Assessing Health Literacy Levels of Hispania	c Patients with Type 2 Diabetes at a Federally
Qualified Health Ce	enter in Rural Kansas

By

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Assessing Health Literacy Levels of Hispanic Patients with Type 2 Diabetes at a Federally

Qualified Health Center in Rural Kansas

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Abstract

Problem: Hispanic adults have been associated with the lowest levels of health literacy (U.S. Department of HHS, 2010). The high prevalence of low health literacy and type 2 diabetes (T2D) among the Hispanic population likely contributes to the disproportionate burden of diabetes-related complications among Hispanic populations (Chukwueke & Cordero-MacIntyre, 2010).

Project Aims: The aim of this project was to determine the readability level of current diabetes education materials provided to patients and assess the health literacy level of Hispanic patients with T2D in a health center in rural Kansas.

Project Method: The Fry Readability Formula was used to assess the readability level of current diabetes patient education materials (PEMs) in both English and Spanish. The Newest Vital Sign (NVS) screening tool was administered to 25 Hispanic patients with T2D. NVS scores of 0 to 3 were indicated at risk for limited health literacy; while, those scored 4 to 6 were considered to have adequate health literacy.

Results: The Fry Readability Formula estimated diabetes PEMs were written at an eighth-grade reading level. Out of the 25 patients who participated in the study, 20 (80%) scored at risk for limited health literacy via the NVS assessment. Further analysis found a significant association between health literacy level and gender (p=0.0092) and native language (p=0.041227). **Conclusion:** Findings from this study revealed an overall gap between the average health literacy level of the study sample and the estimated readability level of current diabetes PEMs. In order to improve the delivery of diabetes self-management education and support (DSME/S) among this population, providers must be aware of patients with limited health literacy and incorporate more effective teaching strategies to ensure an understanding.

Dedication

To my Father who gave me the greatest gift anyone could give another person, he believed in me. I am perpetually grateful for your love, strength, and support. You helped me cultivate the inner strength and perseverance needed to weather any storm. I know you're smiling down proudly from heaven. I love you and miss you every day. To my Mother and best friend, thank you for always modeling the utmost strength, courage, and work ethic. All that I am you helped me to be.

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Assessing Health Literacy Levels of Hispanic Patients with Type 2 Diabetes at a Federally

Qualified Health Center in Rural Kansas

Diabetes affects 30.3 million people in the United States (U.S.) or 9.4% of the population. Approximately 90 to 95% of those diagnosed with diabetes have type 2 diabetes (T2D) (Centers for Disease Control and Prevention [CDC], 2017a). Over time, diabetes can cause damage to the body's blood vessels, organs, and nerves. As a result, diabetes-complications arise, such as heart disease, stroke, and lower limb amputations (World Health Organization [WHO], 2018). In addition to the physical and emotional costs, diabetes imposes substantial economic burden to society. The American Diabetes Association [ADA] estimated the economic cost of diabetes in the U.S. in 2017 was 327 billion, reflecting a striking 26 percent increase in economic cost since 2012 (ADA, 2018).

Racial and ethnic minorities experience disproportionately higher rates of T2D (Attridge, Creamer, Ramsden, Cannings-John, & Hawthorne, 2014). Hispanics are the largest minority in the United States, representing 17.8 percent of the population in 2016 (United States Census Bureau, 2017). The risk of diagnosed diabetes was 66 percent higher among people of Hispanic origin compared to non-Hispanic whites (NHW) (Go et al., 2014). A combination of multiple factors including genetic susceptibility, socioeconomic barriers, cultural differences, and environmental influences likely contributes to the significant variation in disease incidence and prevalence among Hispanics compared to NHW (CDC, 2017b).

Despite the increasing trend of diabetes among Hispanics and the rapid perpetual growth of the Hispanic population in the U.S., Hispanics experience exceedingly higher rates of diabetes related complications. These include diabetic neuropathy, lower limb amputation, stroke, and

nephropathy (Chukwueke & Cordero-MacIntyre, 2010). Further, Hispanics are 1.4 times more likely to die from diabetes-related complications compared to NHW (CDC, 2017b).

The Institute of Medicine (IOM) declared health equity as one of the six dimensions of quality care in its seminal report (IOM, 2001). Health equity implies that every individual is given an equal opportunity to be healthier (Braveman, Arkin, Orleans, Proctor, & Plough, 2017). This requires advocacy and action to remove barriers that impede an individual's ability to access, understand, and obtain health, such as low health literacy. Health literacy is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decision" (IOM, 2004, p.32; National Institutes of Health, National Library of Medicine, 2015). In the U.S., it was estimated that nearly one out of every four Americans had low health literacy (Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, & Rudd, 2005). Although individuals across all populations are affected by low health literacy, racial and ethnic minority population groups are impacted most. Data from the 2003 National Assessment of Adult Literacy (NAAL) found that Hispanics in the U.S. had the lowest levels of health literacy compared to any other population group (Kutner, Greenberg, Paulsen, & Jin, 2006). Consequently, Hispanics are often challenged to comprehend and integrate the complex self-management demands crucial to chronic disease management.

The presence of low health literacy in minority populations with T2D needs to be considered in clinical practice settings. Poor diabetes self-management (DSM), diabetes knowledge, and diabetes related outcomes have been associated with low health literacy (Osborn, Bains, & Egede, 2010). According to the American Diabetes Association (ADA), diabetes self-management education and support (DSME/S) provides the foundation of care for individuals with T2D. DSME/S refers to the ongoing, collaborative process between the patient

and healthcare team (Beck et al., 2017). This process facilitates the knowledge, skills, and support necessary to implement lifestyle changes, improve health outcomes, and self-manage diabetes. DSME/S programs have been associated with improved hemoglobin A1c (Hba1c), reduced diabetes related complications, and enhanced quality of life (Brunisholz et al., 2014). However, low health literacy has been found to significantly hinder one's ability to overcome the challenges of diabetes self-management (Powers et al., 2015).

The 2016 Centers for Medicare and Medicaid Services (CMS) Quality Strategy proposed two goals highlighting the role low health literacy plays in health disparities. The first goal stated to "improve safety and reduce unnecessary and inappropriate care by teaching health care professionals how to better communicate with people of low health literacy...", while the second goal stated to "enable effective health care system navigation empowering persons and families through educational and outreach strategies that are culturally, linguistically, and health literacy-appropriate" (p. 12). A call to action has been emphasized by numerous organizational bodies to recognize low health literacy as a mediator to poor health outcomes and an obstacle to achieving health.

Statement of the Problem

Low health literacy in conjunction with T2D induces substantial burden to society. Studies have found the Hispanic population to have lower levels of health literacy than any other population group in the U.S. (Sentell and Braun, 2012; U.S. Department of Health and Human Services, 2010). The high prevalence of low health literacy and T2D among the Hispanic population elicits an extensive public health concern in the U.S. Recognizing low health literacy as an independent predictor of poor diabetes self-management and disease related outcomes highlights the importance of assessing health literacy. The Federally Qualified Health Center

(FQHC) where this project was conducted suspected lower health literacy in Hispanic patients with T2D; however, no formal evaluation had been implemented. Furthermore, their diabetes patient education materials had never been evaluated for their readability level.

Literature Review

This author conducted a literature review to explore the impact of low health literacy on health outcomes, the prevalence of low health literacy among minority populations, and factors that hinder diabetes self-care management. Next, a synthesis of health literacy screening instruments was undertaken to determine which tool would be most suitable for this project. The databases utilized included PubMed, CINHAL, ProQuest, and Google Scholar. Studies were identified using the following search terms: health literacy and assessment, health literacy and diabetes, Hispanics and diabetes, diabetes management, health literacy and minorities, health equity, readability and instrument. Inclusion criteria were studies that were peer-reviewed, available in English, and validated the health literacy screening tool. Studies were excluded if they were published prior to 2010 and if primary research included pediatric and/or adolescent participants. A quality improvement project was introduced based on the information gathered from this literature review.

Impact of Low Health Literacy

Several studies have suggested that health literacy is a greater predictor of health outcomes than age, education level, race, employment, or income (Calvo, 2015; Miller, 2010). There is a higher prevalence of chronic disease among individuals with low health literacy along with poor disease-related knowledge and a limited ability to effectively manage the condition(s) (IOM, 2004). Further, low health literacy has been associated with poor health outcomes, particularly for those with chronic conditions such as depression, diabetes, and heart failure (Bauer et al.,

2013; Peterson et al., 2011; Sarkar et al., 2010). Fabbri et al. (2018) explored the impact of health literacy on mortality and hospitalizations in a total of 2,487 patients with heart failure (HF). Results indicated a strong association between low health literacy and increased risk of death and hospitalization in patients with HF. Low health literacy has also been associated with poor health-related quality of life (HRQoL) and poor health-related behaviors (Friis, Lasgaard, Rowlands, Osborne, & Maindal, 2016). A cross-sectional study examined the impact of low health literacy on behavior and HRQoL in patients without known vascular disease. The study found that patients with low health literacy were more likely to be overweight/obese and engage in poor health related behaviors, including smoking and decreased physical activity (Jayasinghe et al., 2016).

