AN EXPLORATORY PILOT STUDY:
INVESTIGATING HEALTH LITERACY’S ROLE IN DIABETES MANAGEMENT

by

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Abstract

**Purpose:** Investigate relationships between health literacy (HL), socio-demographics, diabetes self-management, and diabetic outcomes.

**Background/Theoretical Framework:** HL has established relationship between diabetes knowledge and self-care activities. Low HL and socio-demographic factors act as barriers to positive health outcomes in patients with diabetes. The Causal Pathways Between Limited Health Literacy and Health Outcomes Framework guided this study.

**Methods:** An exploratory pilot design utilizing convenience sampling implemented within two rural primary care clinics. Data was gathered regarding patient socio-demographics and diabetes self-management. Two validated HL tools were utilized: REALM-SF and Newest Vital Sign (NVS). Quantitative analysis included descriptive statistics, regression, and multiple regression.

**Results:** REALM-SF found to be a predictor for diabetic self-care activities: medication adherence \( (p = .032) \) and foot care \( (p = .025) \). One socio-demographic predictor, age \( (p = .008) \), was established for REALM-SF. The socio-demographic predictors for NVS were level of education \( (p = .013) \) and age \( (p = .004) \). Diabetic outcome of A1c was found to be predicted by level of education \( (p = .040) \), while associated complications was predicted by age \( (p = .005) \).

**Conclusions and Implications:** Assessment of HL is feasible in primary care settings and can provide pertinent information while opening lines of communication. Additionally, socio-demographic factors, specifically age and level of education, can affect HL and diabetic outcomes.

**Keywords:** Health literacy, type 2 diabetes
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The concept of health literacy first emerged in the 1990s (Pleasant, Cabe, Patel, Cosenza, & Carmona, 2015). While the definition has evolved over time, the primary notion has always evolved around a patient’s ability to understand their health. Currently, health literacy is defined as “the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions” (Patient Protection and Affordable Care Act, 2010, p. 473). Management and control of chronic illnesses, such as diabetes mellitus, requires a variety of skills that involve health literacy.

Diabetes is a multifaceted metabolic disease process that is characterized by impaired glucose regulation (American Diabetes Association [ADA], n.d.). This impairment can lead to multiple complications on both the microvascular (such as nephropathy, retinopathy, and neuropathy) and macrovascular (such as cerebrovascular accident and myocardial infarction) level (Golden, Thomas, & Porter, 2015). Management of diabetes is complex and requires patients to be diligent and proactive in their healthcare. While all utilized interventions are necessary, they are also expensive.

Prior research has been conducted focusing on the relationship that health literacy plays in the management and care of patients diagnosed with diabetes mellitus. In a systematic review completed by Al Sayah, Majumdar, Williams, Robertson, and Johnson (2012), it was reported that levels of low health literacy were linked with decreased diabetic knowledge. However, Al Sayah et al. (2012) also explain that there was inconsistent evidence regarding the role low health literacy played in diabetes-related care. It has been recommended that in order to provide effective patient
education and improve glycemic control, an individual’s health literacy level needs to be assessed (Tang, Pang, Chan, Yeung, & Yeung, 2007). This health literacy level can provide information to discuss allowing a patient-centered approach to be implemented.

**Significance of Problem**

The prevalence of diabetes mellitus is increasing. The World Health Organization (WHO) (2016) reports that in 1980 there were 180 million individuals with a diagnosis of diabetes. However, that number jumped to 422 million in 2014 (WHO, 2016). Additionally, the Centers for Disease Control and Prevention (CDC) reports that in 2012 diabetes mellitus had an estimated total cost of $245 billion (2017), increasing to $327 billion in 2017 (ADA, 2018). The Centers for Disease Control and Prevention (CDC) also predicts that the number of patients diagnosed with diabetes will increase from 8 per 1,000 in 2008 to 15 per 1,000 in 2050 (2010). With this increase in prevalence, it is imperative that patient’s disease processes are effectively managed. While providers can implement appropriate interventions, if a patient will not follow through, treatment will be ineffective. Research has demonstrated that health literacy is a very compelling predictor for a patient’s health status (Watts & Stevenson, 2017). While this evidence has been established, the assessment of patient’s health literacy levels is not widely completed. This gap in practice could play a role in poor patient self-care management due to decreased knowledge.

**Expanded Purpose**

The purpose of this capstone project was to further investigate this gap in practice. The project was implemented within two outpatient primary care clinics. Reports pulled from the electronic health record reveal that combined, both offices see
approximately eighty to one hundred patients monthly that are diagnosed with type 2 diabetes (T2D). Further assessment of the role health literacy plays in diabetes management can potentially impact the practices and interventions implemented to care for patients diagnosed with T2D.

Advanced practice nurses (APN) are responsible for assessing, managing, and providing education to patients regarding his/her health. If a patient is not able to understand and comprehend what is being explained, he/she may not follow the recommended plan of care, potentially resulting in unfavorable patient outcomes. This can lead to more complications and the need for more advanced interventions that increase the complexity of care provided.

By investigating the relationships between all of the variables, the project aimed to understand and improve the outcomes for this population addressing DNP Essential VII (American Association of Colleges of Nursing [AACN], 2006). The knowledge gained from the project can allow the APN to understand the studied relationships and in turn provide appropriate care to patients. Additionally, the project aimed to further and improve advance nursing practice addressing DNP Essential VIII (AACN, 2006). By understanding the investigated relationships, the APN can further educate across all disciplines so that all members of the health care profession are aware of the importance that health literacy plays in the care of patients.

Research Question

The research question for this exploratory pilot study was: In adult patients ages 18 to 89 diagnosed with T2D in the rural primary care outpatient setting, does health literacy affect patient’s diabetic outcomes as evidenced by self-care, glycemic control,
and diabetes related complications? The study has two primary goals: investigate the role that health literacy has on diabetic outcomes as well as investigate the role that patient socio-demographics has on health literacy and diabetic outcomes.

**Review of Literature**

Health literacy is a relatively new concept, and due to its immaturity is continually evolving (Berkman, Davis, & McCormack, 2010). When first introduced, the definition of health literacy focused on basic reading and math skills and how these skills applied to an individual’s health (Berkman et al., 2010). However, as time progressed, the definition was expanded to now include the ability for an individual to communicate effectively, the ability to navigate different health services, as well as the ability to comprehend concepts related to the individual’s health (Berkman et al., 2010).

Pleasant et al. (2015), report that health literacy was first introduced in the 1990s. The Agency for Healthcare Research and Quality (AHRQ) completed their first systematic review researching health literacy in 2004, with a subsequent systematic review completed in 2011 (AHRQ, 2011). According to the AHRQ, in 2003 approximately 80 million adults in the United States had limited health literacy (AHRQ, 2011). Additionally, the systematic review completed in 2004 revealed that a relationship between low health literacy and poor health outcomes was present, yet the degree of the relationship was uncertain (AHRQ, 2011).

**Health Literacy & Health Outcomes**

Due to the significance that health literacy can play in an individual’s health outcome, the concept was included in Healthy People 2010 (U. S. Department of Health and Human Services [USDHHS], Office of Disease Prevention and Health Promotion
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[ODPHP], 2000) as well as Healthy People 2020 (USDHHS, ODPHP, 2017). In Healthy People 2010, the primary goal of including the concept was to decrease health disparities (USDHHS, ODPHP, 2000). In Healthy People 2020, the primary focus is still improving health literacy of the population; however, the goal has shifted focus from the patient to the medical providers utilizing educational materials that patients can understand, providers assessing patients understanding of directions, and provider’s offices offering to assist patients with filling out medical forms (USDHHS, ODPHP, 2017).

