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Exploring the Predictive Relationship Between General Health Literacy Levels and Prenatal Care Health Literacy Levels

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EXPLORING THE PREDICTIVE RELATIONSHIP BETWEEN GENERAL HEALTH
LITERACY LEVELS AND PRENATAL CARE HEALTH LITERACY LEVELS

BY

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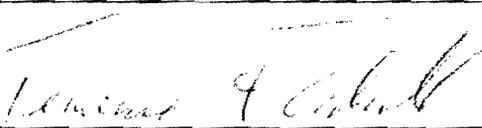
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Seton Hall University

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ABSTRACT

EXPLORING THE PREDICTIVE RELATIONSHIP BETWEEN GENERAL
HEALTH LITERACY AND PRENATAL CARE HEALTH LITERACY

Rhonda M. McCathern

Seton Hall University
2011

Background & Purpose of the Study: Health Literacy is important to physician-patient communication and health outcomes. However, disease and content specific health literacy has yet to be explored fully to determine its relationship to general health literacy. Prenatal care is the care that is important to mother and child during pregnancy. Prenatal Care is the content specific health literacy to be explored in this study. The purpose of this study was to determine if there was a predictive relationship between general health literacy and prenatal care health literacy in pregnant women seeking prenatal care.

Methods: The study was designed to measure general health literacy and the Prenatal Care Test of Functional Health Literacy, to measure prenatal care health literacy. A sample of 90 pregnant women engaging in prenatal care participated in the study.

Results: All of the participants' demonstrated adequate levels of general health literacy and high levels of prenatal care knowledge. Subsequent reliability calculations showed that the Short Test of Functional Health Literacy in Adults) and the Prenatal Care Test of Functional Health Literacy knowledge portion

might not be reliable in this sample. However, the results were important for clinical and theoretical relevance. General health literacy was found to be correlated with prenatal care knowledge. No correlations were found between general health literacy and prenatal care attitudes. No differences were found between general or prenatal care health literacy and trimester of pregnancy. Finally, a factorial analysis was performed and differences were found between education level and prenatal care attitudes. All results were statistically significant at the alpha level of 0.05.

Conclusion: The findings of this study suggest that further research should be undertaken to explore and improve the reliability of the Short Test of Functional Health Literacy in Adults and the Prenatal Care Test of Functional Health Literacy knowledge in pregnant women seeking prenatal care. Finally, the differences in attitudes scores among pregnant women of different educational level provide opportunity for improvements in clinical encounters. Further clinical and theoretical relevance and future direction are discussed further.

Chapter 1

INTRODUCTION

Background of the Problem

Preventive healthcare refers to behaviors that will prolong one's healthy life or practices that otherwise lessen the effects of disease, chronic illness, or debilitating ailments (Jayanti & Burns, 1998). A decision to utilize or not utilize preventive healthcare depends on a variety of factors and influences. During the past few decades, public health efforts have been initiated to improve the health of Americans in order to prevent illness and prolong death. Even so, the intended clients do not always use many preventive health programs.

Researchers have been analyzing barriers that impede individual utilization of important health services and have found reasons behind underutilization to be enormous and multifaceted. Many of the reasons are consistent and categorized across diseases, populations, and other sociodemographic factors. Potential barriers identified for not participating in healthcare services include system-related, socioeconomic and attitudinal (Kiely and Kogan, 1994). The majority of barriers documented in the literature are stratified across specific health related conditions, populations and other socioeconomic factors. However, it may be possible to apply the

cross section of barriers to other health related sectors that have yet to be fully explored in the literature. This would mean that researchers, healthcare providers and policy makers alike would be able to implement strategies to address barriers regardless of the disease or content specific area of needs.

Understanding barriers and the role they play in healthcare can provide insight into policies engaged at preventive healthcare. Whether an individual engages in preventive health depends on a variety of factors (Jayanti & Burns, 1998). However, individuals must have a specific level of knowledge, motivation and consciousness in order to seek out that care (Jayanti & Burns). Many Americans are battling diseases and illnesses that could have been prevented. Behaviors associated with lifestyle attribute to much of the morbidity and mortality (Palmer & Midgette, 2008). Therefore, understanding and researching barriers along with seeking ways to implement preventive healthcare, public health professionals and healthcare providers may be able to implement systems targeted at improving knowledge and understanding of health related behaviors, which would ultimately improve the health of the nation by decreasing cost, decreasing morbidity and mortality and prolonged life.

With a projected increase in health disparities, poor health outcomes and longer life spans, health literacy has come to the forefront of healthcare (Egbert & Nanna, 2009; Hasnain-Wynia & Wolf, 2010; Institute of Medicine, 2004). Health literacy is an important part of the communication that occurs

between healthcare providers and patients during a medical encounter (Powell, 2009; Schwartzberg, VanGeest & Wang, 2005). Health literacy, as defined by the United States Department of Health and Human Services (USDHHS), is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions” (United States Department of Health and Human Services, 2001, p. 16). Health literacy means more than transmitting information or developing skills to be able to read pamphlets or make appointments; it requires the ability to be able to navigate or function within the realm of healthcare. Specifically, it involves having functional health literacy (Zang, Thumboo, Fong & Chuen, 2009). Functional health literacy is defined as having the ability to apply reading and numeracy skills in a healthcare setting (Andrus & Roth, 2002). It is best described as having two components: reading comprehension and numeracy (Baker, Williams, Parker, Gazmararian & Nurss, 1999). Reading comprehension is the ability to read and understand written words containing health related information, while numeracy refers to the ability to read and understand numbers. Individuals with low functional health literacy have difficulty understanding consent forms, prescription labels and other health related information (Potter & Martin, 2005; Parker, Wolf & Kirsch, 2009; Shieh & Halstead, 2009).

When tested for health literacy with one of the established tools for health literacy assessment, an individual generally falls into one of three

categories: inadequate, marginal or adequate (Parker, Baker, Williams & Nurss, 1995). Individuals with inadequate health literacy often misread basic materials such as an appointment slip. Those with marginal health literacy often have difficulty comprehending more complicated information such as that found in health educational pamphlets. Individuals with adequate health literacy are typically able to understand most printed health material. (Chew, Bradley & Boyko, 2004).