Additionally, those with low health literacy are less likely to use preventative services, such as vaccinations, mammograms, etc., and have an increased risk of hospitalization (Wolf, Feinglass, Thompson, & Baker, 2010). A retrospective study investigated the association between low health literacy and utilization of health care services and costs in 92,749 veterans. The study found that individuals with inadequate or marginal health literacy utilized health care services more frequently and experienced significantly higher health care costs compared to individuals with adequate health literacy (Haun et al., 2015). Mitchell, Sadikova, Jack, and Paasche-Orlow (2012) conducted a secondary analysis of the data from the subjects of the Project RED and the RED-LIT trials. The authors examined the relationship between health literacy and 30-day readmission rates after discharge from an urban safety net hospital. Health literacy was measured using the Rapid Estimate of Adult Literacy in Medicine (REALM) to 703 study participants. Results suggested that low health literacy was an independent predictor of

hospital readmission and emergency department utilization within 30 days of discharge (Mitchell et al., 2012).

Similarly, Rasu, Bawa, Suminski, Snella, and Warady (2015) explored health literacy's impact in terms of healthcare utilization and expenditure. The study used estimates from the Medical Expenditure Panel Survey (MEPS) which represented roughly 503,374,648 weighted individuals nationally from 2005 to 2008. Results from database analysis concluded that individuals with basic or below basic health literacy have greater healthcare utilization and healthcare expenditures, such as spending more money on prescriptions than individuals with above basic health literacy levels. Further, extrapolated national estimates found that the annual costs for prescriptions alone for adults with low health literacy levels could potentially reach 172 billion (Rasu et al., 2015). Consequently, low health literacy is associated with higher annual health care costs than those with higher health literacy.

Prevalence of Low Health Literacy Among Hispanic Populations

The Hispanic population is currently the fastest growing minority population in the U.S (Calvo, 2015). According to Krogstad and Gonzalez-Barrera (2015), nearly 73% of Hispanic individuals living in the U.S. speak Spanish at home. Non-native English speakers and those with low English proficiency have been found to have lower health literacy and worse health outcomes than those who are native English speakers (Aponte & Nokes, 2015). It has been reported that Hispanic adults have lower health literacy levels than any other population group in the U.S. (U.S. Department of Health and Human Services, 2010). Sentell and Braun (2012) explored the relationship between limited-English proficiency and low health literacy in a diverse population-based sample. Findings indicated that the prevalence of low health literacy was 45.3% in Hispanics compared to 18.8% in non-Hispanic whites.

In addition, findings derived from the 2003 National Assessment of Adult Literacy (NAAL) indicated nearly 65 percent of Hispanics tested in Spanish were found to have low or inadequate health literacy (Kutner et al., 2006). Screening for health literacy could improve the level of care delivered to Hispanics by recognizing the need to implement strategies to improve communication and patient education (Calvo, 2015).

Barriers to Diabetes Self-Management

According to the 2017 National Standards for Diabetes Self-Management Education and Support, diabetes self-management (DSM) is the most crucial element to managing diabetes (Beck et al., 2017). Optimal DSM includes monitoring blood glucose levels, taking medications as prescribed, eating healthy meals, utilizing beneficial coping mechanisms, and reducing the risk of diabetes complications (Haas et al., 2013). Reducing barriers that hinder DSM are essential to achieving optimal diabetes outcomes (Jones, Crabb, Turnbull, & Oxlad, 2014). Five major barriers that hinder DSM among individuals with T2D include: (a) brief office visits and limited access to health care; (b) low health literacy; (c) lack of diabetes knowledge; (d) inadequate financial resources; (e) poor provider communication and support; and (f) lack of family support (Ahola & Groop, 2012; Grant & Steadman, 2016; Reyes, Tripp-Reimer, Parker, Muller, & Laroche, 2017).

Brief office visits and limited access. Limited patient-provider interactions due to brief office visits inadequately addresses diabetes self-management education and support (DSME/S) (Grant & Steadman, 2016). Further, shortages of essential health care providers (i.e., diabetes educators, dieticians, endocrinologists, primary care providers) as well as busy providers during office visits limits the time available to discuss DSME/S with patients (Jones et al., 2014). A study by Kruse et al. (2013) found that the average time for discussing DSME/S between the health care

provider(s) and the patient was 5.2 minutes. Additionally, limited access to health care facilities requires patients to travel long distances for follow-up appointments and health care services. Consequently, limited access contributes to fewer routine diabetes appointments, less early detection of diabetes complications, and poor health outcomes (Grant & Steadman, 2016).

Low health literacy. DSM is without a doubt complex in nature but can be substantially more challenging for those with low health literacy (Bailey et al., 2014). Numerous studies have found an association between low health literacy and diabetes distress, poor glycemic control, insufficient diabetes knowledge, and an increased risk of diabetes complications (Osborn, Bains, & Egede, 2010; Pandit et al., 2014; Sarkar et al., 2010). Aguayo- Mazzucato et al. (2019) found that individuals with low health literacy had difficulty reading information on pill bottles, understanding nutrition labels, and interpreting blood sugar values.

Conversely, Ahola and Groop (2012) found that low health literacy was not associated with one's ability to monitor their blood glucose, but rather, one's ability to correctly interpret and act upon blood glucose results. Low health literacy has been linked to poor diabetes self-management behaviors, which directly influence one's ability to recall medication instructions and maintain adequate glucose control (McCarthy et al., 2012). Similarly, Chahardah-Cherik, Gheibizadeh, Jahani and Cheraghian (2018) found that higher levels of health literacy directly correlated with increased adoption of DSM behaviors.

Lack of diabetes knowledge. Lack of diabetes knowledge is another major barrier to DSM. Several studies have indicated a profound association between inadequate diabetes knowledge and poor glycemic control (Kueh, Morris, Borkoles, & Shee, 2015; Shams, Amjad, Seetlani, & Ahmed, 2016; Worku, Abebe, & Wassie, 2015). Further, patients who are more knowledgeable

about their diabetes are more likely to engage in DSM behaviors (Al-Qazaz et al., 2011; Barbara & Krass, 2013; Kueh et al., 2015).

Inadequate financial resources. Financial difficulty imposes a disproportionate burden to individuals with T2D (Campbell et al., 2017; Morris & Chasens, 2017). Inadequate financial resources hinder one's ability to implement DSM. This may include difficulty affording costly medications and diabetes supplies and incorporating healthy foods in their diet (Grant & Steadman, 2016; Morris & Chasens, 2017). Jesse and Rutledge (2012) found that those with T2D and limited financial resources were more likely to disengage from the community and not routinely follow up with their health care provider. Similarly, Campbell et al. (2017) identified financial barriers as a significant contributor to medication nonadherence and poor diabetes outcomes.

Stiffler, Cullen, and Luna (2014) conducted a qualitative study to better understand barriers to diabetes self-care from the patient's perspective. Those with T2D reported being unreceptive to a provider's recommendations if he/she failed to realize the patient's financial limitations. Synthesis of the literature highlighted the importance of health care clinicians recognizing their client's financial concerns and challenges when discussing DSME/S (Grant & Steadman, 2016; Morris & Chasens, 2017; Stiffler, Cullen, & Luna, 2014).

Poor provider communication and support. Provider support and communication is key to facilitating DSME/S (Reyes et al., 2017). Effective communication between the patient and provider can influence positive attitudes towards T2D and motivate patients to adopt DSM behaviors (Edelman et al., 2019). Effective provider communication is noted as non-judgmental, empathetic, and motivating (Grant & Steadman, 2016). In addition, providers who communicated dietary strategies that integrated individual preferences and cultural beliefs were

more likely to improve their patients' DSM skills and diabetes outcomes (Grant & Steadman, 2016). According to Stiffler et al. (2014), patients who view their providers as partners in decision making were much more likely to adhere to DSM recommendations and medication regimens.

Lack of family support. Family support is another important facilitator to DSM. Baghikar, Benitez, Fernandez Pineros, Gao, and Baig (2019) conducted a qualitative study of 27 Hispanic adults with T2D. The study found that family members who participated in medication management (i.e. reminders to take medication, assistance with organizing medications) greatly influenced diabetes medication adherence. Similarly, a qualitative study conducted by Reyes et al. (2017) suggested that family support influenced positive DSM behaviors in T2D patients. The study also found that support from family members was essential when it came to dietary modifications and monitoring dietary intake.

