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# AN EXAMINATION OF THE IMPACT OF HEALTH LITERACY ASSESSMENT ON INCARCERATED INDIVIDUALS WITH A DIAGNOSIS OF TYPE 2 DIABETES

By

Josi Rhea Rotunno

### DNP PROJECT

Submitted to Northern Michigan University In partial fulfillment of the requirements For the degree of

## DOCTOR OF NURSING PRACTICE

School of Nursing

October 2020

### SIGNATURE APPROVAL FORM

## AN EXAMINATION OF THE IMPACT OF HEALTH LITERACY ASSESSMENT ON INCARCERATED INDIVIDUALS WITH A DIAGNOSIS OF TYPE 2 DIABETES

This DNP project by Josi Rhea Rotunno is recommended for approval by the student's Faculty Chair, Committee, and Interim Associate Dean/Director in the School of Nursing

#### ABSTRACT

## AN EXAMINATION OF THE IMPACT OF HEALTH LITERACY ASSESSMENT ON INCARCERATED INDIVIDUALS WITH A DIAGNOSIS OF TYPE 2 DIABETES

#### By

#### Josi Rhea Rotunno

Low health literacy levels limit healthcare outcomes in a variety of diagnoses. Having a low health literacy level can significantly impact an individual's ability to manage their condition. Among these individuals are incarcerated individuals, who are especially vulnerable to low health literacy levels. Due to regulations of the correctional facility, along with the vulnerability of the population, it is often difficult to get approval for studies and to make changes within this setting. The stigma of incarceration, along with the difficulty in navigating the correctional setting regulations, often create barriers to making changes that could improve the health of incarcerated individuals. Few studies have been completed on health literacy levels of incarcerated individuals. The Newest Vital Sign is a reliable and valid tool that is being used in a multitude of settings and languages to assess health literacy levels. The purpose of this project was to determine health literacy levels of incarcerated individuals with type 2 diabetes in a Midwestern facility along with the impact of educational materials provided over a one-month period of time. Using the appropriate tools to determine health literacy along with proper literacy-leveled education is paramount to positive health outcomes. This project aimed to focus on type 2 diabetes and health literacy factors associated with disease management.

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JOSI R. ROTUNNO

October 31, 2020

### DEDICATION

This DNP project is dedicated to my husband, Sean. He has helped me through countless hours of hard work and has done everything under the sun to make my life easier. Sean has worked especially hard to ensure that I have time to work on my DNP project and still have time to relax and cool down. My parents, Erica and Andrew Denman, have spent countless hours supporting and encouraging a drive to obtain more knowledge.

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#### **Chapter One**

#### **Background and Significance**

#### **Health Literacy and Diabetes**

The epidemic of diabetes has reached new levels, currently listed in the top 10 causes of American deaths (Centers for Disease Control and Prevention [CDC], 2017). A recent report published by the CDC (2017) looked at those living with diabetes or prediabetes in the United States and found concerning evidence in relation to diabetes. The CDC (2017) report states there are currently "30 million diagnosed with diabetes and 84 million with prediabetes that has the potential of becoming type two diabetes" (para. 1). With further evaluation, this study found that education and those diagnosed with diabetes had an inverse relationship (CDC, 2017). Education has been identified numerous times in the literature as a viable way to increase patient compliance for disease management (Sarac et al., 2017). With the growth of chronic conditions, it is essential to take proactive measures to improve health outcomes.

Diabetes is a disease that is rapidly increasing in the United States, leading to a multitude of complications and spending. This disease has several different categories, with the most common types including type 1 diabetes and type 2 diabetes. Type 1 diabetes generally manifests in children and young adults (American Diabetes Association, 2020). This condition results in little to no production of insulin from the beta cells in the pancreas, which typically occurs when the immune system attacks the body's cells (American Diabetes Association, 2020). Insulin is a hormone released by the pancreas and allows the body to uptake sugar from the bloodstream for energy. In type 2 diabetes, the body is still producing insulin, but it may not be enough insulin, or the body may be resistant to insulin (American Diabetes Association, 2020). This condition generally manifests in those who are overweight or obese, and usually older than 18, though children may also develop it. Each type of diabetes can potentially result in damage to the kidneys, nerves, eyes, and heart valves if it is not managed correctly (American Diabetes Association, 2020). Management of type 1 diabetes generally requires insulin, diet modification, exercise management, and counseling. Management for type 2 diabetes typically requires oral medication and, in severe cases, may require insulin. To obtain successful outcomes for this condition, an understanding of the disease process and treatment is necessary.

Though health literacy may be interpreted and defined in many ways, each one reaches the same conclusion. Health literacy is generally defined as the ability to obtain, process, understand, and apply health knowledge (CDC, 2019). A person with low health literacy may not have access to information related to their health. They may be unable to understand or use the information that they have received or, alternatively, failed to receive the health information altogether (due to the patient declining information or a failure by the practitioner to provide it).

In 2019, the CDC examined three categories of health literacy: literacy, numeracy, and ability to problem solve with technology (CDC, 2019). The data were measured using both the paper and computer methods for measuring health literacy. According to the CDC (2019), the most recent health literacy report shows that "only 9% of the participants scored in the highest category in relation to health numbers and only 12% scored in the highest category for health proficiency" in the United States (para. 1). This statistic suggests that 91% of Americans are not able to properly apply numerical information in a way that benefits them the most, and 88% of Americans are not able to use health information in a way that results in the most positive health outcomes (CDC, 2019). Assessment of health literacy can provide a reliable tool for healthcare professionals to use when dispensing health information. This may better assist health care providers in preparing the most appropriate information tailored to the specific patient's needs.

The Newest Vital Sign is a tool developed by Pfizer (2020) in recent years to quickly and efficiently assess health literacy levels. This tool consists of a food nutrition label and a series of six questions to assess health literacy levels. This includes questions related to calorie intake, carbohydrate intake, saturated fat intake, daily servings, and allergies. The Newest Vital Sign may be viewed in Appendix E. The Newest Vital Sign has been proven a reliable and valid method in the assessment of health literacy (Russell et al., 2019). This assessment tool currently comes in two approved languages: Spanish and English. Several variations and wordings of this assessment tool are now in the making. Scoring of the six questions indicates a category of health literacy levels for that specific patient. A score of zero to one suggests low health literacy, a score of two to three indicates a possibility of low health literacy, and a score of four to six indicates adequate health literacy (Pfizer, 2020). The administration of this test will assist healthcare providers in understanding a patient's ability to comprehend and apply health information. Through this assessment, a healthcare provider may better help a patient in self-care activities and promote overall well-being.

#### **Statement of Problem**

Proper management of diabetes relies on patient understanding of their condition along with patient participation in self-care and ongoing, routine health visits with a healthcare provider. Health literacy has the potential to positively or negatively affect health outcomes, especially for those with diabetes. In individuals with diabetes, a high health literacy level is preferred to achieve positive health outcomes, whereas individuals with a lower health literacy level will have difficulty managing their condition, have gaps in their care, and misuse health information. Understanding health literacy is a pivotal component in proper management of diabetes for positive health outcomes. Those with a low health literacy level generally have a more difficult time locating, understanding, and using the information they receive, leading to gaps in care and misuse of health information. Understanding health literacy and the effect it has on those diagnosed with diabetes can better assist providers and patients in meeting the needs necessary to maintain an appropriate level of health.

The relationship between diabetes and health literacy levels is not entirely black and white, though it is known that explicit health literacy does impact diabetes management in specific ways. An article published in 2017 looked at health literacy levels and risk factors for the management of diabetes. This article stated that certain factors, such as diet and exercise, were positively impacted by those who had higher health literacy levels (Proteroe, Rowlands, Barlam, & Levin-Zamir, 2017). By providing the proper education related to diet and exercise, a provider may give the right tools to the patient to better manage their diabetes diagnosis. An additional study, published in 2018, looked at the effects of diabetes education and health literacy on diabetes outcomes. This study discovered that those with lower health literacy levels were more likely to have adverse health outcomes (Vandenbosch et al., 2018). Also, this study found that, regardless of health literacy level, diabetes education related to self-management was beneficial to all levels of health literacy (Vandenbosch et al., 2018). Education, regardless of the level of health literacy, has been proven successful in managing diabetes diagnoses, though predicting health literacy levels could improve health outcomes through more appropriate education materials.

#### **Statement of Purpose**

The purpose of this DNP project was to determine health literacy levels of incarcerated individuals with type 2 diabetes in a Midwestern facility along with the impact of educational material provided over a one-month period. As more people are acquiring a diagnosis of

diabetes, and a large percentage of the population is not at an adequate health literacy level to apply health information, health literacy assessment is essential in managing and promoting positive health outcomes in those diagnosed with diabetes. This project can better predict the impact low health literacy has on diabetes management and health outcomes.

**Research Question:** Is there a relationship between providing educational material based upon the Newest Vital Sign scores and health literacy levels after one month?

**H**<sub>0</sub>: There is no relationship between the Newest Vital Sign score, individualized educational material, and health literacy levels.

 $H_{a:}$  There is a relationship between the Newest Vital Sign score, individualized educational material, and health literacy levels.

Proposing an appropriate project can best determine if there is a significant relationship between health literacy assessments, education, and literacy levels in those diagnosed with diabetes.

#### Methods

Due to regulations, the information could not be accessed from the electronic medical record to identify individuals with type 2 diabetes. Individuals were asked to participate in a voluntary DNP project through a JPay announcement. This announcement was available to all incarcerated individuals through each of their JPay accounts via computer access. This announcement gave a synopsis of the DNP project and asked for volunteers to send a kite to Healthcare (the standard term for a medical center in a correctional setting). A kite consists of a form that the individual fills out and places in a box that goes directly to Healthcare nurses. The use of the kite ensured that only Healthcare staff were eligible to read the information and protected participant identity. Participants were then called to Healthcare to meet on a one-on-one basis to discuss the project, confidentiality, and the Health Insurance Portability and

Accountability Act (HIPAA). After forms were signed, participants produced a form of verification of type 2 diabetes medications, which could consist of them telling the researcher the drugs they currently take. Ability to verify resulted in a check in the *yes* box for medication verification or insulin use. The inability to verify did not prevent further participation in this project.