Many factors have been associated with both the inadequate and marginal health literacy levels. However, important to this research is the fact that health literacy is independently associated with lower use of preventive health services (Mancuso, 2009; Scott, 2002). Lower use of preventive health services ultimately leads to poorer health outcomes; applying this general finding to the specific area of interest in this research study, prenatal care utilization, specifically relevant to this research is the fact that low use of prenatal care services leads to poor birth outcomes (Daniels, 2006).

While you can't tell by looking at someone if they have limited health literacy skills, there are some red flags that have been documented as telltale signs of literacy issues. Incomplete or incorrectly completed registration or health forms, inappropriately taking medication and lack of follow through on ancillary services such as laboratory test or consultant visits are good indicators of limited literacy issues (Weiss, 2007). As practitioners and

educators become aware of the high numbers of individuals that have inadequate health literacy skills, there is increased pressure to identify those patients who have inadequate health literacy skills in order to provide assistance to ensure they are provided with optimal healthcare (Egbert & Nanna, 2009; Parker, Wolf & Kirsch, 2009; Rowlands, 2009.). Optimal healthcare includes reduce cost and more efficient and cost-effective healthcare. This has also become mandatory under the Patient Protection and Affordable Care Act (2010) established precedence by ensuring that Americans have the insurance necessary to seek appropriate healthcare as well as the removing barriers to accessing care. Additionally, the President established, within the department of Health and Human Services, a council to be known as the National Prevention, Health Promotion and Public Health Council to help begin to develop a National agenda for prevention and health promotion. However, general tests of health literacy currently available, such as the Test of Functional Health Literacy Assessment (TOFHLA) or the Rapid Estimate Adult Literacy in Medicine (REALM), do not assess content specific or disease specific healthcare proficiencies (Cancer, HIV/AIDS, hyperstension, etc.), and therefore, are not true indicators of one's particular proficiency in health literacy specifically (Chew, Bradley & Boyko, 2004; Mancuso, 2009).

Applying the concerns discussed herein to the particular issue of adequate prenatal care is critical to successful maternal and child health.

This is because prenatal care is critical to improving maternal and child health outcomes. Thus, it becomes important to ensure that a woman's general health literacy level is not mistaken for her actual prenatal care health literacy level.

Prenatal care is the care a woman gets while she is pregnant (American College of Obstetrics and Gynecology, 1997). A doctor, midwife or other healthcare professional can provide this care. The goal of prenatal care is to monitor the progress of pregnancy and to identify potential problems before they become serious for either the mother or the unborn child to improve the birth outcome. For example, it is clear from the literature that women who seek a healthcare provider regularly during pregnancy have healthier babies and are less likely to have poor birth outcomes than women who do not engage in prenatal care or enter later in the pregnancy (Lewis, Matthews & Heuser, 1996).

One of the high priority issues defined in Healthy People 2010 (2000) and again in Healthy People 2020 (2010), the national goals and objectives framework for improving the health of the nation, is the attainment of adequate prenatal care for all women (United States Department of Health and Human Services, 2000; United States Department of Health and Human Services, 2010). This framework, asserts a goal of reaching 90% engagement in prenatal care for pregnant women. There are higher rates of late prenatal care engagement among low income, low education-level

women, Hispanic women, and African American women. (Zaid, Fullerton & Moore, 1996). The literature is not clear on what defines late prenatal care. However, much of the literature suggests that prenatal care should begin in the first trimester (Adams, Gavin & Benedict, 2005; Alexander & Kotelchuck, 2001; Cokkinides, 2001; Nothnagle, Marchi, Egerter & Braveman, 2000). Therefore, late prenatal care could be considered engagement after the first trimester. The rate of prenatal care engagement in the first trimester for populations considered in Healthy People 2010 has increased from 76% to 83% with 74% of these women receiving adequate prenatal care (United States Department of Health and Human Services, 2000). Similarly, the goal for Healthy People 2020 is 77.9% of women receiving adequate prenatal care (United States Department of Health and Human Services, 2010).

Public health efforts towards increasing access to early prenatal care have been concentrated on all major ethnic groups who have a high risk of prenatal illness, increased disability and mortality rates, low income and low educational attainment, as well as unmarried and young women (Adams, Gavin & Benedict, 2005; Cokkinides, 2005; Higgins, Murray & Michelle, 1996; Nothnagle, Marchi, Egerter & Braveman, 2000). Thus, the relationship between level of adequacy and likelihood of achieving positive, immediate birth outcomes and the long term healthcare of both mother and child is critical (Kogan et al., 1998; United States Department of Health and Human Services, 2000).

Prenatal care has been studied in many populations. There is extensive research that reports barriers that impede enrollment into prenatal care (Daniels, Godfrey & Mayberry, 2006; Omar, Schiffman & Bauer, 1998; Sunil, Spears, Hook, Castillo & Torres, 2010). These barriers include transportation/parking difficulties, child-care issues, fear of and negative attitude toward healthcare providers, access to care, limited availability of providers and insurance eligibility (Cokkinides, 2001; Daniels, Godfrey & Mayberry; Sunil, Spears, Hook, Castillo & Torres). It is important to note that health literacy was not listed as a barrier to prenatal care utilization, thus making this a researchable topic for the healthcare arena.

Much of the health literacy literature focuses on general health literacy. However, because general health literacy does not measure content or disease specific health literacy, researchers are beginning to explore disease specific tools to measure health literacy. Measurement tools have been created in the areas of cancer, dental and nutrition to test for content specific health literacy (Diamond, 2007; Gong, Lee, Rozier, Pahel, Richmann & Vann, 2007; Jeppesen, Coyle & Miser, 2009; Lee, Rozier, Lee, Bender & Ruiz, 2007). Since research is focusing on these disease or content specific measures of health literacy, it is becoming more important to develop a health literacy measurement tool focused at assessing prenatal care health literacy. This would prove to be timely and contribute significantly to the prenatal care and health literacy literature since no tool currently exists. Concern has been

expressed recently in the literature about predictions being made about specific content health literacy based on general health literacy scores. Consequently, it is becoming increasingly important that healthcare providers and public health professionals determine strategies to ensure that women engaging in prenatal care are adequately obtaining, processing and understanding content specific to prenatal care.