Predominant Health Literacy Screening Instruments

Health literacy has been assessed by a variation of reliable instruments. Wallace (2010) emphasized the importance of utilizing an instrument that measures skills particular to diabetes management when assessing health literacy in the diabetic population. This includes instruments that measure the patients' ability to "read written words, comprehend pros, and comprehend and conduct numerical calculations" (p. 223). The three most commonly used instruments are: (a) Rapid Estimate of Literacy Medicine (REALM); (b) Test of Functional Health Literacy (TOFHLA); and (c) The Newest Vital Sign (NVS). An appropriate health literacy instrument was selected based on validity/reliability, use in T2D populations, ease of administration and scoring, time, availability in Spanish, and training requirement.

The Rapid Estimate of Adult Literacy in Medicine (REALM). The REALM was the first screening instrument developed to evaluate patients' literacy in primary care and research settings. The REALM is a 125-word recognition test that identifies patients with low or limited literacy skills (Davis et al., 1991). Patients are asked to read the health-related words aloud and scored based on word recognition and pronunciation. The raw score is then construed into the corresponding grade level range: less than or equal to sixth grade (low literacy), seventh to eighth grade (marginal literacy), and greater than or equal to ninth grade (adequate literacy). Administration and scoring of the REALM has been estimated to take approximately three to five minutes. A few years later, a shortened version of the REALM was developed (Davis et al., 1993). The word recognition test was condensed to 66 words and estimated to take one to two minutes to administer and score. The validity of the REALM and shortened REALM was established by demonstrating a highly positive correlation with two widely used standardized reading recognition tests, the Slosson Oral Reading Test (r= 0.95) and the Peabody Individual Achievement Test Revised (r= 0.98) (Davis et al., 1991; Davis et al., 1993). The test-retest reliability of the REALM was 0.98 and reliability remained exceptional with the shortened REALM, at 0.99 (Davis et al., 1991; Davis et al., 1993).

There are numerous advantages of the REALM and shortened REALM. The instruments are easy and quick to administer and can be utilized in various health care settings. In addition, multitudinous studies have utilized the REALM or shortened REALM to identify patients with limited literacy for decades (Duell, Wright, Renzaho, & Bhattacharya, 2015). However, a major limitation of both versions of the REALM is that it does not measure other important components of health literacy, including numeracy and word comprehension. The REALM instrument can simply offer insight regarding one's ability to read and pronounce health related

terms (Dumenci, Matsuyama, Kuhn, Perera, & Siminoff, 2013). According to Duell et al. (2015) "incorporation of a numeracy element provides a more accurate health literacy assessment... (p. 1305)." An additional limitation is that all forms of the REALM are only available in English.

The Test of Functional Health Literacy in Adults (TOFHLA). The TOFHLA was developed to measure a patient's ability to read and articulate health-related information commonly found in health-care settings (Parker, Baker, Williams, & Nurss, 1995). The test is comprised of three reading comprehension sections and one numeracy section. A sum of the total sections produces a score from 0 to 100. The score is then categorized into the corresponding level of health literacy: adequate, marginal, or inadequate. The content validity was determined using hospital medical texts. Adequate validity was established by correlation of the TOFHLA to the REALM (r=0.84). The estimated time to administer and score the test was approximately 22 minutes (Parker et al., 1995). Later, a condensed version was developed referred to as the short-TOFHLA. Administration and scoring of the short-TOFHLA estimated to take seven minutes (Baker, Williams, Parker, Gazmararian, Nurss, 1999).

A major advantage to the TOFHLA is the ability to measure multiple components of health literacy, including reading, comprehension, and numeracy skills (Baker et al., 1991; Parker et al., 1995). Further, Duell et al. (2015) found that the short-TOFHLA instrument was used in over half of the 626 health literacy articles synthesized as the sole instrument to measure health literacy or as the comparison instrument for validation. Although the TOFHLA is available in both English and Spanish, there is no reported data on the validity and reliability of the Spanish version. Subsequently, limitations of the TOFHLA are the unknown validity and reliability of the Spanish version and the length of time required to complete and score the test (Duell et al., 2015).

The Newest Vital Sign (NVS). The NVS was developed in 2005 as a brief screening tool to determine risk of limited health literacy in the outpatient primary care settings (Weiss et al., 2005). The use of this tool helps providers acclimate their communication and teaching practices to the patient's health literacy level (Weiss et al., 2005). The instrument consists of a nutritional label associated with six questions that measure the patient's reading, comprehension, and numeracy skills. Administration and scoring take approximately three to five minutes and scores are translated as "high likelihood of limited literacy," "possible limited literacy", or "adequate literacy". A score of fewer than four answers correct indicates the possibility of limited literacy. The NVS consists of both an English and Spanish version of the test. The Spanish version was established by translation and back-translation of the English version. Validity and internal consistency of the NVS was established by measuring correlations with TOFHLA scores. The internal consistency of the NVS in English was good at 0.76, however, correlation with the TOFHLA was poor (r=0.59, P<.001). Similarly, the internal consistency of the Spanish version of the NVS was 0.69 and demonstrated unacceptable validity with the TOFHLA (r=0.49, P<.001) (Polit & Beck, 2004; Weiss et al., 2005). However, a recent study developed to validate the NVS in the United Kingdom reported a much stronger correlation to TOFHLA (Rowlands et al., 2013).

Advantages of the NVS include its ease of administration and timeliness, availability in English and Spanish, and its ability to measure reading, comprehension, and numeracy (Heinrich, 2012; Rowlands et al., 2013; Welch, VanGeest, & Caskey, 2011). A cross-sectional study investigated the applicability and timeliness of using the NVS to measure health literacy in various primary care settings. The study found that the NVS was widely accepted, administered in less than three minutes, and provided reliable results comparable to extensive literacy tests

(Shah, West, Bremmeyr, & Savoy-Moore, 2010). Additionally, the NVS has been used across various races and ethnicities, including African Americans, Hispanics, Chinese, and Caucasians. Assessment of health literacy with the NVS has also been conducted on patients with various health conditions, including diabetes, heart failure, chronic pain, and HIV (Shealy & Threatt, 2016). Limitations of the NVS include less than optimal reliability and validity, it has been studied less extensively in comparison to the REALM and TOFHLA, and scores are distinguished into vague categories, that is, "high likelihood," and "possibly limited" (Griffin et al., 2010; Heinrich, 2012; Weiss et al., 2005).

Limitations of Previous Screening Instruments

Health literacy is a broadly defined, multifaceted concept that encompasses communication, culture, language, context, and/or technology (Mancuso, 2009). The REALM, TOFHLA, and NVS have proven to be effective and useful tools in assessing one's ability to comprehend and perform routine healthcare related tasks. However, several constraints ensue with the assessment of health literacy. Each instrument measures health literacy based on different definitions and constructs of heath literacy (Griffin et al., 2010). There is not an instrument available that measures the full set of skills and knowledge associated with health literacy. In addition, cofounders such as cognitive defects and test anxiety are not considered when measuring health literacy (Mancuso, 2009). Also, integration of health literacy assessments into clinical practice has received much controversy over the years. Barriers to implementing health literacy assessments into clinical practice include time limitations and concerns related to the potential shame and embarrassment associated with illiteracy. However, studies have indicated that health care clinicians routinely overestimate their patients' ability to comprehend

medical information (Wallace, 2010). This highlights the value of assessing health literacy to ensure patient education and information is tailored to the health literacy level of the patient.

Readability Formulas

According to the Joint Commission on Accreditation of Healthcare Organization [JCAHO], the availability of clear and easily understood patient information materials is an incumbent part of the accreditation process for healthcare facilities (Badarudeen & Sabharwal, 2010). Yet, patient education materials are often written at a level too complex for the average patient to read and comprehend (Coco, Colina, Atcherson, & Marrone, 2017; Wolff et al., 2016). Numerous readability formulas have been developed to predict the reading level an individual must possess to comprehend the written material(s). Some of the most commonly used readability formulas in healthcare settings include the Flesch-Kincaid Formula, the Fry Readability Formula, the Fog Index, and the SMOG readability formula (Badarudeen & Sabharwal, 2010). Almost all formulas measure readability based on the average number of words per sentence and average number of syllables per word. Results are then translated into the corresponding U.S. grade level (Friedman & Hoffman-Goetz, 2006).

Several limitations exist with the use of readability formulas. It is important to note that each formula uses slightly different criteria to predict the grade level required. Further, readability formulas do not measure an individual's level of comprehension. Most formulas neglect key factors that influence one's comprehension, such as, format of the text, illustrations, and motivation of the reader (Badarudeen & Sabharwal, 2010). Lastly, although numerous readability formulas exist in English there is only a limited number of readability formulas validated for Spanish texts.

