of (91.3), the highest imputed health literacy score possible. The lowest possible imputed health literacy score was (15.6) for non-Hispanic African-American, male, less than 9th grade education, and 85 years old or greater. For the purpose of calculating the DAHL score, four variables were recoded (age, gender, education, and race/ethnicity) in accordance with the methods described by Hanchate et al. (2008). (Interview weights)

Derived from the following:

Gender was a dichotomous variable (RIAGENDR) defined as: (1) Male, and (2) Female (reference group). (Interview weights)

Age was a continuous variable expressed in years based on the question "How old are you or what is your birth date? that was recoded to categorical groups based on U.S. Census classification of civilian, non-institutionalized population of older people: (1) 55-59 yrs old, (2) 60-64 yrs old, (3) 65-69 yrs old, (4) 70-74 yrs old, (5) 75-79 yrs old, (6) 80 and older. NHANES 2009-2010 does not collect exact age for persons older than 80 yrs old. Using U.S. Census 2010 information of older adults age 65 and older were able to estimate the number of adults older than 80 who would potentially be older than 85 years old. This study then conducted a random sample of the population older than 80 (n=64) and recoded their age to 85. This study further define the variables by collapsing categories and recoding (RECODED_AGE_GROUPS): (1)

55-69 years old (reference group), (2) 70-74 years old, (3) 75-79 years old, (4) 80-84 years old, and (5) 85 years old or greater. (Interview weights)

Education was a categorical variable (DMDEDUC2) based on the question "What is the highest grade level of school you completed or the highest degree you received?" defined as: (1) less than 9th grade education, (2) 9-11th grade education (includes 12th grade with no diploma), (3) HS grad/GED or equivalent, and (4) Some college/College graduate or greater (reference group). (Interview weights)

Race/ethnicity was a categorical variable (RIDRETH1) based on the question "Do you consider yourself to be Hispanic or Latino" and "What race do you consider yourself to be"? Defined as: (1) Mexican American, (2) Other Hispanic, (3) Non-Hispanic White, (4) Non-Hispanic Black, and (5)Other Race - including Multi-racial. Recoded to (RECODED_RACE_ETH) as (1) Non-Hispanic White (reference group), (2) Non-Hispanic Black, (3) Hispanic, and (4) Other Race - including Multi-racial. (Interview weights)

Self-reported diabetes: The first question in the diabetes questionnaire asked: "Other than during pregnancy, have you been ever been told by a physician that you have diabetes or sugar diabetes?" The response options for this dichotomous variable (DIQ010) were: (1) Yes, (2) No, and (3) Borderline. (MEC weights)

Glycohemoglobin: HbA1c is a blood test to measure the average blood glucose level for the previous 120 days. According to clinical recommendation 6.5% or greater, indicate a diagnosis of diabetes (NCHS/NHANES, 2010). This response was a continuous variable (LBXGH). (MEC weights)

Fasting plasma glucose: Blood was drawn in the morning after participants completed a 9-hour fasting period (NCHS/NHANES, 2010). Fasting levels great or equal to 7.0 mmol/L (126 mg/dL), confirms a positive diagnosis for diabetes mellitus (WHO, 2006). This response was a continuous variable (LBXGLU). (Fasting weights)

2-hour glucose (oral glucose tolerance test): Consisted of a three -step laboratory exam. First, a baseline blood sample was drawn. Second, the participant was administered a measured dose of glucose (according to weight; maximum 75g) to ingest orally within a 5 minute time frame. Third, blood sugar level was checked after a two hour interval. Glucose levels ≥11.1 mmol/L (200 mg/dL) at 2 hours check, confirms positive diagnosis of diabetes mellitus (NCHS/NHANES, 2010). This response was a continuous variable (LBXGLT).(OGTT weights)

Physical activity: This measure will be based on the 3 question (PAQ620, PAQ625, PAD630) related to moderate exercise. (a) “Do you do any moderate-intensity sports, fitness, or recreational activities that cause a small increase in breathing or heart beat such as brisk walking, bicycling, swimming, or golf for at least 10 minutes?” (b) “In a typical week, on how many days do you do moderate-intensity sports, fitness, or recreational activities?” and (c) “How much time do you spend doing moderate-intensity sports, fitness, or recreational activities in a typical day?” Following physical activity guidelines from the U.S. Health and Human Services (ODPHM, 2008), participants were classified as meeting the minimum exercise recommended for diabetic adults if they exercised 30 minutes a day at least 5 days a week. The recoded dichotomous variable (PHYS_ACTV) classified respondents as: (1) Yes, and (2) No (reference group). (Interview weights)

Time since last diabetes specialist: This was an ordinal variable based on the question (DIQ230) “When was the last time you saw a nurse educator or dietician or nutritionist for your diabetes?” Response options included: (1) 1 year ago or less, (2) More than 1 year ago but no more than 2 years ago, (3) More than 2 years ago but no more than 5 years ago, (4) More than 5 years ago, and (5) Never (reference group). (MEC weights)

Taking diabetes medication: Based on the questions (DIQ050) “Are you taking insulin now?” or (DIQ070) “Are you now taking diabetic pills to lower your blood sugar?” These are sometimes called oral agents or oral hypoglycemic agents.” The response options for this dichotomous variable were: (1) Yes, and (2) No (reference group). (MEC weights)

Physician visit: was an ordinal variable (DID250) based on the question “How many times have you seen this doctor or other health professional in the past 12 months?” Then recoded (RECODED_PHY_VISIT) as response options: (1) 1-3 times, (2) 4-12 times, (3) 13 or more times, and (4) None (reference group) (MEC weights)

Frequency of foot exam: an ordinal variable based on the questions (DID341) “Past year how many times doctor checked feet for sores?”, (DID350) “How often do you check your feet?”

Recoded as (RECODED_FEET_CHECKED) if any of the above were greater than 1 time (1) Yes, and (2) No (reference group). (MEC weights)

Check blood sugar: Based on the question (DID260) "How often do you check blood sugar/glucose?" Coded as: (1) Yes and (2) No (reference group),. (MEC weights)

Time since last eye exam: was an ordinal variable (DIQ360) based on the question "When was the last time you had an eye exam in which the pupils were dilated?" The response options included (1) less than 1 month ago, (2) 1-12 months ago, (3) 13-24 months ago, (4) greater than 2 years ago, and (5) Never (reference group). (MEC weights)

Uncontrolled high blood pressure: a measured systolic blood pressure of 140/90 mm Hg or more (Chobanian, 2003), based on an average of three measurements. The mean of 3 systolic and diastolic measures were calculated and recoded to a new variable labeled (BP_STATUS). This was a continuous variable later recoded to (1) controlled, and (2) uncontrolled (reference group). (MEC weights)

Uncontrolled triglycerides: a measured value above 200 mg/dL was considered uncontrolled triglycerides. This was a continuous variable later recoded to a new variable (RECODE_trig): (1) controlled and (2) not controlled (reference group)

Covariates

Insurance type based on questions: (HIQ011) “Are you covered by health insurance?” “No” recoded in the same variable as 0. (HIQ031A) “Are you covered by private health insurance?” “Yes” recoded in the same variable as 1. (HIQ031B) Are you covered by Medicare?” “Yes” recoded in the same variable as 3. (HIQ031C) “Are you covered by Medi-gap?” “Yes” coded in the same variable as 3. (HIQ031D) “Are you covered by Medicaid” “Yes” recoded in the same variable as 3. (HIQ031F) “Are you covered by military health insurance?” “Yes” recoded in the same variable as 3. (HIQ031H) “Are you covered by a state-sponsored health insurance?” “Yes” was recoded in the same variable as 3. (HIQ031I) “Are you covered by any other government health insurance?” “Yes” recoded in the same variable as 3. Then a new variable was created (INS_TYPE) by computing the SUM function and adding the values of all the above variables where (1) no Insurance (2) private Insurance, (3) government Insurance, and (4) private and government insurance (reference group), (Interview weights)

Family history of diabetes was a categorical variable (MCQ300C) based on the question “Including living and deceased, were any of your close biological that is, blood relatives including father, mother, sisters or brothers, ever told by a health professional that they had diabetes?” and the response options were: (1) Yes or (2) No. (MEC weights)

BMI: was a continuous variable (BMXBMI). Recoded (RECODED_BMI) to categories (1) BMI < 18.5 (reference group), (2) BMI 18.5-24.9, (3) BMI 25-29.9, and (3) BMI >30. (MEC weights)

Duration of diagnosis: Among participants with self-reported diabetes, this study coded (YRS_SINCE_DIAGNOSIS) duration of diabetes as the numeric value of the participant's current age minus the value obtained from of the question (DID040) "How old were you when a health professional told you, you have diabetes?" This was a continuous variable. (MEC weights)

Ratio of family income to poverty: The poverty income ratio (PIR) was based on family income divided by the poverty level for that family. This was a continuous variable. Recoded as (RECODED_PVT_Ratio) (1) 1-100% (reference group), (2)101-200%, (3) 201-300%, (4) 301-400%, (5) 401-500%, and (6) above 500%. (Interview weights)

Marital Status: Participants selected one of the following options (1) married/living with partner (reference group), (2) widowed/divorced/separated, (3) never married)

Statistical Analysis

Research question one used DAHL score as the independent variable in which respondents were classified into three groups: inadequate, marginal, and adequate. The dependent variables were: HbA1c percentage, OGTT scores, and fasting glucose plasma scores. Research question two used the computed literacy score as the dependent variables and seven separate diabetes management behaviors to test the hypothesis. The aim of this study was to predict and assess the relationship of the DAHL status to diabetes biomarkers and self-management behaviors. Statistical analyses were conducted using IBM SPSS Statistics V23.0. Type 1 error was set at a significance level of alpha 0.05 or less. Data from the 2009-2010

NHANES were downloaded from the Center for Disease Control and Prevention, National Center for Health Statistics web site (http://www.cdc.gov/nchs/nhanes/nhanes2009-2010/nhanes09_10.htm). The sample consisted of 779 participants who were ≥ 55 years of age and older and diagnosed with diabetes mellitus by a doctor or through biomarker testing.

First, descriptive statistics and preliminary analyses (independent sample t-tests and chi-square) were computed to describe the participants' characteristics. Cross-tabulations were used to determine if differences among groups were large enough to indicate a relationship between the variables. Assumptions were checked before conducting the required analysis for each hypothesis. First univariate regression was performed in order to calculate baseline results. Hierarchical regression modeling was performed to test the hypotheses and to determine the strength of the relationship between the dependent variables (HbA1c, fasting glucose plasma, and two-hour oral glucose tolerance test) and independent variables (DAHL score). For the second research question this study tested the states hypotheses by using logistic regression because it is known to be an efficient way to control for many potential confounders at one time. Data was selected to include only those participants who had known knowledge of their diabetes positive status. In this study the responses "Don't Know" and "Refused" were treated as missing data. All statistical analysis was done using the complex sample module in SPSS unless otherwise stated in each table. First, separate regressions were analyzed to determine the individual contribution to the outcome variable without controlling for the confounding variables. Second, separate regressions where analyzed controlling for confounders.

Proposed Analysis: *Hypotheses 1a-c*.

This study analyzed independent sample t-test in order to see if a relationship between the levels of HL and the HbA1c, OGTT, and FBG. Hierarchical multiple regression analyses was used in order to model, examine, and test the strength of the relationship between health literacy score and the continuous dependent variables (HbA1c, OGTT, FBG) while controlling for the effect of covariates (duration of diagnosis, BMI, family history, poverty ratio, marital status, and insurance status).

Proposed Analysis: *Hypotheses 2a-g and 3a-b..*

First, data was selected for individuals who responded "yes" to the question, "Did your doctor diagnose you with diabetes"? Only individuals with DM were included in the analysis. The sample size for research question two was (n=542). Separate binomial logistic regression tests were performed to examine the relationship between DAHL levels and seven individual predictor variables of proper diabetes self-management behaviors (physical activity, taking oral hypoglycemic medication, diabetes specialist visits in the past year, target BP, daily glucose check, and taking insulin), adjusting for potential confounders (duration of diagnosis, BMI, family history, poverty ratio, and insurance status).

<u>Strengths of Study</u>

In conventional national health research studies, health literacy is commonly not measured. The use of a proxy health literacy classification known as the DAHL instead of a comprehensive competency-based measure (e.g., TOFHLA, REALM), provides an opportunity to move health literacy research forward. The imputed approach for measuring health literacy that is enlisted in this study has potential for advancing our understanding of the association between health literacy and diabetes outcomes and self-management behaviors. This approach allows researchers the opportunity to measure health literacy at a population level with a method that has proven validity and reliability.

Protection of Human Subjects

This research protocol was reviewed and approved as an exempt review by the UNTHSC Institutional Review Board in Fort Worth, Texas. This protocol has been designated Exempt Protocol 2012-212. Detailed view available in Appendix D.

CHAPTER IV

RESULTS

Overview

Chapter four describes the study sample and presents the results from the present study. Data from the NHANES 2009-2010 cycle were examined for this study. SPSS 23.0 was used for all statistical analyses in the present study using weighted statistics. The present study of older adults with diabetes involves two research questions, each of which pertain to the roles that health literacy plays in diabetes outcomes and self-management behaviors. The hypotheses are as follows: (1) Older adults with higher DAHL scores will present better diabetes biomarker levels; (2) Among older adults with diabetes, those with adequate DAHL scores, will exhibit better diabetes self-management practices. Descriptive statistics for all NHANES data are shown first, followed by tables of preliminary analyses. All results are weighted counts and percentages. This chapter describes the results and summary of the findings from the study.

Table 2.
Baseline characteristics, all adults age 55 and older and adults diagnosed with diabetes, ≥55 years old, NHANES 2009-2010

Characteristics		All Adults (n=2,501)	Diabetic Adults (n=779)
		Frequency (%)	Frequency (%)
Gender	Male	1158 (46.3%)	383 (49.2%)
	Female	1343 (53.7%)	396 (50.8%)
Race/ Ethnicity	Non-Hispanic White	1951 (78.0%)	527 (67.7%)
	Non-Hispanic Black	235 (9.4%)	106 (13.6%)
	Hispanic	188 (7.5%)	84 (10.8%)
	Other/Mixed Race	128 (5.1%)	62 (7.9%)
Age	55-64 years old	1176 (47.0%)	308 (39.5%)
	65-74 years old	765 (30.6%)	271 (34.8%)
	75-84 years old	560 (22.4%)	142 (18.2%)

	85 years or older	----	58 (7.5%)
Education	Less than 9th grade	208 (8.3%)	99 (12.7%)
	9-12 grade	340 (13.6%)	135 (17.3%)
	HS Diploma/GED	623 (24.9%)	178 (22.9%)
	Some college/AA	698 (27.9%)	214 (27.5%)
	College or above	628 (25.1%)	150 (19.2%)
Marital Status	Married	1583(63.3%)	454 (58.3%)
	Widowed	415 (16.6%)	148 (19.0%)
	Divorced	298 (11.9%)	106 (13.6%)
	Separated	38 (1.5%)	8 (1.0%)
	Never married	110 (4.4%)	45 (5.8%)
	Living with partner	58 (2.3%)	18 (2.3%)
Poverty Ratio	0-100%	215 (8.6%)	84 (10.8%)
	100%-200%	455 (18.2%)	175 (22.5%)
	200%-300%	418 (16.7%)	145 (18.6%)
	300%-400%	275 (11.0%)	88 (11.3%)
	400%-500%	920 (36.8%)	226 (29.0%)
Type of Health Insurance	Insured	2303 (92.1%)	725 (92.7%)
	Not Insured	198 (7.9%)	54 (6.9%)
Health Literacy Level	Adequate HL	---	378 (48.5%)
	Marginal HL	---	203 (26.1%)
	Inadequate HL	---	194 (24.9%)

Note: Colum percentage=100

[a] Sample sizes do not always equal column totals due to missing data.

[b] Percentages are MEC weighted statistics

Table 3.

Mean diabetes biomarker score and health literacy score by level, adults age 55 and older with DM, NHANES 2009-2010

DAHL Levels			Mean	SE
Adequate	Mean	Glycohemoglobin (%)	6.8400	.093
		DAHL Scores	85.6207	.376
Marginal	Mean	Glycohemoglobin (%)	6.7969	.101
		DAHL Scores	71.1932	.236
Inadequate	Mean	Glycohemoglobin (%)	6.9653	.103
		DAHL Scores	52.3955	.694

Note: Complex Sample Descriptive Procedure

General Characteristics of the Study Population

Tables 2**.** are the general characteristics of the study frequency and percentages for the 2009-2010 NHANES data file using weighted data. The study population consisted of 10,537 persons in the NHANES 2009-2010 cycle. For the purposes of this study, this study included only those participants classified as being age 55 and older (n=2,501). Of these, 779 (31.1%) individuals were classified as diabetic by virtue of self-report or by meeting clinical definitions of diabetes mellitus through elevated biomarker results. The number of male 399 (49.2%) and female 380 (50.8%) participants was closely represented in the sample. The mean age of the entire 55 years and older study population was 68.2 years old compared to the diabetic 55 years and older study sample which had a slightly younger mean age of (66.6 years old). The study sample generally consists of Non-Hispanic White (67.7%), Married (58.3%), with HS education or less (52.9%), and Insured (92.7%).