Statement of the Problem

The problem of health literacy is widespread. According to the National Assessment of Adult Literacy (NAAL), nearly 9 out of 10 adults lack proficient health literacy and, therefore, may not have the skills required to manage their health and prevent disease (Kirsch, Jungeblut, Jenkins & Kolstad, 1993). Persons with limited health literacy skills are more likely to skip important preventive healthcare measures, encounter more barriers to receiving necessary healthcare services, and less likely to understand medical advice regarding their health (Phipps & Espey, 2007). Additionally, when compared to individuals possessing adequate health literacy skills, studies have shown that patients with limited health literacy skills enter the healthcare system when they are sicker and are more likely to become hospitalized. These individuals incur higher healthcare cost, increase the burden upon the healthcare system and have poorer health outcomes (Bennett et al., 1998).

The current healthcare system assumes a high level of health literacy. Individuals are expected to be able to obtain, process and understand and make medical decisions based on what could possibly be complex health related information. However, nearly half of the adult population in the United States has difficulty assessing health information and services (Institute of Medicine, 2004). This disparity in the healthcare system can affect the decisions that pregnant women make regarding engaging in prenatal care.

Prenatal care, when sought early and continued throughout pregnancy, can improve pregnancy outcomes (Herbst, Mercer, Beazley, Meyer & Carr, 2003; Lewis, Matthews & Heuser, 1996; Taylor, Alexander, Hepworth, 2005). Prenatal care, beginning optimally in the first trimester of pregnancy, provides an opportunity to encourage healthy maternal behaviors, treat chronic conditions, intervene with mothers who engage in risky health behaviors, screen for birth defects, and manage problems associated with pregnancy, such as gestational diabetes and pregnancy induced hypertension (Cokkinides, 2001; Daniels, Godfrey & Mayberry, 2006).

The health literacy skill of an individual directly affects their health care. Health literacy deficits are a significant barrier to adequate healthcare. Without the ability to understand health related information, one cannot make informed decisions regarding their healthcare (Institute of Medicine, 2004). Current literature indicates that proper knowledge and understanding of the importance of healthcare and preventive services should improve health

outcomes across populations; additionally that understanding health-specific information should facilitate compliance to care protocols and communication between patients and providers, and improve overall health. However, it is clear that individuals with low health literacy have difficulty communicating effectively in provider settings as well as engaging in preventive health services.

What has not been determined or documented in the literature are two things: first, whether a relationship exists between general health literacy level, as measured by the STOFHLA, and prenatal care health literacy level, as measured by the Prenatal Care Test of Functional Health Literacy, a tool designed to measure prenatal care disease-specific health literacy level; and second, whether it is possible to predict a woman's prenatal care health literacy level (as measured by the Prenatal Care Test of Functional Health Literacy), if their general health literacy level, as measured by the STOFHLA, is known.

Further, researchers have begun to challenge the relevance of the widely used and accepted STOFHLA health literacy score and its meaning to different populations by developing new disease-specific health literacy measurement tools. As discussed earlier, general literacy varies in different contexts. Individuals need to be able to understand content specific to the disease or discipline area of concern. The current tools employed to test general health literacy level aforementioned are not content specific, and

therefore raise a serious concern about whether the scores are indicating an individual's health literacy level in a disease-specific area. This further suggests the next step, which is to understand the nature and scope of the relationship that may exist between the STOFHLA health literacy score and these new disease-specific health literacy tools scores, and whether there is a prediction that can be made about an individual's disease-specific health literacy level (such as about their prenatal care health literacy level), if their standard health literacy level, as measured by the STOFHLA, is known. This level of understanding is necessary for healthcare providers and public health organizations to better educate and communicate with those most at risk and ultimately, reduce the number of poor birth outcomes and decrease infant mortality rates.

Purpose of the Study

In reviewing the literature, particularly regarding the findings of Krueger & Scholl (2000), Johnson et al. (2007), Lewis and colleagues (1996) and Taylor et al. (2005), all have shown the existence of a direct relationship between prenatal care services and improved birth outcomes. While there have been some findings reported, most notably by Endres (2004) and by Bennett et al. (2006, 2007), all around pregnancy, prenatal care and health literacy, no direct relationship between general health literacy and prenatal care health literacy is yet ascertained. So from the literature and the findings from the pilot, the purpose of this dissertation study was to determine if there

is a predictive relationship between general health literacy level, as measured by The Short Test of Functional Health Literacy in Adults (STOFHLA), and prenatal care health literacy level, as measured by the, Principal Investigator created, Prenatal Care Test of Functional Health Literacy survey instrument, in pregnant females to determine if indeed, knowing the general health literacy level would predict the level of prenatal care literacy level, thus eliminating the need for disease or health content specific measurement tools.

Significance of the Study

Current literature indicates that proper knowledge and understanding of the importance of healthcare and preventive services should improve health outcomes across populations; additionally that understanding health-specific information should facilitate compliance to care protocols and communication between patients and providers, with the end result being the improvement of overall health (Jayanti & Burns, 1998; Palmer & Midgette, 2008). However, it is clear that individuals with low health literacy have difficulty communicating effectively in provider settings as well as engaging in preventive health services (Arthur, Geiser, Arriola & Kripalani, 2009)

The significance of this study lies in understanding what has not been fully explored in the literature. First, as previously stated is whether a relationship exists between general health literacy and prenatal care health

literacy level and secondly, whether it is possible to predict a woman's prenatal care health literacy level if their general health literacy level is known.

This second issue is particularly intriguing for several reasons. First, the literature is replete with information suggesting relationships existing between health literacy levels and lower socioeconomic and sociodemographic populations. Second, the STOFHLA is a tool utilized frequently in the clinical setting to assess patients' health literacy level. Third, in the general literacy context, findings in the literature show that a given level of general literacy does not necessarily correlate directly with a similar level of content specific literacy. Fourth, poor patient outcomes are related to several factors, some of which include the provider-patient relationship, health literacy level and utilization of preventive healthcare services. Fifth, individuals with higher general literacy levels are more familiar with medical conditions affecting them or the need for preventive care services. Sixth, and more specific to my particular area of interest, poor birth outcomes are attributed to underutilization of preventive prenatal care services. Integrating these concepts, it may appear that there is a direct relationship between general health literacy level and disease-specific health literacy level, such that an intuitive assumption is made: that a particular level of health literacy suggests a particular similar level of disease-specific health literacy, but this not conclusively clear and has never been quantified.