With health literacy being included within different government initiatives, research has also been conducted to investigate potential risk factors for low health literacy. Rikard, Thompson, McKinney, and Beauchamp (2016) report that gender, increased age, low income, low education level, and minority groups are all risk factors for low health literacy. Rikard et al. (2016) also reported several assets that can improve health literacy. Voting, volunteering, library use, and being married were found to promote health literacy (Rikard et al., 2016).

**Health Literacy & Diabetic Outcomes.** With the discovery that health literacy can act as a barrier to positive health outcomes, research has been conducted regarding the relationship it plays with diabetes mellitus. In a systematic review completed by Al Sayah et al. (2012), authors investigated the impact health literacy has on clinical outcomes, behavior indicators and patient-reported outcomes, and patient-provider interaction indicators. The review revealed that there was a consistent direct relationship between health literacy and diabetes knowledge as well as a direct relationship between health literacy and self-care activities (Al Sayah et al., 2012).
Due to the complexity of managing diabetes mellitus, understanding the role health literacy plays is imperative. In a study conducted by Osborn, Bains, and Egede (2010), researchers investigated the relationship between health literacy, diabetes self-care, and glycemic control. The study concluded that health literacy did not have a direct effect on diabetes self-care or glycemic control, however health literacy did have an indirect effect on the two variables through social support such as family, friends, caregivers, and providers (Osborn et al., 2010). In a similar study conducted by Tang et al. (2007), authors investigated the relationship between health literacy, complication awareness, and diabetes control in patients with type 2 diabetes mellitus. The study concluded that patients with appropriate complication awareness and treatment management were more likely to have controlled hemoglobin A1c results as compared to others with inappropriate awareness and treatment management (Tang et al., 2007).

**Health Literacy & Self-Management Skills**

While diabetes self-care and glycemic control are key components to diabetes treatment, self-management is also vital. Mackey, Doody, Werner, and Fullen (2016) investigated the relationship that health literacy has on self-management skills in chronic disease management, including diabetes mellitus. The systematic review concluded that there was a significant relationship between low health literacy and poor self-efficacy, as well as an association between low health literacy and belief regarding control of current condition (Mackey et al., 2016). Both self-efficacy and belief are considered to be key components to the development of self-management; therefore, low health literacy may be a potential barrier to the development of effective self-management (Mackey et al., 2016).
Health Literacy & Quality of Life

Disease management is key in caring for patients with a diagnosis of diabetes mellitus. However, it is equally important to evaluate and assess a patient’s quality of life. In a study conducted by Al Sayah, Qiu, and Johnson (2016), the relationship between health literacy and health-related quality of life in patients with type 2 diabetes was investigated. Authors concluded that low health literacy was associated with changes in health-related quality of life, specifically within the mental health domain (Al Sayah et al., 2016). While no causal relationship has been demonstrated, the authors did report that participants with adequate health literacy were less likely to have changes in their health-related quality of life (Al Sayah et al., 2016). The authors further report that more research is needed to establish if the improvement of health literacy would in turn improve health-related quality of life within the diabetes population (Al Sayah et al., 2016).

Health Literacy & Policy

Health literacy has recently been brought into the forefront of health care by several pieces of legislation. According to Koh et al. (2010), these policies include (a) Patient Protection and Affordable Care Act, (b) National Action Plan to Improve Health Literacy from the Department of Health and Human Services, (c) Plain Writing Act. Each of these initiatives address health literacy in a different way. For example, the National Action Plan to Improve Health Literacy has seven goals aiming to improve the health literacy of the nation. While each of these goals is slightly different, the overarching concept is to make health-care more easily understood and accessible for all individuals (USDHHS, ODPHP, 2010). The Plain Writing Act of 2010 also requires that health
related documents are written so that the general public can understand the information and material being provided (Plain Writing Act, 2010).

**Conceptual Framework**

The framework utilized to guide this capstone proposal will be the Causal Pathways Between Limited Health Literacy and Health Outcomes conceptual framework developed by Paasche-Orlow and Wolf (2007). This framework looks at the potential causal relationship between health literacy and health outcomes by investigating different variables. Socio-demographic factors, such as race/ethnicity, age, education attainment, employment status, and social support can potentially affect health literacy (Paasche-Orlow & Wolf, 2007). The framework then investigates how health literacy can affect three different domains: access and utilization of health care, provider-patient interaction, and self-care, all of which can affect an individual’s health outcomes. (Paasche-Orlow & Wolf, 2007). Each domain is further subdivided into patient factors and non-patient factors (Paasche-Orlow & Wolf, 2007).

This framework was selected due to it being directly applicable to providing care to patients with diabetes. The proposed capstone project will focus on the socio-demographic information affecting health literacy, as well as the patient factors within the self-care domain of the framework. The four patient factors within the self-care domain identified by Paasche-Orlow and Wolf (2007) are: motivation, problem solving, self-efficacy, and knowledge/skills. Each of these factors are directly applicable to a patient with a diagnosis of diabetes mellitus. For example, patients must be motivated to follow recommended dietary restrictions as well as take medications as prescribed. Additionally, patients must possess self-efficacy and believe that they are capable of
maintaining their health and following through with the recommendations and treatments that are provided.

**Methods**

**Design**

This capstone project was a pilot exploratory study investigating the potential relationship between health literacy and diabetes management. Additionally, the role that patient demographics play in health literacy and diabetes management was also investigated. Pilot studies are utilized to test the proposed methods on a small-sample prior to the study being conducted on a larger scale (Polit & Beck, 2012). The purpose of a pilot study is to obtain information for improving the project. The study design was also exploratory in nature. Polit & Beck (2012) explain that exploratory research investigates the nature of a phenomenon with the goal of understanding both the manifestation of the phenomenon but also the factors effecting it. This capstone project was exploratory due to the study exploring the phenomenon of health literacy as well as its compounding factors.

**Setting**

This capstone project was implemented in two rural outpatient primary care health clinics. One office was located in the Southern Tier of Western New York. The area has a total population of 3,969 with a median age of 39 (U.S. Census Bureau, 2010) and a median household income of $35,156 (U.S. Census Bureau, 2011). The second office was located in Northwestern Pennsylvania. This area has a total population of 17,980 with a median age of 40.6 (U.S. Census Bureau, 2010) and a median household income of $43,686 (U.S. Census Bureau, 2011). Both offices are
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operated by the same organization, which in total has five primary care outpatient offices. Both offices provide care to patients by two nurse practitioners. Additionally, both practices are staffed by receptionists, licensed practical nurses, and medical assistants. On site, the first office had an outpatient laboratory office where ordered laboratory testing can be completed and was in close proximity to a local hospital where ordered imaging could be completed. The second office has both an outpatient laboratory and imaging onsite for ordered testing to be completed.