The Fry Graph Readability Formula. The CDC has recommended the use of the Fry Graph Readability Formula to evaluate the readability level of written materials (CDC, 2009). This formula predicts the required grade level required based on the average number of syllables and average number of sentences from three 100-word passages. Next, the two values are plotted on a standard fry graph, and their intersection generates the predicted grade level of readability (Badarudeen & Sabharwal, 2010). The Fry Graph Readability Formula has been validated in English and Spanish texts and takes into account that Spanish texts often have a greater number of syllables compared to English texts at the same grade level (Friedman & Hoffman-Goetz, 2006). Further, it can be administered manually without the use of a computer software program.

In conclusion, readability is a complex, multi-faceted concept affected by a number of different factors. Readability formulas are useful tools to assess the complexity of written materials in healthcare (CDC, 2009). For this project, the Fry Graph Readability Formula will be used to predict the readability level of diabetes education materials. This formula was selected based on ease of administration and validation in both English and Spanish text.

Definitions Conceptual and Operational

Health Literacy

Conceptually, health literacy is defined as "an individual's capacity to obtain, comprehend, and integrate basic health information and services necessary to make appropriate health decisions" (IOM, 2004, p.32; National Institutes of Health, National Library of Medicine, 2015). Operationally, health literacy will be measured using the Newest Vital Sign (NVS).

Readability

Conceptually, readability is defined as "the sum total of all elements within a given piece of printed material that affects the success a group of readers have with it" (Dale & Chall, 1949,

p. 23). Operationally, readability is defined as the quantitative estimate of reading difficulty from printed diabetes education materials provided to patients (Friedman & Hoffman-Goetz, 2006).

Readability of both Spanish and English materials will be determined by using the Fry Graph Readability Formula.

Diabetes Self-Management Education

Conceptually, diabetes self-management education (DSME) is the collaborative, ongoing process of facilitating the skill, knowledge, and ability required for diabetes self-care, which includes: 1) assessment of the individual's education needs; 2) identification of the individual's diabetes self-management goals; 3) education and behavioral intervention directed toward assisting the individual to achieve self-management goals; and 4) evaluation of the individual's fulfilment of self-management goals (American Association of Diabetes Educators, 2011;Funnell et al., 2008). Operationally, DSME is defined as an individual's ability to progress towards and attain specific learning, behavioral, and clinical improvement outcomes. For the purpose of this project, DSM is the ability to articulate diabetes specific knowledge, perform diabetes related skills, and identify individualized goals related to DSM.

Project Aims

This quality improvement project consists of three aims: (1) determine the readability level of current diabetes education materials provided to patients, (2) assess the health literacy level of Hispanic patients with T2D, and (3) make recommendations for improving diabetes education materials to enhance teaching of Hispanic patients with T2D.

Project Questions

1. What is the prevalence of low health literacy among Hispanic patients with T2D at a FQHC in rural Kansas?

- 2. What is the readability level of current patient education materials utilized at a FQHC in rural Kansas?
- 3. What recommendations could improve diabetes education materials to enhance teaching of Hispanic patients with T2D?

Theoretical Framework

The IOWA Model was used as the guiding framework for this DNP project. The IOWA Model was designed to translate evidence-based knowledge into clinical practice to improve quality of care (Titler et al., 2001). The first step is to identify a problem-focused or a knowledge-focused trigger where evidence-based change is needed. The increasing prevalence of low health literacy in minority populations and individuals with chronic conditions is a significant public health concern. At the Heart of Kansas (HOK) Family Care Clinic in rural Kansas, there is not a diabetes nurse educator or dietitian nearby. In fact, the closest diabetes educator is in a city nearly an hour away from HOK. Concern regarding the PCP facilitating DSME to Hispanic patients with T2D led to the identification of this gap in care. The next step was to determine whether the problem (trigger) is a priority for the organization. Frequently missed diabetic follow-up appointments along with poor diabetes related outcomes were an overall concern for the HOK organization and had attributed to worse health outcomes and substantial healthcare related costs. Problems that are associated with increased organizational costs or poor clinical outcomes are more likely to receive organizational buy-in (Titler et al., 2001). The third step was to formulate a team of stakeholders to develop, evaluate, and implement the evidence-based practice. For this project, the team of stakeholders included the providers, nurses, secretaries, and bilingual Spanish certified medical assistants (CMAs) at HOK. Next, existing research related to the desired practice change is gathered, critiqued, and

synthesized. In this project, a literature search was conducted to determine the background and significance of low health literacy, barriers to diabetes self-management, and predominant health literacy instruments and readability formulas utilized in healthcare. In the fifth step, the team determines whether sufficient evidence exists to implement a practice change. If so, the sixth step involves implementation into a pilot practice change (Titler et al., 2001).

The final step is evaluation of the pilot practice change. This step is essential in determining whether the evidence-based change improved patient care and/or achieved desired effects. If the pilot practice change resulted in improved outcomes an organizational practice change is implemented. Based on findings from the health literacy assessments and readability level of current diabetes education materials, appropriate diabetes education materials and communication strategies was recommended to improve quality of care in Hispanic patients with T2D at HOK.

Methodology

Design

A quality improvement (QI) and comparative analysis design was used for this DNP project. The Project Director obtained quality improvement designation approval August 30, 2019 (Appendix C). This project consisted of three aims: 1) to determine the readability level of current diabetes education materials provided to patients; 2) assess the health literacy level among Hispanics with T2D; and 3) make any necessary recommendations based on these findings. The Project Director used the IOWA model as the guiding framework for the study.

A letter was sent to the clinic's Medical Director of the study site describing the purpose and procedure of the study. A letter of support was obtained from the Medical Director signifying the clinic's collaboration and involvement in this QI project (Appendix A). Providers

at the clinic were contacted for their voluntary participation in the study. Three providers agreed to participate in the study and were asked to construct a list of eligible patients using the clinic's electronic health record (EHR) database.

Protocol. Providers and staff who chose to participate in the study attended an on-site meeting in the conference room during their hour lunch break. The Project Director discussed the background and significance of low health literacy, and project aims and objectives. In addition, staff were trained on administration of the NVS screening tool. At the conclusion of the meeting, the Project Director obtained copies of current diabetes patient education materials that were kept in each exam room and frequently utilized by the providers at the clinic. The readability level of current diabetes patient education materials at HOK was determined using the Fry Graph Readability Formula. Calculations and scoring were performed by hand independently by the project director and a trained bilingual Spanish medical assistant.

The Newest Vital Sign assessment was offered to eligible patients in either English or Spanish based on the patient's native or predominant language (Appendix B). The Project Director or one of the three bilingual certified medical assistants (CMAs) administered the NVS assessment. Verbal consent was obtained prior to administration of the NVS. The Project Director was present during each NVS assessment to ensure the assessment was conducted in a timely manner. Estimated administration time was between three and six minutes. The purpose of the screening tool was to assess the patient's ability to read and interpret a nutrition label, which in turn reflected the skills needed to comprehend and employ a provider's medical instruction. These health literacy skills are known as "the understanding and application of words (prose), numbers (numeracy), and forms (documents)" (Pfizer Inc, 2011, p. 4). The patient was given a sheet of paper with an ice cream nutrition label and asked a series of six questions related

to it. Throughout administration of the NVS, the patients were able to use the calculator provided to them if desired, and able to refer to the ice cream nutrition label as often as they needed to. Multiple studies have demonstrated that poor comprehension of nutrition labels is highly associated with low literacy and numeracy skills (Powers, Trinh, & Bosworth, 2010; Sharif et al., 2014). Responses to each question were classified as correct, incorrect, or "I don't know." A score of four or more correct answers indicated adequate health literacy, whereas, a score below four suggested risk of limited health literacy (Weiss et al., 2005).

Setting of Study

The project was conducted at The Heart of Kansas Family Health Clinic (HOK) in Great Bend, Kansas. In Great Bend, approximately 19.9 percent of the population is of Hispanic or Latino origin. It was estimated that nearly 7.5 percent of the population in Kansas speak Spanish in their household; nearly 18 percent of the population in Great Bend speak Spanish in their household (U.S. Census Bureau, 2018). HOK is a rural, federally qualified health center (FQHC) that predominately provides health services to underserved individuals who are uninsured or use Medicaid, Medicare, or Farm Worker programs. HOK was recognized as a patient-centered medical home in 2016. The patient-centered medical home model of care emphasizes replacing episodic care with coordinated, long-term provider-patient relationships. A medical home achieves this through excellent communication strategies, monitoring quality outcomes and performance, and providing a high level of accessibility to patients. The medical team at HOK consists of five providers, including one physician, one physician assistant (PA), three APRNs, two licensed practical nurses (LPNs), and three bilingual certified medical assistants (CMAs).