The predictive element of the second question is important also because, if, as the literature states, currently accepted health literacy tools are being employed during the health encounter to assess patients' health literacy level which appear to be somewhat simplistic in their application to true health understanding. Incorrect assumptions about what level of understanding patients may have about their specific condition and care may be overestimated. Such error could be contributing to poorer patient outcomes and poorer provider-patient encounters that are reported in the literature as associated with health literacy and general literacy scores. Since it is also known from the literature that poor utilization of prenatal care services results in poorer birth outcomes, and that in certain lower socioeconomic, sociodemographic, educational and general literacy populations that lower health literacy levels predominate, it becomes clear that understanding, and not assuming, what the STOFHLA score can or cannot predict about a patient's level of understanding about their health condition or need for preventive services is what can potentially improve all aspects of their healthcare encounter and outcome. Applying this to my area of interest particularly, this means that understanding the predictive capability of the STOFHLA health literacy score in regard to a pregnant female's understanding of and need for prenatal care services throughout their pregnancy will provide a better understanding of how to improve birth

outcomes in the populations identified with historically lower STOFHLA scores and poorer birth outcomes.

Further, researchers have begun to challenge the relevance of the widely used and accepted STOFHLA health literacy score and its meaning to different populations by developing new disease-specific health literacy measurement tools (Diamond, 2007; Gong, Lee, Rozier, Pahel, Richmann & Vann, 2007; Jeppesen, Coyle & Miser, 2009). As discussed earlier, the level of health literacy varies in different contexts. Individuals need to be able to understand content specific to the disease or discipline area of concern. The current tools employed to test general health literacy level aforementioned are not content specific, and therefore raise a serious concern about whether the scores are indicating an individual's true health literacy level in a disease-specific area. This further suggests the next step, which is to understand the nature and scope of the relationship that may exist between the STOFHLA health literacy score and these new disease-specific health literacy tools scores that have already been created such as the dental health literacy tool, and whether there is a prediction that can be made about an individual's disease-specific health literacy level (such as about their prenatal care health literacy level), if their standard health literacy level, as measured by the STOFHLA, is known. This level of understanding is necessary for healthcare providers and public health organizations to better educate and communicate

with those most at risk and ultimately, reduce the number of poor birth outcomes and decrease infant mortality rates.

Research Questions and Hypotheses

Due to an absence of information about the predictive relationship between general health literacy and prenatal care health literacy, the research questions and hypotheses for this study are:

RQ1. What are the general health literacy scores of pregnant women as measured by the Short Test of Functional Health Literacy in Adults (STOFHLA)?

RQ2. What are the prenatal care scores of pregnant women as measured by the Principal Investigator created tool entitled the "Prenatal Care Test of Functional Health Literacy?"

No hypotheses were stipulated for research questions 1 and 2 as these were purely descriptive questions.

RQ3. Is there a significant relationship between general health literacy, as measured by the STOFHLA, and prenatal care health literacy level, as measured by the Prenatal Care Test of Health Literacy, in pregnant females?

H3. There is a relationship between general health literacy and prenatal care health literacy.

Here the literature speaks clearly to the idea that where general literacy is concerned, people may have high general literacy levels, yet may not have correspondingly high levels of literacy when measured in a specific context or subject matter.

Following these findings and extending an analogy to health literacy, the next question is based on the very simple idea that one may not automatically assume, where health literacy is concerned, that it is possible to predict an individual's disease-specific health literacy level, such as in prenatal care, if their general health literacy level is known, as measured by the STOFHLA.

RQ4. Is it possible to predict the level of prenatal care health literacy a pregnant female will have (as measured by the Prenatal Care Test of Health Literacy) if the individual's general health literacy level is known, as measured by the STOFHLA?

H4. Short Test of Functional Health Literacy scores will predict Prenatal Care Health Literacy.

The following research questions are based on the data collected from the demographic survey, which allows analysis at a greater level of understanding among and between groups and health literacy levels as follows:

RQ5a. Is there a difference in general health levels between first, second and third trimester pregnant females?

H5a. There is a difference in general health literacy levels between first, second and third trimester pregnant females.

RQ5b. Is there a difference in prenatal care health literacy scores between first, second and third trimester pregnant females?

H5b. There is a difference in prenatal care health literacy scores between first, second and third trimester pregnant females?

Since there is no literature to date on this subject, hypotheses 5a and 5b are based on David Kolb's experiential learning theory (Healey & Jenkins, 2000; Kolb & Fry, 1975). There should be a higher level of learning for each trimester of pregnancy.

RQ6. What are the differences in prenatal care health literacy scores when pregnant women are grouped by educational attainment, ethnicity and age?

H6. There is a significant difference in prenatal care health literacy scores when pregnant women are grouped by educational attainment, ethnicity and age.

This hypotheses, H6, is based on the literature in which it is stated that knowledge increases with higher educational attainment and age and that

specific ethnicity is associated with higher literacy levels (Armstrong, Rose, Long & Shea, 2006; United States Department of Education, 2006).

Theoretical Framework

While the theories that attempt to explain health literacy are scarce in the literature, the social ecological theory (Matson-Koffman, Brownstein Neiner, & Greaney, 2005) provides a lens for understanding health literacy and its relationship to healthcare services.

Health literacy consists of a myriad of factors. Understanding them requires looking beyond one's cognitive, affective or social resources. The social ecological theory (Matson-Koffman, Brownstein, Neiner & Greaney, 2005) acknowledges the complexity of interactions among people and environments. It also recognizes that these relationships are interwoven.

According to the social ecological theory, context may be understood in terms of various social systems that influence a woman's understanding of prenatal care. The theory consists of three levels of influence on health literacy, including intrapersonal factors, interpersonal factors and community factors. Intrapersonal factors include characteristics, knowledge and skills. Interpersonal factors include social support and influences, the quality and nature of human interactions, peers and family. Finally, community includes two components, environmental and structural. These are factors such as health policy and a community's ability to promote health (Matson-Koffman, Brownstein, Neiner, & Greaney, 2005).