Study Participants and Recruitment

Participants were recruited utilizing a convenience sampling method. At the end of each week, the following week’s schedule was assessed by the principal investigator (PI). The and patient’s active problem lists were reviewed. All patients meeting inclusion criteria of between the ages of 18 and 89 with a diagnosis of type 2 diabetes mellitus were identified and a list, using patient names, was created by the PI. The list was kept securely at the receptionist’s desk in a folder. Once patients checked in for their appointment, the PI was notified and invited the patient to participate in the study. The list was also kept at the licensed practical nurse and medical assistant’s station in a folder. This was done to prevent any potential study participant from being missed. The lists were kept within folders to protect patient privacy and confidentiality. Each morning the daily schedule was reviewed to be certain all potential study participants had been identified and were included within the list. Office staff was instructed to notify the PI if any potential patients were added to the daily schedule throughout the course of the day. This was done to allow the PI to review the active problem list to ascertain whether the patient met the inclusion criteria and to allow for recruitment if appropriate. At the
end of each clinical day the list was destroyed by shredding, insuring patient confidentiality and privacy.

Variables

Within the first analysis, health literacy was the independent variable and was measured using an interval level of measurement. The dependent variable within this analysis was diabetes management and was measured using both ordinal and interval/ratio levels of measurement. In the second analysis, patient socio-demographics were the independent variables measured on an ordinal level of measurement. The dependent variables within this analysis were (a) health literacy measured using an interval level of measurement and (b) diabetes management measured using both ordinal and interval/ratio levels of measurement.

Tools

Socio-demographic. The socio-demographic (SD) form asked participants to answer questions regarding known risk factors for low health literacy. Known risk factors are: gender, age, length of time with diabetes diagnosis, education level and income (Rikard et al., 2016). For the questions regarding length of diabetes diagnosis, education level, and income, participants are provided with ranges and instructed to select the most appropriate category pertaining to them (see Appendix A).

SDSCA. The SDSCA is a tool that was utilized to assess the participant’s diabetes management (see Appendix B). The questionnaire assesses the participant’s self-care within five different areas: diet, exercise, blood sugar testing, foot care, and smoking status (Toobert, Hampson, & Glasgow, 2000). The tool asks participants questions regarding each of the five areas and participants are asked to respond with
how many days over the past week they have engaged in that activity. In a study to assess the reliability and validity of the SDSCA, researchers analyzed seven prior studies utilizing the tool and concluded that while it is brief, the tool demonstrates adequate validity and test-retest reliability (Toobert et al., 2000).

**REALM-SF.** The REALM-SF is a tool that was utilized to assess the participant’s health literacy level (see Appendix C). The tool provides participants with seven common medical terms and then asks the individual to read them out-loud. Appendix D demonstrates how to administer and score participants. If the participant is unable to read all of the terms, it is considered to be an indication for low health literacy (Agency for Healthcare Research and Quality, 2016). While the tool is brief and can be administered quickly, researchers concluded that it was valid ($r=0.94$, $P<0.001$) and reliable ($r=0.95$, $P=<0.001$) (Arozullah et al., 2007).

**Newest Vital Sign.** The Newest Vital Sign (see Appendix E) is a tool that provides patients with a nutritional label (see Appendix F) and then they are asked to answer questions based upon the information provided within the label. The assessment is scored based upon the number of questions the participant is able to answer correctly and the scorer is provided with categorical ranges of literacy. For example, 0 to 1 questions answered correctly corresponds with a high likelihood of limited literacy, 2 to 3 indicates possible limited literacy, and 4 to 6 indicates adequate literacy (Pfizer, 2011). In a study completed to test the reliability of the tool, researchers reported the tool had appropriate sensitivity as well as demonstrated validity ($r=0.59$, $P=<.001$) (Weiss et al., 2005).
**Diabetes complication.** The diabetes complication checklist (see Appendix G) is the final tool that was utilized. The tool will provide a list of potential complications associated with diabetes that can be cross referenced with the active problem list to see which are applicable to the participant. Examples of complications include hypertension, dyslipidemia, cardiovascular disease (including coronary artery disease, peripheral artery disease, myocardial infarction, and abdominal aortic aneurysm), and neuropathy (AACE/ACE, 2015). Each potential complication that was documented on the patient’s active problem list was recorded on the tool. Additionally, all of the hemoglobin A1c results for the past year, up to four readings, was recorded. These values were averaged together to gain an estimate of glycemic control for the last year. If the participant had not been a patient of the office for a year, available results were averaged providing an estimate for the length of duration they have been seen within the office.

**Procedure**

Once IRB approval was granted, recruitment of participants began. When a potential study participant arrived for their appointment and checked in, they were approached by the PI. The PI explained the proposed study, how the data was going to be collected, and any potential risks to the patient. Additionally, the PI explained to the patient that participation was completely voluntary. If the individual was agreeable to participating, written consent was obtained.

Once consent was obtained, all participants were assigned a number and an individual folder. The number was marked on all participant forms and on the outside of the folder. This allowed for data to be linked and contained in one location. The
utilization of a participant number allowed the researcher to de-identify all participant responses, in accordance with HIPAA legislation (U.S. Department of Health & Human Services, 2015). Once assigned a number and folder, the participant was asked to fill out the SD form and the SDSCA while waiting to be called back for their scheduled appointment. If a participant was called for the appointment before completing the SDSCA form, the participant was able to complete this form in the examination room while waiting for the medical provider. Once the patient was roomed and the SDSCA was completed, the PI administered the REALM-SF and the Newest Vital Sign. If the provider was ready to see the patient, the PI administered the REALM-SF and the Newest Vital Sign before the patient was discharged. After the administration and completion of these tools, the PI then accessed the patient record and gathered the biometric data needed to complete the diabetes complication checklist. Participant folders were kept in a locked box that only the PI had access too. Additionally, a log was created that linked the participant’s number in the study to the medical record number. The log was saved on a password protected computer that only the PI had access to. Both the participant folders and a printed copy of the log created linking participants with medical record will be stored securely in the School of Nursing until May of 2021, after which the material will be destroyed by shredding.

**Ethical Considerations**

IRB approval was provided by the University at Buffalo Institutional Review Board (see Appendix H). Written consent was utilized to establish participants willingness to be included within the study. All participants received a pen embossed with the University of Buffalo logo in appreciation of their participation. This gift was of nominal
monetary value. No patient identifying factors were used to comply with HIPPA legislation. Additional considerations in regard to HIPAA legislation include the protection of study materials to protect participant confidentiality. For the purposes of this study, confidentiality was protected by using a password protected computer and a lock box; principal investigator was the only individual with access to either.

**Data Analysis**

Data analysis was conducted using Statistical Package for the Social Sciences (SPSS), version 24. All of the gathered data was entered into an Excel spreadsheet that was then uploaded into SPSS. Descriptive statistics of mean, range, and percentage were used to describe the demographic data. The statistical analyses utilized for this project included regression and multiple regression. The study utilized regression to analyze the relationship that health literacy has on diabetes management. Regression analysis is used to predict the dependent variable based upon the independent variable (Polit & Beck, 2012). For this capstone project, the independent variables were the health literacy tools utilized and the dependent variables were diabetes management as evidenced by hemoglobin A1c and diabetes associated complications.

Multiple regression was utilized to complete the second analysis assessing the impact that socio-demographics have on health literacy and diabetes management. Multiple regression is utilized when an analysis has multiple independent variables predicting the outcome of the dependent variable (Polit & Beck, 2012). By increasing the number of independent variables, the predictions created by the analysis improves (Polit & Beck, 2012). For this capstone project, within the multiple regression analyses
the independent variables were socio-demographics as well as the health literacy results and the dependent variable was diabetes management.