Nearly 11% of the study sample had an income below the federal poverty line (U.S. Census Bureau, 2004). Compared to the overall 55+ year old population, older adults with diabetes mellitus were lower-income, less educated, older, more likely not married or living with a partner, and belonging to an ethnic minority. Using the NHANES 2009-2010 data, this study calculated a proxy health literacy score among all adults 55 years and older with DM. There were 379 (48.5%) with adequate HL (≥76), 203 (26.1%) with marginal HL (63-75), and 194 (24.9%) with inadequate HL (≤62). Table 3. reports the mean for HL and the biomarkers tests, adequate HL score was 85.62, the mean marginal HL score was 71.19, and the mean inadequate HL score was 52.39.

Descriptive (Adults older than 55 years old, DM, NHANES 2009-2010)

This study used SPSS Complex Samples to complete the analysis for the present study since the module accounts for complex (stratified/clustered) sampling designs, correctly calculating standard errors with weighted data. First, separate plan files were created which took into account the design strata, cluster, and sample weight information. When DIQ data was merged with MEC examination data or other laboratory data, the MEC examination weights (WTMEC2YR) were used for analysis as recommended by NHANES 2009-2010 analytic notes. When DIQ data was merged with laboratory sub-sample data, sub-sample weights (WTSOG2YR or WTSAF2YR) were used for the analysis. DAHL used interview weights (WTINT2YR) since it was derived from demographic data.

Table 4.
Frequency of selected socio-demographic characteristics, adults 55 years and older with diabetes mellitus, stratified by self-report status, NHANES 2009-2010

Characteristic		Doctor diagnosed you with diabetes		
		Yes	No	Borderline
		Frequency (%)	Frequency (%)	Frequency (%)
Gender	Male	260 (48.0%)	102 (49.3%)	18 (60.7%)
	Female	282 (52.0%)	105 (50.7%)	11 (39.3%)
Race/ Ethnicity	Non-Hispanic White	339 (62.5%)	156 (75.4%)	25 (87.5%)
	Non-Hispanic Black	89 (16.5%)	18 (8.6%)	1 (3.2%)
	Hispanic	62 (11.4%)	24 (11.4%)	2 (7.8%)
	Other/Mixed Race	52 (9.5%)	9 (4.7%)	1 (1.6%)
Age	55-64 years old	207 (38.1%)	86 (41.7%)	10 (36.1%)
	65-74 years old	208 (38.4%)	56 (27.1%)	8 (27.8%)
	75-84 years old	92 (16.9%)	44 (21.2%)	8 (26.3%)
	85+ years old	35 (6.5%)	21 (10.0%)	3 (9.7%)
Education	< 9th grade	79 (14.5%)	22 (10.7%)	1 (2.2%)

	9-11th grade	102 (18.8%)	33 (15.9%)	2 (6.8%)
	HS /GED	114 (20.9%)	55 (26.5%)	7 (25.3%)
	AA	154 (28.3%)	50 (24.2%)	11 (37.7%)
	≥ college	93 (17.1%)	47 (22.7%)	8 (26.9%)
Marital Status	Married	322 (59.5%)	116 (55.9%)	14 (46.7%)
	Widowed	96 (17.7%)	46 (22.3%)	7 (27.3%)
	Divorced	76 (14.0%)	24 (11.5%)	6 (19.2%)
	Separated	5 (1.0%)	2 (1.2%)	0 (0.6%)
	Never married	35 (6.4%)	9 (4.5%)	2 (6.2%)
	Living with partner	7 (1.3%)	10(4.6%)	0 (0.0%)
Poverty Ratio	0-100%	56 (11.7%)	23 (12.4%)	2 (7.3%)
	100%-200%	134 (27.9%)	35 (19.3%)	4 (13.1%)
	200%-300%	89 (18.6%)	45 (24.4%)	4 (14.1%)
	300%-400%	59 (12.0%)	23 (12.6%)	4 (13.0%)
	400%-500%	143 (29.7%)	57 (31.3%)	14 (52.6%)
Type of Health Insurance	No Health Insurance	30 (5.5%)	21 (10.0%)	3 (9.1%)
	Private	147 (27.2%)	61 (29.4%)	9 (30.8%)
	Government sponsored	151 (27.9%)	46 (22.5%)	3 (9.0%)
	Private and government	213 (39.5%)	78 (37.9%)	14 (51.0%)

[a] Sample sizes do not always equal column totals due to missing data.
[b] Column percentage=100
[c] MEC Weighted percentages

Table 4 presented data on the frequency of selected health measures by self-report status. This study compared those who self-reported a having diabetes mellitus to those who reported "no" or "borderline"**.** Results indicated that (33.6%) of the study participants with diagnosed (self-report/biomarker testing) DM were unaware of their diabetes positive status. These individuals were more likely to be Male, Non-Hispanic White, 55-65 years of age, widowed/separated, with college education, income 401-500%% above the poverty line, and uninsured. These finding contradict what is readily known about individuals who are most at high risk for developing diabetes. These finding revealed that the individuals who were most likely to be unaware of their positive diabetes status, were those who mistakenly considered themselves statistically a low risk group.

Table 5.
Frequency of diabetes self-management behaviors by self-report status, adults with diabetes mellitus, ≥ 55 years old, NHANES 2009-2010

		Doctor diagnosed you with diabetes		
		Yes	No	Borderline
Characteristic		N (%)	N (%)	N (%)
Time since you saw DM specialist	< 1 year ago	205 (38.4%)	---	---
	1-2 yrs ago	31 (5.7%)	---	---
	2-5 yrs ago	63 (11.7%)	---	---
	5+ yrs	77 (14.4%)	---	---
	Never	159 (29.8%)	---	---
Taking insulin				---
(n=772)	Yes	135(26.4%)	1 (0.7%)	38 (100%)
	No	378 (73.6%)	21(99.3%)	---
Taking hypoglycemic oral medication (n=609)				
	Yes	408 (80.4%)	---	---
	No	97 (19.2%)	---	---
Check eyes for retinopathy (n=531)				
	< 1 month ago	72 (13.6%)	---	---
	1-12 months ago	286 (53.8%)	---	---
	13-24 months ago	75 (14.1%)	---	---
	Great than 2 years	75 (14.2%)	---	---
	Never	23 (4.3%)	---	---
Meets recommended physical activity	Yes	50 (9.7%)	19 (8.4%)	6 (16.1%)
(n=772)	No	463 (90.3%)	202 (91.6%)	32 (83.9%)
Uncontrolled high	Yes	129 (27.8%)	50 (25.5%)	7 (18.3%)
blood pressure	No	335 (72.2%)	145(74.5%)	30 (81.7%)
(n=696)				
	Never	4 (1.0%)	---	---

Number of times you saw doctor in the past year (n=435)	1-4	341 (78.5%)	---	---
	5-8	42 (9.6%)	---	---
	9-12	39 (9.0%)	---	---
	12+	8 (1.8%)	---	---
Daily Glucose Check (n=530)	Yes	438 (82.7%)	---	---
	No	92 (17.3%)	---	---
Check feet for sores Daily (n=532)	Yes	403 (75.7%)	---	---
	No	129 (24.3%)	---	---

Note: triglycerides, insulin, and blood pressure variables were collected on the entire sample. Variable pertaining to diabetes were only answered by individuals who completed the diabetes questionnaire.

[a] Sample sizes do not always equal column totals due to missing data.

[b] Column percentage=100

[c] MEC Weighted (%) percentages

Table 5**.** indicates that among participants with known diabetes, (61.5%) had not seen a diabetes specialist in the past year. Generally, the study sample (90.3%) did not meet the recommended daily physical activity regardless of known diabetes status. The participants had mostly well controlled hypertension (72%), participants with known diabetes were taking insulin (17.5%). Over 60% of the participants saw a doctor at least once in the past year, taking hypoglycemic oral medication (9%), taking insulin (18%), checked their blood sugar daily (83%), had well controlled triglyceride levels (82%), checked their feet for sores (75%), and (67%) had their eyes dilated to check for retinopathy in the past 2 years. A small number of participants who had previously answered that they did not have DM, acknowledged they were presently taking insulin (0.7%) and/or blood sugar lowering medications (1.46%).

HbA1c, Fasting glucose, OGTT and health literacy by level

Preliminary analysis included assessing all the assumptions to be able to conduct the statistical analysis. In the descriptive statistics tables, cell boxes with bold numerals show a statistical significance. All categorical variables were dummy coded to allow for correlations and regression analysis. Chi-square and independent sample t-tests were used to examine differences according to health literacy level for all independent variables, including covariates and dependent variables (HbA1c, FBG, and OGTT). Simple linear regressions were run when both the independent and dependent variables were continuous and point-biserial correlations when the independent variable was a dichotomous variable (Adequate = 0 or 1; Marginal = 0 or 1; and Inadequate =0 or 1) and the dependent variable continuous (HbA1c, FBG, and OGTT). Finally, main results are presented for each hypothesis at the end of each section followed by a summary of the results.

Cross-tabulations

Cross-tabulations were created between level of health literacy and the covariates in research question one. Next we performed the chi-square test of independence in order to determine if a relationship between the dichotomous independent variables (adequate, marginal, and inadequate health literacy) and the covariates. First, the assumptions for chi-square were checked and found to be acceptable.

In Table 6. if p-value was greater than .05, therefore, the study failed to reject the Ho. Concluding that the pattern between the variables in the sample were not strong enough to allow us to conclude that there was a significant relationship. If the p-value was less than .05, the study rejected the Ho, concluding that the pattern of the relationship between the two variables in the sample were strong enough to allow us to conclude there was a significant relationship. Significant results appear in bold.

Table 6.
Frequency of demographic and diabetes related characteristics by health literacy level, adults age 55 and older with diabetes, NHANES 2009-2010

Characteristic		Adequate Frequency (%)	Marginal Frequency (%)	Inadequate Frequency (%)
BMI (n=418)	(1) Normal	43 (11.5%)	20 (10.4%)	25 (10.88%)
	(2) Overweight	**97 (26.6%)***	69 (35.9%)	78 (40.4%)
	(3) Obese	**224 (61.5%)***	103 (53.6%)	**90 (46.6%)***
Family History of DM (n=726)	(1) Yes	**216 (52.6%)***	107 (26.1%)	89 (21.4%)
	(0) No	**182 (44.3%)**	117 (28.4%)	112 (27.3%)
Health Insurance Type (n=772)	(1) Uninsured	21 (0.05%)	15 (7.3%)	17 (8.71%)
	(2) Private Health	**149 (39.6%)****	**41 (20.1%)***	**29 (14.8%)***
	(3) Government	**73 (19.4%)***	52 (25.6%)	**72 (36.9%)***
	(4) Private and Government	133 (35.3%)	95 (46.7%)	77 (39.4%)
Poverty Ratio (n=687)	(1) 1-100%	**19 (5.4%)***	**24 (13.4%)***	**38 (23.3 %)***
	(2) 101-200%	**52 (14.9%)***	54 (30.3%)	**62 (38.0%)****
	(3) 201-300%	66 (19.0%)	36 (20.2%)	37 (22.7%)
	(4) 301-400%	49 (14.1%)	23 (12.9%)	**10 (6.1%)****
	(5) 401-500%	**161 (46.4%)***	41 (23.0%)	**16 (9.8%)****
Marital Status (n=668)	(1) Married	158 (36.6%)	129 (30.7%)	140 (32.8%)
	(2) Sep/Wid/Div	71 (55.5%)	29 (22.9%)	**28 (21.6%)****
	(0) Not Married	16 (43.9%)	15 (34.5%)	**9 (21.6%)****

Note: * Significant at p<.01 level, ** Significant at p<.05 level, Row = 100 percent
Note: Sample sizes do not always equal the column totals due to missing data

These findings show among the adequate level of health literacy, there are higher rates of obesity, family history of diabetes, private health insurance, having a poverty ratio 401-500% above the poverty line, and being married in comparison to the marginal and inadequate HL levels. Among individuals who self- reported a positive DM status, those with adequate HL had an average of 10.3 years since diagnosis, those with marginal HL, had known for nearly 14 years, and those with inadequate HL had known for 15.3 years.

Table 7.
Chi- square association between the covariates and health literacy level, adults with diabetes mellitus, 55 years and older, NHANES 2009-2010

Characteristics	x^2	df	Sig	OR
BMI 1=Underweight * adequate	.957	16	.246	.301
BMI 2=Normal * adequate	.098	16	.850	1.06
BMI 3=Overweight * adequate	12.162	16	**.002***	**.584**
BMI 4=Obese * adequate	10.181	16	**.005***	**1.58**
BMI 1=Underweight * marginal	1.041	16	.186	---
BMI 2=Normal * =marginal	.386	16	.577	.926
BMI 3=Overweight * =marginal	3.249	16	.137	1.22
BMI 4=Obese * =marginal	1.324	16	.232	.886
BMI =Underweight * =inadequate	3.838	16	**.025***	**10.3**
BMI 2=Normal * =inadequate	.068	16	.818	**.997**
BM 3I=Overweight * =inadequate	4.764	16	.075	1.61
BMI 4=Obese * =inadequate	6.419	16	.061	.623
Close relative has dm * adequate	4.959	16	**.040***	**.716**
Close relative has dm * marginal	.493	16	.343	1.12
Close relative has dm * inadequate	3.520	16	.088	1.38
No Health Insurance * adequate	1.231	16	.236	.677
Private Health Insurance * adequate	42.060	16	**.000****	**3.08**
Government Sponsored * adequate	14.377	16	**.013****	**.524**
Private & govt Sponsored * adequate	5.405	16	.108	.708
No Health Insurance * marginal	.818	16	.486	1.12
Private Health Insurance * marginal	8.283	16	**.041****	**.555**
Government Sponsored * marginal	.052	16	.817	1.00
Private and Government Sponsored * =marginal	6.425	16	.105	1.55
No Health Insurance * inadequate	.136	16	.790	1.42
Private Health Insurance * inadequate	21.268	16	**.003****	**.360**
Government Sponsored * inadequate	21.524	16	**.004****	**2.17**
Private and Government Sponsored * inadequate	.015	16	.936	.999
poverty ratio 1 * adequate	20.515	16	**.001****	**.262**
poverty ratio 2 * adequate	32.595	16	**.001****	**.342**

poverty ratio 3 * adequate	.290	16	.662	.878
poverty ratio 4 * adequate	2.108	16	..288	1.48
poverty ratio 5 * adequate	59.702	16	**.000****	**4.26**
poverty ratio 1 * marginal	.122	16	.674	1.20
poverty ratio 2 * marginal	4.040	16	.150	1.49
poverty ratio 3 * marginal	.033	16	.866	.981
poverty ratio 4 * marginal	.429	16	.643	1.17
poverty ratio 5 * marginal	7.206	16	.081	.577
poverty ratio 1 * inadequate	27.576	16	**.001****	**3.44**
poverty ratio 2 * inadequate	21.154	16	**.002****	**2.44**
poverty ratio 3 * inadequate	.967	16	.484	1.21
poverty ratio 4 * inadequate	6.69	16	**.052***	**.419**
poverty ratio 5 *inadequate	47.580	16	**.003****	**.172**
Never Married * adequate	.372	16	.686	.825
Married * adequate	23.46	16	**.003***	**2.06**
Wid/Sep/Divc * adequate	22.13	16	**.004***	**.482**
Never Married * adequate	1.63	16	.376	1.52
Married * adequate	6.55	16	.056	.655
Wid/Sep/Divc * adequate	4.08	16	.205	1.40
Never Married * inadequate	.347	16	.446	.800
Married * inadequate	8.851	16	**.001***	**.609**
Wid/Sep/Divc * inadequate	11.28	16	**.000****	**1.76**

[2]Weighted MEC data
* p < .05 , ** p < .001

A chi-square test (shown in Table 7.) for association was conducted between the covariates and the three levels of health literacy. This study used Rao-Scott adjusted chi-square to determine statistical significance. There was a statistical significance between the variables body mass index (over weight and obese) in the adequate level and underweight in the inadequate level, family history of DM in the adequate level, poverty ratio (100-200%; 400-500%) in the adequate and inadequate level, insurance type (private; government sponsored) in all three health literacy levels, and marital status (adequate and inadequate levels).