Providers at HOK serve a patient population with a variety of health care needs such as acute and chronic illnesses, language barriers, counseling, and financial limitations.

Sample

Purposive sampling was used to obtain a sample size of 25 Hispanic patients with T2D at HOK. The following inclusion criteria was used to identify study participants: men and women of Hispanic or Latino origin, age 18 years or older, a diagnosis of T2D for at least 6 months, and had a scheduled office visit between September 2019 and October 2019. Exclusion criteria included men and women not of Hispanic or Latino origin, less than 18 years of age, and individuals who presented to the clinic for counseling services but were not scheduled to see the provider. The providers constructed a list of eligible patients with the date and times of their appointments.

Data Collection Plan

Data from the NVS screening tool was collected over a two- week period from patients who meet inclusion criteria and wished to voluntarily participate in the study. Data collection was kept strictly anonymous. Patients were assigned a study identification number prior to administration of the NVS. Scoring sheets only included the study identification number to ensure confidentiality. All scores were written in black or blue ink on a specialized NVS scoring sheet. The Project Director was on site during data collection to assist staff. In addition, the Project Director was present during each NVS assessment.

Setting Facilitators and Barriers

Several facilitators and barriers influenced the implementation of this DNP project. It was crucial for the providers and ancillary staff at HOK to have a clear understanding of what health literacy is and how it can affect health outcomes. During the pre-implementation phase, the Project Director presented an overview of health literacy and explained the project in detail to the staff at HOK during a team meeting. Two staff members expressed uncertainty and discomfort with administration of the NVS. To overcome this barrier, the Project Director met with each staff member individually and employed the teach-back method to ensure effective administration of the NVS. Several staff members verbalized feeling more comfortable and confident with the NVS tool after they practiced administering the questions a couple of times.

Clear and direct communication was noted as the most essential facilitator for this DNP project. Project details could never be assumed and needed to be clearly communicated by the Project Director daily. Additionally, the Project Director's daily presence at the study site during the implementation phase was another vital facilitator for three identifiable reasons: (1) to provide additional support; (2) establish open communication between team members; (3) and address concerns and potential barriers as soon as they occurred.

Protected Health Information

Participation in this project was strictly voluntary and all information was kept confidential. To protect the privacy of study participants during the selection process all Protected Health Information (PHI) was reviewed on-site with the provider. Study participants were each assigned a study identification number to ensure patient identifiers or PHI were not linked. A verbal consent was obtained prior to administration of the NVS. Study participants were instructed their right to refuse/skip questions or withdraw from the NVS assessment at any

time. The Project Director was on-site to collect the completed NVS assessments. Scores of each study participant's NVS assessment were reviewed by the Project Director and uploaded to a secured Microsoft Excel Spreadsheet. Once the NVS scores were uploaded, they were shredded by the Project Director. The primary focus of this QI project was to assess health literacy among the study population; however, unidentified demographic information such as age, ethnicity, gender, and native language was gathered and analyzed.

Results

Descriptive statistics were generated for analysis. Measures of central tendency were used to assess the average risk of low health literacy among the study population. An in-depth evaluation of categorical variables such as gender, age, and native language were analyzed using the Chi-square statistic and bivariate analysis. Finally, a comparative analysis was performed to evaluate whether the readability level of diabetes PEMs was at an appropriate level for the study population.

Data Analysis

From September 3rd to September 13th, 32 patients were asked to voluntarily participate in this QI study. Five patients declined participation in the study due to time constraints, and two patients were uninterested in participating in the study. A total of 25 patients participated in the study and completed the NVS assessment. Out of the 25 participants, 13 (52%) were male and 12 (48%) were female. In addition, out of the 25 participants, 15 (60%) reported Spanish as their native language and completed the Spanish version of the NVS, and 10 (40%) reported English as their native language and completed the English version of the NVS. The average age of the

sample population was 53.7 years. Frequency and distribution related to age are displayed in a table and histogram (Figure 1).

The NVS scores were aggregated into the three categories. Out of the 25 participants, 18 (72%) scored at risk for limited health literacy, two (8%) scored as marginal health literacy, and five (20%) scored as adequate health literacy (Figure 2). The mean NVS score of the study population was 1.72, indicating at risk for limited health literacy. As determined by the NVS scale developers, participants with NVS scores of 0 to 3 were indicated at risk for limited health literacy; while, those who scored 4 to 6 were considered to have adequate health literacy.

Therefore, it was concluded that 80% of study participants were at risk of limited health literacy.

The Chi-square test and bivariate analysis was performed to evaluate whether there was an association between health literacy level (limited or adequate) and the study participants' gender, age, and native language. Results indicated the association between health literacy level and the study participants' gender and native language was significant. A total of 15 participants reported Spanish as their native language and completed the Spanish version of the NVS. Of these 15 participants, 14 scored as limited health literacy and one scored as adequate health literacy on the NVS. In comparison, a total of ten participants reported English as their native language and completed the English version of the NVS; six participants were identified as limited health literacy and four scored as adequate health literacy on the NVS (see Appendix D). To determine whether this association was significant the Chi-square test was performed (Table D1). The p-value was significant (p= 0.041227), indicating that an association between health literacy level and the study participants' native language was significant. Additionally, out of 12 female participants, seven scored as limited health literacy and five scored as adequate health literacy. Whereas, all 13 male participants scored as limited health literacy on the NVS

(Appendix E). Again, the Chi-square test was performed and determined a highly significant association was present (p= 0.0092) (Table E1). Correlations between health literacy level and age less than 60 years of age and age 60 years and over are represented as well (Appendix F). However, this association did not reveal a statistical significance (p= 0.5201) (Table F1).

A comparative analysis was performed to evaluate whether the readability level of diabetic PEMs was at an appropriate reading level based on the average health literacy level of the study population. The American Medical Association (AMA) and National Institutes of Health (NIH) recommend that patient education materials are written at a reading level below sixth-grade for the "average" adult. Doak, Doak, and Root (1996) recommended patient education materials should be written at a fifth to sixth grade reading level, or third to fifth grade level for low-literacy populations.

The Fry Readability assessment was performed on three 100-word passages from diabetic PEMs in both Spanish and English used at HOK clinic (Appendix G). To account for differences in the structures of English words compared to Spanish words, 67 is subtracted from the total syllable count of each 100-word passage in Spanish (Gilliam et al., 1980). The estimated reading level for both Spanish and English diabetes PEMs was eight-grade (Figure G1).

Discussion

This project consisted of several aims, however, the primary aim was to assess the risk of low health literacy among Hispanic patients with T2D at a FQHC. Health literacy was evaluated using the validated and brief six-question screening tool, The Newest Vital Sign. Findings indicated that 80% of participants were at risk of limited health literacy and merely 20% had adequate health literacy. The average score on the NVS assessment tool was 1.7, suggesting the study population is at considerable risk of low health literacy.

The second aim of this QI project was to determine the readability level of current diabetic PEMs utilized at the study site. The Joint Commission on Accreditation of Healthcare Organization (JCAHO) mandates the availability of clear and easily understood PEMs as part of the accreditation process for healthcare facilities (Badarudeen & Sabharwal, 2010). Several health organizations recommend the use of PEMs that are written below a six-grade reading level to ensure the majority of patients are able to interpret the information (Centers for Disease Control and Prevention, 2017). The readability level of both Spanish and English PEMs was determined using the Fry Graph Readability Formula. It was found that diabetes PEMs were estimated to be at the eight-grade reading level. This suggested that the diabetes PEMs often utilized in the clinic are not meeting reading ease standards, and are most likely too complex for patients to comprehend.

The third and final aim of the QI project was to offer recommendations for improving diabetes education materials to enhance teaching of Hispanic patients with T2D. Findings from the health literacy assessment indicated that future diabetes PEMs should be directed towards providing education to individuals with limited health literacy.

Impact of Results on Practice

Studies have found the Hispanic population to have the highest prevalence of low health literacy compared to any other population group in the United States (U.S. Department of Health and Human Services, 2010). Further, Hispanics with T2D disproportionally experience higher rates of diabetes related complications (Chukwueke & Cordero-MacIntyre, 2010). The health literacy assessment implemented in this study indicated that 80% of the sample population was at risk of limited health literacy. In addition, it was estimated that readability of diabetes PEMs at

HOK were written at an eighth-grade reading level. Moving forward, these findings may enable providers at HOK to recognize low health literacy as an independent predictor of diabetes management, and successively utilize more appropriate PEMs to enhance diabetes teaching to Hispanic patients with T2D. This study emphasized the importance of using validated tools to assess health literacy and evaluate readability of patient education materials.