The 28 participants received numerical order based upon inmate IDs. Each inmate ID was given a number to correspond with its position in the sequence. These numbers were then divided into two groups, with the even numbers being in one group and the odd numbers being in the other group. The participants were then all given the Newest Vital Sign health literacy assessment. Those participants of the odd-numbered group received traditional education currently used at this Midwestern facility. The participants in the group of even numbers received educational material from the American Diabetes Association tailored to match their Newest Vital Sign score. The Newest Vital Sign health literacy assessment was given again after one month to determine if there were changes to literacy level. This data was then entered into an Excel database and later as an SPSS dataset. The most appropriate project design for this project was quasi-experimental with interrupted pretest and posttest design. This allowed for the manipulation of a variable from a nonrandom convenience sample. The data were collected, entered into an Excel spreadsheet, and then finally placed in SPSS. Using the SPSS software, an independent t-test was used to compare the two groups.

#### **Introduction to Theoretical Framework**

Theoretical frameworks can easily be incorporated into each aspect of nursing to tailor care in an individualized way. Virginia Henderson created the nursing need theory to help meet individual patient needs (Petiprin, 2020). This theory is founded on 14 primary needs for

everyone, some of which include food and water, the practice of religion, and self-expression. This theory also has three assumptions: that nurses care for patients day and night, nurses assist in patient care until a patient can care for himself or herself, and nurses should be appropriately educated in both the arts and sciences (Petiprin, 2020.). This theory focuses on topics such as the importance of health literacy and proper education to help patients manage their health outcomes. This theory proves vital in managing chronic conditions in those with low health literacy levels.

#### **Chapter Two**

#### **Literature Review**

#### **Health Literacy Levels**

There is a continuous growth of low health literacy as populations with limited education in health continue to age and technology continues to create more complex systems. Among those affected by health literacy are those with a specific and common chronic diagnosis—type 2 diabetes. According to the CDC (2017), nearly "10% of those who live in the United States of America have diabetes with nearly one-quarter of those being undiagnosed cases" (para. 2). Also, a large percentage of Americans qualify as prediabetics within the prediabetes range. With this percentage of the population having diabetes or prediabetes, the topic of health literacy and its impact on an individual's diet and exercise habits is well-timed.

**Diabetes management.** According to the American Diabetes Association Consensus Report (2019), three main aspects are essential in diabetes management. These three aspects include "exercising 150 minutes per week, improving eating habits, and maintaining an initial body weight loss of 7–10%" (p. 1). Some additional recommendations in this report include "increase in daily fiber intake through fruits and vegetables, 45% of calories being from carbohydrates, 35%–40% being from fats, and 16%–18% being from protein" (American Diabetes Association Consensus Report, 2019, p. 1). This plan should be modified to each individual to obtain the suggested percentage of weight loss. The recommended carbohydrate intake for someone with diabetes may be less than the average person at 130 g per day. In contrast, protein and fiber intake, along with fat, should be increased in those with a diabetes diagnosis (American Diabetes Association Consensus Report, 2019). Through understanding health literacy, providers may be able to provide more appropriate education related to the topic of diet and exercise in those who need to manage diabetes.

**Health literacy.** Health literacy is a complex definition that is often difficult to separate from literacy itself. Those who can function at a high level of literacy may still lack in understanding topics related to health. Healthy People 2020 discusses several different aspects that go into determining health literacy. Among these aspects includes the ability to "read and comprehend health-related materials such as the reading of discharge instructions" (U.S. Department of Health and Human Services, 2020, para. 1). Several personal characteristics may hide health literacy levels allowing a person to present as if they have a high health literacy level (U.S. Department of Health and Human Services, 2020, para. 1). Elements such as "high verbal fluency may mask low health literacy," resulting in a provider assuming a patient can understand materials provided at a higher health literacy level (U.S. Department of Health and Human Services, 2020, para. 1). Improving awareness of health literacy in the clinical setting can better prepare practitioners to offer proper materials, such as discharge paperwork, education material, and prescription labels through the use of screening tools.

**Health literacy screening.** One screening tool, in particular, has offered recent evidence of its success in screening for low health literacy levels in those diagnosed with diabetes: the Newest Vital Sign. The Newest Vital Sign was created by Pfizer (2020) and can be administered over a few minutes. This tool consists of a food label along with a series of six questions related to reading, interpreting, and applying knowledge regarding the food label. This tool rates participants within three categories: high likelihood of low health literacy, the possibility of low health literacy, and adequate health literacy. One additional benefit of this tool is its ability to be delivered in both the Spanish and English languages. A study published in 2018 looked at the

test-retest reliability of this tool. This study found that "in-person and phone administration of this test performed at a similar level" (Russell et al., 2019, p. 471). Also, this study found that the "Newest Vital Sign offers a high level of test-retest reliability in samples that are retested within a short time span" (Russell et al., 2019, p. 752). Several studies have been completed on the use of the Newest Vital Sign and its relation to health literacy, as well as the effect of low health literacy on diabetes. These studies have shown, on several occasions, the concerns and disparities related to a combination of both low health literacy and diabetes.

**Quality of life.** With health literacy being a newer topic within the healthcare setting, there are up-and-coming studies relating health literacy to several different outcomes in those diagnosed with diabetes. In 2015, Sayah, Qiu, and Johnson completed a survey to determine the association between quality of life in those diagnosed with diabetes and health literacy levels. This survey included 1,948 participants with type 2 diabetes (p. 1,487). These participants ranged in age from "54.6 to 74.6 years of age" (Sayah et al., 2015, p. 1,487). Nearly "45% of the participants were female, and almost 13% of those had inadequate health literacy levels" while participating in this year-long study (Sayah et al., 2015, p. 1,487). Through a longitudinal study, Sayah, et al. (2015) attempted to assess health literacy and quality of life over one year through the use of "three screening tools: EuroQol-5 Dimension scale (EQ-5D), Mathematical Competence Scale (MCS), along with EuroQol-5 Dimension Five Level scale (EQ-5D-5L) and Short Form (SF-12)" (p. 1,487). Descriptive statistics were tested through the use of a chi-square test (Sayah et al., 2015, p. 1,489). Through this study, it was found that one-third of the participants had a low self-efficacy score, 12% had inadequate health literacy scores, and 19% screened positive for depression (Sayah et al., 2015, p. 1,489). In conclusion, based on this

study, providers need to offer educational material at the appropriate reading level to promote self-efficacy and overall quality of life.

**Diet and exercise impact.** A study published in 2018 looked at the impact of low health literacy levels on the ability of those with diabetes to follow diet and exercise regimens. The 649 participants of this cross-sectional study were participants in a support group for those with type 2 diabetes (Juul, Rowlands, & Maindal, 2018, p. 331). These participants were asked to answer four questionnaires: the "Summary of Diabetes Self Care Activities (SDSCA), European Health Literacy Survey Questionnaire Short Version (HLS-EU-Q16), Diabetes Health Literacy Scale, and Treatment Self Regulation Questionnarie (TSRQ)" (Juul et al., 2018, p. 332). In combination, these scales were used to measure diet and exercise through a self-reported method (Juul et al., 2018, p. 332). Additional measurements included "motivation to complete activities, health literacy, and diabetes-specific health literacy" (Juul et al., 2018, p. 333). This study adjusted for education and included three categories: age, gender, and amount of time with a diabetes diagnosis (Juul et al., 2018). Linear regression was used for this study, and results suggested that health literacy and the amount of self-motivation present directly influence the outcomes in those with type 2 diabetes (Juul et al., 2018). Providers may benefit from this study in better understanding the interactions between self-motivation and health literacy. By providing appropriate education, a provider has a better understanding of the patient's individual needs and can encourage a patient to self-motivate.

**Health literacy and management.** A study published in 2017 looked at the relationship between health literacy levels, diabetes, and diabetes management. This study had a total of 232 participants complete the examination with over 100 of them being men and approximately 100 of them being women (Tseng, Liao, Wen, & Chuang, 2017). This cross-sectional study required

participants to complete three surveys: the Newest Vital Sign, a diet inventory, and a diet knowledge survey (Tseng et al., 2017). Information such as weight, past glycosylated hemoglobin (hemoglobin A1c) levels, and demographic factors, such as education, age, gender, and career choice, were all factored into the study (Tseng et al., 2017). This study, in particular, looked at a theoretical framework based on the stage of change. This study started with a meeting with a dietician, followed by a 24-hour intake assessment (Tseng et al., 2017). Based on this assessment, participants were then placed into a specific group. The participants were asked to complete a Diabetic Nutrition Knowledge Survey, which has been verified to have a high level of internal consistency (Tseng et al., 2017). The Newest Vital Sign was then used, due to its reliability score, to assess the health literacy levels of the participants (Tseng et al., 2017). This study discovered that health literacy negatively affected hemoglobin A1c minimally and indirectly but did not directly affect glycemic control (Tseng et al., 2017). This study went on to discuss that none of the relationships are cut and dried; each is interconnected. For participants to improve diabetes management, the focus should be placed on education, not only to improve overall health literacy, but also to ensure participants understand and are ready for change.

#### **Tools for Measurement**

**Health literacy tools.** Health literacy assessment in those with a diagnosis of diabetes could serve as a tool to ensure the proper level of education is provided to promote better health outcomes. The Newest Vital Sign is a relatively new tool. A study completed by Heinrich (2012) looked at the relationship between demographics, health literacy assessment, and diabetes outcomes. A cross-sectional study was conducted of 54 participants with type 2 diabetes (Heinrich, 2012). This study consisted of "23 females and 31 males ages 19–66 with nearly half being Black, 25% being Latino, and 25% being White" (Heinrich, 2012, p. 218). The Newest

Vital Sign was used to assess the health literacy levels of these participants. Approximately 65% of the participants qualified as having low health literacy, with the majority of those being minority populations (Heinrich, 2012). This study goes on to discuss that education seemed not to affect the health literacy levels of those who participated (Heinrich, 2012). This study suggests the importance of assessing health literacy in those diagnosed with diabetes to ensure the proper educational material is being provided to ensure positive health outcomes.