Results

Sample Characteristics

A total of 83 participants were recruited; 10 declined (12%) leaving a total of 73 participants recruited for the study. As Table 1 depicts, in regards to gender, the sample was relatively equal (36 males and 37 females). Age range was 37 to 79 years with a mean age of 56.1 years. The majority of participants had a diagnosis of diabetes for greater than five years (57.5%) and 19.2% (14) of the sample had a diagnosis of diabetes for three to five years. Level of education for the sample was varied. Over half of the sample had a high school diploma or equivalent (57.5%) while almost a quarter of the sample had completed some college (24.7%). Income for the sample was wide ranging, however, over half of the sample had an annual income of $20,000 or less. The majority of participants were non-smokers, 64.4%.

Health Literacy, Hemoglobin A1c, and Associated Complications

Newest Vital Sign. Linear regression was completed to determine if the Newest Vital Sign scores were a predictor for hemoglobin A1c and associated complications. Level of significance was set at p<.05. Regression results concluded that the Newest Vital Sign could not be used to predict hemoglobin A1c ($p = .975, R = .044, R^2 = .000, R^2_{adj} = -.014, F = .001, Beta t = .031$) or associated complications ($p = .693, R = .047, R^2 = .002, R^2_{adj} = -.012, F = .157, Beta t = -.396$). Table 2 demonstrates the results yielded from these analyses.
REALM-SF. Linear regression analysis was also conducted to determine if the REALM-SF scores were a predictor for diabetic outcomes measured by hemoglobin A1c and associated complications. Regression results demonstrate that the REALM-SF is not a predictor for hemoglobin A1c ($p=.867$, $R=.020$, $R^2=.000$, $R^2_{adj}=-.014$, $F=.028$, $\beta =.167$) or associated complications ($p=.112$, $R=.188$, $R^2=.035$, $R^2_{adj}=.022$, $F=2.588$, $\beta =1.609$). Table 2 provides the results produced from these analyses.

Health Literacy and SDSCA

Newest Vital Sign. Results produced from the linear regression analysis to determine if the Newest Vital Sign scores were predictors for the self-care questions asked within the SDSCA were all insignificant.

REALM-SF. Linear regression was conducted to determine if the REALM-SF scores were predictors of the self-care questions asked within the SDSCA. Regression results conclude that the REALM-SF scores could be utilized as a predictor for two questions asked within the SDSCA. Question 9, regarding foot care ($p=.025$, $R=.263$, $R^2=.069$, $R^2_{adj}=.056$, $F=5.280$, $\beta =2.298$) and question 11 regarding medication adherence ($p=.032$, $R=.252$, $R^2=.063$, $R^2_{adj}=.050$, $F=4.799$, $\beta =2.191$) yielded significant results. Table 3 yields the results from these analyses.

Hemoglobin A1c, Associated Complications, and Socio-demographics

Forward multiple regression was completed to determine which independent socio-demographic variables (gender, age, length of time with diabetes, level of education, income, smoking status) were predictors of hemoglobin A1c and associated complications. Level of education was established to be a predictor of hemoglobin A1c ($p=.040$, $R=.241$, $R^2=.058$, $R^2_{adj}=.045$, $F=4.382$, $\beta =-2.093$). Analysis led to the
exclusion of gender, age, length of time with diabetes, income and smoking status as a predictor for hemoglobin A1c. Age was concluded to be a predictor for associated complications ($p=.005$, $R=.327$, $R^2=.107$, $R^2_{adj}=.095$, $F=8.526$, $Beta \ t=2.920$). Analysis also led to the exclusion of gender, length of time with diabetes, level of education, income and smoking status as a predictor for associated complications. Table 4 reports the results yielded from these analyses.

**Health Literacy and Socio-demographics**

Forward multiple regression was conducted to determine which independent socio-demographic variables (age, gender, length of time with diabetes, level of education, income, smoking status) could be predictors for how an individual will score on the Newest Vital Sign and REALM-SF. Level of education ($p=.013$, $R=.290$, $R^2=.084$, $R^2_{adj}=.071$, $F=6.527$, $Beta \ t=2.555$), age ($p=.004$, $R=.386$, $R^2=.149$, $R^2_{adj}=.124$, $F=6.111$, $Beta \ t=-2.302$), and gender ($p=.001$, $R=.453$, $R^2=.205$, $R^2_{adj}=.170$, $F=5.933$, $Beta \ t=2.213$) were concluded to be predictors of the Newest Vital Sign. Analysis led to the exclusion of length of time with diabetes, income, and smoking status as predictors for the Newest Vital Sign. Age was concluded to be a predictor for the REALM-SF ($p=.008$, $R=.308$, $R^2=.095$, $R^2_{adj}=.082$, $F=7.426$, $Beta \ t=2.725$). Analysis excluded gender, length of time with diabetes, level of education, income, and smoking status as predictors for the REALM-SF. Table 5 reports the results produced from these analyses.

**Discussion**

**Health Literacy**

Results from this research demonstrate that assessment of health literacy can assist providers when caring for patients with T2D. While neither the REALM-SF nor
Newest Vital Sign were found to be predictors for hemoglobin A1c or associated complications, the REALM-SF was found to be a predictor for self-care questions asked within the SDSCA. One question that the REALM-SF was found to predictor for is, “On how many of the last seven days did you check your feet?” A weak positive relationship was established between the HL tool and this question; allowing for the inference that the higher an individual scores on the tool the more days of the week their feet will be checked. While this finding may appear irrelevant, diabetic foot ulcers are an extremely common complication of diabetes that are associated with lower extremity amputation and increased mortality (Ndosi et al., 2017). It is reported that up to 25% of diabetic patients will experience a diabetic foot ulcer in their lifetime (Ndosi et al., 2017). Frequent assessment of an individual’s feet allows for early identification of abnormalities, allowing for early intervention to occur. Implementation of the REALM-SF can assist providers in predicting which patients will be diligent in checking their feet frequently, and which patients may need additional education regarding the importance of frequent foot monitoring.

The REALM-SF was also found to be a predictor for medication adherence, a conflicting result compared to Bains and Egede (2011). The medication adherence question asked by the tool is, “On how many of the last seven days did you take your recommended diabetes medications?” A weak positive relationship was recognized; allowing one to infer that the higher an individual scores on the REALM-SF the more days throughout the week the prescribed diabetic medications will be taken. Medication adherence is paramount in controlling T2D and regulating blood glucose levels. While the American Association of Clinical Endocrinologists (AACE)/American College of
Endocrinology (ACE) guidelines recommend lifestyle and dietary modifications to be tried first, if those changes are unsuccessful in controlling blood glucose levels, anti-diabetic medications must be introduced (2018). Utilization of the REALM-SF can assist providers in determining which patients are more likely to be adherent to their prescribed medication regimen, therefore, increasing the likelihood of blood glucose regulation and decreasing potential complications. Additionally, a low score on the REALM-SF could alert providers that the patient in question may need additional reinforcement and education on the importance of taking anti-diabetes medications as prescribed.