Study Limitations

There were several limitations to this study. The first limitation is related to the small sample size of 25. Due to the small sample size the findings are not generalizable to a larger population. Another limitation effecting generalizability of the results is that data was collected from a single clinic site. However, findings are consistent with current literature reporting the increased risk of limited health literacy in non-English speaking and Hispanic populations (cite?). An additional limitation was that three bilingual CMAs delivered the Spanish version of the NVS to participants who were predominately Spanish speaking. The language barrier between study participants and the project director posed a significant challenge during the project implementation phase, considering the project director was unable to speak or interpret Spanish. Although the project director was present during each NVS assessment, uncertainty exists in whether each NVS assessment was delivered as consistently as instructed. A final limitation was related to the readability assessment. The Fry readability formula was used to evaluate a limited number of diabetes PEMs, and therefore cannot represent the readability level of all diabetes PEMs at the study site.

Dissemination of Results

The findings from this QI project will be disseminated through multiple avenues. First, results and recommendations were discussed with the providers at HOK and plan to be presented

to the healthcare staff during the monthly staff meeting in December 2019. In addition, study findings were shared with the providers and diabetes educators at Cray Diabetes Self-Management Center in Kansas City to discuss potential interventions aimed at improving diabetes education amongst this population. Lastly, the project findings will be presented at the University of Kansas School of Nursing Doctor of Nursing Practice Project Public Presentation.

Future Implications for Practice

Findings from this study revealed an overall gap between the average health literacy level of Hispanic patients with T2D and the estimated readability level of current diabetes PEMs. In order to improve the delivery of DSME/S among this population, providers must be aware of patients with limited health literacy and incorporate more effective teaching strategies to ensure an understanding. Future implications for practice may be to implement a process to continually evaluate PEMs, remove complex and outdated PEMs, and acquire new patient education materials that follow recommended guidelines for easy to read patient education materials. In the guiding framework *Simply Put*, the CDC and U.S. Department of Health and Human Services provide various strategies for improving patient education materials to enhance patient understanding (CDC, 2010). The guide provides practical ways to communicate and display complex health information to improve patient engagement and understanding.

Numerous diabetes PEMs have been developed specifically for individuals with low health literacy. Based on the readability of current diabetes PEMs, it is crucial for providers to establish new patient educational materials directed towards teaching individuals with limited health literacy. The first diabetes PEMs recommended is the Diabetes Literacy and Numeracy Education Toolkit (DLNET). The DLNET is a widely used 24-module diabetes resource that

helps facilitate clear communication between the provider and the patient (Wolff et al., 2009). The modules in this toolkit are written at a low-grade reading level, use color coding, and include pictures on each page to provide instructions on various diabetes self-care strategies (Wolff et al., 2009). An example of one of the educational materials provided in the DLNET is demonstrated in Figure 3. Additionally, Lilly Diabetes creates PEMs directed towards individuals across all health literacy domains. Resources from Lilly Diabetes are frequently utilized in healthcare facilities, including The University of Kansas Health Systems. Figure 4 illustrates "the Spinner," which helps patients estimate the number of carbohydrates in some common foods (Lilly Diabetes, n.d.). Diabetes PEMs created by Lilly Diabetes and provided in the DLNET are available in Spanish and English.

The findings discovered throughout this QI project may provoke several questions for future research. It would be beneficial for future studies to examine specific interventions aimed at improving the health literacy in Hispanic patients with T2D. Another area of future research is the implementation of diabetes PEMs that are indicated for individuals with limited health literacy and written at an appropriate reading level. Future studies may evaluate the use of new diabetes PEMs and its effect on diabetes self-management and diabetes related outcomes over time.

Conclusion

According to the ADA, assessing patients' health literacy level is instrumental to delivering DSME and developing a comprehensive plan of care (Funnell et al., 2009). Low health literacy is a substantial barrier to patients achieving diabetes self-management skills. However, increased provider awareness of low health literacy can result in improved communication, education, and patient-provider interactions. This QI project was undertaken

because of providers' concerns about the study populations' ability to comprehend and apply complex diabetes education. The purpose of the study was to assess the risk of limited health literacy within the target population and to evaluate the readability level of current diabetes PEMs. Results indicated that 80% of the study participants were at risk of limited health literacy; and the readability of current diabetes PEMs utilized at the clinic site were estimated to be written at a much higher reading level than what is recommended. In addition, in this study, lower health literacy scores were associated with male gender and non-English native speakers.

Further, findings from this study helped emphasize the significant prevalence of low health literacy in Hispanics with T2D. Tailoring current diabetes PEMs to enhance the teaching and understanding of this population is crucial to improve disease self-management and overall health outcomes. Diabetes PEMs created by the DLNET and Lilly Diabetes are merely a few recommended resources specifically indicated for individuals with limited health literacy. As previously mentioned, limited health literacy is a significant barrier to effective diabetes self-management. Healthcare clinicians need to be aware of individuals with low health literacy and present diabetes information in ways they can understand.

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Appendix A: Letter of Support

Dear Karli Lapointe and JoAnn Peterson,

On behalf of Heart of Kansas Family Healthcare Clinic in Great Bend, Kansas, please accept this letter signifying our collaboration with and support of Karli Lapointe Doctor of Nursing Practice Project Assessing Health Literacy Levels of Hispanic Patients with Type 2 Diabetes at a Federally Qualified Health Center in Rural Kansas. We are interested in the opportunity to improve educational strategies and tools that promote diabetes education and treatment plan compliance for our patients.

We understand that Karli Lapointe will need access to the electronic medical record to accompils a retrospective chart review. We understand that all patient identifiers will be removed with data collection. We also understand that Karli Lapointe will share findings or results with Jackie Reed, APRN and our clinic.

As the clinic's Medical Olrector, I have read the quality improvement proposal and support the involvement of our clinic in this project.

(Signature)		Heart of Kanaas Family Health Care, Inc 1905 19th Street Great Bend, KS 57530
	Jean Pringle, 1개.D.	

Appendix B: The Newest Vital Sign (English)

Score Sheet for the Newest Vital Sign Questions and Answers READ TO SUBJECT: This information is on the back of a container of a pint of ice cream. yes no 1. If you eat the entire container, how many calories will you eat? Answer: 1,000 is the only correct answer 2. If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have? Answer: 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." 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? Answer: 33 is the only correct answer 4. If you usually eat 2500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving? Answer: 10% is the only correct answer READ TO SUBJECT: Pretend that you are allergic to the following substances: Penicillin, peanuts, latex gloves, and bee stings. 5. Is it safe for you to eat this ice cream? Answer: No 6. (Ask only if the patient responds "no" to question 5): Why not? Answer: Because it has peanut oil. Interpretation Number of correct answers: 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.

Nutrition Facts		
Serving Size		½ cu
Servings per container		
Amount per serving		
Calories 250	Fat Cal	12
		%D'
Total Fat 13g		20%
Sat Fat 9g		409
Cholesterol 28mg		129
Sodium 55mg		29
Total Carbohydrate 30g		129
Dietary Fiber 2g		
Sugars 23g		
Protein 4g		89
*Percentage Daily Values (DV)	are based on a	
2,000 calorie diet. Your daily va	,	
be higher or lower depending or	n your	
calorie needs. Ingredients: Cream, Skim N	Alle Liquid	
Sugar, Water, Egg Yolks, Brown		
Milkfat, Peanut Oil, Sugar, Butte		
Carrageenan, Vanilla Extract.	n, oak,	

Appendix B: The Newest Vital Sign (Spanish)