Independent sample t-test:

First, independent sample t-tests were calculated to determine if a difference existed between the mean of two independent groups (adequate HL, Yes=1 and No=0; marginal HL, Yes=1 and No=0; inadequate HL, Yes=1 and No=0) and (1) the continuous covariates. This study determined whether the differences between the two groups were statistically significant at (ρ =.05). Next, independent sample t- test were analyzed for each of the continuous dependent variables (HbA1c; FBG, OGTT) by level of health literacy

Table 8.
Independent sample t-test glycohemoglobin and adequate, marginal, and inadequate health literacy, adults 55 years and older with diabetes mellitus, NHANES 2009-2010

		Means	SD	Mean Difference	95% CI Difference Lower	Upper	t	Sig
Adequate	No	6.627	.808					
	Yes	6.554	.700	.0731	.0724	.0739	199.59	**.000**
Marginal	No	6.595	.758					
	Yes	6.584	.759	.0110	.0102	.0118	26.50	**.000**
Inadequate	No	6.565	.721					
	Yes	6.673	.854	-.1086	-.1094	-.1077	-257.17	**.000**

[1]Complex samples procedure

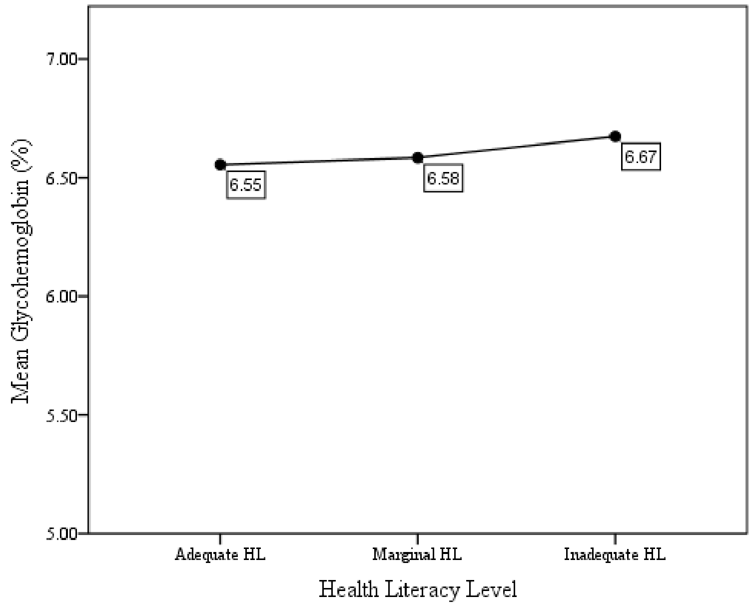

Figure 1c. Line graph of mean HbA1c by DAHL level (adequate, marginal, inadequate) adults 55 and older, with diabetes, NHANES 2009-2010
[1]Omitted extremes HbA1c values

Table 8. showed that there was a statistically significant difference in mean HbA1c score between adequate and non-adequate HL groups, with adequate HL group scoring higher than non-adequate HL group, 6.554 ± .070 [mean ± SE], $t(16)=92.829$ $p=.000$. Marginal HL mean HbA1c score was 6.584 ± .080, $t(16) =82.09$, $p=.00$ lower than non-marginal HL group. Inadequate HL mean HbA1c score was 6.673 ± .059, $t(16) =112.05$, $p=.000$ higher than non-inadequate HL group. HbA1c % increased as health literacy level decreased. Figure 1c. showed a visual representation of the means, adequate health literacy group had the lowest mean HbA1c percentage of the three levels and inadequate health literacy group the highest HbA1c % mean. There was significant difference in HbA1c score for adequate (0 and 1), marginal (0 and 1), and inadequate (0 and 1).

In the pre-analysis this study conducted an independent sample t-test in order to determine if there was a significant difference between two groups (adequate and non-adequate; marginal and non-marginal; inadequate and non-inadequate) and HbA1c. Next, this study calculated the Pearson correlation in order to describe the association between HL and HbA1c when both variables were continuous. The Pearson correlation coefficient between proxy health literacy scores and HbA1c percentage was r= - .054, $p < .01$, suggested weak negative linear correlation.

Next, a simple linear regression was used to determine how much variation in HbA1c was explained by HL scores, where $r^2 = .003$, meaning that 0.3% of the total variation in HbA1c % was be explained by health literacy score. Therefore, suggesting that there are many other factors that could be influencing HbA1c scores. The regression equation was: HbA1c = 6.806 – (.003) (HL score). t = -1.255, and p-value = .227. At the $\alpha = .05$ level of significance, there exist enough evidence to conclude that health literacy score is not useful as a predictor of glycohemoglobin percentage scores. For every unit increase in health literacy (shown in Figure 1d.), results indicate a -.003 decrease in the glycohemoglobin score.

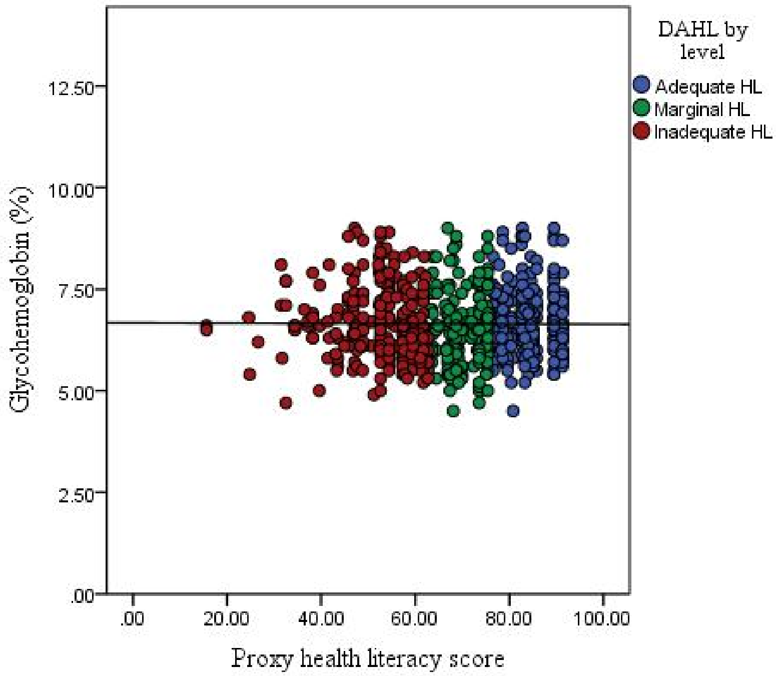

Figure 1d. Scatterplots of HbA1c scores and DAHL proxy score by level of literacy score, adults 55 and older with diabetes, NHANES 2009-2010

Fasting Blood Glucose and DAHL Level

The assumption of no extreme outliers was assessed by running boxplots and it was found that the data had extreme outliers and was not normally distributed. This study looked at the Q-Q plots to conduct visual inspection at the type of non-normal distribution of the data to thereby choose the correct transformation. This study observed an extremely positive skewness in the histograms and therefore conducted inverse transformations of the dependent variable fasting blood glucose (FBG) in an attempt to correct the violation of extreme outliers and non-normality.

The decision to utilize data transformations was taken with caution to ensure that data was not altered and hinder interpreting the correct results. Subsequently, it was determined that even after applying an inverse transformation to correct the positive skewness of the data, we were unable to achieve approximately normal distribution. Therefore, it was decided that we would return to the original data set and instead, omit the extreme outliers. The decision to omit outliers was taken for two reasons: (1) after inverse transformation, the assumption was not corrected (2) we were able to retain more integrity of the data by using a different approach of transformation

Table 9.
Independent sample t-test fasting blood glucose and adequate, marginal, and inadequate health literacy, adults 55 years and older with diabetes mellitus, NHANES 2009-2010

t-test for Equality of Means								
		Means	SD	Mean Difference	95% CI Difference Lower	Upper	t	Sig
Adequate	No	129.02	26.65					
	Yes	123.02	17.82	5.99	5.97	6.01	66.40	.000
Marginal	No	125.28	22.22					
	Yes	128.53	24.93	-3.24	-3.27	-3.22	57.69	.000
Inadequate	No	124.89	20.67					
	Yes	129.48	28.18	-4.58	.0114	-4.61	53.34	.000

Note: Fasting Glucose Sub-sample MEC weighted analysis

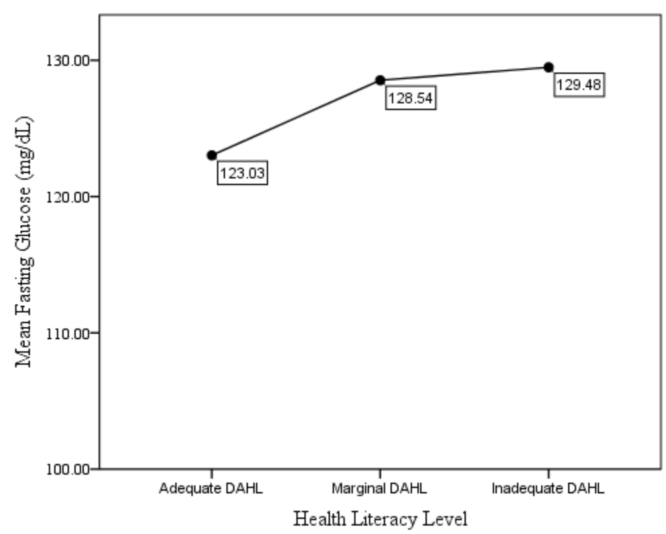

Figure 2c. Line graph of mean FBG by DAHL level (adequate, marginal, inadequate) adults 55 and older, with diabetes, NHANES 2009-2010

The FBG mean (shown in Table 9.) was 129.02 ± 1.614 when adequate HL=0, and 123.02 ± 1.85 when adequate HL=1. For adequate HL and FBG, the mean difference of 5.996 (CI -.675 to 12.667), t (15)= 66.40, p=.000. The independent sample t-test determined that there was a difference in mean FBG scores and adequate HL. The FBG mean was 125.28 ± 1.23 when marginal HL=0, and 128.53 ± 2.22 when marginal HL=1. For marginal HL and FBG, the mean difference of -3.248 (CI -9.774 to 3.278), t (15) = 57.69, p=.000. The FBG mean was 124.89 ± 1.065 when inadequate HL=0, and 129.48 ± 2.42 when inadequate HL=1. For inadequate HL and FBG, the mean difference of -4.589 (CI -10.964 to 1.786), t (15) = 53.34, p=.000. The independent sample t-test determined at α= 0.05 level of significance, that there was statistically significant difference in FBG scores for adequate, marginal, and inadequate health literacy. The Levene's test of equality of variances had a sig. of (*p=.000*) for all levels of HL and FBG, therefore it violated the assumption for homogeneity.

Next, a simple linear regression was run when both the outcome and predictor variables were continuous variables. The linear regression established had an intercept of 140.093, a slope of -.190 and Wald *F(1, 328)=4.198, p=.05.* The Pearson correlation was r = -.119, therefore suggesting a moderate weak negative correlation. The r^2 = .014, meant that 1.4% of the explained variability in FBG was due to the linear relationship between HL score and fasting blood glucose. In Fig 2d. a downward negative trend was observed, meaning that as health literacy score increased, FBG score decreased. For every unit increase in health literacy score, there was a -.190 decrease in fasting blood glucose score (shown in Figure 2d.). There is enough evidence to conclude that health literacy score is a useful predictor of fasting blood glucose scores.

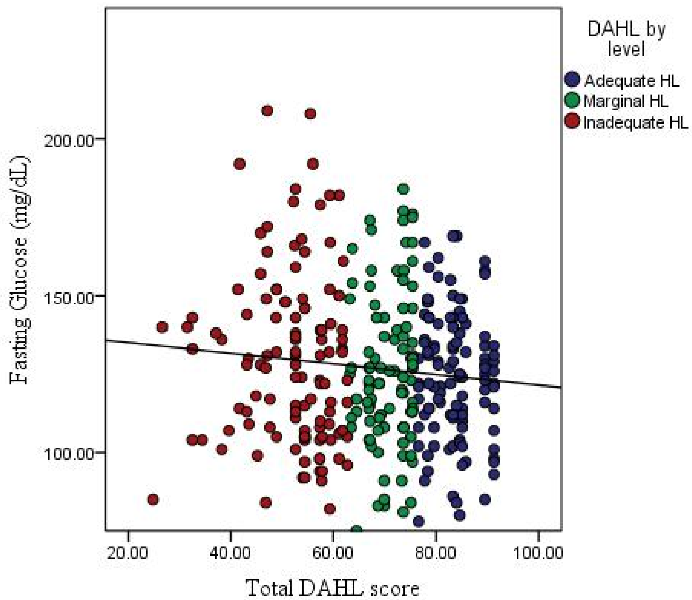

Figure 2d. Scatterplot of FBG and HL by level, adults 55 years and older, NHANES 2009-2010
[1]Omitted extreme values. NHANES 2009-2010
[2]Fasting Glucose MEC weights

Research Question 1. Among older U.S adults with diabetes, does proxy health literacy predict diabetes biomarker test scores (HbA1c, FBG, and OGTT)?

Associations between the predictor variables (adequate, marginal, and inadequate health literacy) and the outcome variables (i.e. HbA1c, FBG, and OGTT), were examined first through correlations and then hierarchical multiple linear regression analysis. Dummy variables were created for all dichotomous predictor variables to be able to run correlations and multiple regression analyses. Point -biserial correlations were calculated when the independent variable was a dichotomous variable and the dependent variable continuous. Point-biserial correlations was used to examine the strength of the relationship but the direction between the two variables.

The predictors were entered simultaneously in 2 blocks (1) demographic/family characteristics and diabetes characteristic; (3) proxy health literacy score. This study performed hierarchical multiple regression modeling to determine if health proxy health literacy scores could predict HbA1c, FBG, or OGTT by taking into account the effect of covariates (years since diabetes diagnosis, BMI, family history of diabetes, poverty ratio, marital status, and insurance status. The hierarchical multiple regression analysis allows the importance of the independent variable to be assessed after all covariates have been controlled for. Covariates were inputted in blocks, followed by the true variable of interest (HL level).

Table 10.
Pearson correlations of HbA1c and FBG and covariates, adults 55 and older with diabetes, NHANES 2009-2010

Independent variables	HbA1c	Sig.	FBG	Sig.
Poverty Ratio Ⱦ				
0-100%	-.018	.368	.015	.426
101-200%	-.063	.119	**.139***	**.039**
201-300%	.030	.283	.080	.157
301-400%	.041	.220	**-.150***	**.029**
401-500%	---	---	---	---
Health insurance				
Uninsured	.060	.128	.037	.323
Private	-.014	.398	-.068	.196
Government	**.088***	**.049**	.111	.081
Private and Government	---	---	---	---
Marital Status				
Never Married	-.006	.455	-.007	.466
Married	.036	.248	.054	.248
Wid/Sep/Div	---	---	---	---
Body Mass Index Ⱦ				
Underweight	-.059	.133	-.058	.231
Normal	-.005	.466	**.154***	**.026**
Overweight	-.110	.019	-.048	.273

Obese	---	---	**---**	**---**
Years Since Diagnosis	**.205**	**.000**	.086	.139
Close Relative has DM	.054	.156	**.128***	**.050**
Proxy DAHL Score Ɨ	-.009	.430	**-.196***	**.006**

*Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).
Ɨ Point-biserial correlations due to the dummy variable created for the analysis.

The respective Pearson (r) and point-biserial correlations (r_{pb}) between covariates and the two diabetes biomarker tests are provided in Table 10. HbA1c had statistically significant linear association to "government sponsored health insurance" (r=.088, $p < .05$) and "number of years since diabetes diagnosis" (r=.205, $p < .001$). Fasting blood glucose had statistically significant linear relationship to "poverty ratio 101-200% above the poverty threshold" (r= .139, $p < .05$); "poverty ratio 301-400% above the poverty threshold" (r= -.150, $p < .05$); "BMI normal" (r= -.154, $p < .05$); "relative has diabetes" (r = .128, $p < .05$) and "health literacy proxy score" (r= -.196, $p < .05$).