**Reliability assessment.** To properly use the Newest Vital Sign tool, it is essential to understand the implications of the instrument and its reliability. A study completed in 2019 looked at opioid use and the administration of the Newest Vital Sign over the phone and in person. Sociodemographic characteristics were collected as well as setting, pain score, last medication received, and time of previous medication (Russell et al., 2019). There were 216 participants in total with nearly 70 of those receiving the in-person second interview and about 150 receiving the phone interview (Russell et al., 2019). The average "age of participants was 43 with one-third being male and half being white" (Russell et al., 2019, p. 1). Those who participated in the group in person were assessed in person, and those who were assessed over the telephone were given supplies in an envelope (Russell et al., 2019). Chi-square, Fisher's exact test, and Kruskal-Wallis tests were used to examine the Newest Vital Sign scores and the variation between groups (Russell et al., 2019). This study discovered that the Newest Vital Sign is a reliable tool that is best used when administered over a short time frame and is effective over telephone contact.

Based on the literature available, it is clear to see that the Newest Vital Sign, though new, is successful in predicting health literacy levels and is a reliable tool to use in this context. Low health literacy levels can have an enormous impact on the quality of life and health outcomes,

resulting in disorders such as depression, specifically in those diagnosed with diabetes. Low health literacy levels are an issue in addressing diet and exercise regimens in those diagnosed with diabetes. Also, it has been discovered that low health literacy levels can negatively impact physiological components such as hemoglobin A1c and glycemic control in those diagnosed with diabetes. Health literacy levels, when assessed, can better ensure providers are giving the proper education to secure positive patient outcomes. Though there is research on diabetes and the Newest Vital Sign, there are very few studies relating this specific tool with diabetes management and effects in the incarcerated population. A study that directly connects the Newest Vital Sign tool to health outcomes in those with diabetes could provide the information necessary for providers to address things such as diet, exercise, and body mass index. Tying in a nursing framework that focuses on patient needs and independence can concentrate on patients obtaining the proper knowledge to care for themselves through literacy assessment.

#### **Theoretical Framework**

Nursing theories relate in several ways to different specialties and general nursing practice. Each theory can link back to the nursing metaparadigm through health, nursing, environment, and person. Virginia Henderson is among the nursing theorists who have founded a theory in nursing, the nursing need theory which is useful in many different specialties. This theory, based on patient needs, looks at three other aspects of nursing. The first assumption includes the caring element and states that "nurses care for a patient until he or she can care for him or herself" (Petiprin, 2020, para. 1). The second assumption suggests that nurses will devote all time to patients, providing around the clock nursing care (Petiprin, 2020). Though interpretation can change from nurse to nurse, this theory requires nurses to be willing to provide the care necessary to ensure positive patient outcomes through teaching and time devotion. The

final assumption requires nurses to have an education in not only nursing science but also the arts (Petiprin, 2020). This model then goes on to describe 14 components that define the active duties of a nurse (Petiprin, 2020). A few of these needs critical to nursing, according to Henderson, include "breathing, eating and drinking adequately, sleep and rest, select suitable clothing, avoid danger, worship one's faith, and play" (Petiprin, 2020, para.1). With this model, nurses must be able to recognize the physiological, sociological, psychological, and spiritual aspects of a patient. The nurse must be able to identify the patient's ability to meet these needs and understand where partial or full assistance is necessary until a patient can meet his or her needs on his or her own. Through the application of this theory to those diagnosed with diabetes, health literacy can be managed in a way that promotes appropriate patient outcomes in those diagnosed with diabetes.

This theory relates to the nursing metaparadigm through four aspects: health, environment, nurse, and person. The nursing need theory defines the person as a whole individual (Petiprin, 2020). Requiring nurses to have an education in art means nurses must understand and be aware of the cultures in nursing and how they may impact and shape the person and his or her decisions in healthcare. This theory enables nurses to work through all levels of care with the patient around the clock to ensure that physiological as well as emotional needs are being met. This method will assist in the health of the patient and their ability to maintain health on their own. Henderson considers the environment to include both external stimuli that act on the patient as well as internal impulses; this theory also includes family as part of the environment (Petiprin, 2020). Through each of these aspects, the nurse has the responsibility to understand the environment affecting the patient to ensure that care is performed consistently based on an arts and science education until the patient can care for himself or herself.

Henderson's nursing need theory can be applied to the issue of health literacy in those diagnosed with diabetes today. In recognizing the patient, the nurse must understand the physiological condition, diabetes, and the pathophysiology of this condition. The nurse must also understand the psychological, sociological, and spiritual aspects concerning this condition. Through education in the sciences and arts, the nurse can adequately understand the pathophysiology of the disease and the risks of mental illnesses, such as depression, due to the condition. The nurse will also be able to understand the possible difficulty with social interactions and the contradictions between spirituality and medical treatment. The nurse with this education will better understand the effect of health literacy and the possible causes of low health literacy. The nurse will recognize when physiological, psychological, sociological, and spiritual aspects have limited the patient's health literacy. Education in arts and science will help a nurse to identify when the needs of these specific patients are not being met through the understanding of these four aspects and using tools that can eliminate gaps within care.

With diabetes diagnosis and health literacy, nurses will understand through Henderson's theory that around the clock care is necessary for the management of this condition. As a nurse, around the clock care does not merely mean assessing blood sugar and providing insulin or oral medication as prescribed. A nurse practicing with Henderson's nursing need theory will further understand the need to evaluate sociological components, such as health literacy. Through this assessment, the nurse can determine where conditions are present and prevent gaps in care. Through the use of the Newest Vital Sign assessment tool, the nurse can assess where low health

literacy is present. Through this, the nurse can provide the proper education during each encounter, around the clock, until the patient can care for themselves.

Following Henderson's nursing need theory requires nurses to supplement or assist with care until the patient can provide full care. Through the Newest Vital Sign, nurses can recognize health literacy levels early on. This tool can help nurses tailor education material based on patient-specific needs to ensure that this education is consistently provided. Providing this education on diabetes can always ensure that patients can understand materials such as food labels, medication labels, and exercise regimens in a way that is beneficial to their health outcomes. Through each of these three assumptions, nurses will help assist patients in meeting the 14 needs described by Henderson until they can meet the requirements alone.

Henderson's nursing need theory allows nurses to meet each of these 14 components through the management of diabetes outcomes with the assessment of health literacy. Through health literacy assessment and management in diabetes, nurses can adequately educate patients on eating and drinking correctly to maintain proper nutrition, but also meet spiritual needs. Nurses can assist patients in understanding and performing specific exercises that provide comfort and health to the patient and aid in weight management. Nursing can adequately educate patients in order to prevent exposure to environmental dangers, such as medication errors and foods high in sugar, based on individual literacy needs. Nurses have the duty to ensure that the four aspects of the metaparadigm are being met through recreation, social gatherings and events, education, and support. Through Henderson's nursing need theory, nurses can close the gaps in care and manage health literacy in those with diabetes to ensure proper health outcomes and needs are being met consistently.

#### **Chapter Three**

#### Methods

#### Purpose

The purpose of this DNP project was to determine health literacy levels of incarcerated individuals with type 2 diabetes in a Midwestern facility along with the impact of educational materials over a one-month time frame. The goal of this project was to determine if health literacy levels are changed with diet and exercise suggestions from the American Diabetes Association by providing individuals with educational material that is appropriate for health literacy levels in comparison to traditional education. This project has the potential to supplement research already offered on the impact of health literacy on those with a diagnosis of type 2 diabetes. This project can provide additional information as to whether the Newest Vital Sign tool can be used quickly to increase compliance and, in the future, diminish long-term care costs.

#### Sample

Many individuals are being provided with educational material in a written form that they cannot understand or apply due to low health literacy levels. This leads to an inability to comply with diet and exercise regimens that would best promote positive health outcomes. Participants were selected by convenience sampling. Volunteers were sought for participation from a population of 1,700 incarcerated individuals at a Midwestern facility. A sample of 1,016 participants was identified to gain a 95% confidence level (Creative Research Solutions, 2020). Participants were of the male gender, due to the population of the Midwestern correctional facility. Participant were between 18 years of age and 70 years of age with a diagnosis of type 2 diabetes and were incarcerated. Excluding factors for this research project included those who

did not speak English as their primary language, those under the age of 18, and those who did not choose to participate or finish the entire project.

The initial sample size was 28 participants to begin this research project. Participants were called to come to Healthcare individually. At that time, each participant met with the researcher to discuss the details of the research project. Participants were given the HIPAA form, educated on their rights as participants before signing the document, and reassured that no harm or punishment would occur for non-participation. Participants were then given the Informed Consent Form located in Appendix F, and this was read to each individual. After signing this, participants were given a copy of the Informed Consent Form to keep.

Each participant was put in numerical order according to their inmate ID. Each inmate ID was given a number. Participants were then divided into two groups: even numbers and odd numbers. Each participant was given the Newest Vital Sign assessment (a questionnaire). Even numbered individuals were then given an education from the American Diabetes Association based upon the health literacy level score they received. The odd numbered individuals were given the Newest Vital Sign assessment and then were given the traditional education that is already being provided at this setting for diet and exercise. Participants were handed the printed educational materials before they left Healthcare. After one month of having the reading material available to them, participants returned to retake the Newest Vital Sign assessment. Reassessing this allowed for the visualization of changes in health literacy levels by comparing the pretest and posttest.

Participants ranged in age from 20 years old to 70 years old. The sample consisted of 15 White participants, 12 Black participants, and one Indigenous person's. This information was obtained through the Midwestern public offender information website. Academic levels ranged from finishing eighth grade, obtaining a General Educational Development (GED), all the way to earning a bachelor's degree. Participants were asked to state their highest level of education with the first Newest Vital Sign quiz. This information is shown in more detail in Table 2. Participants needed to be receiving oral or insulin medication for diabetes management. A majority of these participants reported taking insulin for type 2 diabetes treatment.

#### **Project Approval**

Institutional Review Board (IRB) approval was amongst the support needed to begin this DNP research project. Full Board Review was required, as this research project worked directly with a vulnerable population. The meeting for IRB approval took place on April 29, 2020, at 8:00 in the morning. This meeting resulted in approval, pending required changes. Among these changes were simplifying the consent form to a lower reading level, adding in the risk of financial stressors related to purchasing healthier food from the store, and confidentiality from correctional staff. Also, it was suggested that the project be assessed at a few different intervals: one week and one month. It was decided that participants would be evaluated at one month and three months, though constraints only allowed for assessment at the one-month interval. These changes were submitted to the IRB Board. IRB approval was obtained from Northern Michigan University on May 11, 2020. Consent was also obtained from the facility and state research department. Permission was obtained to use the Newest Vital Sign and teaching material from the American Diabetes Association before the start of the project. This information may be viewed in Appendix C and Appendix D.