Some of the research done in the area of health literacy points to this framework for understanding health literacy (Higgins, Begoray & MacDonald, 2009). The emphasis is redirected from the individual to systems to help understand how people live their lives. The social ecological theory promotes understanding of the factors associated with behavior change. Elder et al. (2007) advises tailoring ecological models for different behavior or health conditions to better understand the causes and nature of a disease or behavior. Recognizing the internal and external influences that are important to understanding health literacy, the social ecological theory is being used as the framework for this study.

Conceptual Framework

Baker (2006) developed a conceptual model that views health literacy in the real world as a product of individuals' capabilities and the demands of health information messages delivered by the healthcare system (Figure 1). In this model, the healthcare sector shares responsibility for making sure that individuals can use health information effectively.

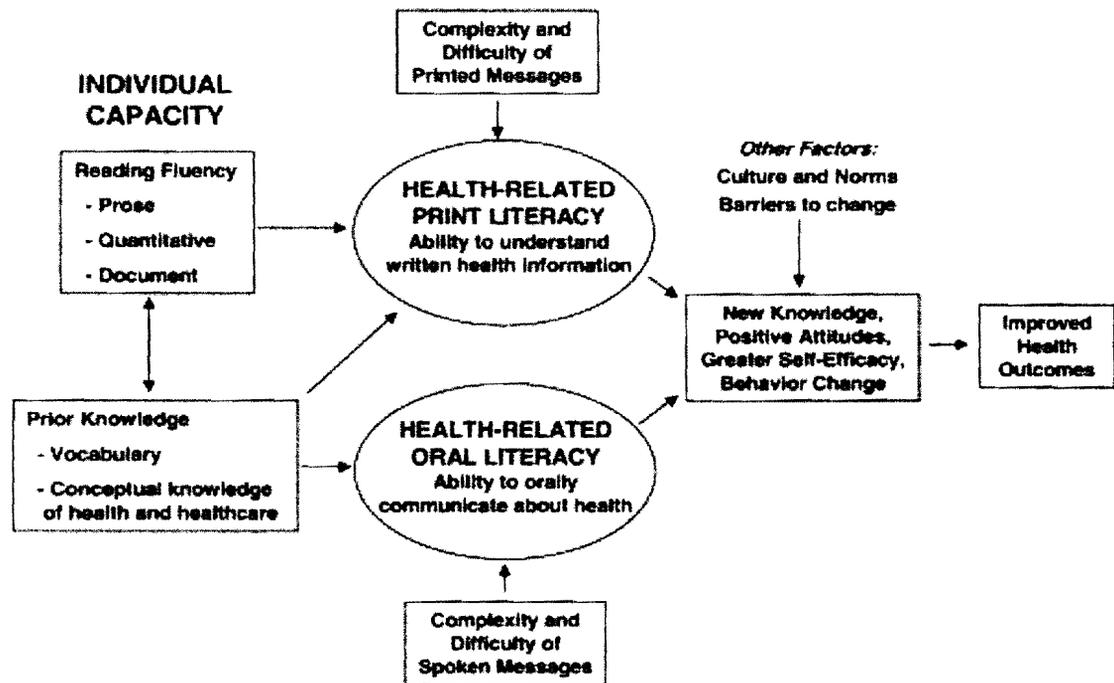


Figure 1. Conceptual model of the relationship between individual capacities, health-related print information and oral literacy as it relates to health outcomes. (Baker, 2006)

This model is broken into two domains, individual capacity and health literacy. The first domain within the model is individual capacity. These are the resources that a person needs in order to effectively deal with health information, healthcare personnel and the healthcare system. This includes reading fluency and prior knowledge. Reading fluency is the ability to process written material and form new knowledge and consist of three subcomponents; prose, quantitative and document literacy. The three components come from the National Assessment of Literacy study (NALS) (Kirsch, 2002). This study conducted by the United States Department of Health and Human Services in 1992 and was repeated in 2003 to assess the literacy of Americans. This study will be discussed at length in the literature review (Kirsch).

In the Baker model the first component is prose literacy, which is the ability to read and understand text, quantitative literacy, which is the ability to apply arithmetic operations and user numerical information in printed materials and finally document literacy, which is the ability to locate and use information in documents (Baker, 2006).

The second component of the first domain is prior knowledge (Baker, 2006). Here, prior knowledge is what an individual knew at the time before reading the health materials or speaking to a healthcare professional. It consists of vocabulary or knowing what individual words mean and conceptual knowledge or understanding aspects of the world. (Baker).

When looking into the Baker model and taking into consideration the complexity of difficulty of the written or spoken messages, a person's individual capacity will determine their ability to understanding written and oral communication (Baker, 2006). Finally, other factors such as cultural and barriers to change as well as all the other factors along with ones' new knowledge, attitude and self-efficacy will ultimately affect the health outcome (Baker).

Thus, health literacy is determined by characteristics of both the individual and the healthcare system. Understanding this model is critical to understanding the importance of all factors intrinsic to improving health literacy.

The second domain within the Baker model is health literacy. This domain is divided into two sections, print and oral literacy (Baker, 2006). The health related written and oral literacy depends on the individual's health related reading ability and their vocabulary, familiarity with health concepts and the difficulty of the print and spoken word. Their corresponding health literacy is determined by the characteristics of both the individual and the health system. Health literacy is the key factor that will lead to the acquisition of new knowledge, greater self-efficacy and positive health behaviors that leads to better health (Baker).

It is important to establish a framework for understanding behaviors. It is also important to understand the theories that provide a framework for

understanding health literacy and its' components. However, in order to fully understand the importance of all of these factors, it is critical to understand what is currently expressed in the literature. This provides a basis for understanding this topic as well as a guide the framing the content of this research.