Table 11
Hierarchical regression analysis, HbA1c and health literacy, adults 55 and older with self-reported diabetes, NHANES 2009-2010

Glycohemoglobin				t	Sig.	95.0% CI for B	
	B	SE	Beta			Lower	Upper
Variables	6.53	0.31		21.30	0.00	5.93	7.14
PVT							
0-100%	-0.17	0.17	-0.06	-0.96	0.34	-0.50	0.17
101-200%	-0.17	0.12	-0.09	-1.40	0.16	-0.40	0.07
201-300%	0.01	0.13	0.01	0.10	0.92	-0.24	0.26
301-400%	0.02	0.14	0.01	0.12	0.91	-0.26	0.30
401-500%	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Insurance Status							
Uninsured	0.38	0.23	0.09	1.68	0.09	-0.07	0.83

	B	SE	Beta	t	Sig.	Lower	Upper
Private	0.06	0.11	0.03	0.52	0.60	-0.16	0.27
Government	**0.24**	**0.11**	**0.13**	**2.25**	**0.03***	0.03	0.45
Govt/Private	---	---	---	---	---	---	---
Marital Status							
Married	0.01	0.18	0.00	0.04	0.97	-0.35	0.37
Sep/Wid/Div	0.05	0.10	0.03	0.55	0.58	-0.14	0.24
Never Married	---	---	---	---	---	---	---
BMI							
Underweight	-0.73	0.52	-0.07	-1.40	0.16	-1.75	0.29
Normal	-0.09	0.16	-0.03	-0.54	0.59	-0.40	0.23
Overweight	**-0.19**	**0.10**	**-0.11**	**-1.97**	**0.05***	-0.38	0.00
Obese	---	---	---	---	---	---	---
Yrs since diagnosis	**0.01**	**0.00**	**0.21**	**4.04**	**0.03***	0.01	0.02
Family history	0.10	0.09	0.06	1.16	0.25	-0.07	0.27
DAHL score	0.00	0.00	-0.03	-0.45	0.66	-0.01	0.01

a. Dependent Variable: Glycohemoglobin (mg/dL)
b. Complex Samples Procedure Weighted by MEC 2 Year MEC Weight
Model: Glycohemoglobin (mg/dL) = (Intercept) + YRS_SINCE_DIAGNOSIS + MCQ300C + dummy_BMI_1 + dummy_BMI_2 + dummy_BMI_3 + dummy_pvt_1 + dummy_pvt_2 + dummy_pvt_3 + dummy_pvt_4 + dummy_ins_type_1 + dummy_ins_type_2 + dummy_ins_type_3 + Dummy_MARTL_1 + Dummy_MARTL_2 + DAHL_SCORES

Table 12
Hierarchical regression analysis, FBG and health literacy, adults 55 and older with self-reported diabetes, NHANES 2009-2010

Fasting Blood Glucose				t	Sig.	95.0% CI for B	
	B	SE	Beta			Lower	Upper
(Constant)	128.82	16.70		7.71	0.00	95.82	161.83
Poverty Level							
0-100%	3.37	8.80	0.04	0.38	0.70	-14.02	20.76
101-200%	9.62	6.12	0.18	1.57	0.12	-2.48	21.73
201-300%	**12.41**	**6.41**	**0.20**	**1.94**	**0.05**	-0.25	25.08
301-400%	-3.23	7.27	-0.04	-0.44	0.66	-17.60	11.14
401-500%	---	---	---	---	---	---	---
Insurance Status							
No Insurance	10.91	13.53	0.07	0.81	0.42	-15.82	37.64
Private	7.39	5.34	0.13	1.38	0.17	-3.17	17.95
Government	7.59	5.01	0.13	1.52	0.13	-2.31	17.49
Govt/Private	---	---	---	---	---	---	---

Marital Status							
Married	1.51	7.84	0.02	0.19	0.85	-13.99	17.01
Sep/Wid/Div	2.16	4.63	0.04	0.47	0.64	-7.00	11.32
Never Married	---	---	---	---	---	---	---
BMI							
Underweight	-42.68	35.22	-0.10	-1.21	0.23	-112.28	26.93
Normal	10.98	6.24	0.15	1.76	0.08	-1.35	23.31
Overweight	-2.51	4.94	-0.04	-0.51	0.61	-12.28	7.26
Obese	---	---	---	---	---	---	---
Yrs since diagnosis	0.06	0.19	0.02	0.30	0.77	-0.33	0.44
Family history	**10.20**	**4.40**	**0.18**	**2.32**	**0.02**	1.51	18.90
DAHL score	**-.39**	**.17**	**-.20**	**-2.22**	**0.03**	-0.74	-0.04

a. Dependent Variable: Fasting Glucose (mg/dL)

b. Complex Samples Procedure Weighted by Fasting Subsample 2 Year MEC Weight

Model: Fasting Glucose (mg/dL) = (Intercept) + YRS_SINCE_DIAGNOSIS + MCQ300C + dummy_BMI_1 + dummy_BMI_2 + dummy_BMI_3 + dummy_pvt_1 + dummy_pvt_2 + dummy_pvt_3 + dummy_pvt_4 + dummy_ins_type_1 + dummy_ins_type_2 + dummy_ins_type_3 + Dummy_MARTL_1 + Dummy_MARTL_2 + DAHL_SCORES

Table 13.
Summary of hierarchical regression analysis testing HbA1c, FBG and Health Literacy controlling for covariates, U.S adults 55 years and older with diabetes, NHANES 2009-2010

	R^2	F	ΔR^2	ΔF	Sig. F change	Model P-value
HbA1c						
Block 1	.089	2.363	.089	2.363	.004**	.004**
Block 2	.089	2.214	.001	.198	.657	**.006****
			Full Model: R^2 = .089, F(15, 635) = 2.214, ρ = < .01			
FBG						
Block 1	.124	1.480	.124	1.480	.125	.125
Block 2	.153	1.749	.029	4.950	.028	**.048***
			Full Model: R^2 = .153, F(15, 160) = .671, ρ = .810			

Note: Complex samples procedure.

Hierarchical multiple regression analysis was done in complex samples analysis to explore the association between HbA1c and health literacy (shown in Table 11), controlling for six covariates. Predictors were entered in 2 blocks; (Block 1: marital status, health insurance type, poverty ratio, body mass index, years since diabetes diagnosis, family history of diabetes;

Block 2: health literacy score). The hierarchical multiple regression with HbA1c as the outcome variable revealed that Block 1, which contained the demographic characteristics and diabetes related factors (family history, years since diagnosis, and BMI) explained 9% in predictive capacity. The addition of proxy health literacy score, increased the predictive capacity by 0.01%. This change in R^2 was not statistically significant, $p = .657$. Adding the health literacy to the model did not explain any of the variance observed in HbA1c. After accounting for covariates, this study found that the relationship between HbA1c and health literacy was fully mediated by the control factors and HL did not contribute to the model.

Together the predictors (demographics, family history of DM, years since diabetes diagnosis, BMI, and proxy health literacy) accounted for 9% of the variation in HbA1c and the overall model was found to have a statistically significant predictive capacity, $p < .05$. Thought the full model was statistically significant, DAHL score did not contribute anything above and beyond once covariates were accounted for. Therefore, hypothesis 1a. was supported in the regression analysis with the use of complex samples procedure. Table 11. presents the variables that made a unique statistically significant contribution to the model, having overweight BMI, government sponsored health insurance and years since diabetes diagnosis.

Government sponsored health insurance: $\beta = t(355) = 2.25$, $p = .003$, $pr^2 = .393$, as it increases from (0 to 1), glycohemoglobin score increases by 0.13

Overweight BMI: $\beta = t(355) = 1.97$, $p = .05$, $pr^2 = .380$, Overweight BMI goes up from (0 to 1), glycohemoglobin score decrease by -.011

Years since DM Diagnosis: β = t(355)= -.197, $p = .028$, $pr^2 = .488$, number of years since diagnosis increases, glycohemoglobin score increase by .21

The hierarchical multiple regression with FBG (shown in Table 13) as the outcome variable revealed that the control factors alone (marital status, poverty ratio, insurance type, family history of DM, years since diagnosis, and BMI) in Block 1 did not predict Fasting blood glucose scores to a statistically significant degree. Introducing the DAHL level in Block 2 did contribute to the regression model by 3% in increased variability. Together the demographic, family history of DM, years since diagnosis, BMI and DAHL level accounted for 15.3% of the variation in FBG. The R^2 change meant that proxy HL scores did have an effect above and beyond the effects of the control variables. The overall model did significantly predict FBG, F (15,160) = .671, $p = .05$. Table 12. presents the most significant contributors to the model were poverty ratio 301-400%, close relative with DM and HL score.

Poverty 201-300%: β = t(161)= 2.25, $p = .003$, $pr^2 = .393$, as it increases from (0 to 1), FBG score increases by 0.13

Family History of DM: β = t(161)= 1.97, $p =.05$, $pr^2 = .380$, Family history of DM goes up from (0 to 1), FBG decrease by -.011

DAHL Score: β = t(161)= -.197, $p = .028$, $pr^2 = .488$, as proxy health literacy score increases, fasting blood glucose score increase by .21, Therefore, hypothesis 1b. was supported in the regression analysis with the use of complex samples procedure. The full model, controlling for covariates was not statistically significant. The addition of DAHL scores made a unique contribution though the full model was not found to be significant.

Research Question 2: Among U.S adults with diabetes, is DAHL status associated with indicators of proper diabetes self-management (IPDSM), adjusting for potential confounders?

Indicators of proper diabetes management behaviors and health literacy

Research question two analyzed the likelihood (OR) of experiencing commonly known indicators of proper diabetes self-management behaviors. Data were first checked for any outliers using P-P plots. This study used chi-square (x^2) to analyze (shown in Table 15.) diabetes related health behaviors by level of health literacy. Second, the study explored the association between HL and the binary health behaviors (taking insulin, taking blood sugar control medication, daily exercise, daily glucose check, going to a DM specialist, controlled BP, by using the complex sample logistic regression (CSLR). In logistic regression analysis (the largest value is reference category), all variable that were labeled “never, no, or none” were recoded to the largest value for each of its category.

Table 14.

Cross-tabulation of indicators of proper diabetes management stratified by DAHL level, older adults age 55 and older with diabetes, NHANES 2009-2010

		Adequate HL N (%)		Marginal HL N (%)		Inadequate HL N (%)	
Characteristic		No	Yes	No	Yes	No	Yes
Taking insulin	Yes	86 (56.4%)	66 (43.6%)	107 (70.7%)	45 (29.3%)	111 (72.9%)	41 (27.1%)

(n=768)	No	312 (50.6%)	304 (49.4%)	458 (74.4%)	158 (25.6%)	462 (75.0%)	154 (25.0%)
Taking oral hypoglycemic medications (n=604)	Yes	**234 (53.6%)**	**203 (46.4%)**	318 (72.8%)	119 (27.2%)	322 (73.6%)	115 (26.4%)
	No	**71 (42.6%)**	**96 (57.4%)**	130 (77.7%)	37 (22.3%)	133 (79.7%)	34 (20.3%)
Saw DM specialist in the past year	Yes	113 (53.2%)	99 (46.8%)	94 (61.2%)	59 (26.8%)	198 (62.4%)	126 (26.4%)
	No	172 (53.9%)	147 (46.1%)	235 (61.6%)	84 (26.4%)	129 (61.1%)	78 (27.4%)
Check feet for sores daily (n=528)	Yes	232 (54.7%)	192 (45.3%)	306 (72.2%)	118 (27.8%)	310 (73.0%)	114 (27.0%)
	No	51 (49.4%)	53 (50.6%)	81 (77.6%)	23 (22.4%)	76 (73.0%)	28 (27.0%)
Physical Activity (n=768)	Yes	23 (35.7%)	42 (64.3%)	51 (79.2%)	14 (20.8%)	55 (85.0%)	10 (15.0%)
	No	375 (53.3%)	328 (46.7%)	515 (73.2%)	188 (26.8%)	517 (73.5%)	186 (26.5%)
Check eyes for retinopathy (n=528)	Yes	193 (52.9%)	172 (47.1%)	119 (72.9%)	4 4 (27.1%)	271 (74.2%)	94 (25.8%)
	No	88 (54.3%)	75 (45.7%)	123 (75.5%)	40 (24.5%)	114 (70.2%)	49 (29.8%)
Controlled high blood pressure (n=692)	Yes	230 (49.0%)	240 (51.0%)	349 (74.3%)	121 (25.7%)	360 (76.7%)	**110 (23.3%)**
	No	130 (58.4%)	92 (41.6%)	160 (72.0%)	62 (28.0%)	155 (69.6%)	**67 (30.4%)**
Check blood glucose (n=526)	Yes	236 (53.4%)	206 (46.6%)	320 (72.5%)	122 (27.5%)	328 (74.1%)	114 (25.9%)
	No	47 (56.3%)	37 (43.7%)	65 (77.2%)	19 (22.8%)	56 (66.5%)	28 (33.5%)

Note: column percentages=100, percentages do not reflect sample size in each cell due to weighted analyses

All expected cell frequencies were greater than five as presented in Table 14. There was a statistically significant association between “taking oral hypoglycemic meds” and adequate health literacy, χ^2 (1) = 6.244, p = .039 and “having controlled high blood pressure” and inadequate health literacy, χ^2 (1) = 8.093, p = .048. All associations with p-values greater than .05 are therefore non-significant.

Table 15.

Chi-square associations between indicators of proper diabetes management by health literacy level, adults 55 years and older with diabetes, NHANES 2009-2010

	X^2	Sig.
Saw diabetes specialist in the past year		
(Yes) *adequate	.026	.914
(Yes) * marginal	.008	.948
(Yes) * inadequate	.074	.848
Taking insulin now		
(Yes) * adequate	1.476	.467
(Yes) * marginal	.794	.521
(Yes) * inadequate	.244	.653
Take oral hypoglycemic medications (Yes) * adequate	6.244	**.036***
(Yes) * marginal	1.636	.316
(Yes) * inadequate	2.575	**.036***
Daily feet check		
(Yes) * adequate	1.117	.295
(Yes) * marginal	1.436	.275
(Yes) * inadequate	.000	.997
Exercises		
(Y)* adequate	8.317	.063
(Yes) * marginal	1.276	.166
(Yes) * inadequate	4.704	.097
Retinopathy check		
(Yes) * adequate	.090	.815
(Yes) * marginal	.395	.610
(Yes) * inadequate	.920	.328
Controlled BP		
(Yes) * adequate	8.093	.242
(Yes) * marginal	4.375	.153
(Yes) * inadequate	1.312	**.048***
Daily glucose check		
(Yes) * adequate	.249	.681
(Yes) * marginal	.855	.483
(Yes) * inadequate	2.184	.101

[1]Complex sample weighted data, cscrosstab procedure

Table 16.
Univariate logistic regression. Indicators of proper diabetes self-management behaviors associated with adequate, marginal, and inadequate health literacy, older adults age 55 and older with diabetes mellitus.

		Health Literacy Level		
Characteristic		Adequate Odds Ratio Confidence Interval p-value	Marginal Odds Ratio Confidence Interval p-value	Inadequate Odds Ratio Confidence Interval p-value
Taking Insulin	No	1.00	1.00	1.00
	Yes	.794 (.957–1.13), 0.32	1.20 (.908-1.23), 0.435	1.11 (.952-1.022), 0.427
Taking Oral Hypoglycemic Meds	No	1.00	1.00	**1.00**
	Yes	.642 (.858–1.023), 0.136	0.642 (.88–1.11), 0.856	**1.036 (1.00-1.068), 0.03**
Daily Physical Activity	No	1.00	1.00	1.00
	Yes	1.06 (.971-1.163), 0.172	1.043 (.895-1.21), 0.57	1.019 (.931-1.11), 0.668
Check feet for Sores	No	1.00	**1.00**	1.00
	Yes	1.075 (.992-1.165), 0.76	**.740 (.599-.915), .008**	1.006 (.955-1.06), 0.823
Eyes dilated	No	1.00	1.00	1.00
	Yes	.968 (.885-1.057), 0.442	0.962 (.962-.825), 0.60	.989 (.942-.989), 0.640
Controlled BP	No	1.00	1.00	**1.00**
	Yes	0.992 (.906-1.08), 0.859	1.056 (.976-1.14), 0.16	**1.042 (1.00-1.08), 0.041**
Check glucose daily	No	1.00	1.00	1.00
	Yes	1.027 (.950-1.11), 0.475	1.025 (.872-1.20), 0.85	1.008 (.949-1.07), 0.790
Saw DM specialist	No	1.00	1.00	1.00
	Yes	1.07 (.980-1.17), 0.118	0.980 (.897-1.07), 0.67	0.982 (.89-1.07), 0.67

Note: Complex Sample Logistic Procedure

In univariate logistic regression, this study predicted the odds of the 8 indicators of proper self-management and health literacy by level, without controlling for covariates. In Table

16. this study found three significant associations. In the marginal HL level, Daily feet check Wald F =5.77, *p* = 0.29, OR = .740, CI [.60, .91]; in the inadequate HL level, taking oral hypoglycemic medication Wald F = 5.77, p = .029, OR = 1.036, CI [1.00, 1.068]; and in the inadequate HL level, controlled BP, Wald F = 4.938, p = .041, OR = 1.042, CI [1.00, 1.08].

Next, logistic regression was performed to ascertain the effect of health literacy level, controlling for covariates (BMI, PVT, marital status, years since diagnosis, family history of DM, and insurance type) and 8 indicators of proper diabetes management (insulin use, oral hypoglycemic medication, seeing a DM specialist in the past year, target BP, physical activity, eye check, and feet check). Results of the separate CSLR analyses predicting the presence of diabetes related indicators of proper self-management with health literacy are provided in Tables 17-24.

Predicting the Odds of Insulin Use

Table 17.
Complex sample logistic regression analysis of indicator of proper diabetes management (insulin use) and health literacy, adults 55 and older with diabetes, NHANES 2009-2010. (n = 768)

			95% CI		Hypothesis Test			OR	95% CI for Exp (B)	
Taking Insulin	B	SE	Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	-1.89	.81	-3.61	-.16	-2.32	16	.03	.15	.03	.85
Poverty Ratio										
0-100%	-1.20	.38	-2.00	-.40	-3.18	16	**.01**	**.30**	**.13**	**.67**
101-200%	-.17	.40	-1.01	.68	-.41	16	.68	.85	.36	1.97
201-300%	-.12	.42	-1.01	.77	-.28	16	.78	.89	.37	2.16
301-400%	-.32	.74	-1.89	1.24	-.44	16	.67	.72	.15	3.47

401-500%	.00[a]	.	.	.	.	16	.	1.00	.	.
Health Insurance										
Uninsured	0.66	0.44	-0.28	1.59	1.49	16	0.16	1.93	0.76	4.90
Private	0.20	0.40	-0.66	1.05	0.49	16	0.63	1.22	0.52	2.87
Government	-0.02	.35	-0.75	0.71	-0.06	16	0.95	0.98	0.47	2.04
Private/ Govt	.000[a]					16		1.00		
Marital Status										
Married	-0.45	0.53	-1.58	0.67	-0.86	16	0.40	0.63	0.21	1.95
Sep/Wid/Div	-0.16	0.58	-1.39	1.07	-0.28	16	0.78	0.85	0.25	2.90
NeverMarried	.000[a]					16		1.00		
BMI										
Underweight	-29.57	1.09	-31.89	-27.25	-27.0	16	**---**	**---**	---	**---**
Normal	-0.53	0.50	-1.58	0.52	-1.07	16	0.30	0.59	0.21	1.69
Overweight	-1.11	0.41	-1.97	-0.24	-2.71	16	**0.02**	**0.33**	**0.14**	**0.79**
Obese	.000[a]					16		1.00		
Health Literacy										
Adequate	-0.19	0.64	-1.54	1.17	-0.29	16	0.77	0.83	0.21	3.21
Marginal	-0.57	0.39	-1.40	0.27	-1.44	16	0.17	0.57	0.25	1.31
Inadequate	.000[a]					16		1.00		
Years since DM diagnosis	0.10	0.02	0.05	0.15	4.39	16	**0.00**	**1.11**	**1.05**	**1.17**
Close relative had DM	-0.68	0.38	-1.49	0.13	-1.79	16	0.09	0.50	0.22	1.13

Dependent Variable: Taking insulin now (reference category = No)
Model: (Intercept), PVT, BMI, Insurance, MRTL, YRS since DX, Family DM History, DAHL_LEVELS

(1) Results: HL regressed on Insulin Use

Wald F (1, 16) = 538.88 , $p < .05$ (shown in Table 17). In Block 0, the Nagelkerke R^2 was 31.7%. The full model explained 32.4% (Nagelkerke R^2) of the variance in insulin use. Of the seven predictor variables only three were statistically significant: PVT 0-100%; Overweight BMI; and Years since diagnosis (as shown in Table 17.). There was 70% lower odds of insulin use for individuals who were 0-100% below the poverty line, t (16) = -3.18, p = .01, OR = .30. The odds of insulin use increased 11% for each additional year that an individual had since DM diagnosis, t (16) = 4.39, p = .000, OR = 1.11. There was 67% lower odds of insulin use for individuals with BMI overweight, t (16) = -2.71, p = .02, OR = .33. Uninsured, t (16) = 1.49, p = 0.16, OR = 1.93 and marginal health literacy, t (16) = -1.44, p = .17, OR = 0.57, were influential but not significant predictors of insulin use at the probability level p < .20.