#### Sample Collection

The sample collection was done in a manner to ensure staff at the facility did not know which individuals were participating in the research project. Protecting participant identity was necessary to prevent retaliation or different treatment from the correctional staff. Volunteers were selected by sending out a JPay notice asking for volunteers, ages 18 to 70 with Type 2 Diabetes, who were willing to participate in a project related to health literacy. Individuals were instructed to send a note to Healthcare, leaving it in the confidential Healthcare box with identifying information on it. Individuals were then identified and spoken to about the project on a one-on-one basis. The consent form was read to each individual. Individuals were given a blank copy of the consent form to keep and signed the consent form and HIPAA form.

Upon completion of the consent form and HIPAA form, participants were ensured that their identity would be confidential. This also confirmed that no volunteer knew of another volunteer's involvement. Information could be entered into a printed Excel sheet and taken out of the facility to be stored appropriately. Following the initial identification, no volunteer was identified using any identifying factors. Each volunteer was determined via the corresponding number they were assigned.

#### **Design and Procedures**

An issue was identified throughout the facility: Participant reading levels were incompatible with the reading material provided. The issue was brought to the researcher's attention through complaints of incarcerated individuals about lack of education. Goals were set to accomplish the project and to seek new information. A plan was put into place to collect quantitative as well as demographic information. Demographic information consisted of race and patient identifying information. Quantitative data consisted of health literacy levels. Data was collected following a quasi-experimental design. The sample was a convenience sample, as it was taken from the Midwestern correctional facility due to the availability of participants. A report was sent out through inmate JPay asking for volunteers with type 2 diabetes.

This report asked those who wanted to volunteer to send a kite to Healthcare. These letters were placed directly in Healthcare's mailbox at the facility to ensure staff had no way of knowing who would like to participate in this project. Each person who sent a kite was asked to come to Healthcare for a one-on-one visit. This visit consisted of confirmation of type 2 diabetes through verification of medication, learning about the project, being educated on HIPAA, and signing the HIPAA form and the consent form (if the individual decided to participate). A participant could show the researcher evidence of medication for type 2 diabetes (the researcher's only way to verify type 2 diabetes without access to an electronic medical record) to verify the diagnosis. If the participant could produce a medication, the researcher was able to check a box on an Excel spreadsheet used for recording data. This researcher did not exclude any participants from the project based on their ability to produce a medication for verification of diagnosis.

Participants were split into the two groups, and everyone was given the Newest Vital Sign health literacy assessment. These scores were placed into an Excel spreadsheet on a secure computer along with the corresponding participant age and race. Participants were then given the educational material and were retested using the Newest Vital Sign after one month. Educational material for the experimental group for scores zero to one can be seen in Appendix G and Appendix H. Educational material for scores two to three can be seen in Appendix I and Appendix J. Educational material for scores four to six can be seen in appendices K through N. All participant scores were placed in the Excel spreadsheet under the corresponding test number next to the corresponding assigned number of the participant. The data collection process lasted for a total of one month. Participants were seen on an individual one-on-one basis for each Newest Vital Sign assessment.

#### Measures

Several tools may be used to measure health literacy levels. The Newest Vital Sign was chosen for this specific project. This tool is an observational tool and allows the observer to monitor and check off participant actions over time to determine their health literacy level. This instrument takes approximately three minutes to administer and consists of giving participants an ice cream label. After having time to look over the label, the participants are then asked a series of questions. This quiz asks a series of questions that encourage participants to read, synthesize, and apply information from the ice cream label. The first four questions look at calorie consumption, carbohydrates, serving size, and saturated fat. The observer checks the corresponding *yes* or *no* box according to how the patient answers the question. The fifth question assesses the participant's ability to find allergy information on the food label. If the participant does not answer correctly, the box is checked *no*, and the quiz is complete. The sixth question asks for a simple explanation related to the answer to the fifth question.

Following the quiz, the participant's scores are added up. A score of zero to one suggests a high probability of limited health literacy. A score of two to three is indicative of limited health literacy. A score of four to six indicates adequate health literacy. Permission to use this assessment tool was obtained from Pfizer before initiating the project, which may be seen in Appendix C.

#### Reliability

The Newest Vital Sign has proven to be a sound and valid source when assessing health literacy levels. This tool has been confirmed to be reliable by authorities such as Russell et al., who used the tool to evaluate its reliability in person and over the phone (2019). Russell also determined that this tool is consistent when testing and retesting participants (2019). In addition to this, other studies compared the Newest Vital Sign to assessments such as the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA) and found the Newest Vital Sign to be "more comprehensive" than other reviews (Haung, Shiyanbola, Smith, & Chan, 2018, p. 1). Chronbach's alpha was found to be "0.78 when looking at numeracy and 0.91 when examining document literacy," indicating that this tool is reliable and would lose reliability as questions are removed (Haung, 2018, p. 1).

#### Validity

Internal consistency is more than adequate in studies that looked at the use of the Newest Vital Sign in both children and adults (Driessnack, Chung, Perkhounkova, & Hein, 2014). The Newest Vital Sign has shown to have a "positive predictive value of 91% and a negative predictive value of 24%" (Driessnack, 2014, p. 1). This indicates that there is a strong likelihood that those who have low health literacy levels will be identified as such. Though this runs a risk of false positives for low health literacy, it ensures that fewer people are being given reading material that they are unable to comprehend and apply due to health literacy level.

#### **Data Analysis**

Using SPSS, a t-test was used to compare the means of health literacy levels at each of the two intervals. Percentages were used to track the changes in health literacy level scores for each group. Information such as ethnicity, education level, and age were also collected for statistical analysis from the public offender tracking site and from participants. Following the collections of data, all data will be stored in a locked cabinet for seven years and then will be destroyed.

#### **Chapter Four**

#### **Data Analysis**

The purpose of this DNP project was to determine health literacy levels of incarcerated individuals with type 2 diabetes in a Midwestern facility along with the impact of educational material provided over a one-month time-frame. The goal of this information is for providers to better understand what method of providing educational material is best for promoting health literacy levels and understanding of the information provided. This information is necessary for the future nursing care and education of incarcerated individuals. Though this project looks specifically at those incarcerated with type 2 diabetes, this project can be adjusted to other chronic health conditions. This project also aims to evaluate the educational material provided to different incarcerated individuals. By using existing educational material for the control group, this will be compared to the experimental group to determine if the standard education is appropriate for incarcerated individuals at this specific Midwestern facility.

#### **Demographics**

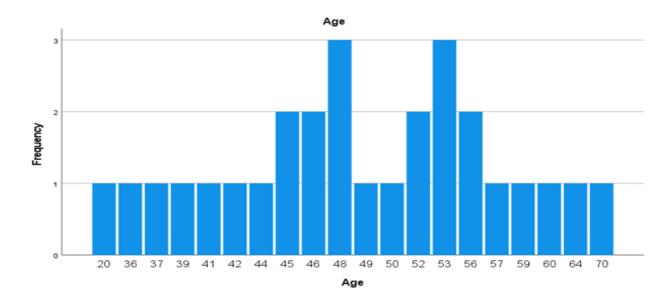
A total of 28 participants were recruited using the JPay method for this project. Of these participants, all 28 were of the male gender, as this convenience sample was collected from a group of male incarcerated individuals at a Midwestern correctional facility. Each individual reported their education level during the first assessment. Educational levels ranged from an eighth grade education to bachelor's degrees, including GEDs.

Participants were asked to show medication as evidence of type 2 diabetes. A large majority of these participants reported being on insulin two times a day while the rest were able to present a medication used for type 2 diabetes with the participant's name on it. The insulin was kept in Healthcare, while medications were kept in individuals' cells. The majority of the

population were White and Black, with one participant being an Indigenous person. Participant ages ranged from 20 years of age up to 70 years of age. Following the first round of the Newest Vital Sign and the receipt of educational material, one participant chose to withdraw from this research project.

## **Descriptive Statistics**

This DNP research project consisted of a sample of 28 male individuals. Note: one participant withdrew from the study before the completion of the research project. The sample population had a range of 50 years, with the youngest being 20 years old and the oldest being 70 years old. When analyzing statistics, it was noted the mode of the sample was 48 and 53 years old. The mean age for this sample population was 48.89 years old. The following graph shows the breakdown of participants based upon age range.



*Figure 1*. Age of Participants Frequency Table. Each bar in this diagram represents a specific age group.

The sample for this DNP research project contained only three races. The largest race represented in this research project was White, with 53.9% of participants being White. The next largest race identified in this research project was Black (42.9%). Only one participant was an Indigenous person, representing 3.6% of the sample population. In addition to age and race, education was taken into consideration when looking at the sample population of this project. Table 1

Race	Number of Participants	Percentage
Black	12	42.9%
White	15	53.6%
Indigenous Persons	1	3.60%

*Note.* The percentage of participants for each race consisted of nearly half White and half Black with a small percentage of Indigenous persons.

When evaluating the educational level of the sample population, there was a wide range of education, from an eighth grade education to four years of college and/or a bachelor's degree. One participant did not report an educational level. The majority of participants in this project completed a 12<sup>th</sup> grade education or a GED. Only three of the 28 participants in this project completed a four-year college degree, making up 10.7% of the sample population. In evaluating medications used for this sample population, eight out of the 28 participants used oral medicines to treat their type 2 diabetes diagnosis, making up 28.6% of the sample population. Of the 28

participants, 20 used insulin to manage their type 2 diabetes diagnosis. This constitutes 71.4% of the sample.

Table 2

Educational Level of Participants

Education	Number of Participants	Percentages
Not reported	1	3.60%
8 <sup>th</sup> Grade	1	3.60%
10 <sup>th</sup> Grade	3	10.70%
11 <sup>th</sup> Grade	2	7.10%
12 <sup>th</sup> Grade/GED	18	64.3%
3 Year College	1	3.60%
4+ Year College	2	7.10%

*Note.* Half of the participants had a 12<sup>th</sup> grade education.