Chapter II

REVIEW OF THE RELATED LITERATURE

Health Literacy

General Literacy

Literacy and health literacy are not the same. Although health literacy is important and the general focus of this review, it is equally important to understand the underlying base concept, general literacy. There is a significant overlap between literacy and health literacy, but there are content-specific demands that distinguish the two concepts. Illiteracy is often associated with individuals who have the barest of language skills. The United National Educational Scientific and Cultural Organization (UNESCO) defines an person as someone “who cannot, with understanding, both read and write a short, simple statement on his everyday life (Zarcadoolas, Peasant & Greer, 2006, p. 45). The United States Census (2003) defines illiteracy as having less than a ninth grade education. By such a definition, America has a large population that is almost illiterate, since about 20% of the population has less than a ninth grade education (US Census). However, further examination of literature on this broad definition of illiteracy shows that

the definition is very unclear in identifying individual knowledge in general and in specific to health knowledge.

Adult literacy is greatly concerning for Americans (Kirsch, Jungeblut, Jenkins & Kolstad, 2002). Because of its impact on health in the United States, it is of growing interest to researchers, healthcare providers and policy makers. Literacy is not always associated with reading alone. It is often associated with a constellation of skills including reading, writing, basic mathematical calculations, and speech (National Institute on Literacy, 2007). Speech and speech comprehension falls under the umbrella of oral literacy, while reading and writing are often associated with print literacy. Basic print literacy is the ability to read, write and comprehend basic written language that is familiar and for which an individual has some background knowledge. In essence, literacy is a continuum of skills rather than an all-or-nothing proficiency. It is only meaningful within a situation and/or cultural context (Kirsch, Jungeblut, Jenkins & Kolstad, 1993).

Education level is often associated with literacy level; the higher the level of education the higher the literacy level (Kutner, Greenberg, Jin, Boyle, Hsu & Dunleavy, 2007). People with less than or some high school education had much lower literacy levels than high school graduates, those with GEDs or those with further education. Research has shown, specifically through the International Adult Literacy Survey (Kirsch, 2001), that the connection between educational attainment and literacy levels, while strong, is not

exclusive. Although plausible, we cannot assume that because someone has a higher level of education that they will also have a higher level of general health literacy.

The research has also shown that disparities exist between urban populations and their rural counterparts (Ompad, Galea, Caiffa & Vlahove, 2007). Zahand, Sciefe and Francis (2009) also found disparities in health literacy skills between rural and urban populations in that Individuals in rural populations have lower health literacy than those of their urban counterparts. When compared to urban individuals, rural individuals had lower health, document, prose and quantitative literacy.

Literacy is an important and well-known correlate of health status and health promoting behaviors (Baker, Williams, Parker, Gazmararian & Nurss, 1999). Because functional literacy varies based on context and setting, an individual may have adequate literacy in a home or work setting, but may have marginal or inadequate literacy in the healthcare arena (Dewalt, Berhman, Sheridan, Lohr & Pignone, 2004). This makes individuals vulnerable in the healthcare setting and makes it much more difficult to navigate through the healthcare process which could ultimately lead to poorer health outcomes. These findings also support the general statements made concerning general literacy proficiency in varied contexts. (Kirsch, Jungeblut, Jenkins & Kolstad, 1993).

As individuals navigate through the healthcare process they use various forms of communication in order to effectively interact with providers. The skills needed to perform these tasks are critical to receiving adequate healthcare. All of the above research links race, age, language, socioeconomic status and education with reading ability. The relationship of these factors to literacy is magnified in the context of health.

National Assessment of Adult Literacy

The National Assessment of Adult Literacy (NAAL) was extremely important as the first national measure of literacy, providing systematic feedback to the education system and to the healthcare system about how literate American adults are. In 1992 and again in 2003 the United States Department of Education conducted the National Assessment of Literacy. (Kirsch, Jungeblut, Jenkins & Kolstad, 1993; US Department of Education, 2006). In 1992 they found that 90 million adults in the US only demonstrated skills in the two lowest levels (below basic and basic) of a four level assessment of literacy and did not see themselves as being able to read or write (Kirsch, Jungeblut, Jenkins & Kolstad, 1993; US Department of Education, 2006). The figure 90 million is derived from about 40-45 million individuals who self-identified as functionally illiterate and 50 million who have marginal functional literacy. Their scores indicate that they cannot perform basic reading tasks necessary to completely function in society. Among this group, 66-97% described themselves as being able to read or write "well or

very well” in the English language. Only 14-25% requested assistance from family or friends for literacy tasks (Kirsch, Jungeblut, Jenkins & Kolstad). This means they are probably not receiving optimal healthcare.

In 2003, the NALS survey was re-administered as the National Assessment of Adult Literacy (NAAL). This survey also used a nationally representative sample consisting of 19,714 adults who participated in the assessment (United States Department of Education, 2006). Several concepts in the 2003 version measured literacy differently from the 1992 NALS study, including the addition of the health literacy component. The assessment revealed that there had been no significant changes in the literacy level of American adults during the 10-year period (Kishch, 2001). However, the number of Americans who still tested in the lowest 2 of 4 levels of literacy increased from 90 million to 93 million adults (43%). This means that 43% of the population cannot perform basic reading tasks necessary to function in society. However, most of these same adults describe themselves as being able to read and write well or very well in the English language.

Recognizing how important health literacy is to society, a small health literacy component was added to this survey in 2003 with specific health literacy questions. In the early nineties, little had been done to explore the relationship between illiteracy and health.

Health literacy

As already explained, health literacy is the ability to use general literacy skills to function effectively as a healthcare consumer, and includes the ability to read and comprehend prescription bottles, appointment slips, or basic health information. These skills are necessary not only to manage disease but also to find one's way around a medical facility or clinic and to complete medical forms, so that effective medical care can be obtained (Davis, Meldrum, Tippy, Weiss & Williams, 1996; Shaw, Huebner, Armin, Orzech, Vivian, 2009).

Health literacy is defined by the United States Department of Health and Human Services as, "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" (United States Department of Health and Human Services, 2001, p. 16). It is an important part of the communication that occurs during a medical encounter. Many components of a medical encounter are affected by health literacy including: taking medication, understanding disease related information, learning about and taking advantage of health promotion, or accessing healthcare (Baker et al., 1996; Berkman, Pignone, Sheridan, Lohr, Lux et al, 2004). According to the Council of Scientific Affairs of the American Medical Association Ad Hoc Committee on Health Literacy (1999), an individual's health literacy may be significantly worse than their general literacy. Therefore, it is plausible for an

individual to have a high level of general health literacy but have a low level of health literacy or even for an individual to have a high level of health literacy and a low level of general literacy.