The odds ratio for adequate HL was OR=.83, CI = [0.21, 3.21] indicates that as HL changes from 0 to 1 (inadequate HL to adequate HL), the odds of insulin use decreases. Since the confidence interval crossed 1, therefore adequate HL is not a reliable predictor of insulin use. If an individual with adequate HL (compared to an individual with inadequate HL), they would be 1.2 times less likely to use insulin. For marginal HL, OR = .57, CI = [0.25, 1.31] it indicated that when HL changed from 0 to 1 (inadequate HL to marginal HL), then subjects are about 1.7 times less likely to use insulin. Since the confidence interval crossed 1, marginal HL is nor a reliable predictor of insulin use. Health literacy was not statistically significant.

Table 18.
Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (oral hypoglycemic agents) with the health literacy predictor, controlling for covariates, older adults 55 years and older, with diabetes, NHANES 2009-2010. (n = 604)

Taking oral hypoglycemic medication	B	SE	95% CI		Hypothesis Test			OR	95% CI for Exp (B)	
			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	2.81	1.05	.60	5.03	2.69	16	.02	16.69	1.82	
Poverty Ratio										
0-100%	0.47	0.28	-0.13	1.06	1.65	16	0.12	1.59	0.88	2.90
101-200%	0.82	0.39	-0.01	1.65	2.09	16	**0.05**	**2.26**	**0.99**	**5.19**
201-300%	0.52	0.54	-0.63	1.67	0.96	16	0.35	1.68	0.53	5.33
301-400%	1.69	0.55	0.52	2.86	3.07	16	**0.01**	**5.41**	**1.69**	**17.40**
401-500%	.000[a]							1.00		

Health Insurance										
Uninsured	-0.19	0.52	-1.30	0.91	-0.37	16	0.72	0.82	0.27	2.49
Private	0.56	0.38	-0.23	1.36	1.50	16	0.15	1.76	0.79	3.91
Government	0.21	0.23	-0.29	0.70	0.88	16	0.39	1.23	0.75	2.02
Private and Govt	.000[a]					16		1.00		
Marital Status										
Married	-1.18	0.83	-2.94	0.57	-1.43	16	0.17	0.31	0.05	1.78
Sepr/Wid/Dircd	-1.37	0.86	-3.20	0.46	-1.59	16	0.13	0.25	0.04	1.58
Never Married	.000[a]					16		1.00		
BMI										
Underweight	-1.31	1.11	-3.66	1.05	-1.18	16	0.26	0.27	0.03	2.85
Normal	-0.67	0.44	-1.61	0.27	-1.51	16	0.15	0.51	0.20	1.31
Overweight	-1.00	0.46	-1.97	-0.02	-2.17	16	**0.05**	**0.37**	**0.14**	**0.98**
Obese	.000[a]					16		1.00		
Health Literacy										
Adequate	-0.12	0.48	-1.15	0.91	-0.25	16	0.81	0.89	0.32	2.47
Marginal	0.10	0.56	-1.08	1.28	0.17	16	0.86	1.10	0.34	3.59
Inadequate	.000[a]					16		1.00		
Years since DM diagnosis	-0.04	0.02	-0.07	0.00	-2.27	16	**0.04**	**0.97**	**0.93**	**1.00**
Close relative had DM	-0.06	0.45	-1.00	0.89	-0.12	16	0.90	0.95	0.37	2.44

Dependent Variable: oral hypoglycemic meds (reference category = No)
Model: (Intercept), PVT, BMI, Insurance, MRTL, YRS since DX, Family DM History, DAHL
a. Set to zero because this parameter is redundant.

(2) Results: HL regressed on Oral hypoglycemic medication

In the logistic regression model, it was found that the predictor variables, did not significantly predict oral hypoglycemic medication use, Wald F (1, 16) = .424, *p* = .856 (shown in Table 18.). In Block 0, the Nagelkerke R^2 was 13.9%. The full model explained 14.1% (Nagelkerke R^2) of the variance in oral hypoglycemic medication use. Of the seven predictor variables only four were statistically significant: PVT 101-200%; PVT 301-400%; Overweight BMI; and Years since diagnosis (as shown in Table 18).

The odds of oral hypoglycemic medication use increased by 2 times the likelihood for individuals who were 101-200% above the poverty line, t (16) = 2.09, p = .05, OR = 2.26. Since the confidence interval crossed 1, PVT 101-200% above the poverty line is not a reliable predictor of oral hypoglycemic medication use. The odds of oral hypoglycemic medication use increased by 5 times the likelihood for individuals who were 301-400% above the poverty line, t (16) = 3.07, p = .01, OR = 5.41. Since the confidence interval confidence interval does not cross 1, results indicate with confident that the relationship between "PVT 301-400% above the national poverty line" and "oral hypoglycemic medication use" found in this sample would be found in 95% of samples from the same population. For every 1 year increase in total number of years since diabetes diagnosis, [t (16) = -2.27, p = .04, OR = .97], the odd of using oral hypoglycemic medication decreased by 3%. In addition, because both confidence values are less than 1, results indicate with confident that the relationship between oral hypoglycemic medication use and total number of years since DM diagnosis found in this sample would be found in 95% of samples from the same population.

PVT 0-100%, [t (16) = 1.65, p = 0.12, OR = 1.59]; private health insurance, [t (16) = 1.50, p = 0.015], married, [t (16) = -1.43, p = .17]; and normal BMI, [t (16) = -1.51, p = .17, OR = 0.51], were influential but not significant predictors of oral hypoglycemic medication use at *p* = <.20. The odds ratio for adequate HL was OR=.89, CI = [0.32, 2.47] indicates that as HL changes from 0 to 1 (inadequate HL to adequate HL), the odds of oral hypoglycemic medication use decreases. Since the confidence interval crossed 1, therefore adequate HL is not a reliable predictor of oral glucose lowering medication use. For individuals with marginal HL, OR = 1.10, CI = [0.34, 3.59] it indicated that when HL changed from 0 to 1 (inadequate HL to marginal HL), then subjects are about 1.1 times more likely to use oral blood glucose lowering medication. Since the confidence interval crossed 1, marginal HL is nor a reliable predictor of oral blood glucose lowering medication use. Health literacy was not statistically significant.

Table 19

Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (daily physical activity) with the health literacy predictor, controlling for covariates, older adults 55 years and older, with diabetes, NHANES 2009-2010. (n = 768)

Daily Physical Activity	B	SE	95% CI		Hypothesis Test			OR	95% CI for Exp(B)	
			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	2.86	1.40	-5.83	.12	-2.04	16	.06	.06	.00	1.13
Poverty Ratio										
0-100%	1.11	.71	-.39	2.61	1.57	16	.14	3.04	.68	13.66
101-200%	1.18	.93	-.78	3.15	1.28	16	.22	3.27	.46	23.37
201-300%	.83	.89	-1.06	2.71	.93	16	.37	2.29	.35	15.08
301-400%	1.50	.80	-.20	3.20	1.87	16	.08	4.46	.82	24.42
401-500%	.000[a]							1.00		
Health Insurance										
Uninsured	.11	.79	-2.01	1.32	.44	16	.66	.71	.13	3.73
Private	-.87	.45	-.84	1.07	.25	16	.81	1.12	.43	2.90
Government	0.17	.84	-2.66	.92	-1.03	16	.32	.42	.07	2.51
Private/Govt	000[a]							1.00		
Marital Status										
Married/Partner										
Sep/Wid/Div	-.31	1.16	-2.78	2.16	-.27	16	.79	.73	.06	8.63
Never Married	-.74	1.11	-3.10	1.62	-.67	16	.51	.48	.04	5.04
	.00[a]	.	.	.	.	.	.	1.00	.	.
BMI										
Underweight	-24.3	1.11	-26.7	-21.9	-21.8	16	.000	.000	.000	.000
Normal	-1.26	.75	-2.85	.32	-1.69	16	.11	.28	.06	1.38
Overweight	-.75	0.74	-2.32	.82	-1.01	16	.33	.47	.10	2.27
Obese	.000[a]							1.00		

Close relative had DM	.03	.34	-.68	.74	.09	16	.93	1.03	.51	2.09
HL		.								
Adequate	1.26	87	-.59	3.11	1.45	16	.17	3.53	.56	22.40
Marginal	.68	.67	-.74	2.11	1.02	16	.32	1.98	.48	8.25
Inadequate	.000[a]							1.00		
Yrs since diagnosis	-0.02	.03	-.09	.04	-.72	16	.48	.98	.91	1.05

Dependent Variable: Daily Physical Activity (reference category = No)
Model: (Intercept), RECODED_PVT_RATIO, INS_TYPE, RECODED_MARTL, RECODED_BMI, DAHL_LEVELS, YRS_SINCE_DIAGNOSIS, MCQ300

(3) Results: Hl regressed on Daily physical activity

The logistic regression model was statistically significant, Wald F (1, 16) = 645.47, $p < .05$ (shown in Table 19.). In Block 0, the Nagelkerke R^2 was 10.7%. The model explained 13.4% (Nagelkerke R^2) of the variance in doing daily physical activity. Of the seven predictor variables none were statistically significant (as shown in table 19). After controlling for the confounders, HL contributed 2.7% of variability to the model. PVT 0-100% below the poverty line, t (16) = 1.57, p = 0.14, OR = 4.46; PVT 301-400% above the poverty line, t (16) = 1.57, p = 0.14, OR = 4.46; Normal BMI, t (16) = -1.69, p = .11, OR = 0.28; and adequate health literacy were influential but not significant predictors of the likelihood of daily physical activity at the probability level <.20.

The odds ratio for adequate HL was OR= 3.53, CI = [0.56, 22.47] indicates that as HL changes from 0 to 1 (inadequate HL to adequate HL), the odds of daily physical activity increased. Since the confidence interval crossed 1, therefore adequate HL is not a reliable predictor of daily physical activity. If an individual with marginal HL (compared to an individual with inadequate HL), they would be 3.5 times more likely to do daily physical activity. For marginal HL, OR = 1.98, CI = [0.48, 8.25] it indicated that when HL changed from 0 to 1 (inadequate HL to the other two categories (adequate HL and marginal HL)), then subjects are about 2 times more likely to do daily physical activity. Since the confidence interval crossed 1, marginal HL was not a reliable predictor of daily physical activity. Health literacy was not a statistically significant predictor of daily physical activity.

Table 20.
Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (controlled blood pressure) with the health literacy predictor, controlling for covariates, older adults 55 years and older, with diabetes, NHANES 2009-2010. (n = 692)

Controlled Blood Pressure Status	B	SE	95% CI		Hypothesis Test			OR	95% CI for Exp (B)	
			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	2.30	.98	.22	4.38	2.34	16	.03	9.95	1.24	79.55
Poverty Ratio										
0-100%	.18	.56	-1.00	1.36	.32	16	.75	1.20	.37	3.89
101-200%	-.23	.46	-1.21	.75	-.50	16	.62	.79	.30	2.12
201-300%	.05	.51	-1.04	1.14	.10	16	.92	1.06	.35	3.14
301-400%	.02	.48	-1.00	1.04	.04	16	.97	1.02	.37	2.83
401-500%	.00	.	.	.	.	.	.	1.00	.	.
Health Insurance										
Uninsured	-.61	.70	-2.09	.87	-.88	16	.39	.54	.12	2.38
Private	.73	.48	-.29	1.75	1.52	16	.15	2.07	.75	5.74
Government	.17	.33	-.54	.87	.50	16	.62	1.18	.58	2.39
Private and Govt	.00	.	.	.	.	.	.	1.00	.	.
Marital Status										
Married/Partner	-1.03	.67	-2.46	.39	-1.54	16	.14	.36	.09	1.48
Sep/Wid/Div	-1.19	.70	-2.68	.30	-1.69	16	.11	.30	.07	1.35
Never Married	.00	.	.	.	.	.	.	1.00	.	.
BMI					.					
Underweight	.25	1.46	-2.84	3.34	17	16	.87	1.28	.06	28.35
Normal	.45	.40	-.40	1.29	1.12	16	.28	1.57	.67	3.65
Overweight	.18	.31	-.48	.84	.58	16	.57	1.20	.62	2.31
Obese	.00	.	.	.	.	.	.	1.00	.	.

Health Literacy										
Adequate	-.07	.46	-1.04	.90	-.16	16	.88	.93	.35	2.46
Marginal	-.22	.29	-.84	.39	-.77	16	.45	.80	.43	1.48
Inadequate	.00	.	.	.	.	.	.	1.00	.	.
Years since DM diagnosis	-0.02	0.01	-0.05	0.00	-1.90	16	.08	0.98	0.96	1.00
Close relative had DM	-.35	.18	-.74	.04	-1.92	16	.07	.70	.48	1.04
Dependent Variable: Blood Pressure Status (reference category = Uncontrolled) Model: (Intercept), RECODED_PVT_RATIO, INS_TYPE, RECODED_MARTL, RECODED_BMI, DAHL_LEVELS, YRS_SINCE_DIAGNOSIS, MCQ300										

(4) Results: HL regressed on Blood Pressure

The logistic regression model predicting controlled blood pressure, was not statistically significant, Wald F (1, 16) = 1.727, p = .542 (shown in Table 20). In Block 0, the Nagelkerke R^2 was 8.2%. The model explained 8.4% (Nagelkerke R^2) of the variance controlled BP. Of the seven predictor variables, none were statistically significant (as shown in table 20). The following were influential but not significant predictors of the likelihood of controlled blood pressure at the probability level (p < .20). Subject who were married, compared to never married, t (16) = -1.54, p = 0.14, OR = .36; had 64% less odds of having controlled BP. Sep/Wid/Div compared to married and never married, t (16) = -1.69, p = .11, OR=.30, meaning the odds of having controlled BP, decreased. For every one unit increase in total years since DM diagnosis, t (16) = -1.90, p = .08, OR=.98, the odds of having controlled BP decreased by 2%. Having family history of diabetes, t (16) = 1.92, p = 0.08, OR = .70. decreased the odds of having controlled BP by 30%/.

The odds ratio for adequate HL was OR= .93, CI = [.35 – 2.46] indicates that as HL changes from 0 to 1 (inadequate HL to adequate HL), the odds of having controlled BP decreased. Since the confidence interval crossed 1, therefore adequate HL is not a reliable predictor of having lower BP. If an individual with marginal HL (compared to an individual with inadequate HL), they would be 7% times less likely to do have controlled BP. For marginal HL, OR = .80, CI = [0.43, 1.48] it indicated that when HL changed from 0 to 1 (inadequate HL to marginal HL), they were 20% less likely to do daily physical activity. Since the confidence interval crossed 1, marginal HL is not a reliable predictor of having controlled BP. Health literacy was not statistically significant.

Table 21.

Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (daily glucose check) with the health literacy predictor, controlling for covariate, older adults 55 years and older, with diabetes, NHANES 2009-2010. (n = 526)

Daily Glucose Check	B	SE	95% CI		Hypothesis Test			OR	95% CI for Exp (B)	
			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	1.17	.54	.03	2.31	2.17	16	.05	3.22	1.03	10.09
Poverty Ratio										
0-100%	.51	.59	-.74	1.77	.86	16	.40	1.67	.48	5.85
101-200%	.55	.54	-.59	1.70	1.02	16	.32	1.74	.55	5.45
201-300%	.43	.33	-.27	1.13	1.29	16	.21	1.54	.76	3.10
301-400%	-.17	.85	-1.98	1.64	-.20	16	.85	.84	.14	5.16
401-500%	.000							1.00		
Health Insurance										
Uninsured	-1.40	.55	-2.58	-.23	-2.54	16	**.02**	**.25**	**.08**	**.79**
Private	-.12	.56	-1.30	1.06	-.21	16	.83	.89	.27	2.89
Government	.46	.62	-.85	1.78	.75	16	.46	1.59	.43	5.90
Private and Govt	.00	.	.	.	.	.	.	1.00	.	.
Marital Status										
Married/Partner	.15	.58	-1.08	1.37	.25	16	.81	1.16	.34	3.95
Sep/Wid/Div	-.16	.48	-1.18	.87	-.32	16	.75	.85	.31	2.38
Never Married	.00	.	.	.	.	.	.	1.00	.	.
BMI										
Underweight	-2.96	.97	-5.01	-.91	-3.06	16	**.01**	**.05**	**.01**	**.40**
Normal	-.23	.69	-1.70	1.23	-.34	16	.74	.79	.18	3.44
Overweight	-.77	.42	-1.66	.12	-1.84	16	.08	.46	.19	1.13
Obese	.000							1.00		

Health Literacy	.11	.39	-.71	.93	.29	16	.78	1.12	.49	2.54
Adequate	.28	.40	-.57	1.14	.71	16	.49	1.33	.57	3.12
Marginal Inadequate	.00	.	.	.	.	.	.	1.00	.	.
Years since DM diagnosis	.00	.01	-.03	.02	-.14	16	.89	1.00	.97	1.02
Close relative had DM	.61	.33	-.09	1.32	1.85	16	.08	1.85	.92	3.74
Dependent Variable: Daily Glucose Check (reference category = No) Model: (Intercept), RECODED_PVT_RATIO, INS_TYPE, RECODED_MARTL, RECODED_DAHL_LEVELS, YRS_SINCE_DIAGNOSIS, MCQ300C										

(5) Results: Hl regressed on Daily Glucose Check

The logistic regression model predicting daily glucose check was not statistically significant, Wald F (1, 16) = 538.88, *p* = .205. In Block 0, the Nagelkerke R^2 was 11.4%. The model explained 11.6% (Nagelkerke R^2) of the variance in daily glucose check. Of the seven predictor variables two were statistically significant (as shown in table 21.)

The odds of daily glucose check decreased by 75% for individuals who were uninsured, t (16) = - 2.54, *p* = .02, OR = .25, [CI= 0.08, 0.79]. Since the confidence intervals did not cross 1, results indicate with confident that the relationship between daily glucose check and being uninsured found in this sample would be found in 95% of samples from the same population. The odds of daily glucose check, decreased 95% for subjects with underweight BMI, t (16) = - 3.06, *p* = .01, OR = 0.05. Since the confidence interval does not cross 1, results indicate with confident that the relationship between daily glucose check and underweight BMI, found in this sample would be found in 95% of samples from the same population.

The odds of daily glucose check decreased by 54% for individuals with BMI overweight, t (16) = -1.84, p = .08, OR = .46; family history of DM, t(16) = 1.85, *p* = .08, OR = 1.85, were influential but not significant predictors of insulin use at the probability level *p* < .20. The odds ratio for adequate HL was OR= 1.12, *p* = .78, CI = [0.49 – 2.54] indicates that as HL changes from 0 to 1 (inadequate HL to adequate HL), subjects are 1.12 more likely to do daily glucose check. The confidence interval crosses 1, therefore adequate HL was not a reliable predictor of daily glucose check. For marginal HL, OR = 1.33, *p* = 0.49, CI = [0.57, 3.12] it indicated that when HL changed from 0 to 1 (inadequate HL to marginal HL)), then subjects are about 30% more likely to do daily glucose check. Since the confidence interval crossed 1, marginal HL is not a reliable predictor of daily glucose check. Health literacy was not statistically significant.

Table 22.

Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (diabetes specialist in the past year) with the health literacy predictor, controlling for covariates, older adults 55 years and older, with diabetes, NHANES 2009-2010. (n = 535)

Diabetes Specialist	B	SE	95% CI		Hypothesis Test			OR	95% CI for Exp (B)	
			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	-.274	.84	-2.04	1.50	-.33	16	.75	.76	.13	4.46
Poverty Ratio										
0-100%	-.50	.53	-1.62	.61	-.95	16	.35	.60	.20	1.85
101-200%	.19	.35	-.54	.93	.55	16	.59	1.21	.58	2.53
201-300%	.11	.44	-.83	1.05	.25	16	.80	1.12	.44	2.86
301-400%	-.68	.45	-1.64	.28	-1.50	16	.15	.51	.19	1.32
401-500%	.000	.	.	.	.			1.00		
Health Insurance										
Uninsured										
Private	.80	.56	-.39	1.99	1.43	16	.17	2.23	.68	7.32
Government	-.34	.41	-1.22	.54	-.82	16	.42	.71	.30	1.71

Private and Govt	.63	.38	-.17	1.43	1.67	16	.11	1.88	.85	4.16
	.00							1.00		
Marital Status										
Married/Partner	.05	.53	-1.07	1.17	.09	16	.93	1.05	.34	3.21
Sep/Wid/Div	-.08	.54	-1.23	1.08	-.14	16	.89	.93	.29	2.93
Never Married	.00	.	.	.	.	.	.	1.00	.	.
BMI										
Underweight	-27.4	.52	-28.51	-26.31	-52.7	16	.00	.00	.00	.00
Normal	-.05	.30	-.69	.60	-.16	16	.88	.95	.50	1.81
Overweight	-.70	.27	-1.27	-.13	-2.59	16	**.02**	**.50**	**.28**	**.88**
Obese	.	.	.	.	.	.	**.**	**.**	**.**	**.**
Health Literacy										
Adequate	.096	.35	-.66	.85	.27	16	.79	1.10	.52	2.33
Marginal	.165	.36	-.59	.92	.46	16	.65	1.18	.55	2.51
Inadequate	.00	.	.	.	.	.	.	1.00	.	.
Years since DM diagnosis	.003	.012	-.023	.028	.219	16	.83	1.01	.98	1.02
Close relative had DM	-.282	.290	-.903	.326	-.994	16	.33	.745	.405	1.38

Dependent Variable: Seen a diabetes health specialist in the past year (reference category = No)
Model: (Intercept), RECODED_PVT_RATIO, INS_TYPE, RECODED_MARTL, RECODED_BMI, DAHL_LEVELS, YRS_SINCE_DIAGNOSIS, MCQ300C
a. Set to zero because this parameter is redundant.

(6) Results: Hl regressed on “saw DM specialist in the past year”

The logistic regression model was statistically significant, Wald F (1, 16) = 767.42, $p < .05$. In Block 0, the Nagelkerke R^2 was 10.3%. The model explained 10.4% (Nagelkerke R^2) of the variance in “ saw DM specialist”. Of the seven predictor variables only one was statistically significant: Overweight BMI (as shown in Table 22), t (16) = -2.59, *p* = .02, OR = .50, CI = [.28, .88]. The odds of seeing a diabetes specialist in the past year decreased for subject with BMI overweight compared to those who had underweight, normal, and obese BMI level. The confidence interval did not cross 1, therefore the relationship between overweight BMI and saw diabetes specialist in the past year, found in this sample would be found in 95% of samples from the same population.

PVT 301-400%, t (16) = -1.50, *p* = 0.15, OR = .51, CI = [.16, 1.32]; Uninsured, t (16) = 1.43, *p* = 0.17, OR = 2.23, CI, [.68 – 7.32]; and Government sponsored health insurance, t (16) = 1.67, *p* = 0.11, OR = 1.88, CI = [.85, 4.16] were influential but not significant predictors of insulin use at the probability level <.20.

The odds ratio for adequate HL was OR= 1.10, *p* = .78, CI = [0.52 – 2.33], this indicates that as HL changes from 0 to 1 (inadequate HL to adequate HL), subjects were 1.10 times more likely to "see a DM specialist". The confidence interval crosses 1, therefore adequate HL was not a reliable predictor of daily glucose check.

For marginal HL, OR = 1.18, *p* = 0.65, CI = [0.55, 2.51] it indicated that when HL changed from 0 to 1 (inadequate HL to marginal HL), then subjects are about 65% less likely to "see a diabetes specialist" within the past year. Since the confidence interval crossed 1, marginal HL is not a reliable predictor of seeing a DM specialist. Health literacy was not statistically significant.

Table 23.
Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (recommended feet check for sores) with the health literacy predictor, controlling for covariates, older adults 55 years and older, with diabetes, NHANES 2009-2010. (n = 528)

	B	SE	95% CI	Hypothesis Test	OR	95% CI for Exp(B)

Feet check for sores			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	.81	1.08	-1.49	3.10	.75	16	.47	2.24	.23	22.21
Poverty Ratio										
0-100%	.28	.37	-.51	1.06	.75	16	.46	1.32	.60	2.88
101-200%	-.35	.35	-1.09	.40	-.98	16	.34	.71	.34	1.49
201-300%	.09	.63	-1.25	1.43	.14	16	.89	1.09	.29	4.19
301-400% 401-500%	.00	.	.	.	.	.	.	1.00	.	.
Health Insurance										
Uninsured	.55	.80	-1.16	2.25	.68	16	.51	1.73	.31	9.51
Private	-.98	.46	-1.96	-.01	-2.1	16	.05	.37	.14	.99
Government	-.20	.29	-.82	.41	-.71	16	.49	.82	.44	1.50
Private and Govt	.00	.	.	.	.	.	.	1.00	.	.
Marital Status										
Married	0.66	0.76	-0.95	2.27	0.87	16	0.40	1.93	0.39	9.66
Sep/Wid/Div	0.57	0.83	-1.20	2.33	0.68	16	0.51	1.76	0.30	10.30
Never Married	.000[a]					16		1.00		
BMI										
Underweight	-2.86	.98	-4.93	-.79	-2.9	16	.01	.06	.01	.45
Normal	-.29	.60	-1.56	.98	-.48	16	.64	.75	.21	2.66
Overweight	-1.07	.43	-1.97	-.16	-2.5	16	.02	.34	.14	.85
Obese	.00	.	.	.	.	.	.	1.00	.	.
Health Literacy Adequate	.02	.46	-.95	.99	.04	16	.97	1.02	.39	2.68
Marginal	.02	.33	-.68	.73	.07	16	.94	1.02	.51	2.07
Inadequate	.00	.	.	.	.	.	.	1.00	.	.
Years since DM diagnosis	0.01	0.02	-0.02	0.05	0.68	16	0.50	1.01	0.98	1.05
Close relative had DM	.605	.335	-.104	1.314	1.80	16	.089	1.831	.901	3.723

Dependent Variable: Feet check (reference category = No)
Model: (Intercept), RECODED_PVT_RATIO, INS_TYPE, RECODED_MARTL, RECODED_BMI, DAHL_LEVELS, YRS_SINCE_DIAGNOSIS, MCQ300C

(7) Results: Hl regressed on Daily Feet Check

The logistic regression model was not statistically significant, Wald F (1, 16) = 1.628, p = .555. In Block 0, the Nagelkerke R^2 was 15.6%.The model explained 15.6% (Nagelkerke R^2) of the variance in daily feet check for sores. Of the seven predictor variables only three were statistically significant: private health insurance; underweight BMI; and obese BMI (as shown in Table 23.)

The odds of daily feet check use decreased for individuals who had private health insurance, t (16) = -2.10, p = .05, OR = .37, CI [.14,.99]. Since the CI does not cross 1, results indicate with confident that the relationship between private health insurance and daily feet check, found in this sample would be found in 95% of samples from the same population. The odds of daily feet check use decreased by 94% for subject with underweight BMI, t (16) = -2.90, *p* = .01, OR = 0.06, CI = [.01, .45]. Since the CI does not cross 1, the relationship between underweight BMI and daily feet check, found in this sample would be found in 95% of samples from the same population.

The odds ratio for obese BMI decreased, OR= .34, CI 0.95 = [0.14, 0.85]) indicates that as BMI obese level changes from 0 (underweight, normal, overweight) to 1 (obese). The confidence interval crosses 1, therefore it can be confident that the relationship between obese BMI and daily feet check, found in this sample would be found in 95% of samples from the same population. There were no other influential predictors of daily feet check at the probability level <.20.

The odds ratio for adequate HL was OR= 1.02, *p* = .97, CI = [0.39 – 2.68] and marginal HL, OR = 1.024, *p* = 0.94, CI = [0.51, 2.07], the odds of daily feet check do not change (because OR is equal to approximately 1.00. Health literacy was not statistically significant.

Table 24.

Complex sample logistic regression analysis predicting the presence of diabetes self-management behavior (recommended eye check) with the health literacy predictor, controlling for covariates, older adults 55 years and older, with diabetes, NHANES 2009-2010 (n=531)

Eyes Checked	B	SE	95% CI		Hypothesis Test			OR	95% CI for Exp(B)	
			Lower	Upper	t	df	Sig.		Lower	Upper
(Intercept)	1.21	.54	.06	2.36	2.22	16	.041	3.34	1.06	10.55
PVT Ratio										
0-100%	-.20	.41	-1.06	.67	-.48	16	.639	.82	.35	1.95
101-200%	.00	.34	-.72	.72	.00	16	0.99	1.00	.49	2.05
201-300%	-.40	.43	-1.32	.53	-.91	16	.377	.67	.27	1.69
301-400%	-.21	.36	-.98	.56	-.58	16	.571	.81	.37	1.75
401-500%	.00	.	.	.	.	.	.	1.00	.	.
Health Insurance										
Uninsured	-1.95	0.48	-2.97	-0.93	-4.06	16	**0.01**	**0.14**	**0.05**	**0.39**
Private	-0.70	0.38	-1.51	0.11	-1.83	16	0.09	0.50	0.22	1.12
Government	-0.93	0.39	-1.75	-0.10	-2.39	16	**0.03**	**0.39**	**0.17**	**0.90**
Private/Govt	.000[a]					16		1.00		
Marital Status										
Married	0.20	0.42	-0.69	1.08	0.47	16	0.643	1.22	0.50	2.95
Sep/Wid/Div	-0.28	0.37	-1.05	0.50	-0.75	16	0.462	0.76	0.35	1.65
Never Married	.000[a]					16		1.00		
BMI										
Underweight	0.60	1.38	-2.33	3.53	0.43	16	0.670	1.82	0.10	34.11
Normal	-0.75	0.40	-1.59	0.10	-1.87	16	0.080	0.47	0.20	1.11
Overweight	-0.31	0.35	-1.06	0.44	-0.87	16	0.395	0.73	0.35	1.55
Obese	.000[a]							1.00		
Health Literacy										
Adequate	-0.24	0.30	-0.89	0.40	-0.79	16	0.439	0.79	0.41	1.50
Marginal	-0.09	0.27	-0.66	0.47	-0.35	16	0.732	0.91	0.52	1.60
Inadequate	.000[a]							1.00		

Years since DM diagnosis	0.02	0.01	-0.01	0.05	1.33	16	0.20	1.02	0.99	1.05
Close relative had DM	-0.48	0.23	-0.97	0.01	-2.09	16	**0.05**	**0.62**	**0.38**	**1.01**
Dependent Variable: Eyes Checked(reference category = No) Model: (Intercept), RECODED_PVT_RATIO, INS_TYPE, RECODED_MARTL, RECODED_BMI, DAHL_LEVELS, YRS_SINCE_DIAGNOSIS, MCQ300C a. Set to zero because this parameter is redundant.										

(8) Results: Hl regressed on "Eyes Checked for Retinopathy in the past year"

The logistic regression model was not statistically significant, Wald F (1, 16) = 9.34, *p* = .252. In Block 0, the Nagelkerke R^2 was 11.8%. The model explained 12.0% (Nagelkerke R^2) of the variance in insulin use. Of the seven predictor variables only two were statistically significant: Uninsured: t (16) = - 4.06, p = .001, OR = 0.14, CI [.05, .39]; and government health insurance: t (16) = -2.39, p = 0.03, OR = .39, CI [0.17, 0.90], (as shown in Table 24.)

The odds of having eyes checked for retinopathy within the past year increased 2%, t(16) = 1.33, p = .20, OR = 1.02, , CI = [.99, 1.05]. The confidence interval cross 1, the results indicate with confident that the relationships between (uninsured and government insurance alone) and eye check in the past year, found in this sample would be found in 95% of samples from the same population. Private only health insurance, t (16) = -1.83, *p* = 0.09, OR = .50, CI = [.22, 1.12]; Normal BMI, t (16) = 1.87, *p* = 0.08, OR = 0.47, CI, [.20 – 1.11]; and number of years since DM diagnosis, t (16) = 1.67, *p* = 0.09, OR = 0.50, CI = [.22, 1.12]. The odds ratio for adequate HL was OR= 1.02, *p* = .20, CI = [0.99 – 1.05], were influential but not significant predictors of insulin use at the probability level <.20. For adequate HL, OR = 0.79, $p = 0.43$, CI = [0.41, 1.50]. there was a 43% decrease on odds that subject would have an eyes exam for retinopathy in the past year compared to subject who had inadequate HL. For marginal HL, OR = 0.91, $p = 0.73$, CI = [0.52, 1.62] it indicated that when HL changed from 0 to 1 (inadequate HL to marginal HL)), then subjects were 9% less likely to “check eyes for retinopathy” within the past year. Health literacy was not statistically significant.