## **Inferential Statistics**

Statistical analysis for this research project utilized paired t-tests. This test used the initial scores of the Newest Vital Sign as well as the Newest Vital Sign scores at the one-month mark. The p value for this project yielded .110, which is not a statistically significant difference. The degrees of freedom for this research project was 26 (df=26). The mean difference between the initial Newest Vital Sign score and following the one-month interval was -.222 with a 95% confidence interval from the lower level of -.498 to the upper level of .054. These results

indicate that assessing health literacy levels and providing education tailored to literacy level showed no significant difference than that of the control group. Tailoring educational material based upon The Newest Vital Sign scores provided no significant change in final health literacy levels when comparing literacy levels to those who received the standard education.

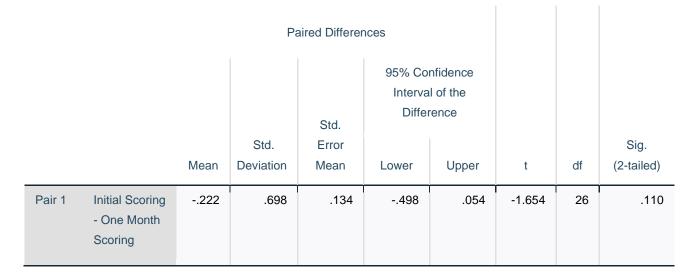


Figure 2. Paired T-Test. Initial and one-month scoring yields a significance of .110.

## Discussion

Based on the findings in this DNP project, assessing health literacy using the Newest Vital Sign tool and providing individualized education does not result in significantly different Newest Vital Sign scores following one month. In comparison to other similar studies, these results do differ in their failure to yield significant results. This DNP project, however, is one of the few studies that have been completed in the correctional setting and the only one of its kind conducted in a Midwestern facility, making comparisons difficult.

## **Clinical Implications**

This DNP project concluded that there was no significant difference between the experimental and control groups. This serves as important information within the clinical setting. Assessing health literacy using the Newest Vital Sign resulted in proper measurement of health literacy levels in incarcerated individuals. However, tailoring education to the individuals in the experimental group did not show any significant results in the overall health literacy level of these individuals. Within the clinical setting, this does not mean that assessing health literacy levels is not essential.

Health practitioners in the practice setting should continue to assess a patient's educational level and primary language. Based on this data, it may not be beneficial to provide education specific to each individual. This likely will waste time for practitioners, as it yields no significant changes in health literacy levels.

## **Recommendations for Future Research**

Future research may take into consideration the period of time over which the project is conducted. Providing individuals with a more extended period may offer more information as to individuals' ability to comprehend and retain information that is provided. Also, conducting this study on a more widely diverse population may better take into account ethnicity and gender differences.

## Strengths

There are several strengths to this project that make it a reliable source to use for future practitioners. The strengths of this project include the sample and the instrument that was utilized. The sample was collected from a Midwestern correctional facility. There has been little to no research looking at examples of incarcerated individuals and health literacy. This project can be used in comparison to other studies outside the facility and can supplement further

research that has been done on incarcerated individuals. The Newest Vital Sign is a robust tool with high reliability and validity components. This tool has been successful in tracking health literacy in several different populations with chronic diseases. This project has also proven to be reliable when monitoring a sample over an extended period.

The researcher gave the Newest Vital Sign quiz to each individual on a one-on-one basis. Individuals were not able to talk with each other until after the examination was complete. Participants were not given the results or answers to the questions. This strength ensured that participants were not able to share information about the quiz with other individuals and confirmed that there was no chance of sharing quiz questions or answers. The data that was collected was relatively easy to analyze, and the results were generalizable. Though this project has several strengths, weaknesses led to the project not reaching its potential.

## Limitations

Limitations of this project started with limits of regulations on the Electronic Medical Record (EMR). The facility and state did not provide authorization for the use of the EMR for this project. This resulted in an inability to confirm diabetic cases. Participants were then asked to show medications or state that they were on insulin, with no method of confirmation.

Additionally, though the Newest Vital Sign does come with a Spanish component, those who do not speak English as their first language were not asked to participate. Therefore, this project is not generalizable to participants who do not speak English as their first language. For those participants who are entirely illiterate, there was an inability to provide educational information. Those who are illiterate were still able to participate in the project and were given educational material, regardless of their ability to read and understand it. This project was completed at a men's correctional facility. This ensures that data is not generalizable to the female population, as women were not looked at for this project. Also, there were only three races presented in this project Black, White, and Indigenous persons. This serves as a limitation, as it is not representative of all the races present in Midwestern correctional facilities.

An additional limitation consisted of the time-frames with which individuals were given the educational material and retested. Another measurement of health literacy following three months may have been beneficial in assessing knowledge retention in these individuals.

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## Appendix A

## **IRB** Approval

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NORTHERN UNIVER	WWW.rimu.edu/graduatestudies
Memorandum	ι.
<b>TO</b> :	Josi Denman School of Nursing
CC:	Jamie Crabb School of Nursing
FROM:	Dr. Lisa Schade Eckert Dean of Graduate Education and Research
DATE:	May 11, 2020
SUBJECT:	IRB Proposal HS20-1130 "The Impact of a Health Literacy Assessment on Those with a Diagnosis of Type Two Diabetes" IRB Approval Date: 5/11/2020 Expiration Date: 5/10/2021 Proposed Project Dates: 5/1/2020 – 5/14/2020

- A. If a subject suffers an injury during research, or if there is an incident of non-compliance with IRB policies and procedures, you must take immediate action to assist the subject and notify the IRB chair (dereande@nmu.edu) and NMU's IRB administrator (leckert@nmu.edu) within 48 hours. Additionally, you must complete an Unanticipated Problem or Adverse Event Form for Research Involving Human Subjects
- B. Please remember that informed consent is a process beginning with a description of the project and insurance of participant understanding. Informed consent must continue throughout the project via a dialogue between the researcher and research participant.
- C. If you find that modifications of investigators, methods, or procedures are necessary, you must submit a Project Modification Form for Research Involving Human Subjects before collecting data.

D. If you complete your project within 12 months from the date of your approval notification, you must submit a Project Completion Form for Research Involving Human Subjects. If you do not complete your project within 12 months from the date of your approval notification, you must submit a Project Renewal Form for Research Involving Human Subjects. You may apply for a one-year project renewal up to four times. Failure to submit a Project Completion Form or Project Renewal Form within 12 months from the date of your approval notification will result in a suspension of Human Subjects Research privileges for all investigators listed on the application until the form is submitted and approved.

All forms can be found at the NMU Grants and Research website: http://www.nmu.edu/grantsandresearch/node/102

## Appendix B

## Department approval



GOVERNOR

STATE OF MICHIGAN DEPARTMENT OF CORRECTIONS LANSING HEIDI E. WASHINGTON DIRECTOR

Ms. Josi Denamn DenmanJ@michigan.gov

Re: Accessibility of Prenatal Genetic Screening Services among Incarcerated Women in the United States

March 5, 2020

Ms. Josi Denman:

We have reviewed the documentation you submitted regarding the above referenced research project. Our review of materials submitted indicates that the study is likely to produce useful findings regarding The Impact of a Health Literacy Assessment on Those with a Diagnosis of Type Two Diabetes.

After review of all documentation, we are hereby issuing approval for you to proceed with your study, as required by PD 01.04.120. Your proposal has also been reviewed and approved by the Correctional (CFA) and Health Care staff. Please note that **you will need to work directly with CFA to establish the terms of Bellamy Creek's participation.** We have provided a copy of this letter to CFA so they are aware of our approval of your study. Norma Killough is the main contact for CFA and she may be reached at (517) 335-2334.

Approval of this research study is subject to the following conditions:

- Participation by the study subjects is strictly voluntary. Potential study subjects will be
  advised that no benefit or negative consequence will accrue to them as the result of their
  decision to participate or not in the survey;
- All data from this study, including the identity of the study participants will be kept strictly confidential and no identifying information or information which could lead to discovery of the identity of the study participants will be included in any report or other presentation of the study;
- Data collected for this study will not be accessible to anyone other than the researchers and will be maintained in a location which is physically secure (in the case of paper records) or electronically secure (in the case of computerized records);
- And, you will provide copies of any publications or presentation resulting from this
  research to the Office of Research and Planning.

If you have any questions, or if we can be of any further assistance, please let me know. Sincerely,

Kenneth Jay Bush

Kenneth J. Bush, Departmental Specialist Risk/Classification and Program Evaluation Section Office of Research and Planning

cc: R. Douglas Kosinski, Supervisor, Program Evaluation Section Norma Killough, Correctional Facilities Administration