Health literacy is content specific. Medical content involves unfamiliar and complex vocabulary and concepts. Many patients lack the appropriate skills needed to actively participate in their healthcare, even though understanding these concepts are critical for optimal healthcare. This can lead to inadequate healthcare, increased healthcare costs, poorer health outcomes and ultimately a sicker nation (Hester, 2009; United States Department of Health and Human Services, 2000).

Health literacy and preventive services

People with limited health literacy skills generally have poorer overall health according (Baker et al, 1997). Low health literacy is a significant problem associated with suboptimal use of preventive medicine, including medical screenings, lack of knowledge about health, difficulty following instructions of healthcare providers and poor health outcomes (Jayanti and Burns, 1998; Lindau et. al, 2002). Health promotion and disease prevention behaviors studies also suggest a link between health literacy levels, use of health screening techniques, and health behaviors. For example in 2001, Fortenberry found lower REALM scores correlated with prediction for gonorrhea testing, self-inspection for gonorrhea and self-efficacy in care seeking. Supporting this conclusion was the finding that patients scoring

lower on the REALM rated themselves as more likely to acquire gonorrhea within the next 12 months. Higher health literacy level was also independently associated with knowledge of cervical cancer screening even when education, ethnicity, insurance status and age were controlled (Lindau, et. al, 2002). Using the REALM as the basis for their health literacy assessment, Lindau and colleagues found similar results. In a population of 529 women, they found that those participants with lower health literacy skills were less likely to engage in cervical cancer screenings. Similarly, in study of the initiation and continuance of breastfeeding in community based mothers, researchers found that women with low health literacy were more likely to forgo breastfeeding or engage in breastfeeding for a shorter period of time than those with higher health literacy (Kaufman, Skipper, Small, Terry & McGrew, 2001).

Additional studies indicate that persons with limited health literacy skills are more likely to skip important preventive measures such as mammograms, Pap smears, and flu shots (Gazmararian, Williams, & Baker, 2002). When compared to those with adequate health literacy skills using the Test of Functional Health Literacy Assessment (TOFHLA), studies have shown that patients with limited health literacy skills enter the healthcare system when they are sicker (Bennett, et. al, 1998). Individuals with limited reading skills were also less likely to utilize medical screening than those with stronger reading skills (Davis, Arnold, Berkel, 1996).

Because functional literacy varies based on context and setting, an individual may have adequate literacy in a home or work setting, but may have marginal or inadequate literacy in the healthcare arena (DeWalt & Pignone, 2005). For example, a person who has completed high school may still be unable to navigate the healthcare system, leading to inadequate healthcare and poorer outcomes. As individuals navigate through the healthcare process they use various forms of communication in order to effectively interact with providers. Higher or improved levels of health literacy are needed to improve this communication. The skills needed to perform these tasks are critical to receiving and complying with appropriate healthcare.

Measurements of Health Literacy

Thinking back to Baker's conceptual frame, Baker (2006) suggests that several factors contribute to the measurement of one's health literacy level, including prior knowledge, reading fluency, culture and social norms, barriers, complexity of health information and oral complexity, which is the ability to understand complex and difficult printed messages. It is important to have a reliable and valid instrument for testing health literacy to allow researchers to assess people's literacy and so that interventions and strategies to improve healthcare encounters can be suggested. It is also important to have a reliable tool so that health care providers can appropriately assess a patient's health literacy level in order to ensure that information is appropriately

conveyed and that the appropriate care is being rendered. Confirming the reliability and validity of such tests in different populations and contexts ensures that the intended components of health literacy are being measured and that the same information will be obtained regardless of the population of research or the number of times the tool is administered to a specific group (Baker, 2006). The current tools used to measure health literacy have confirmed reliability and validity and will be discussed in detail in Chapter 3 the methodology section.

Three instruments are most commonly used by researchers to measure health literacy: The Wide Range Achievement Test-Revised (WRAT-R), the Rapid Test of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFLHA). The Wide Range Achievement Test – Revised (WRAT-R), is used to assign a grade level to one's knowledge. As was discovered in the literature, grade level alone is not an adequate measure of health literacy since inadequate or marginal health literacy can be found across all educational levels (Kirsch, 2003). The Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFLHA) are the most commonly used measures of health literacy (Institute of Medicine, 2004) and will be the focus of this discussion.

Rapid Estimate of Adult Literacy in Medicine (REALM)

The REALM is a medical word-recognition test that can be scored in under three minutes, making it ideal for use in clinical settings (Davis et. al, 1991). The REALM, which uses health related words to assess literacy, is helpful in identifying individuals with poor reading ability. However, it may not always capture individuals with inadequate health literacy because, as stated earlier, reading does not relate to comprehension. This means that just because a person can read or pronounce a word does not mean they know the meaning of the word. Similarly, if a person is unable to read, they are less likely to comprehend the word. Therefore, the REALM falls short in its ability to identify an individual's health literacy status. Additionally, the REALM does not test one's ability to read and understand numbers because there are no numerical components to the test (Davis). This becomes relevant in healthcare when testing one's ability to comprehend dosages and other numerical computations in the healthcare setting.

Lindau, Basu and Leitsch (2006) used the REALM to explore health literacy as a predictor of follow-up after an abnormal pap smear. The study included 68 women with abnormal pap smears. They found that women who had low health literacy scores were less likely to follow up within one year.

The REALM was also used to establish correlations between beliefs about medication and adherence (Gatti, Jacobson, Gazmararian, Schmotzer and Kripalani, 2009). Based on REALM scores, only 40.3% of the patients

could read at a high school level. However, 72% reported having a high school education. They found no associations between health literacy and adherence or beliefs.