**Socio-demographics**

**Hemoglobin A1c.** Hemoglobin A1c (A1c) is a level of measurement that can be utilized to determine diabetes control. This value provides practitioners with an average blood glucose level over a span of time, allowing the provider to determine if the disease process is being managed appropriately. The analyses determined that level of education was found to have a weak negative relationship with hemoglobin A1c. This result allows for the inference to be made that if an individual has a high level of education, their A1c will be lower and a marker for diabetic control. Additionally, one could predict that if an individual has a lower level of education, management of hemoglobin A1c can be more difficult. One of the reasons management could be more difficult is due to the lack of understanding. If an individual does not understand the pharmacologic and non-pharmacologic interventions being prescribed, he/she is less likely to follow through. Take for example insulin injections. While insulin injections are a common intervention prescribed to manage diabetes, they can also be uncomfortable,
inconvenient, and difficult for individuals to complete. If an individual's diabetic disease process requires insulin for proper management, but the individual is unable to understand the importance of the injections there is the possibility that the individual will be noncompliant. This noncompliance can result in poor diabetes management, demonstrated by increased A1c values.

**Associated Complications.** Age was determined to have a strong positive relationship with associated complications. Due to this result, one can infer that as an individual ages the number of associated complications he/she is afflicted with will also increase. This relationship demonstrates the importance of assessment and evaluation for known associated complications in all patients with a diagnosis of diabetes. For example, the AACE/ACE (2018) provides the recommendation that patients with a diagnosis of diabetes have a target blood pressure of less than 130/80 due to the known increased risk for cardiovascular events. Additionally, guidelines are provided for target cholesterol levels in an effort to combat macrovascular disease as well as interventions to prevent microvascular complications (AACE/ACE, 2018).

**REALM-SF.** Age was found to have a strong positive relationship with the REALM-SF, allowing the prediction to be made that the older an individual is the higher their score will be on the HL tool. Age is one of the variables outlined in the Causal Pathways Between Limited Health Literacy and Health Outcomes framework that was utilized to guide this study (Paasche-Orlow & Wolf, 2007). The conceptual model explains that certain variables, including age, can impact an individual’s health literacy level (Paasche-Orlow & Wolf, 2007). Increased age is commonly associated with limited and low health literacy scores, contradicting the results discovered from this study. It is
reported that in adults ages 65 to 75 years old, 23% have a below basic level of health literacy, and 28% have only a basic level of health literacy (Bach, 2018). Furthermore, in adults over the age of 75, 39% have a below basic level of health literacy, and 31% have a basic level of health literacy (Bach, 2018). As an individual ages, the chances of exposure to medical terminology also increases. Due to the REALM-SF requiring participants to read aloud seven medical terms, increased exposure to medical terminology could potentially allow for better performance when completing this health literacy tool.

**Newest Vital Sign.** Multiple socio-demographics were found to have significant relationships with the NVS. Level of education was found to have a moderate positive relationship with the HL tool. This relationship allows one to infer that an individual with a higher level of education would score higher on the tool. This tool requires participants to navigate a nutrition label and answer mathematical questions regarding serving sizes and appropriate portions. Higher levels of education are often exposed to advanced reading, science, and mathematical courses; all skills that would make completion of this HL tool relatively straightforward. Age was found to have a strong negative relationship with the NVS, inferring that younger individuals scored higher on the tool and older individuals scored lower. This result is consistent with the increased focus on nutrition in recent decades. Additionally, this result is consistent with the common association of low and limited health literacy as age increases. Both variables found to be predictors for the Newest Vital Sign are consistent with variables that can impact health literacy outlined in the Causal Pathways Between Limited Health Literacy and Health Outcomes framework (Paasche-Orlow & Wolf, 2007).
Due to nutrition playing an extensive role in the management of diabetes, these findings can help providers to better manage a patient’s disease process. Marincic et al. (2017) report that patients that worked with a dietician to manage diet exhibited reductions in key values, specifically A1c. While evaluation and recommendations from a dietician have been shown to be beneficial there can be barriers to access and affordability of this modality, preventing the referral from being completed. If referral to a dietician is not possible the NVS could be utilized as an option, offering providers insight into the patient’s current level of understanding regarding nutrition labels. Implementation would allow for assessment of a patient’s understanding of nutrition labels. If a patient is unfamiliar with the different components of a label, it will become evident and the provider can act accordingly.

**Sample Characteristics**

While the study was implemented within two rural primary care outpatient clinics, the information gathered regarding average annual income for the sample population was surprising. Within the sample, over fifty percent of the sample had an annual income less than $20,000. Management of diabetes is costly. The CDC (2017) reports that in 2012, medical costs for an individual with diabetes was $13,700, with $7,900 directly attributed to the diagnosis. Considering these potential costs, it becomes evident that the financial impact of diabetes on this sample are less than ideal, leaving patient’s in an extremely challenging situation. Both dietary management and prescribed pharmacologic treatments can be expensive, compounding the samples financial constraints. With this in consideration, providers must carefully select
medications keeping in mind financial circumstances. Additionally, providers must be mindful of resources available when recommending dietary modifications.

These financial circumstances can also affect an individual's HL level. The framework utilized to guide this study, the Causal Pathways Between Limited Health Literacy and Health Outcomes, explains that income can impact an individual's HL level, in turn affecting their self-care (Paasche-Orlow & Wolf, 2007). Knowledge of this impact, highlights the importance of assessing a patient's income when determining plan of care. Bach (2018) explains that while health literacy is commonly thought to only pertain to being able to understand instructions being given, the phenomena is actually much more encompassing and involves an individual's ability to navigate challenges involved with healthcare. For example, one challenge that falls under health literacy is an individual's ability to get and pay for medicines (Bach, 2018). When taking into consideration the low income found within the study's sample population, compounded by the knowledge that obtaining and paying for medications is a form of health literacy, it becomes apparent that health literacy level should continually be assessed.

**Implications to Practice**

While prior research had concluded that health literacy plays a role in diabetes management, completion of HL assessments is not common in every day practice. This study found that assessment of an individual's HL level is feasible in a primary care setting. Completion of the two tools utilized within this study took approximately two minutes (REALM-SF) and five minutes (Newest Vital Sign) respectively. When implementing a tool, administration can be completed by any part of the medical team, it is not something that must be completed by the provider. Additionally, there was no cost
associated with the tools utilized in this study. Many HL tools can be located online through governmental sites such as the Agency for Healthcare Research and Quality. These tools have open access and are free. While many may consider the cost of the tool a barrier to implementation, this online free access removes that limitation.

Assessment of health literacy also provides practitioners with knowledge that can be instrumental when developing a plan of care. Take for example an individual with a new diagnosis of diabetes that the provider would like to start on medication. Based upon the findings from this study, if the REALM-SF were completed, the provider could predict whether the individual will be adherent to the medication regimen. This prediction allows the provider to better develop a plan of care tailored to the individual’s needs. By developing an individualized plan of care, the likelihood of an individual being adherent to the prescribed treatment plan increases.

Completion of both HL assessment tools utilized in this study required the participant to verbally respond to questions being asked about either a nutrition label (NVS) or reading a list of words aloud (REALM-SF). By being a part of the assessment process, it opened lines of communication between the individual and the healthcare provider completing the assessment. Keeping communication between individual and provider open, allowed for individuals to feel comfortable discussing questions that may have been difficult during the assessment. According to the Emergency Care Research Institute (ECRI), in 2018 health literacy is considered to be one of the top ten patient safety concerns for healthcare organizations (2018). It is recommended that patients and family members become more involved in all aspects of the plan of care in order to improve HL. While there is no quick fix, completion of a HL tool can be used as a
starting point to encourage open communication and involvement of the patient and family.