# Appendix C

# Pfizer Newest Vital Sign Tool Approval

	Terms and Conditions of Use
reprodu	c. ("PFIZER") grants you a non-exclusive, non-transferrable and non-assignable permission to use and se the Questionnaire for the purposes of conducting a study for academic or medical purposes so long as you the following terms and conditions of use:
1.	You agree not to adapt, alter, amend, abridge, modify, condense, or make derivative works, in particular not
2.	to produce electronic versions of, or translate the Questionnaire without PFIZER's prior written consent. You shall not reproduce the Questionnaire except as is necessary for conducting the study. You shall not distribute, publish, sell, rent, license, transfer or provide copies of the Questionnaire by any means whatsoever to third parties that are outside the scope of the study without the prior written agreement of PFIZER.
3.	Copyright: You acknowledge PFIZER's copyright in the Questionnaire and shall not contest such copyright or perform any act or omission adverse to such exclusive right.
4.	or perform any act or omission adverse to such exclusive right. You will include PFIZER's copyright ownership statement on all copies of the Questionnaire in the same form as it appears on the document that you are downloading from this web site.
5.	You agree that any and all copyrights in any form or format of the Questionnaire, including translations, migrations to electronic platform and other derivative works, are owned exclusively by PFIZER. You agree and undertake not to remove the copyright notices which appear on the Questionnaire and not to represent in any way whatscever that you have any ownership in the Copyright. You acknowledge specifically that
	your use of the Questionnaire does not and will not oreate any right, title or interest thereof for you other than the right to use the Questionnaire under these Terms & Conditions. To the extent any benefits attached to the rights in and to the Questionnaire (or any translations or derivative works) are deemed to acroue to you, you acknowledge that such rights are held on behalf of PFIZER and in furtherance thereof you undertake to assign any and all such accrued rights to PFIZER, and to execute any and all documents necessary to accomplish such assignment.
6.	Translations: If PFIZER grants you express permission to make a translation, upon completion of the project you agree and undertake to forward to PFIZER the final renderings in the target language(s)as MSWord and PDF files, translation reports and translation certificates.
7.	Migration: If PFIZER grants you express permission to make a migration to an alternative data collection modality, you agree to forward to PFIZER the final files in Word and PDF format that portray the electronic version e.g. screenshots, audio files and scripts if electronic format is via telephone.
8.	Version e.g. screenshots, audio mes and scripts in electronic format is via telephone. You agree and undertake not to sell, rent, transfer or incorporate the Questionnaire into materials that could be sold, rented or transferred. The Questionnaire shall remain unbranded. You agree and undertake not to place any branding, names or trademarks on the Questionnaire, and not to alter the Questionnaire in any manner.
9.	manner. You shall provide to PFIZER a copy of all published papers and abstracts of studies or investigations in which the Questionnaire was utilized. In case of any kind of publication or presentation, you shall properly cite the main publication reference(s) about the Questionnaire in the reference section of the publication/presentation. You shall also indicate in any such publication that the Questionnaire permission information may be found at www.pfizerpcoa.com.
10.	Information may be found at www.pricepool.com. Should you desire to use the Questionnaire in a manner not permitted under these Terms & Conditions, please email <u>PRO4@Pfizer.com</u>
11.	You agree and undertake to comply with all directions from PFIZER or its affiliates and representatives, regarding the character and quality of the use of the Questionnaire.
12.	You agree and undertake to comply with all applicable laws and regulations as well as good business practices in connection with the use of the Questionnaire and to give prompt notice to PFIZER if, at any time, you are advised by any appropriate authority that the use of the Questionnaire is not in accordance.
13.	with all applicable laws or regulations or good business practices. You agree and undertake to indemnify and hold PFIZER and its affiliates harmless against any and all claims, loss or damage, including fees, penalties or fines and third party claims, and attorneys' fees arising
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# Appendix D

# American Diabetes Association Educational Material Approval

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American Diabetes Association. Connected for Life	
March 10, 2020	
Josi Denman Northem Michigan University 109 West Baraga Ave Marquette, Michigan 49855	
Permission Request Number: KL031020-JD	
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red by Charlotte M. Carter Charlotte M. Carter

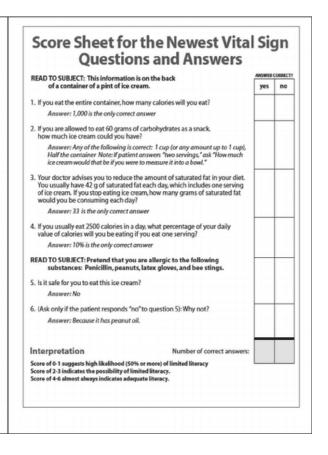
AGREED: DATE:

We elect not to use this material.

## Appendix E

## The Newest Vital Sign Tool

Nutrition Facts Serving Size Servings per container	1/2 cup
Amount per serving Calories 250	Fat Cal 120
	%D\
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%
*Percentage Daily Values (DV) ar 2,000 calorie diet. Your daily valu be higher or lower depending on calorie needs. <b>Ingredients:</b> Cream, Skim Mil Sugar, Water, Egg Yolks, Brown S Milkfat, Peanut Oil, Sugar, Butter, Carrageenan, Vanilla Extract,	ues may your Ik, Liquid Sugar,



## Appendix F

## Informed Consent



Northern Michigan University Informed Consent Form



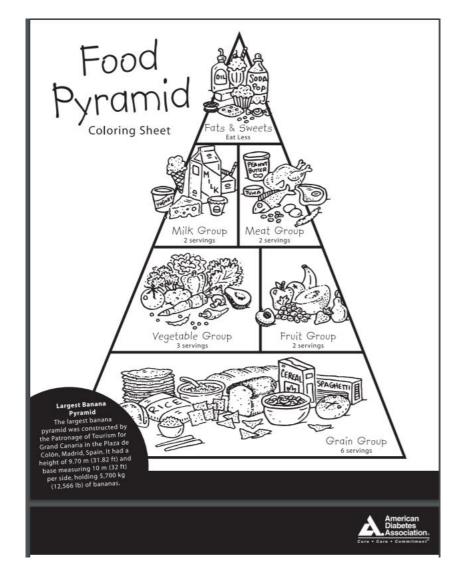
The Impact of a Health Literacy Assessment on Those with a Diagnosis of Type Two Diabetes

 $\beta y$  signing below, I have no questions about, the study. I am willing to participate in the study.

Signature

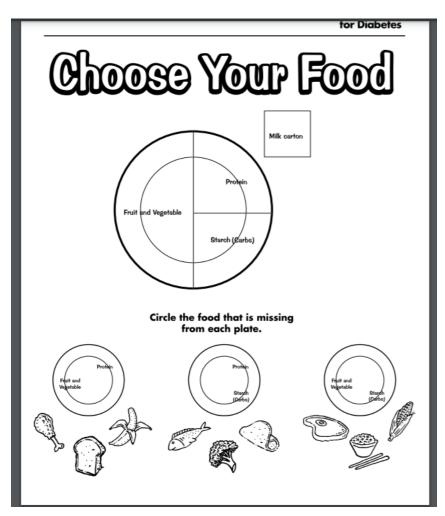
Date Signed

# Appendix G



American Diabetes Association Educational Material- Food Pyramid

## Appendix H



American Diabetes Association Education- Choose Your Food

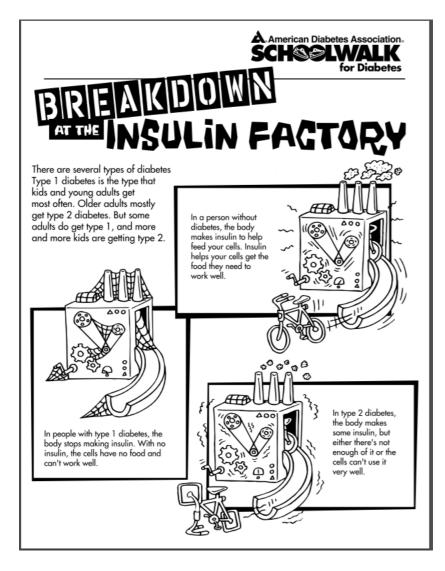
# Appendix I

American Diabetes Education- School Walk

	for Diabetes
	Name: Date:
	Student Notes
n	The body is made up of many systems that do different jobs. For example, the
~	<ul> <li>respiratory system is how your body breathes and gets oxygen.</li> </ul>
	<ul> <li>circulatory system is how your body moves blood throughout the body.</li> </ul>
	digestive system is how your body
0	For most people, the makes insulin. Insulin then acts
9	For most people, the makes insulin. Insulin then acts like a key that opens a lock to let energy into your body's cells.
_	_
3	For people with diabetes, the body does not make enough insulin, or the body cannot use the insulin to get sugars out of the and into the cells for energy.
_	and into the one of the second s
4	When insulin does not act like a key that opens a lock to let energy into your body's cells, it is a
	problem for at least two reasons. One reason is that the cells are not getting the energy they need. Another reason is because the sugars build up in the
	which can harm the body.
0	In cases of type 1 diabetes, the body does not make insulin. Symptoms of type 1 diabetes
0	include: (name at least two)
	1
	2
0	In cases of type 2 diabetes, the body does make insulin, but some how cannot use the insulin to
9	get energy to the cells. A good way to reduce your risk of getting type 2 diabetes is to eat right
	and get a lot of
ຄ	Diabetes affects a lot of people and costs a lot of money to treat. It can lead to very serious health
0	problems, such as heart disease. Diabetes is never contagious, which means
0	There is not a cure for diabetes now, but some day there might be one. Two important ways that
•	everyone can stay healthy is by eating right and exercising regularly. Walking is one of the best
	ways to exercise. What are three other ways you exercise?
	1
	2
	3.

## Appendix J

American Diabetes Association Education- Breakdown at the Insulin Factor



# Appendix K

American Diabetes Association Education- Scavenger Hunt

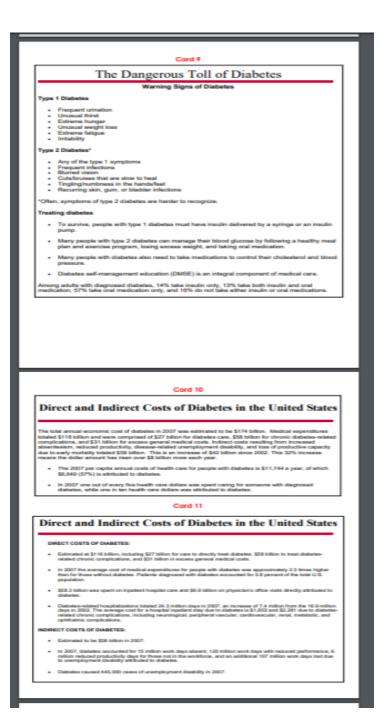
Aftechments for Lesson Man Day 1
Fact Cards for 'Diabetes Statistics Scavenger Hunt'
Complications of Diabetes in the United States
Heart disease and stroke     Heart disease and stroke account for about 65% of deaths in people with diabetes.     Adults with diabetes have heart disease death rates about 2 to 4 times higher than adults without diabetes.     The risk for shoke is 2 to 4 times higher and the risk of death from stroke is 2.8 times higher among people with diabetes.     In women with diabetes.     In women with diabetes have heart disease have increased 23 percent over the past 30 years compared to a 27 percent decrease in women without diabetes. Deaths from heart disease in men with diabetes.     High blood pressure     About 75% of adults with diabetes have blood pressure greater than or equal to 130/80 millinears of menuity (mm Hg) or use prescription medications for hypertension.
Card 2
Complications of Diabetes in the United States
Bindness     Diabetic retiropathy causes 12,000 to 24,000 new cases of blindness each year making diabetics the leading cause of new cases of blindness in adults 20-74 years of age.     Mexican Americans and non-Hispanic blacks are almost telcs as likely to develop diabetic retiropathy as non-Hispanic whes.
Kidney disease Diabetes is the leading cause of kidney failure, accounting for 44% of new cases in 2005. In 2005, 46,739 people with diabetes started dialysis, the treatment for end-stage renal disease (ESRD).
Cord 3
Complications of Diabetes in the United States
Complications of Diabetes in the United States Amputations • In 2004, about 71,000 non-traumatic lower-limb amputations were performed in people with • diabetes. More than 00% of non-traumatic lower-limb amputations are caused by diabetes • The rate of amputation for people with diabetes is 10 times higher than for people without • Advances Americans are 1.8 times as likely to have a lower-limb amputation as non-Hisparic • Non-Hisparic Blacks are 2.7 times as likely to have a lower-limb amputation as non-Hisparic • American Inflams are 3 to 4 times as likely to have a lower-limb amputation as non-Hisparic • American Inflams are 3 to 4 times as likely to have a lower-limb amputation as non-Hisparic • American Inflams are 3 to 4 times as likely to have a lower-limb amputation as non-Hisparic • American Inflams are 3 to 4 times as likely to have a lower-limb amputation as non-Hisparic • Amputation rates are 1.4 to 2.7 times higher in men than women with diabetes.