CHAPTER IV

DISCUSSION

Overview

The primary purpose of his study was to examine the association between health literacy and diabetes outcomes and self-management behaviors among older adults. This study used NHANES 2009- 2010 data for analysis. The analysis was restricted to individuals 55 years and over because chronic complications from diabetes are progressive and manifests more severely in older age. This resulted in a sample size of 779. The first research question investigated the association between HL and DM biomarkers tests. The second research question examined the association between HL and indicators of proper diabetes management.

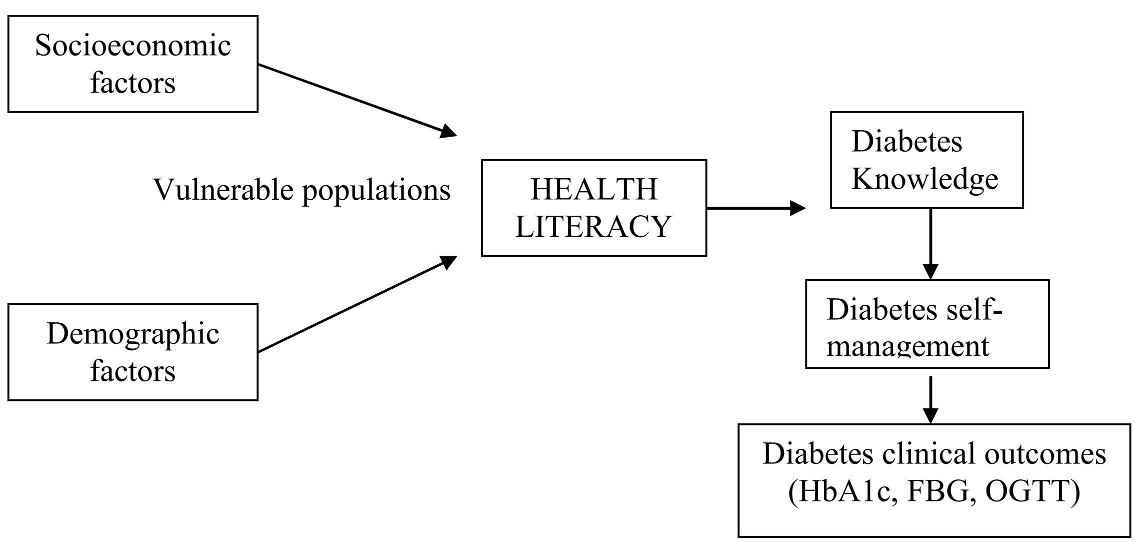

Figure 3. Conceptual framework of socioeconomic and demographic factors, health literacy, and diabetes (type 2) clinical outcomes. (Paasche-Orlow et al, 2007)

Discussion

The conceptual model of health literacy developed by Paasche-Orlow and Wolf (2007) describes the causal pathways between limited health literacy and health outcomes. It describes health literacy as being affected by sociodemographic factors, cognitive, and physical abilities. People who cannot read or understand the words used to describe health problems, diagnostic tests, medications and directions for care may experience confusion in navigating the health care system, and are significantly handicapped in the tasks of self-care or caring for family members. The pathways by which proper diabetes management and control can be achieved are multidirectional. There are many challenges that remain in measuring health literacy, and to date, no national health survey collect information on health literacy. Health literacy is complex and it can not entirely be measured by demographic variables alone. This derived measure of health literacy allows for easy quantification in nationally representative surveys. The need for health education for older adults with diabetes should focus on addressing the known factors that have been found to be barriers to proper diabetes management.

Key Findings: Health literacy and Diabetes Biomarkers Tests

The first research question aimed to determine if an association existed between health literacy and diabetes biomarker test (HbA1c, FBG, and OGTT). Hierarchical multiple regression analysis was done in complex samples analysis to explore the association between HbA1c and health literacy, controlling for six covariates. Predictors were entered in 2 blocks; (Block 1: marital status, health insurance type, poverty ratio, body mass index, years since diabetes diagnosis, family history of diabetes; Block 2: health literacy score). The hierarchical multiple regression with HbA1c as the outcome variable revealed that Block 1, which contained the demographic characteristics and diabetes related factors (family history, years since diagnosis, and BMI) explained 9% in predictive capacity. The addition of proxy health literacy score, increased the predictive capacity by 0.01%. This change in R^2 was not statistically significant, $p = .657$. Adding the health literacy to the model did not explain any of the variance observed in HbA1c scores. After accounting for covariates, this study found that the relationship between HbA1c and health literacy was fully mediated by other factors. Thought the full model was statistically significant, DAHL score did not contribute anything above and beyond once covariates were accounted for.

The hierarchical multiple regression with HbA1c as the outcome variable revealed that Block 1, which contained the demographic characteristics and diabetes related factors (family history, years since diagnosis, and BMI) explained 9% in predictive capacity. The hierarchical linear regression found no association between HbA1c and health literacy score. The association between fasting blood glucose and health literacy was not statistically significant. The full model was not statistically significant [Full Model: $R^2 = .153$, $F\ (15, 160) = .671$, $\rho = .810$]. Though the addition of proxy health literacy to the model did explain some of the variance observed in fasting blood glucose scores. DAHL score did contribute in a small way to the model. The addition of proxy health literacy score, increased the predictive capacity by 3%. This change in R^2 was statistically significant, $p = .028$.

Key Findings: Health literacy and Indicators of Proper Diabetes Self-management Behaviors

In the second research question, this study used hierarchical regression analysis to test the hypothesis that there would be a positive association between Hl and diabetes self-management behaviors. In the separate hierarchical regression analysis, this study found that proxy health literacy level, was not associated with diabetes self-management behaviors. The results revealed that after controlling for potential confounders, health literacy was not found to be a significant contributor in predicting the odds of the eight diabetes self-management behaviors. In doing hierarchical logistic regression, this study was able to identify the total amount of variance that was contributed by HL alone was no greater than 3% of the variance for any of the given diabetes self-management behaviors.

Summary:

The current study is the first to our knowledge to calculate a proxy health using NHANES data. From the seminal study, this study used the proxy score because of its external validity in population-representative samples. The findings highlight the need for continued diabetes education and testing specially among the older population. Health literacy was not found to have a significant association to HbA1c and fasting blood glucose. Our findings also reveal the health literacy was not a significant predictor of self-management behaviors. The finding also provide evidence that is consistent with previous research finding and therefore suggests that a proxy health literacy score can be used to analyze national dataset that create finding that are generalizable to the population. The small correlation values indicate that the associations were weak, and therefore other mediators such as diabetes knowledge may contribute to diabetes self-management.

Limitations

There are several limitations to this study. The use of cross-sectional data does not allow for new knowledge to be gained about the development of diabetes and the response of diagnosed patients to the disease over time. The non-experimental design does not permit conclusions to be drawn about causal relations among the variables. The reliance on self-report measures introduces some uncertainty about the accuracy of the responses. This study does not distinguish between the of diabetes (type 1 or 2) a person has, therefore creating a potential for biased results since those with type 1 diabetes could possibly have better diabetes outcomes because they have lived with the condition for the majority of their life span. The scoring weights for calculating the proxy health literacy scores were derived from a sample of older adults, and therefore, the results are not generalizability to other age groups. NHANES did not collect OGTT, FBG, and Diabetes Questionnaires on all eligible participants in the NHANES 2009-2010 survey, but only for a subsample (i.e., a smaller sample). Some variables of interest had large percentages of missing data, and list-wise deletion was used for analysis, leading to potential bias in results. According to (Langkamp et.al. 2011), if more than 10% of cases were missing a value for the variable of interest, then deleting cases with missing values from the analysis may produce biased results and the conclusions may not be valid for the larger target population. Finally, the use of a proxy measure that contains demographic characteristics does not include traditional methods of calculating health literacy. Though existing approaches to measure health literacy do not consistently measure health literacy the same way and the lack of precise characteristics to accurately measure health literacy remains. Despite the above mention limitations, the data provide vital use for researchers to determine if proxy health literacy can be calculated and found to have consist results as in other research studies.

Significance of the study:

Despite the limitations, this study is significant for four major reasons. First, the use of a database of a nationally representative sample of U.S. adults. Second, by utilizing a proxy measure, the study will contribute to the literature on this imputed method for assessing health literacy, i.e., the DAHL. Third, by studying the association between health literacy and diabetes outcomes, better understanding of the potential barriers to proper diabetes management is gained. Finally, it contributes to the body of knowledge on a topic that has a limited research studies/finding and contribute to the increased demand for research on this increasingly important topic.

The current study also addressed three weaknesses found in the previous health literacy literature. First, previous research findings have limited generalizability because study samples have been recruited from on-going diabetes education programs, medical hospital or clinics, or data retrieved from medical records. These types of study populations do not allow the appropriate sample sizes needed to permit generalizability of the research findings to other larger populations. Second, nearly all of the research studies used of one of the more traditional measures for health literacy. Both the REALM and the TOFHLA are widely used and considered to be a valid and reliable measure for health literacy, but require considerable time to be adequately administered to a study participant. Finally, the various measures and screening tools all evaluate various domains of health literacy: some are based on pronunciation, others on how well a person understand a food label, others use fill-in the blank, while some measure health literacy by how well a patient understands an appointment slip. Current approaches all differ and make it difficult to compare results, thus this study provides a proxy measure that would be easily calculated in both a clinical setting and research settings.

Recommendations for Future Studies

The need to develop a measure for health literacy in national health surveys would allow researcher the opportunity to explore the relationships between health literacy and other health outcomes. Diabetes management and control requires a multidisciplinary approaches in order to encompass the different factors that contribute to better health outcomes. In this study we identified the characteristics of individuals who were not aware of their DM positive status, future studies should focus on finding similar results using other large health surveys. At a community level, health promotion efforts should target a younger demographic group to reduce the prevalence of diabetes after age 55.

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Appendix A .
Health Literacy Assessment Instruments

Instrument	Description of Test	Method of Assessment	Type of Score	Health Focus	Validation
Chew Subjective Literacy Screener	1-item self-reported assessment of confidence in filing out hospital forms; 2 additional items were tested, but didn't increase performance of measure	Self-report	Categorical score: inadequate literacy, literacy	Yes	Partial validation
Demographic Assessment of Health Literacy (DAHL)	A demographic assessment of the likelihood of low health literacy; S-TOFHLA scores predicted from demographic variables: age, gender, race, education	Demographics, used to predict reading ability	1. continuous scores 2. categorical score: 0-53, inadequate 53-100, marginal	Yes	Yes
Hebrew Health Literacy Test	12-item instrument, assessing reading comprehension and quantitative skills (based on the S-TOFHLA)	Reading comprehension (Cloze method) plus quantitative skill test	1. continuous score (0-12) 2. categorical score: 0-2: low 3-10:marginal 11-12:high	Yes	Partial Validation
Literacy Assessment for Diabetes (LAD)	Diabetes specific literacy assessment 60-item word recognition test for diabetes Length <3 minutes	Word recognition	1. continuous scores 2. grade level (4^{th}-16^{th})	Yes	Yes
Medical Terminology achievemen	42-item measure of health literacy: designed with small print size and glossy	Word recognition and	1.continuous score (range NR)	Yes	Partial Validation

t reading Test (MART)	cover to allow patients an excuse for difficulties in completing the task	pronunciation test	2. Categorical score (grade level range NR)		
National Adult Literacy Survey (NALS)	200 questions measuring literacy (prose, quantitative, and document literacy): delivered by item response theory; includes questions on health literacy	Reading passages, documents, word problems	1. continuous score (0-500) 2.grouped into 5 levels 1-5; (5 best) Level 1:<224 Level 2:225-274 Level 3:275-324 Level 4:325-374	No;however, health questions embedded in survey	Yes
Instrument	**Description of Test**	**Method of Assessment**	**Type of Score**	**Health Focus**	**Validation**
National Assessment of Adult Literacy (NAAL)	200 questions measuring functional health literacy (prose, qualitative, and document literacy) delivered by item response theory; includes separate 28 item subtest on health literacy	Reading passages, documents, word problems	1. continuous score (0-500) 2. Grouped into four categories: below basic, basic,intermediate, and proficient literacy level	Yes, separate health literacy assessment	Yes
Newest Vital Sign	Consists of 24 questions and is designed to evaluate patients understanding of current nutrition labels Length is 3 minutes	Document and quantitative literacy skill test	1. continuous score (0-6) 2. Categorical Score: <2: low literacy 2-4 possible low literacy >4: adequate literacy	Yes	Partial validation

Nutritional Literacy Scale (NLS)	28-item assessment of reading comprehension in the context of food content areas such as foods, fiber, calcium, and sugar	Reading comprehension (modified-cloze method)	Continuous score (0-28)	Yes	Yes
Rapid Estimate of Adult Literacy in Medicine (REALM)	8-item screening tool designed to measure adults ability to read common words they will encounter in a medical setting. Length about 1-2 minutes Also available in short form as REALM-SF and ofr special populations as REALD-30 and REALM-Teen	Word recognition and pronunciation	1. continuous score (0-66) 2. Grade level: 0-18:<3^{rd} grade 19-44:4^{th}-6^{th} grade 45-60:7^{th} -8^{th} grade 61-66: >9^{th} grade	Yes	Yes
Short Assessment of Health Literacy for Spanish Adults (SAHLSA)	Spanish version of REALM. 50-item instrument that includes word recognition and comprehension test to examine health literacy for the Spanish-speaking population	Word recognition and reading comprehension	1. Continuous score (0-50) 2. Categorical score: 0-37: inadequate 38-50: adequate	Yes	Yes
Instrument	**Description of Test**	**Method of Assessment**	**Type of Score**	**Health Focus**	**Validation**
Single Item Literacy Screener (SILS)	1-item assessment of whether an individual needs help reading health-related materials	Self-report	Continuous score (0-5) Categorical/cut-off score: SILS 2-5: positive	Yes	Partial validation

			SILS < 2: negative		
Test of Functional Health Literacy in Adults (TOFHLA)	67-item measure of health literacy, including reading comprehension and quantitative skills Also available in short form (S-TOFHLA) and for special populations as British version (UK-TOFHLA) and dental version (TOFHLiD); length about 5-10 minutes	Reading comprehen sion (Cloze method) and quantitativ e skills test Length about 20 to 25 minutes. Available in Spanish and English	1. Continuous weighted score (0-100) 2. Categorical score: 0-59: inadequate 60-74: marginal 75-100: adequate	Yes	Yes
Wide Range Achieveme nt Test, Reading subtest (WRAT)	57-item measure of reading comprehension, arithmetic, and spelling from educational literature. In health related research most investigators only used the reading sub-test. Length about 10 minutes	Word recognitio n and pronunciat ion	Continuous score (0-57)	No	Yes

Source: U.S. Health and Human Services, Agency for Healthcare Research and Quality; March 2011

APPENDIX B.

Definition for the various types of diabetes mellitus. ADA, 2011

Type 1 Diabetes	An autoimmune disease which destroys the insulin producing cells of the pancreas. In type 1 diabetes, the body does not produce insulin. Insulin is a hormone that is needed to convert sugar (glucose), starches and other food into energy needed for daily life. It accounts for 3-5% of all diabetes globally. It most commonly develops in children and young adults but can occur at any age. People with type 1 diabetes are always dependent on insulin injections for survival. Tens of thousands of children and young adults die each year for lack of life-saving insulin. There is as yet no proven widely available therapy to prevent or cure Type 1 diabetes.
Type 2 Diabetes	Due to a combination of insulin resistance and insulin deficiency. It accounts for 95% or more of all diabetes globally. It most commonly occurs in middle-aged and older people but increasingly affects overweight children, adolescents and young adults. It is particularly affecting people in the productive years of the life cycle. People with type 2 diabetes are usually treated with tablets but many also require insulin injections. Type 2 diabetes is a major cause of heart disease and other complications. It can be prevented or significantly delayed by simple and cost effective interventions.
Gestational Diabetes (GDM)	Glucose intolerance with onset or first recognition during pregnancy. GDM affects at least 1 in 25 pregnancies globally. Undiagnosed or inadequately treated GDM can lead to larger than normal babies and higher rates of maternal and infant deaths and fetal abnormalities. Women with GDM and the off spring of GDM pregnancies are at increased risk of developing type 2 diabetes later in life.

Source: Centers for Disease Control and Prevention, 2012

APPENDIX C.