While the assessment of an individual's baseline health literacy level should be commonly completed, it is important to point out that the level is not finite. Humans are constantly changing and can be affected by circumstances, stress, and other variables. For example, after receiving a new diagnosis, an individual that has a prior history of adequate health literacy, may not understand new information being given. It is because of this constant evolution of an individual's health literacy that continual assessments should be completed.

One way of addressing the constantly evolving nature of health literacy is to restructure the way we interact and communicate with patients. Bach (2018) explains that if all health care delivery is structured as though everyone has limited health literacy, then the probability that individuals will understand the information being provided increases. Clear communication is one area for improvement. Techniques involved within this area include making actively listening, using plain non-medical language when explaining topics, limiting content being explained to prevent overwhelming the individual, and to demonstrate how something is done (Bach, 2018). Another area for improvement is when giving out written materials and pamphlets. Rather than giving the materials out for the patient to read following the encounter, it is recommended that the material is reviewed together with the medical professional (Bach, 2018). By reviewing the material together, multiple things occur. The first is that the medical provider knows for certain the information has been provided. Secondly, similarly to when a health literacy tool is utilized, open lines of communication are
created encouraging the patient to ask questions (Bach, 2018). Lastly, the material can be personalized allowing for information specific to the patient to be added.

**Strengths and Weaknesses**

A strength of the study was its quantitative nature. The statistical analysis allowed for concrete values addressing the relationships investigated to be obtained. Internal validity was addressed by only including those participants meeting inclusion criteria and utilizing the SD form to control for contributing factors such as length of time with diabetes and income.

One limitation of the proposed project is that most of the tools utilized are self-reported. If participants are not truthful, it can skew the results of the data potentially creating bias. Poor recall is also a limitation to the study. The tools utilized require an individual to assess their actions over the past week and month. Another limitation was the convenience sampling method and the small sample size, potentially creating bias. Twelve percent of individuals recruited declined to participate for unknown reasons, creating an additional limitation. Participants were only recruited from two offices, limiting the diversity of the sample population to the patients that are seen within these two offices, in turn potentially affecting the external validity of the study. Additionally, the primary investigator was known to the population as a nurse practitioner student, potentially creating social desirability bias and influencing participant responses.

**Conclusion**

While health literacy is a relatively new concept, its role in diabetes management has been established. Despite the limitations of the study, findings reiterate the need for HL to be addressed when caring for an individual with a diagnosis of diabetes. While
many assessments are lengthy and require extensive time, this study demonstrates that HL assessments are feasible using the Newest Vital Sign and REALM-SF. This assessment process opens lines of communication between patient and provider, encouraging the patient to raise questions regarding topics not understood while also providing the practitioner with invaluable information. HL knowledge can help providers identify patients that may require additional guidance and education regarding the importance of medication adherence as well as diabetes self-care. Equally as important, is assessment of patient socio-demographics due to their impact on both HL and diabetic outcomes. This study demonstrates the impact that health literacy can have on diabetes management, and furthers the need for additional research on a larger scale. Additional research reinforcing the impact that HL can have on diabetes management could ultimately lead to health literacy assessments to becoming a standardized part of patient care.
References


Centers for Disease Control and Prevention (CDC). (2010). *Number of Americans with diabetes projected to double or triple by 2050.* Retrieved from https://www.cdc.gov/media/pressrel/2010/r101022.html


U.S. Department of Health and Human Services, Office of Disease Prevention and


# Sample Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>36 (49.3)</td>
</tr>
<tr>
<td>Female</td>
<td>37 (50.7)</td>
</tr>
<tr>
<td>Length of time with diabetes</td>
<td></td>
</tr>
<tr>
<td>&lt; than 1 year</td>
<td>9 (12.3)</td>
</tr>
<tr>
<td>1-3 years</td>
<td>8 (11.0)</td>
</tr>
<tr>
<td>3-5 years</td>
<td>14 (19.2)</td>
</tr>
<tr>
<td>&gt; 5 years</td>
<td>42 (57.5)</td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
</tr>
<tr>
<td>&lt; HSD</td>
<td>5 (6.8)</td>
</tr>
<tr>
<td>HSD/GED</td>
<td>42 (57.5)</td>
</tr>
<tr>
<td>Some College</td>
<td>18 (24.7)</td>
</tr>
<tr>
<td>Associate Degree</td>
<td>2 (2.7)</td>
</tr>
<tr>
<td>Bachelors' Degree</td>
<td>4 (5.5)</td>
</tr>
<tr>
<td>Graduate Degree</td>
<td>2 (2.7)</td>
</tr>
<tr>
<td>Income</td>
<td></td>
</tr>
<tr>
<td>&lt; $10,000</td>
<td>18 (24.7)</td>
</tr>
<tr>
<td>$10,000-$20,000</td>
<td>21 (28.8)</td>
</tr>
<tr>
<td>$20,000-$40,000</td>
<td>12 (16.4)</td>
</tr>
<tr>
<td>$40,000-$60,000</td>
<td>13 (17.8)</td>
</tr>
<tr>
<td>$60,000-$80,000</td>
<td>6 (8.2)</td>
</tr>
<tr>
<td>&gt; $80,000</td>
<td>3 (4.1)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>26 (35.6)</td>
</tr>
<tr>
<td>No</td>
<td>47 (64.4)</td>
</tr>
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</table>

*Note: N=73*
Table 2

*Associations Between Health Literacy Tools and Select Variables*

<table>
<thead>
<tr>
<th>Variable</th>
<th>( p )</th>
<th>( R )</th>
<th>( R^2 )</th>
<th>( R^2_{\text{adj}} )</th>
<th>( F )</th>
<th>Beta</th>
<th>( t )</th>
</tr>
</thead>
<tbody>
<tr>
<td>NVS vs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1c</td>
<td>.975</td>
<td>.044</td>
<td>.000</td>
<td>-.014</td>
<td>.001</td>
<td>.031</td>
<td></td>
</tr>
<tr>
<td>Associated Complications</td>
<td>.693</td>
<td>.047</td>
<td>.002</td>
<td>-.012</td>
<td>.157</td>
<td>-.396</td>
<td></td>
</tr>
<tr>
<td>REALM-SF vs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1c</td>
<td>.867</td>
<td>.020</td>
<td>.000</td>
<td>-.014</td>
<td>.028</td>
<td>.167</td>
<td></td>
</tr>
<tr>
<td>Associated Complications</td>
<td>.122</td>
<td>.188</td>
<td>.035</td>
<td>.022</td>
<td>2.588</td>
<td>1.609</td>
<td></td>
</tr>
</tbody>
</table>