Tet	tal: 23.6 million children and adulta - 7.8% of the population - have diabetes.
Diagn	cosed: 17.9 million people
Undia	gnosed: 5.7 million people
Pre-di	abetes: 57 million people
	186,300 or 0.22% of all people in this age group have diabetes. About one in every 400 to 600 children and addissounth has type 1 diabetes. Two million addessounts (or 1 in 6 overweight addessounth) aged 12-19 have pre-diabetes
:	About one in every 400 to 600 children and adolescents has type 1 diabetes. Two million adolescents (or 1 in 6 overweight adolescents) aged 12-19 have pre-diabetes
•	Type 2 diabetes, although still rare, is being diagnosed more frequently in children and adolescents, particularly in American Indians, African Americans, and Hispanic/Latino Americans.
Are 2	9 years or older:

Total prevalence of diabetes by race/ethnicity	
Non-Hispanic Whites: 14.9 million or 9.8% of all non-Hispanic whites aged 20 years or older have diabetes. Non-Hispanic Blacks: 3.7 million or 14.7% of all non-Hispanic blacks aged 20 years or older have diabetes. Hispanic/Latino Americans: 10.4% of Hispanics aged 20 years or older have diabetes. Among Hispanics, rates 12.6% for Puestro Ricans.	Extinuated age-adjusted total prevalence of diabetes in people sgad 20 years or older, by racelefinicity-United States, 2006 American Index and Assta Mone- Heights: United American Americans, and Non-Heights: Without Control of the State State State Non-Heights: Without Control of the State State State Persons Persons Persons
	a: 16.5% of the American Indiana and Alaska Natives aged 2 have diabetes. Rates vary by region from 6.0% among Alask n Indian adults in southern Arizona.

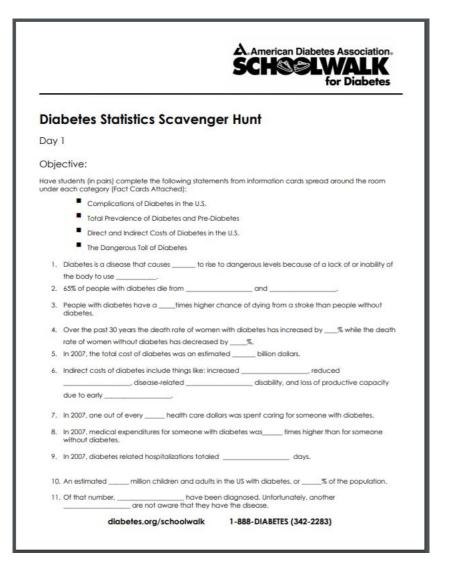
Card 6

1.1	Databates is a chases in which your body vides producing or to unable to use the homore, insulin. The causes blood glucose levels to rise to dempercially high levels. Blood glucose levels that slay legit for an estimated period of inne can lead to serious complications and premate death. fortunatally people with diabetes can take steps to control the disease and lower the risk of complications.			
10 10 10	Dubates is a chronic disease that has no cure. Of the 23.6 million children and adults in the United States who have diabetes, 5.7 million people do not know they have this disease and 57 million people have prive diabetes, 5.4 million set increased risks for developing diabetes.			
1	f present liverds continue, one in three Americans, and 1 in 2 minorthes, born in 2000 will develop fabries in their Helines. Each day, approximately 4,383 people are diagnosed with disbetes. In 2007 1.6 million new cases of diabetes ware diagnosed in people age 20 years or celoir.			
	Cord 7			
Ē	The Dangerous Toll of Diabetes			
	Diposes in the seventh-descript datase in the United States, Since 1997 to 2002, the death rate data to distribute the increased by 45 percent, while the destinative day to feast disease, stoke, and cancer have declined.			
1.1	activated by to promit while the cash-mass are in their transmiss, process, and cash man activate. Based on death cartificate data, diobetes contributed to 233,610 deaths in 2005. Studies that Babetes is generally under-reported on death cartificates, particularly in the cases of other persons with multiples dronce conditions such as heart disease and hypertamion. Because of this, the toll of babetes is believed to be much higher than officially in portical.			
	Many people first become aware that they have diabetes when they are affected by one of its serious and Ne-tweatening complications such as:			
	Heart Disease and Stoke     High Bicot Pyeasars     Bindnese     Kidney Disease     Kidney Disease     Kidney Classase     Annyca System Damage     Annyca System Damage     Annyca Storese			
	Programmy Complications     Sensal Dysfunction     Others			
	Cord 8			
ſ				
	Cord 8 The Dangerous Toll of Diabetes			
- 1	The Dangerous Toll of Diabetes			
	The Dangerous Toll of Diabetes Types of Diabetes Types of Diabetes Types 1 diabetes data proceeding called trade-dependent diabetes medias (DCM) or juvenite-creat diabetes. Type 1 diabetes data cips when the body's termines within a diabete media of the formation of the trade that media			
	The Dangerous Toll of Diabetes Types of Diabetes Types of Diabetes Types 1 diabetes develops when the body's immune system diabetes the calls. IFCM ( or journite-creat diabetes. Types 1 diabetes develops when the body's immune system diabetes to use the body to use as an orgy. Type 1 diabetes to the homore, music, the colding was an orgy of datases the and an occur at any pipe. I diabetes to analy diagnous the colding and the system diabetes and an occur at any pipe.			
	The Dangerous Toll of Diabetes Type of Oabstes mellow provide the second secon			
	The Dangerous Toll of Diabetes Type of Diabete Type of Diabete Type of Diabetes Type of Diabetes Type 1 diabetes one provide the diabete transmission (DCM) or powerine-orised diabetes. Type 1 diabetes one provide the diabetes of the diabetes and the diabetes of the second and the diabetes of the diabe			
	The Dangerous Toll of Diabets           Page of Dabets           Page of Dabets           Type of Dabets			
	The Dangerous Toll of Diabets           Figure of Dabate           Page of Dabate           Type of Dabate <td></td>			
	The Dangerous Toll of Diabets           Page of Dabets           Page of Dabets           Type of Dabets			
	The Dangerous Dallo of Diabetes           Special diabetes         Special diabetes           The Dangerous Dallo of Diabetes         Special diabetes           Special diabetes			
	Department of the set of the			



## Appendix L

American Diabetes Association Education-Fill in the Blank

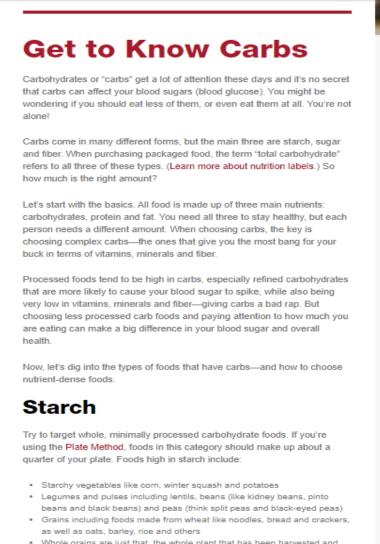


	enger Hunt cont.
<ol> <li>If the present trend continues, one in develop diabetes in their lifetime.</li> </ol>	Americans, and one in minorities, born in 2000 will
8. Every day, approximately pe	ople are diagnosed with diabetes.
I. Diabetes is the <sup>th</sup> deadliest disea	e in the US.
i. What is type 1 diabetes.	
i. What is type 2 diabetes	
. What is the difference between type 1	and type 2 diabetes?
. What is the difference in treating type diabetes?	and type 2
. How many adolescents aged 12-19 ha	
). What are some warning signs of type 1	
Туре 1	Type 2

American Diabetes Association. SCHSOLVALK for Diabetes
21. What percentage of Non-Hispanic whites have diabetes?%
22. What percentage of Non-Hispanic blacks have diabetes?%
23. Approximately what percentage of Hispanic/Latino American have diabetes?
24. Approximately what percentage of American Indians/Alaskan natives have diabetes?%
25. In 2004, how many people had their lower leg amputated because of diabetes?
26. How many new cases of blindness are the result of diabetes each year? to
27. Who is at a greater risk for type 2 diabetes? Types of people:
28. Why is it important to know about diabetes?
diabetes.org/schoolwalk 1-888-DIABETES (342-2283)

## Appendix M

American Diabetes Association Education- Getting to Know Carbs



 Whole grains are just that, the whole plant that has been harvested and dried with little processing. They provide fiber as well as essential vitamins including B and E and other minerals needed for optimal health.