		ANSWER CORRECT ?	
		YES	NO
EAD TO SUBJECT: Est	a información aparece en el reverso de un envase de		
elado.			
Ci de la companya de			
consumido?	odo el helado en el envase, ¿cuántas calorías habrá		
Respuesta	1,000		
Si a usted le recom merienda, ¿cuánto	nendaron consumir 60 g de carbohidratos en la o helado puede comer?		
Respuesta	Cualquiera de: Hasta un máximo de una taza Una taza La mitad del envase Nota: Si el/la paciente responde "dos porciones", pregúntale "¿Cuánto helado seria si usted lo midiera en un plato?" La respuesta correcta es cualquiera de las tres escritas arriba.		
Usted normalment	seja reducir la cantidad de grasas saturadas en su dieta. e consume 42 g de grasas saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día?		
Usted normalment una porción de hel	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de		
Usted normalment una porción de hel grasa saturada con	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día?		
Usted normalment una porción de hel grasa saturada con Respuesta Si usted normalme	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día?		
Usted normalment una porción de hel grasa saturada con Respuesta Si usted normalmen	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día? 33 g		
Usted normalment una porción de hel grasa saturada com Respuesta Si usted normalmer su valor diario de co	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumíria cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción?		
Usted normalment una porción de hel grasa saturada con Respuesta Si usted normalmes su valor diario de c Respuesta Usted es alérgico/a	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción? 10% a las siguientes sustancias: Penicilina, cacahuate (mani),		
Usted normalment una porción de hig grasa saturada con Respuesta Si usted normalmei su valor diario de c Respuesta Usted es alérgico/a guantes de latex y j	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción? 10% a las siguientes sustancias: Penicilina, cacahuate (mani),		
Usted normalment una porción de hig grasa saturada con Respuesta Si usted normalmei su valor diario de c Respuesta Usted es alérgico/a guantes de latex y j	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumíria cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción? 10% a las siguientes sustancias: Penicilina, cacahuate (maní), picaduras de abeja.		
Usted normalment una porción de hel grasa saturada con Respuesta Si usted normalmes su valor diario de ce Respuesta Usted es alérgico/a guantes de latex y ¿ ¿Puede comer este Respuesta	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumíria cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción? 10% a las siguientes sustancias: Penicilina, cacahuate (maní), picaduras de abeja. helado con seguridad?		
Usted normalment una porción de hel grasa saturada con Respuesta Si usted normalmes su valor diario de ce Respuesta Usted es alérgico/a guantes de latex y ¿ Puede comer este Respuesta	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumirio cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción? 10% a las siguientes sustancias: Penicilina, cacahuate (maní), picaduras de abeja. No		
Usted normalment una porción de hel grasa saturada con Respuesta Si usted normalmes su valor diario de c Respuesta Usted es alérgico/a guantes de latex y; ¿Puede comer este Respuesta (Solamente si respo	e consume 42 g de grasa saturada al día, que incluye ado. Si deja de comer helado, ¿cuántos gramos de sumiría cada día? 33 g nte come 2,500 calorías en un día, ¿qué porcentaje de alorías habrá consumido si se come una porción? 10% a las siguientes sustancias: Penicilina, cacahuate (mani), picaduras de abeja. No onde "no" a pregunta 5): "¿por qué no?"		

Información Nutricional	
Tamaño de la Porción	½ taza
Porciones por envase	4
Cantidad por porción	
Calorías 250	Cal Grasa 120
	%DV
Grasa Total 13g	20%
Grasas Sat 9g	40%
Colesterol 28mg	12%
Sodio 55mg	2%
Total Carbohidratos 30g	12%
Fibras Dietéticas 2g	
Azúcares 23g	
Proteína 4g	8%

^{*}Porcentaje de Valores Diarios (DV) se basan en una dieta de 2.000 calorías. Sus valores diarios pueden ser mayores o menores dependiendo de las calorías que usted necesite.

Ingredientes: Crema, Leche Descremada, Azúcar Líquida, Agua, Yemas de Huevo, Azúcar Morena, Aceite de Cacahuate (Maní), Azúcar, Mantequilla, Sal, Carragenina, Extracto de Vainilla.

Appendix C

8/30/2019

Dear Karli Lapointe,

Thank you for submitting your Quality Improvement Determination request.

The KUMC Human Research Protection Program (HRPP) has conducted a review of the above referenced project. The request meets the criteria for QI project and is approved. In the attachment please find the signed approval. Any presentation or publication resulting from this project should explicitly state that it was undertaken as quality improvement.

At this time, IRB review is not required. If a quality improvement protocol is revised to undertake a systematic investigation designed to answer a research question or produce knowledge that would be generalizable beyond the local setting, the HRPP will reevaluate our project's regulatory status.

More information about distinguishing quality improvement from research is available on the OHRP website at: http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html

Best of luck and continued success in this worthwhile endeavor.

Kris Whitaker

Sr.Compliance Specialist

Office of Compliance/HRPP

Ext. 8-1655

Office hours: 7:30 to 3:00 M,T, TH, F- out of the office every Wednesday

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Kansas City, KS 66205

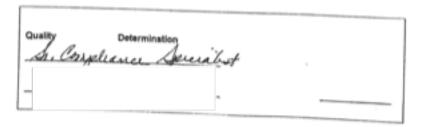


Figure 1: Frequency and Distribution of Age

Age	Frequency
31-40	1
41-50	10
51-60	7
61-70	6
71-80	1

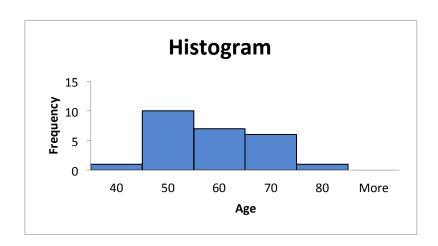
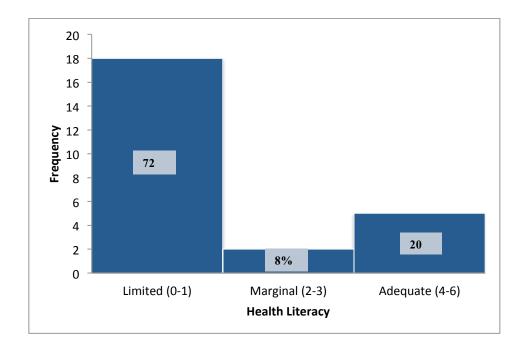


Figure 2: Frequency and Distribution of NVS Scores



Appendix D: Frequency of Health Literacy Levels by Native Language

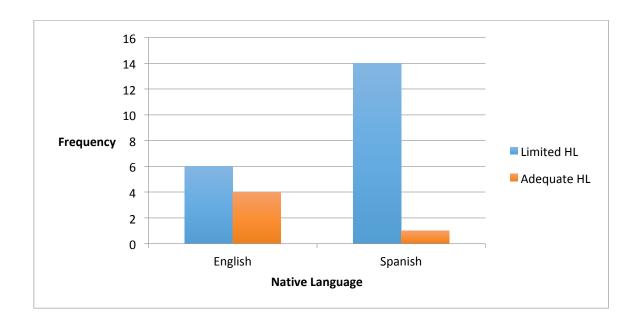


Table D1: Chi-square Test: Health Literacy Level and Native Language

Observed			
Health literacy			
level	Spanish	English	Total
Limited	14	6	20
Adequate	1	4	5
Total	15	10	25
Expected			
Health literacy			
level	Spanish	English	Total
Limited	12	8	20
Adequate	3	2	5
Total	15	10	25
p-value	0.041227		

Appendix E: Frequency of Health Literacy Levels by Gender

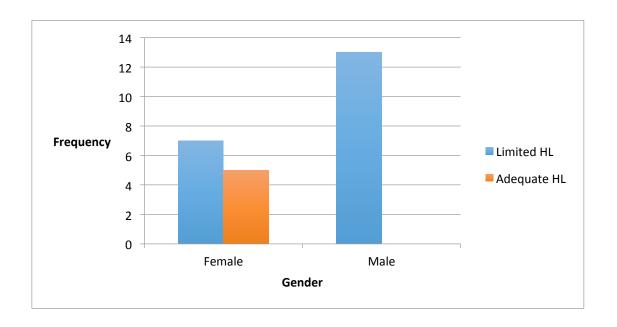


Table E1: Chi-square Test: Health Literacy Level and Gender

Observed			
Health literacy			
level	Female	Male	Total
Limited	7	13	20
Adequate	5	0	5
Total	12	13	25
Expected			
Health literacy			
level	Female	Male	Total
Limited	9.6	10.4	20
Adequate	2.4	2.6	5
Total	12	13	25
p-value	0.009266		

Appendix F: Frequency of Health Literacy Levels by Age

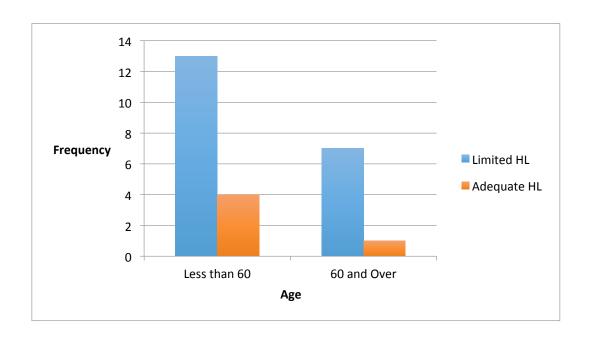


Table F1: Chi-square Test: Health Literacy Level and Age

Observed			
Health literacy	60 and	Less than	
level	Over	60	Total
Limited	7	13	20
Adequate	1	4	5
Total	8	17	25
Expected			
Health literacy	60 and	Less than	
level	Over	60	Total
Limited	6.4	13.6	20
Adequate	1.6	3.4	5
Total	8	17	25
p-value	0.520146		

Appendix G: Fry Readability Formula

Toolkit No. 14: All About Carbohydrate Counting (English)

Toolkit No. 14

All About Carbohydrate Counting

Total syllables: 149
Total Sentences: 149
What is carbohydrate counting?

- Carbohydrate counting is a way to plan your meals.