*Note:* Level of significance set at \( p < .05 \)
Table 3

Association Between REALM-SF and SDSCA

<table>
<thead>
<tr>
<th>Variable</th>
<th>p</th>
<th>R</th>
<th>R²</th>
<th>R²adj</th>
<th>F</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Past 7 day healthful eating plan?</td>
<td>.290</td>
<td>.125</td>
<td>.016</td>
<td>.002</td>
<td>1.135</td>
<td>1.065</td>
<td></td>
</tr>
<tr>
<td>Past month healthful eating plan?</td>
<td>.229</td>
<td>.143</td>
<td>.020</td>
<td>.007</td>
<td>1.476</td>
<td>1.215</td>
<td></td>
</tr>
<tr>
<td>Past 7 days, five or more servings fruits and vegetables?</td>
<td>.960</td>
<td>.006</td>
<td>.000</td>
<td>-0.014</td>
<td>.002</td>
<td>.050</td>
<td></td>
</tr>
<tr>
<td>Past 7 days high fat foods and full fat dairy products?</td>
<td>.962</td>
<td>.006</td>
<td>.000</td>
<td>-0.014</td>
<td>.002</td>
<td>.048</td>
<td></td>
</tr>
<tr>
<td>Past 7 days 30 minutes of physical activity?</td>
<td>.168</td>
<td>.163</td>
<td>.027</td>
<td>.013</td>
<td>1.938</td>
<td>-1.392</td>
<td></td>
</tr>
<tr>
<td>Past 7 days participate in specific exercise program?</td>
<td>.929</td>
<td>.011</td>
<td>.000</td>
<td>-0.014</td>
<td>.008</td>
<td>.090</td>
<td></td>
</tr>
<tr>
<td>Past 7 days test blood sugar?</td>
<td>.972</td>
<td>.004</td>
<td>.000</td>
<td>-0.014</td>
<td>.001</td>
<td>-0.035</td>
<td></td>
</tr>
<tr>
<td>Past 7 days test blood sugar recommended number of times?</td>
<td>.325</td>
<td>.117</td>
<td>.014</td>
<td>.000</td>
<td>.980</td>
<td>.990</td>
<td></td>
</tr>
<tr>
<td>Past 7 days check feet?</td>
<td>.025*</td>
<td>.263</td>
<td>.069</td>
<td>.056</td>
<td>5.280</td>
<td>2.298</td>
<td></td>
</tr>
<tr>
<td>Past 7 days inspect inside of shoes?</td>
<td>.915</td>
<td>.013</td>
<td>.000</td>
<td>-0.014</td>
<td>.011</td>
<td>.107</td>
<td></td>
</tr>
<tr>
<td>Past 7 days take recommended diabetes medications?</td>
<td>.032*</td>
<td>.252</td>
<td>.063</td>
<td>.050</td>
<td>4.799</td>
<td>2.191</td>
<td></td>
</tr>
</tbody>
</table>

Note: *Demonstrates significance, Level of significance set at p<.05
Table 4  

*Association Between Select Socio-Demographics and Diabetic Outcomes*

<table>
<thead>
<tr>
<th>Variable</th>
<th>$p$</th>
<th>R</th>
<th>$R^2$</th>
<th>$R^2_{adj}$</th>
<th>F</th>
<th>Beta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of education vs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1c</td>
<td>.040*</td>
<td>.214</td>
<td>.058</td>
<td>.045</td>
<td>4.382</td>
<td>-2.093</td>
</tr>
<tr>
<td>Age vs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Associated Complications</td>
<td>.005*</td>
<td>.327</td>
<td>.107</td>
<td>.095</td>
<td>8.526</td>
<td>2.920</td>
</tr>
</tbody>
</table>

*Note.* *Demonstrates significance, Level of significance set at $p<.05$
Table 5

*Associations Between Select Socio-Demographics and Health Literacy Tools*

<table>
<thead>
<tr>
<th>Variable</th>
<th>NVS vs.</th>
<th>p</th>
<th>R</th>
<th>R²</th>
<th>R²adj</th>
<th>F</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level of education</td>
<td>.013*</td>
<td>.290</td>
<td>.084</td>
<td>.071</td>
<td>6.527</td>
<td>2.555</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>.004*</td>
<td>.386</td>
<td>.149</td>
<td>.124</td>
<td>6.111</td>
<td>-2.302</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>.001*</td>
<td>.453</td>
<td>.205</td>
<td>.170</td>
<td>5.933</td>
<td>2.213</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

REALM-SF vs.

| Age              | .008*  | .308 | .095 | .082 | 7.426 | 2.725|

*Note.* *Demonstrates significance at p<.05, level of significance set at p<.05*
Appendix A

Socio-Demographic Information

Patient Identification Number _____

1. Gender: Male  Female

2. Age: ___________

For the following questions, please select the option that fits you best.

1. Length of time diagnosed with diabetes
   a. Less than 1 year
   b. 1-3 years
   c. 3-5 years
   d. Greater than 5 years

2. Education level
   a. Less than high school education
   b. High school diploma or GED
   c. Some college
   d. Associates degree
   e. Bachelors degree
   f. Graduate Degree

3. Income
   a. Less than $10,000
   b. $10,000-$20,000
   c. $20,000-$40,000
   d. $40,000-$60,000
   e. $60,000-$80,000
   f. Greater than $80,000
Appendix B

The Summary of Diabetes Self-Care Activities

Participant Identification Number:________

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

<table>
<thead>
<tr>
<th>Diet</th>
<th>On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?</th>
<th>Smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 1 2 3 4 5 6 7</td>
<td>Have you smoked a cigarette—even one puff—during the past SEVEN DAYS?</td>
</tr>
<tr>
<td></td>
<td>0 1 2 3 4 5 6 7</td>
<td>0. No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Yes. If yes, how many cigarettes did you smoke on an average day?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of cigarettes:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?</th>
<th>Blood Sugar Testing</th>
<th>On how many of the last SEVEN DAYS did you test your blood sugar?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7</td>
<td>0 1 2 3 4 5 6 7</td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?</th>
<th>Foot Care</th>
<th>On how many of the last SEVEN DAYS did you check your feet?</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 1 2 3 4 5 6 7</td>
<td></td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exercise</th>
<th>On how many of the last SEVEN DAYS did you inspect the inside of your shoes?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 1 2 3 4 5 6 7</td>
</tr>
</tbody>
</table>

Additional Items for the Expanded Version of the Summary of Diabetes Self-Care Activities.

Self-Care Recommendations

1A. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please check all that apply:
   - a. Follow a low-fat eating plan
   - b. Follow a complex carbohydrate diet
   - c. Reduce the number of

2A. Which of the following has your health care team (doctor, nurse, dietitian or diabetes educator) advised you to do? Please check all that apply:
   - a. Get low level exercise (such as walking) on a daily basis.
   - b. Exercise continuously for at least 20 minutes at least 3 times a week.

3A. Which of the following has your health care team (doctor, nurse, dietitian, or diabetes educator) advised you to do? Please check all that apply:
   - a. Test your blood sugar using a drop of blood from your finger and a color chart.
   - b. Test your blood sugar using a machine to read the results.
### Appendix B continued

<table>
<thead>
<tr>
<th>Diet</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>4A. Which of the following medications for your diabetes has your doctor prescribed? Please check all that apply.</td>
<td></td>
</tr>
<tr>
<td>5A. On how many of the last SEVEN DAYS did you space carbohydrates evenly through the day? OR</td>
<td></td>
</tr>
<tr>
<td>6A. On how many of the last SEVEN DAYS, did you take your recommended diabetes medication?</td>
<td></td>
</tr>
<tr>
<td>7A. On how many of the last SEVEN DAYS did you take your recommended insulin injections?</td>
<td></td>
</tr>
</tbody>
</table>

| Foot Care |
| 9A. On how many of the last SEVEN DAYS did you wash your feet? |

| Medications |
| 10A. On how many of the last SEVEN DAYS did you soak your feet? |

| Foot Care |
| 11A. On how many of the last SEVEN DAYS did you dry between your toes after washing? |
| 12A. At your last doctor’s visit, did anyone ask about your smoking status? |

| Medications |
| 13A. If you smoke, at your last doctor’s visit, did anyone counsel you about stopping smoking or offer to refer you to a stop-smoking program? |

| Diet |
| 8A. On how many of the last SEVEN DAYS did you take your recommended number of diabetes pills? |

| Foot Care |
| 14A. When did you last smoke a cigarette? |

| Diet |
| 14A. When did you last smoke a cigarette? |

### Diet
- c. Eat lots of food high in dietary fiber
- d. Eat lots (at least 5 servings per day) of fruits and vegetables
- e. Eat very few sweets (for example: desserts, non-diet sodas, candy bars)
- f. Eat lots (at least 5 servings per day) of fruits and vegetables
- g. Other (specify):
- h. I have not been given any advice about my diet by my health care team.