Summary of U.S. Studies of the Relationship Between Health Literacy and Diabetes Self-Management and Outcomes (1998-2012)

Author, Year, Study Design, Analysis, Sample Size	**Population and Setting, Health Literacy Measure, Health Literacy Level**	**Variables used in Multivariable Analysis**	**Differences in Outcomes Between Health Literacy Levels**
Williams,Baker, Parker, et al., 1998 cross-sectional Grady Hospital; N=216 UCLA Medical; N=364	Adults with diabetes not previously enrolled in any literacy study at Grady Memorial Hospital, Atlanta, GA and Harbor UCLA Medical Center general medicine Clinic TOFHLA **Literacy Levels:** DM (n = 114): Adequate: 45% Marginal: 11% Inadequate: 44%	Age, Yrs of school completed, Duration of disease	Diabetes: Knowledge measured by 10 item test (unadjusted): Adequate: 6th grade level=2% 7-11th grade level=29% 12th grade level=37% Marginal: 6th grade level=39% 7-11th grade level=39% 12th grade level=15% Inadequate: 6th grade level=78% 7-11th grade level=16% 12th grade level=4% No significant association found between literacy and blood glucose control or blood pressure. A1C levels were somewhat higher among those with lower literacy than those with higher literacy, but

			the difference was not statistically significant (8.3% vs 7.5%; *P* = .16)
Schillinger et al., 2002 Cross-sectional N=408	Adult diabetes patients (>30 yrs old) treated at one of two primary care clinics at San Francisco General Hospital s-TOFHLA (English or Spanish Version) **Inadequate=38%** **Marginal= 13%** **Adequate=49%**	Age, Sex, Race, Education, Insurance, Language, Social support, Depression, Treatment regimen, Yrs with diabetes, Diabetes education, S-TOFHLA score, Accounted for clustering of patients within physicians, Retinopathy and nephropathy models also controlled for hypertension and smoking, extremity amputation, cerebrovascular disease, and ischemic heart disease	Relationship between literacy and HbA1C(adjusted): For every 1-point increase on STOFHLA score, 0.02-point decrease in HbA1C *(P* = 0.02) Literacy and percentage with HbA1C < 7.2% (tight control) (adjusted): Inadequate: 20% Adequate: 33% OR = 0.57, 95%CI (0.32,1.0) *(P* = 0.05) Literacy and percentage with HbA1C > 9.5% (poor control) (adjusted): Inadequate: 30% Adequate: 20% OR = 2.03, 95%CI (1.11, 3.73) *(P* = 0.02) Literacy and self-reported retinopathy (adjusted): Inadequate: 36% Adequate: 19% OR = 2.33, 95% CI (1.19, 4.57) *(P* = 0.01)

			Literacy and self-reported nephropathy (adjusted): OR = 1.71, 95% CI (0.75, 3.90) *(P* = 0.20) Literacy and self-reported lower extremity amputation (adjusted): OR = 2.48, 95% CI (0.74, 8.34) *(P* = 0.14)
Kim et al., 2004 Quasi-experimental, pre and post test N=92	Participants in a diabetes education class at a university hospital in the US <u>S-TOFHLA</u> **Inadequate=15%** **Marginal= 8%** **Adequate=77%**	Age, sex, race, education, income, insurance, type of diabetes, HbA1c level, prior diabetes education diabetes duration, self reported complications, diabetes knowledge scores, self-management behaviors, after 3 months	There was no difference in years with diabetes or level of social support received from family and friends. At baseline, patients with adequate health literacy had better knowledge of diabetes (F=0.014), but health literacy was not associated with HbA1c or self-management behaviors. There were no differences between responders and non-responders in health literacy or other baseline characteristics. At 3 months, paired *t* tests

			showed improvement in HbA_{1c}, knowledge, and self-management behaviors for both literacy groups.
Rothman et al., 2004 Quasi-experimental, pre and post test N=159	Patients in 1 medical clinic in the US REALM 55% <6th grade level	Diabetes Self Management	Among patients with low literacy, intervention patients were more likely than control patients to achieve goal HbA_{1c} levels (≤7.0%) (42% vs 15%, respectively; adjusted odds ratio [OR], 4.6; 95% confidence interval [CI], 1.3 to 17.2; *P* = .02). Patients with higher literacy had similar odds of achieving goal HbA_{1c} levels regardless of intervention status (24% vs 23%; adjusted OR, 1.0; 95% CI, 0.4 to 2.5; *P* = .98).
Morris et al., 2006 Cross-sectional N=1,002	Adults with diabetes in primary care practices in Vermont <u>S-TOFHLA</u> **Inadequate=10%** **Marginal= 7%** **Adequate=83%**	Age, sex, marital status, insurance, income, duration of diabetes, diabetes education, depression, alcohol use, medication use, physician practice	*<u>HbA1c median</u>* No differences in HbA1c levels across groups (adjusted, continuous, TOFHLA scores used):P=0.88 *<u>Foot/leg problem</u>* No difference between inadequate

			and adequate group (adjusted): OR, 0.52; 95% CI: 0.24, 1.16 No difference between marginal and adequate groups (adjusted): OR, 1.39; 95% CI: 0.47, 4.12 *Cerebrovascular disease* No difference between inadequate and adequate group (adjusted): OR, 0.86; 95% CI: 0.39, 1.91 No difference between marginal and adequate groups (adjusted): OR, 0.65; 95% CI: 1.66, 2.57
Schillinger et al., 2006 Cross-sectional N=395 Good	Adult diabetes patients (>30 yrs old) treated at one of two primary care clinics at San Francisco General Hospital s-TOFHLA Mean=20.6 (SD=12.1)	Age, Primary Language other than English, Insurance, Education	HL mediated the direct relationship between education and HbA1c level in a partial mediation model (adjusted path analysis): P<0.05 HL mediated direct relationship between education and HbA1c level in a full mediation model (adjusted path analysis) P=0.03

Sudore et al., 2006 Cross-sectional N=2,512 REFERENCE: Berkman, 20011	Well-functioning Medicare recipients living in the community in Memphis, TN, and Pittsburgh, PA REALM 0-6th grade= 7-8 grade= 9-< grade=	Diabetes (unadjusted)	After adjusting for sociodemographics, health status, and comorbidities, older people with a sixth-grade reading level or lower were twice as likely to have any of the three indicators of poor healthcare access (odds ratio=1.96, 95% confidence interval=1.34-2.88).
Powell et al., 2007 Cross-sectional N=395 Good REFERENCE: Berkman, 20011	Patients with Type 2 Diabetes treated in general internal medicine clinic <u>REALM</u> < 4th grade: 13% 4th -6th :25% 7th-8th grade=19% HS=43%	Education, Age, Race, Gender, Treatment Regimen	Difference in HbA1c level between groups (adjusted) P=0.02
Osborn et al., 2010 Cross-sectional N=383 WORK ON THIS	patients from 2 primary care and 2 diabetes specialty clinics located at 3 medical clinics REALM < 9th grade = 31% ≥ 9th grade = 69%	HbA1c,Age,Year of diagnosed diabetes ,Insulin use African American race	HL not found to be a mediator of relationship between African American race and HbA1C through structural equation modeling
Mancuso et al. 2010 Cross-sectional N=102	Adults with a diagnosis of type 1 or 2 diabetes in 2 urban Midwestern US primary care clinics TOFHLA	Patients trust, depression, diabetes knowledge, Performance of self-care activities	No difference between HL groups in HbA1c (adjusted): P=0.436

REFERENCE: Berkman, 20011	Inadequate: 16% Marginal: 21% Adequate: 63%		
Sarkar et al., 2010 Cross-sectional N=14,357	Adults with pharmacologically treated type 2 diabetes who were seen as Kaiser Permanente Northern California, a no profit, integrated health care delivery system. Validated 3 item instrument: 53% reported problems learning about health 40% need help reading health material 32% were not confident filing out medical form by themselves	Age, sex, race, limited English proficiency , income, problems learning, help reading, help with forms	Patients commonly reported limited health literacy: After adjustment: Problems learning (OR 1.4, CI 1.1-1.7) Needing help reading (OR 1.3, CI 1.1-1.6) Lack of confidence with filing out forms (OR 1.3, CI 1.1-1.6) Were independently associated with significant hypoglycemia

UNT | HEALTH SCIENCE CENTER

Office for the Protection of Human Subjects

DATE: January 2, 2013

TO: Dennis Thombs, PhD
Behavioral and Community Health / SPH

FROM: Brian A. Gladue, PhD, CIP
Director, OPHS / Chair, UNTHSC IRB

PROTOCOL: # 2012-212

The Association of Health Literacy and Diabetes Outcomes and Self-Management Behaviors Among Older Adults

IRB BOARD ACTION AND NOTICE OF APPROVAL

The Office for the Protection of Human Subjects (OPHS) on behalf of the Institutional Review Board (IRB) of the University of North Texas Health Science Center (UNTHSC) has reviewed your protocol and has granted approval for **EXEMPT** status as specified in Federal Regulations 45 CFR 46.101(b), category 4:

> "Research involving the collection or study of data, documents, records, pathological specimens, or diagnostic specimens…if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

Note that you are responsible for complying with all UNTHSC IRB and OPHS policies, decisions, conditions and requirements regarding projects involving human subjects. You are responsible for insuring that the research is implemented as specified in the approved protocol. Unless otherwise authorized by the UNTHSC-IRB, you are responsible for notifying subjects that their participation and information will be used for research purposes. In addition, you are required to use ONLY the IRB approved documents, materials and/or process designated for this protocol.

You must report to the Chair of the IRB any changes affecting the protocol upon which this certification is based. **No changes may be made without prior approval by the IRB** except those necessary to eliminate immediate hazards.

If you have any questions, please contact Amanda Oglesby, Human Subjects Protection Coordinator, at phone (817) 735-5457 in the Office for the Protection of Human Subjects, or send email to amanda.oglesby@unthsc.edu.

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University of North Texas Health Science Center
Office for the Protection of Human Subjects (OPHS) / Institutional Review Board (IRB)

Request for Review of EXEMPT Category Research Project **IRB #** 2012-212

ALL research involving human subjects requires review and consideration by the UNTHSC Office for the Protection of Human Subjects (OPHS) and the Institutional Review Board (IRB). Some research projects may be "exempt" from Full Board Review and thus qualify as "Exempt Category" research. To determine if your research project is in this category, provide information using the following form. Note that proof or declaration of Human Subjects Research Training for all study personnel must accompany this form. Also, incomplete applications and supporting documentation will delay OPHS-IRB review and approval of this project. If it is determined that your research project is NOT Exempt category research, you will need to re-submit a full protocol and a completed Expedited IRB Application Form. Attach page if more space is needed for any of the below. Go to website for guidance on w[illegible]pt.

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BOARD

PROJECT INFORMATION

Faculty Research ☐ **Student Research:** ☐ **Masters** ☒ **Doctoral**

Title of Research Activity:
The Association of Health Literacy and Diabetes Outcomes and Self-Management Behaviors Among Older Adults.

Name of Principal Investigator (Faculty Member): Dennis Thombs, PhD

IRB APPROVED
JAN 02 2013
University of North Texas Health Science Center

Contact Information- Telephone: (817) 735-5439 *Email Address: Dennis.Thombs@unthsc.edu*

Name of Student Investigator: Maria F. Montoya

Contact Information- Telephone: 786-344-6120 *Email Address: mamontoy@live.unthsc.edu*

Department/Program: Behavioral and Community Health / Public Health Research Science

Name(s) of each Co-Investigator (Study Personnel): Subhash Aryal, PhD and Emily Spence-Almaguer, PhD

Project Description: Briefly state the objective(s) and procedures associated with this project. *Recall that incomplete or unclear information will delay OPHS-IRB review and approval* (**attach page if needed**)*:*

We conducted secondary analyses on cross-sectional data from the National Health and Nutrition survey 2009-2010 which is a continuous and annual survey from a nationally representative sample of non-institutionalized civilians age 2 and older. We enlist the use of a novel approach to estimate health literacy based on demographic data that is commonly available in population health surveys.

Obejcetives:
☐ To test the relationship between diabetes biomarkers (HbA1c, OGTT, and fasting plasma glucose) and poor health literacy using a novel imputed measure known as the Demographic Assessment of Health Literacy (DAHL).
☐ Determine if if health literacy is associated with indicators of proper diabetes management.

Educational Practices and Strategies: Yes ☐ **No** ☒ (If Yes, please answer **all** questions below)

Will research involve normal educational practices such as (check appropriate box)?

☐ Regular instructional strategies including those commonly used in a classroom
☐ Special education instructional strategies such as the use of a device for performing skill sets or exercise
☐ Effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
☐ Other: _____
☐ The study does not involve research in educational practices and strategies

Will research be conducted in an established or commonly accepted educational setting (university or teaching hospital)?

Yes ☐ **No** ☐ **[If yes, please answer the question below]**

Where will it be conducted?
Is the educational activity itself part of your research or will the educational activity occur regardless of research?
☐ **Yes, it is part of research**
☐ **No, the practices are normal educational practices that will occur regardless of this research project**

. . .

Survey or Interview Study: Yes ☐ **No** ☒ (If Yes, please answer **all** questions AND attach copy of survey instruments and procedures)

Source of subject population: _____

Age Range of subjects to be included in the survey or interview: _____

Where will the survey/interview occur? (Location of activity): _____

Date(s) survey/interview to be conducted? (Include month and year) From_____ To _____

Will subjects be identified? **Yes** ☐ **No** ☒ Will subject responses be audio, video or digitally recorded? **Yes** ☐ **No** ☐

Will your subjects include children (under age 18)? **Yes** ☐ **No** ☒ **[If Yes, STOP. Project does not qualify as EXEMPT]**

Retrospective Record or Chart Review: Yes ☐ **No** ☒ **(**If "Yes", Please check all that apply)

☐ Retrospective review of medical records: Name of hospital or institution from which records will be obtained:
☐ Employment records ☐ Student records ☐ Other records: _____

Name of institution or agency from which records will be obtained:

If a non-UNTHSC unit will provide records, attach letter from that agency/clinic.

The data were collected during Time Period (month and year): From _____ To _____

Will the investigators have access to subject identifiers? **Yes** ☐ **No** ☐

Will a "master list" of subject identifiers for this data set be kept? **Yes** ☐ **No** ☐ If yes, for how long? _____
If your protocol calls for a "master list" of identifiers then this may NOT qualify for Exempt. Contact OPHS staff for assistance

Use of existing biological specimens: Yes ☐ **No** ☒ If "Yes", Source of specimens (contact name, entity name and address) and attach description of specimens and origin:

Secondary Data Set Study: Yes ☒ **No** ☐ If "Yes", Answer all questions.

Source of data: NHANES data are public use data files downloaded from http://www.cdc.gov/nchs/nhanes/nhanes2009-2010/nhanes09_10.htm . We only use data from NHANES 2009-2010 cycle.
Were the data originally collected for research purposes: **Yes** ☒ **No** ☐ If yes, by UNTHSC researchers? **Yes** ☐ **No** ☒

Is the Source "publicly available"? **Yes** ☒ **No** ☐

Note that "Publicly available" means that the general public can obtain the data. Sources are not considered "publicly available" if access is limited ONLY to researchers. ***NOTE: You must attach a copy of the catalog page/ website page indicating where the dataset can be obtained or located.***

Does the secondary dataset contain personal identifiers? Yes ☐ **No** ☒

Type of identifier (i.e., name, SSN, address, medical record number, etc.):

Public Benefit or Services Programs

Is the study conducted or subject to approval by the federal department or agency head? ☐ **Yes** ☒ **No**

Is the aim to study, evaluate, or otherwise examine one or more of the following [check appropriate box(es)]?

☐ Public Benefit or Service Programs (i.e. Social Security Services, Medicaid, welfare)
☐ Procedures for obtaining benefits or services under those programs
☐ Possible changes in or alternatives to those programs or procedures
☐ Possible changes in methods or levels of payment for benefits or services under those programs

Taste and Food Evaluation

Will this study involve taste evaluation and/or food quality assessment? ☐ **Yes** ☒ **No**

Is the food approved by the Food and Drug Administration (FDA)?☐ **Yes** ☐ **No [if No, STOP. This does NOT qualify as Exempt]**

Will wholesome (no additives) food be consumed? ☐ **Yes** ☐ **No**

Are the food ingredients at or below the level found to be safe by the FDA? ☐ **Yes** ☐ **No**

Do you ever intend to publish or present (oral, poster or written) the results of this project? Yes ☒ **No** ☐

Is an informed consent needed for this research? Yes ☐ **No** ☒

If yes, this project may NOT be Exempt from Full Board or Expedited IRB review and consideration. Please attach a complete protocol form and synopsis along with this application for further review (see OPHS website for Protocol Form and Summary Format guidelines).

ATTACH TO THIS FORM:

- *Certificate of Human Subjects Training* for **all** study personnel. If such documentation is already on file for *all* key personnel, initial here: ____________ [Note that inaccurately claiming that such documentation is on file will significantly delay Review]

(If applicable)

- *Copy of Secondary Data documentation* (examples include: website address or reference information for public use data files; letters of agreement from owners of the dataset, etc.)
- *Copy of Survey or Interview questions* and any research statement or cover letters to be used (if applicable)
- Any other documentation that will assist in a timely review of your project.

SIGNATURES AND ASSURANCE Signature certifies that the Principal Investigator understands and accepts responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform to the OPHS-IRB approved protocol, OPHS-IRB requirements/policies and procedures, and all applicable federal regulations.

[signature] DENNIS L. THOMAS 12-13-2012

PRINCIPAL INVESTIGATOR Signature Print Name Date

NOTE: If this is a "Student Project", the Principal Investigator signing above agrees to be fully responsible for all aspects of this project. Ordinarily this person will also serve as the Faculty Advisor for the Student on this project. The Faculty Sponsor / Advisor may designate an alternate Faculty Sponsor / Advisor who will assume responsibilities on a temporary basis, and will notify the OPHS-IRB of any change in the Faculty Sponsor / Advisor for this project.

Student Investigator's Assurance: By my signature as student investigator, I certify the above applicable assurances and that I will meet with my Faculty Sponsor / Advisor on a regular basis to monitor study progress. If my Faculty Sponsor / Advisor is unavailable, I will meet with his/her designated alternate Faculty Sponsor / Advisor who will assume his/her responsibilities. I also agree to notify the OPHS-IRB of any change in Faculty Sponsor / Advisor

[signature] MARIA F. MONTOYA 12-13-2012

STUDENT INVESTIGATOR Signature Print Name Date