Wondering what the deal is with "refined grains"? Basically, these grains are processed to remove the outer layers and most nutritious parts of the grain, meaning that we're missing out on all the beneficial fiber, vitamins and minerals that the whole grain would typically provide. To avoid diseases caused by vitamin and mineral deficiencies, there are laws in place to make sure that essential vitamins and minerals be added back in during processing—this is what "enriched" means when you see it on the label. Bottom line: when reading the inpredient list look for products that

are processed to remove the outer layers and most nutritious parts of the grain, meaning that we're missing out on all the beneficial fiber, vitamins and minerals that the whole grain would typically provide. To avoid diseases caused by vitamin and mineral deficiencies, there are laws in place to make sure that essential vitamins and minerals be added back in during processing—this is what "enriched" means when you see it on the label. Bottom line: when reading the ingredient list, look for products that list "whole grain" or "whole wheat" as the first ingredient as opposed to "enriched."

## Sugar

Sugar is another source of carbs. There are two main types:

- Naturally occurring sugars like those in milk or fruit
- Added sugars, which are added during processing, like in regular soda, sweets and baked goods

You may have heard added sugars referred to by other names—or seen one of these listed in the ingredients in a food label. Dextrose, fructose, lactose, table sugar, beet sugar, honey, corn syrup, turbinado and agave are just some of the many names for added sugars.

Did you know that you can find the amount of both added and naturally occurring sugars listed in the new nutrition facts label?

Learn how to decode the label

Wondering about sugar substitutes? Get the sugar substitute facts here.

## Fiber

Fiber comes from plant-based foods, including fruits, vegetables and whole intact grains. Fiber acts like your body's natural scrub brush—it passes through your digestive tract, carrying a lot of bad stuff out with it. It also keeps us feeling full, and helps lower cholesterol. Those aren't the only benefits: eating foods higher in fiber can also improve your digestion, help you manage your blood sugar and reduce your risk of heart disease.

People with diabetes and those at risk for diabetes are encouraged to eat at least the same amount of dietary fiber recommended for all Americans. The Dietary Guidelines for Americans recommend a minimum of 14 grams of fiber per 1,000 calories, with at least half of your grains being wholeintact grains. You can find specific recommendations for your age group and gender in the *Dietary Guidelines for Americans* (DGA).

Keep in mind that if you haven't been eating a lot of foods high in fiber on a daily basis, it's important to increase your intake slowly. Even though they are good for you, it can take time for your body to adjust. A sudden increase in eating foods high in fiber (especially foods with added fiber or when using supplements) can cause gas, bloating or constipation. Be sure you are drinking enough water too, because fiber needs water to move

Wondering about sugar substitutes? Get the sugar substitute facts here.

## Fiber

Fiber comes from plant-based foods, including fruits, vegetables and whole intact grains. Fiber acts like your body's natural scrub brush—it passes through your digestive tract, carrying a lot of bad stuff out with it. It also keeps us feeling full, and helps lower cholesterol. Those aren't the only benefits: eating foods higher in fiber can also improve your digestion, help you manage your blood sugar and reduce your risk of heart disease.

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Good sources of dietary fiber include:

- Pulses (like lentils and peas) and beans and legumes (think navy beans, small white beans, split peas, chickpeas, lentils, pinto beans)
- Fruits and vegetables, especially those with edible skin (like pears, apples and beans) and those with edible seeds (like berries)
- Nuts—try different kinds (pumpkin seeds, almonds, sunflower seeds, pistachios, peanuts are a good source of fiber and healthy fat, but watch portion sizes, because they also contain a lot of calories in a small amount!)
- Whole grains such as:
  - Quinoa, barley, brown rice and farro
  - Whole wheat pasta
  - Whole grain cereals, including those made from whole wheat, wheat bran and oats

Foods that are naturally high in fiber and contain at least 2.5 grams are often labeled as a "good source," and foods labeled as "excellent source" contain more than five grams of fiber per serving.

While it's best to get your fiber from food, talk to your diabetes care team to determine if you should consider a fiber supplement.

## Appendix N

American Diabetes Association Education- Making Sense of Food Labels

Reading Food Labels

# Making sense of food labels

Trying to figure out nutritional information on labels and packaging isn't easy. The good news is that we can help. These food labels are especially helpful if you use carb counting to plan your meals!

If you get tripped up on food content claims, you're not alone. Fat free vs. low fat vs. reduced fat. Low cholesterol vs. reduced cholesterol. It's confusing, and it can be tough when you're trying to make the right choices.

### Serving size

Start by looking at the serving size. All of the information on the label is based on the serving size listed. If you eat more, that means you'll be getting more calories, carbohydrates, etc. than what is listed.

### Amount per serving

The information on the left side of the label tells you the total of the different nutrients in one serving of the food. Use these numbers to compare labels of similar foods.

### Calories

Calories are a unit of energy—think of them as the energy your body consumes and uses for bodily functions. Curious how many calories you need? Talk with a registered dietitian nutritionist (RD/RDN).

### Total carbohydrate

Total carbohydrate on the label includes all three types of carbohydrate: sugar, starch and fiber. It's important to use the total grams when **counting carbs** or choosing which foods to include. Below the Total Carbohydrate (carbs), you will find a breakdown of the types of carbohydrate in the food.

### Added sugar

As of January 2021, labels must include added sugar to help you know the difference between sugar that occurs naturally in the food (like yogurt or fruit) and sugar that was added during processing (like in cookies, candy and soda). Many labels have already made the change. Learn more about sugar.

### Fiber

Fiber is the part of plant foods that is not digested—or for some types, only partially digested. Dried beans such as kidney or pinto beans, fruits, vegetables and whole intact grains are all good sources of fiber. The amount of fiber you need depends on your age and gender. Healthy adults need between 25 and 38 grams of fiber a day on average—you can find recommendations for your age group and gender in the *Dietary Guidelines* for *Americans* (DGA) Learn more about fiber

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Fiber is the part of plant foods that is not digested—or for some types, only partially digested. Dried beans such as kidney or pinto beans, fruits, vegetables and whole intact grains are all good sources of fiber. The amount of fiber you need depends on your age and gender. Healthy adults need between 25 and 38 grams of fiber a day on average—you can find recommendations for your age group and gender in the *Dietary Guidelines for Americans* (DGA). Learn more about fiber.

### Sugar alcohols

Sugar alcohols are a type of sugar substitute that have fewer calories per gram than sugars and starches. Sorbitol, xylitol and mannitol are examples of sugar alcohols. If a food contains sugar alcohols, it would be listed on the label under Total Carbohydrate. It's important to keep in mind that foods that contain sugar alcohols are not necessarily low in carbohydrate or calories. And, just because a package says "sugar-free" on the outside does not mean that it is calorie or carbohydrate-free. Always check the label for the grams of total carbohydrate and calories. Learn more about sugar alcohols.

### Fats

Total fat tells you how much fat is in one serving of the food. In general when it comes to fat, try to replace foods high in saturated fat or *trans* fat with foods rich in monounsaturated and polyunsaturated fats to reduce your risk of heart disease. Learn more about fats.

### Sodium

Sodium is the scientific term for salt. It does not affect blood sugar. However, excess dietary sodium increases your risk of high blood pressure and heart disease. With some foods, you can taste how salty they are, such as pickles or bacon. But there is also hidden salt in many foods, like salad dressings, lunch meat, canned soups, chips and other packaged foods. Reading labels can help you find these hidden sources and compare the sodium in different foods. Whether you have diabetes or not, 2300 milligrams (mg) or less per day is the general recommendation. If you have high blood pressure, talk with your health care team to find out the best goal for you.

### List of ingredients

Ingredient lists can be a helpful tool. Ingredients are listed in order by weight with the first ingredient being the highest amount in the food. Knowing the ingredients is useful in making healthy choices like increasing fiber (look for words like whole grain, whole wheat, etc.) or decreasing sugar (look for words like cane sugar, agave, maple syrup, honey, etc.).

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### Percent Daily Values (%DV)

The Percent Daily Values for each nutrient are found in the right column on the label. These tell you what percent of each nutrient the food provides if you were on a 2,000 calorie per day diet. As a general rule of thumb, aim for less than 5% for nutrients you want to limit, such as sodium and saturated fat. Aim for 20% or more for nutrients you want to get more of such as fiber, vitamin D, calcium and iron.

### "Net carbs" and other nutrient claims

You've probably seen the term "net carbs" on some food packages. Many food companies make claims about the amount of carbohydrate in their products. However, "net carbs" doesn't have a legal definition from the FDA, and they are not used by the American Diabetes Association. Always look at the Total Carbohydrate on the Nutrition Facts label first. Checking your blood sugar can help you figure out how specific carbs affect you.

Net carbs isn't the only confusing nutrition claim you'll find on food packages. For example, have you ever wondered what the difference is between fat free, saturated fat free, low fat and reduced and less fat? The government *has* defined some claims that can be used on food packaging. Here's what they mean:

#### **Claims for calories**

- Calories free: less than 5 calories per serving
- Low calorie: 40 calories or less per serving

### Claims for total, saturated and trans fat

- Fat free: less than 0.5 grams of fat
- Saturated fat free: less than 0.5 grams of saturated fat
- Trans fat free: less than 0.5 grams of trans fat
- Low fat: 3 grams or less of total fat
- Low saturated fat: 1 gram or less of saturated fat
- Reduced fat or less fat: at least 25% less fat than the regular version

#### Claims for sodium

- Sodium free or salt free: less than 5 mg of sodium per serving
- Very low sodium: 35 mg of sodium or less
- Low sodium: 140 mg of sodium or less
- Reduced sodium or less sodium: at least 25% less sodium than the regular version

#### **Claims for cholesterol**

- Cholesterol free: less than 2 mg per serving
- Low cholesterol: 20 mg or less
- Reduced cholesterol or less cholesterol: at least 25% less cholesterol
   than the regular version

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- Low sodium: 140 mg of sodium or less
   Reduced sodium or less sodium: at least 25% less sodium than the regular version

#### Claims for cholesterol

- Cholesterol free: less than 2 mg per serving
- Low cholesterol: 20 mg or less
- Reduced cholesterol or less cholesterol: at least 25% less cholesterol than the regular version

#### Claims for sugar

- Sugar free: less than 0.5 grams of sugar per serving
- Reduced sugar: at least 25% less sugar per serving than the regular version
- No sugar added or without added sugars: no sugar or sugar-containing ingredient is added during processing

#### **Claims for fiber**

- High fiber: 5 grams or more of fiber per serving
- Good source of fiber: 2.5 to 4.9 grams of fiber per serving