 12 It can help you manage your blood glucose (sugar).

 Carbohydrates, or carbs, are one of the three main.
- energy sources in food. The other two are protein and of fats. It's the balance between insulin in your body and the carbohydrate you eat that determines how much
- 39 your blood glucose levels rise after you eat. With the right balance of carbohydrate and insulin, your blood 32 glucose level is more likely to stay in your target range.

Counting carbohydrate can help you reach your blood ϑ glucose goals and prevent diabetes complications

You can learn to count carbs to choose what and how much to eat. If you take insulin, you can count carbs to decide how much insulin to take.



Carbohydrate counting can help you choose what and how much to eat.

Which foods have carbohydrate?

Starchy foods, sugars, fruits, milk, and yogurt are mostly carbs. See examples in the chart below. These foods affect your blood glucose much more than other foods, such as meat and meat substitutes, vegetables, or fats.

2. Total syllables: 155... # 2. Total Sentences: # 3. How many grams of carbohydrate are best for me?

The recommended number of servings is based on your weight, activity level, diabetes medicines, and goals for your blood glucose levels. Your dietitian or diabetes educator, can work with you to make a personalized plant. A general guideline is to have

- 45-60 grams of carbohydrate at each meal &
- 15-20 grams of carbohydrate servings at each snack \sim

Carbohydrate foods (Carbs) beans (such as black, · bread, bagels, biscuits, garbanzo, kidney, lima, chapatti, muffins, navy, or pinto beans), crackers, matzoh, and lentils, and peas (such as tortillas ready-to-eat cereal or black-eyed or split peas) cooked cereal • fruit (canned, dried, barley, bulgur, couscous, fresh, and frozen) and grits, kasha, pasta, and fruit juice buttermilk, milk, soy starchy vegetables such milk, and yogurt as cassava, corn, peas, plantains, potatoes, and sweets, such as candy, winter squash, and sweet cookies, cake, brownies, potatoes doughnuts, ice cream,

pancakes and waffles

popcorn, potato chips,

pretzels, and rice cakes

What about other foods such as meats, vegetables, and fats?

Why should I pay attention to serving sizes for carbohydrate foods?

The amount of carbohydrate you eat can make a big difference in your blood glucose. If you eat more carbs than you normally do at a meal, your blood glucose level is likely to be higher than usual several hours afterward.

sugar, and syrup

frozen yogurt, honey, jam, jelly, pie, pudding,

Guía N.º 14 sobre:

Todo sobre el conteo de los carbohidratos

Total Syllables: 196.

De qué se trata el conteo de los carbohidratos?

Total Syllables: 196.

Adjusted

(*Contar carbohidratos es una forma de planificar sus & (*Comidas, ya que puede avudarlo a controlar.) comidas, ya que puede ayudarlo a controlar la glucosa (azúcar) en la sangre. Los carbohidratos son una de 9 Las tres fuentes principales de energía proveniente de 8 Solos alimentos. Las otras dos son la proteína y la grasa El grado de elevación de la glucosa en la sangre que 🔏 ocurre después de comer depende del equilibrio entre 🖔 19 la insulina del cuerpo y lo que consume de carbohidra- 10 tos Si tiene un balance adecuado entre carbohidratos ? oce insulina, es más posible que el nivel de glucosa en la 12 sangre se mantenga dentro de los niveles deseado

Contar carbohidratos puede ayudarlo a lograr los niveles deseados de glucosa en la sangre y a prevenir las complicaciones de la diabetes. Usted puede aprender a contar carbohidratos y a decidir qué comer y cuánto comer. Si se inyecta insulina, puede contar carbohidratos para decidir cuánta inyectarse.

¿Qué alimentos contienen carbohidratos?

Los alimentos que tienen gran cantidad de carbohidratos son: almidones, azúcares, fruta, leche y el yogurt. Vea los ejemplos en el cuadro más adelante. Este tipo de alimentos afecta la glucosa en la sangre mucho más que otros, tales como la carne y los sustitutos de carne, los vegetales o las grasas.

Alimentos que cont	ienen carbohidratos
pan, bagels, biscochos, chapattis, panecillos, galletas, matzoh y tortillas cereal listo para comer o cocido	frijoles (tales como los negros, garbanzos, rojos, habas, pintos, blancos), lentejas y guisantes (como de caritas o chícharos)
cebada, trigo bulgur, cuscús, fécula de maíz, kasha, pasta y arroz	• fruta (enlatada, seca, fresca y congelada) y jugo de fruta
verduras con almidón tales como yuca, maíz, guisantes, plátanos, papas, calabaza de invierno y camotes o batatas	suero de leche, leche, leche de soya y yogur cosas dulces, tales como caramelos, galletas, tortas y pasteles, brownies,
 panqueques y waffles palomitas de maíz, papitas fritas, pretzels y galletas de arroz 	donas, helado, helado de yogur, miel, mermelada, jalea, tartas, budines, azúcar y jarabe de maíz



El conteo de carbohidratos puede ayudarlo a decidir qué comer y cuánto comer.

total syllables: 214. Adjusted. syllabus: 147 ¿Cuántos gramos de carbohidratos me convienen más en cada comida y refrigerio? 24.

La cantidad recomendada de porciones se basa en su peso, nivel de actividad, medicamentos para la diabetes y objetivos que se ha propuesto respecto a sus niveles de glucosa en la sangre. Su nutricionista o educador de la diabetes puede reunirse con usted para personalizar un plane Estas son las guías generales de consumo: • 45-60 gramos de carbohidratos en cada comida

• 15-20 gramos en cada refrigerio #2. Total Syllables: 204 ¿Qué hay sobre otros alimentos, tales como carnes, vegetales y grasas?

Para tener un plan alimenticio equilibrado, deberá 7 incluir alimentos con proteína (como carnel pollo y 8 pescado), vegetales sin almidón (como ensalada y 🛪 brócoli) y una cantidad pequeña de grasa saludable 🞖 (Como aceite de oliva y nueces). Hable con su equipo de cuidado de la salud sobre qué puede comer en las \\. 34comidas y de refrigerio. 4

¿Por qué debo prestarle atención al tamaño de las porciones de los alimentos con carbohidratos?

La cantidad de carbohidratos que coma puede afectar & M mucho la glucosa en la sangre. Si come más carbohidratos de lo que consume generalmente en una comida, será a más probable que tenga un nivel más alto que lo normal VV 58 de glucosa en la sangre varias horas después. 🥱

Table G1: Fry Readability Formula (English)

Passages from Tooklit No.14: All About Carbohydrate Counting

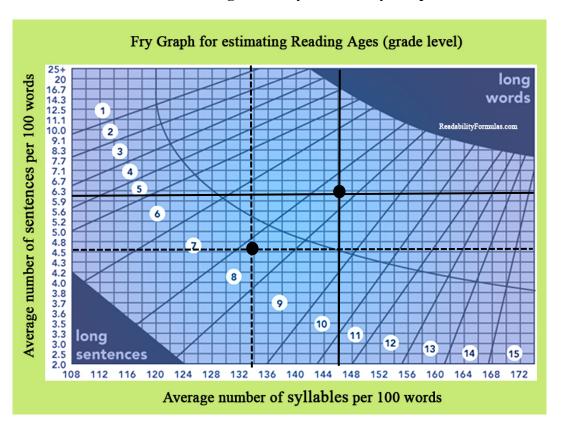
Toolkit No.14	Number of	Number of
	Sentences	Syllables
First 100	7	149
Words		
Second 100	6	138
Words		
Third 100	5	153
Words		
Total	18	440
Average	6	146.6666667

Table G2: Fry Readability Formula (Spanish)

Passages from Toolkit No. 14: All About Carbohydrate Counting

Toolkit No.14	Number of	Number of	Adjusted for
	Sentences	Syllables	Spanish
First 100 Words	5	196	129
Second 100	4	214	147
Words			
Third 100	5	190	123
Words			
Total	14	600	399
Average	4.666666667	200	133

Figure 3: Fry Readability Graph



Key

- Spanish 100-word Sample:
- English 100-word Sample:

PART 1

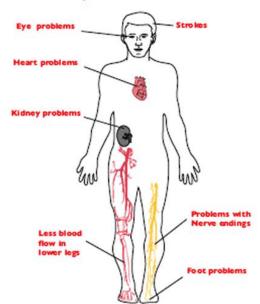
INTRO TO DIABETES

 Diabetes is a disease that causes you to have extra sugar in your blood (high sugar).

High sugar in the blood can cause you problems with:

- Poor vision or blindness
- Kidney disease
- · Heart attacks or strokes
- · Numbness, tingling or pain in your nerve endings
- · Foot sores and foot pain
- · Less blood flow
- Infections
- · But, control of your blood sugar can help to stop these problems!

The Major Problems From Diabetes



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Figure 4: The Spinner



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