### Medications
- c. Test your urine for sugar.
- d. Other (specify):
- e. I have not been given any advice either about testing my blood or urine sugar level by my health care team.
Appendix C

REALM-SF

Patient Identification Number _____

Behavior
Exercise
Menopause
Rectal
Antibiotics
Anemia
Jaundice
Appendix D

REALM-SF Score Sheet

Patient Identification Number _____

<table>
<thead>
<tr>
<th>Patient ID #</th>
<th>Date</th>
<th>Examiner Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Behavior _____
Exercise _____
Menopause _____
Rectal _____
Antibiotics _____
Anemia _____
Jaundice _____

TOTAL SCORE _____

Administering the REALM-SF:

Suggested Introduction:

“Providers often use words that patients don’t understand. We are looking at words providers often use with their patients in order to improve communication between health care providers and patients. Here is a list of medical words.

Starting at the top of the list, please read each word aloud to me. If you don’t recognize a word, you can say ‘pass’ and move on to the next word.”

Interviewer: Give the participant the word list. If the participant takes more than 5 seconds on a words, say “pass” and point to the next word. Hold this scoring sheet so that it is not visible to the participant.
Appendix E

Newest Vital Sign: Score Sheet

Patient Identification Number _____

<table>
<thead>
<tr>
<th>Score Sheet for the Newest Vital Sign Questions and Answers</th>
<th>ANSWER CORRECT?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>READ TO SUBJECT:</strong> This information is on the back of a container of a pint of ice cream.</td>
<td></td>
</tr>
<tr>
<td>1. If you eat the entire container, how many calories will you eat?</td>
<td>Yes</td>
</tr>
<tr>
<td><em>Answer:</em> 1,000 is the only correct answer</td>
<td></td>
</tr>
<tr>
<td>2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?</td>
<td>Yes</td>
</tr>
<tr>
<td><em>Answer:</em> Any of the following is correct: 1 cup (or any amount up to 1 cup), half the container. Note: if patient answers “two servings,” ask “How much ice cream would that be if you were to measure it into a bowl?”</td>
<td></td>
</tr>
<tr>
<td>3. Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 g of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?</td>
<td>Yes</td>
</tr>
<tr>
<td><em>Answer:</em> 33 is the only correct answer</td>
<td></td>
</tr>
<tr>
<td>4. If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving?</td>
<td>Yes</td>
</tr>
<tr>
<td><em>Answer:</em> 10% is the only correct answer</td>
<td></td>
</tr>
<tr>
<td><strong>READ TO SUBJECT:</strong> Pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.</td>
<td></td>
</tr>
<tr>
<td>5. Is it safe for you to eat this ice cream?</td>
<td>Yes</td>
</tr>
<tr>
<td><em>Answer:</em> No</td>
<td></td>
</tr>
<tr>
<td>6. Ask only if the patient responds “no” to question 5): Why not?</td>
<td>Yes</td>
</tr>
<tr>
<td><em>Answer:</em> Because it has peanut oil</td>
<td></td>
</tr>
</tbody>
</table>

**Interpretation**

Score of 0-1 suggests high likelihood (50% or more) of limited literacy.
Score of 2-3 indicates the possibility of limited literacy.
Score of 4-6 almost always indicates adequate literacy.
Appendix F

Newest Vital Sign Nutrition Label

Patient Identification Number _____

Nutrition Facts
Serving Size ½ cup
Servings per container 4

Amount per serving
Calories 250 Fat Cal 120

Total Fat 13g 20%
Sat Fat 9g 40%
Cholesterol 26mg 12%
Sodium 55mg 2%
Total Carbohydrate 30g 12%
Dietary Fiber 2g
Sugars 23g
Protein 4g 8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Appendix G

Patient Identification Number _____

Diabetes Complication Checklist

Hypertension _____________

Dyslipidemia _____________

Coronary Artery Disease _____________

Peripheral Artery Disease _____________

Myocardial Infarction _____________

Abdominal Aortic Aneurysm _____________

Neuropathy _____________

Hemoglobin A1c Results

1. Date: ______ Result: ______
2. Date: ______ Result: ______
3. Date: ______ Result: ______
4. Date: ______ Result: ______
Appendix H

IRB Approval

University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

APPROVAL OF SUBMISSION

October 16, 2017

Dear Filane Godding,

On 10/16/2017, the IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review:</th>
<th>Initial Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of Study:</td>
<td>An Exploratory Pilot Study: Investigating Health Literacy’s Role in Diabetes Management</td>
</tr>
<tr>
<td>Investigator:</td>
<td>Filane Godding</td>
</tr>
<tr>
<td>IRB ID:</td>
<td>STUDY00001817</td>
</tr>
<tr>
<td>Funding:</td>
<td>None</td>
</tr>
<tr>
<td>Grant ID:</td>
<td>None</td>
</tr>
<tr>
<td>IND, IDE, or HDE:</td>
<td>None</td>
</tr>
</tbody>
</table>

Documents Reviewed:
- Godding- HRP-503-Template Protocol 1 With Revisions (3).docx;
- Delevan MOU .pdf;
- Bradford MOU .pdf;
- Godding-HRP-611-HIPAA-PartialWaiver.docx;
- Godding-HRP-502-Consent Document 1.pdf;
- Capstone- Diabetes Complication Checklist form .docx;
- Capstone- SDSCA form .docx;
- Capstone- REALM form .docx;
- Capstone- Patient sociodemographic form.docx;
- Capstone- Newest Vital Sign tool .docx

The IRB approved the study from 10/16/2017 to 10/15/2018 inclusive. The initial study materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Expedited Review. Before 10/15/2018 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review application with required explanations. You can submit a continuing review application by navigating to the active study in Click IRB and selecting ‘Create Modification / CR’. Studies cannot be conducted beyond the expiration date without re-approval by the UBIRB.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.
Appendix I

Introduction
Health literacy has an established relationship with patient outcomes. In diabetes, poor health literacy is associated with lower treatment adherence and complications. This study aimed to investigate the role that health literacy has on outcomes in patients with diabetes.

Methods
The study used a cross-sectional design. Data were collected from a sample of adult patients with diabetes. The primary outcome was health literacy, as assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Rapid Estimate of Adult Literacy in Medicine Short Form (REALM-SF). The study also collected data on other variables, including age, sex, education level, and diabetes severity.

Results
The results showed that health literacy was significantly associated with medication adherence and glycemic control. Higher health literacy was associated with better medication adherence and lower HbA1c levels.

Conclusion
Health literacy is a critical factor in diabetes management. Improving health literacy can lead to better patient outcomes. Further research is needed to understand the mechanisms behind these associations and to develop interventions to improve health literacy in patients with diabetes.