Davis and associates (1996) used the REALM to determine the knowledge and attitudes on screening mammography among low-literate, low income women. Using the REALM as the measure of health literacy, 445 women were interviewed for this study. The mean REALM score was 40, indicating a 4th -6th grade reading level. Ten percent of the women could not read any of the words on the measure. They found that limited literacy skills and lack of knowledge about screening mammography might contribute to underutilization of screening mammograms by low-income women.

The REALM while used extensively in the literature is not able to capture the full complexity of the construct of health literacy. It is simply a word recognition test that determines ones' ability to pronounce a word correctly. In the absence of other measures, the REALM does serve a preliminary basis for assessing some form of basic health knowledge. However, a more comprehensive test of health literacy is yet to be explored.

Test of Functional Health Literacy in Adults (TOFHLA)

To better understand health literacy, the TOFHLA test was created. The TOFHLA was specifically designed to measure "functional health literacy," which as previously stated, is defined as the ability to read and understand basic health-related materials (United States Department of

Health and Human Services, 2001, p. 16.) The test is made up of tasks taken from commonly used hospital texts, including patient education materials, discharge instructions, prescription labels and registration forms (Parker, Baker, Williams & Nurss, 1995). The test is comprised of two components, reading comprehension and numeracy. The reading comprehension section is a 50 item test using the modified Cloze method, in which a word or phrase is taken out of a passage and respondents are asked to choose the appropriate missing item from among multiple choice selections. The multiple-choice options include the correct answer along with three other words that are similar but grammatically or contextually incorrect. Respondents can score into one of three categories: inadequate, marginal and adequate functional health literacy (Parker, Baker, Williams & Nurss)

The numeracy section is a 17-item test using actual hospital forms and prescription labels. It tests a patient's ability to comprehend directions for taking medication, monitoring blood glucose, keeping appointments and obtaining financial assistance (Schwartz et al, 1997). Patients are presented with cue cards or labeled prescription bottles and are asked to respond to oral questions regarding the information they have been presented. The sum of the reading comprehension and the weighted numeracy scores yields the overall TOFLHA score, which places an individual into one of the three health literacy categories: inadequate, marginal or adequate (Parker, Baker, Williams & Nurss, 1995).

So briefly, the TOFHLA measures numerical ability with a 17-item test and reading comprehension with a 50-item test (Parker, Baker, Williams and Nurss, 1995). Pilot studies have been conducted using both the TOFLHA and the REALM. Reliability was calculated using both split half and internal consistency measures. Content validity was enhanced using actual hospital medical text. Concurrent validity was established by determining correlation between the TOFLHA, the WRAT-R and the REALM. The English version of the TOFLHA reliability was 0.92 and the Spanish version was 0.84 meaning the testing showed consistent results after administration (Parker, Baker, Williams and Nurss, 1995).

Mancuso and Rincon (2006) used the TOFHLA to determine the role of health literacy in asthma patients' assessment of healthcare and medical decision-making. One hundred seventy five (175) eligible individuals participated in the study. The TOFHLA was issued in English and Spanish based on primary language preference. They found that lower health literacy was associated with dissatisfaction with the status of asthma and worse assessment of treatment results for asthma and other conditions. Another important finding of this study was that while most of the patients with low health literacy wanted to know of their treatment options, they did not want to be involved in the decision making. Low health literacy was not found to be associated with patients' reports of more difficult access to asthma care (Mancuso and Rincon).

Subsequent to the Mancuso and Rincon, Murphy and colleagues (2010) used the TOFHLA to assess the relationship between health literacy and antiretroviral adherence in HIV-infected adolescents. Of the 186 HIV-infected adolescents, 11.8% had inadequate health literacy, 2.7% had marginal and 85.5% had adequate functional health literacy. Contrary to findings in adult literature for HIV infected-adolescents, there was no association found between health literacy and anti-viral loads or self-efficacy to adhere to HIV medication regimens.

The Test of Functional Health Literacy Assessment in Adults was the seminal comprehensive tool to assess health literacy. However, like the REALM it has its limitations. It also does not assess the complexity of the constructs of health literacy. It is limiting in that it only assesses health information related to a radiological test and Medicaid rights. It does not represent the broad spectrum of health literacy materials. Irrespective of the limitations, it has been used in various disease specific areas to assess health literacy. However, the time it takes to administer does not allow for daily use in clinical settings. Therefore, researchers began to explore the development of a shortened version.

Short-Test of Functional Health Literacy Assessment in Adults (STOFHLA)

In an effort to create an effective brief measurement tool that captured the same information as the Test of Functional Health Literacy Assessment in

Adults (TOFHLA) in less administration time, Baker and colleagues (1999) tested screening questions to identify patients with inadequate or marginal health literacy skills. Therefore, they developed the Short Test of Functional Health Literacy Assessment in Adults (STOFHLA). The STOFHLA has four numeracy items, compared to the seventeen items in the TOFHLA and 2 prose passages, as compared to the 3 passages in the TOFHLA. The correlation between the STOFHLA and the Rapid Estimate of Adult Literacy in Medicine was 0.80. Because of the shortened measurement, (the TOFHLA takes about 22 minutes to complete compared to about 7 minutes for the STOFHLA) the adequate reliability and validity; the STOFHLA is a more practical measurement tool for conducting research (Baker). A copy of the STOFHLA is included in Appendix L. While a copy of the instrument is located in the appendix, this tool was purchased (license number 052/08) for the purpose of this research project. This tool cannot be copied in any shape, form or fashion without permission from the Perppercorn Books & Press.

Sharif and Blank (2010) conducted a study to determine if there was a relationship between child literacy and body mass index. The STOFHLA was selected to measure each parent and child's health literacy level. Children age 6-19 were included in the study. Children were enrolled with one parent or legal guardian who brought them to the clinic visit. The mean score of the children was marginal, while the mean score of the parent was adequate. Of the 78 eligible participants, child health literacy was negatively correlated with

BMI scores in overweight children. This study supports other research that suggests that the higher the educational level the higher the literacy level. This study is important to understand the opportunity for further research in this area disease or content specific literacy. It was also important in understanding the usage of the STOFHLA in children.

Persell and colleagues (2007) tested ambulatory patients to determine if limited health literacy was a barrier to medication reconciliation. Thirty-seven of the 119 participants had inadequate literacy. While most individuals were able to identify the number of medications, those with inadequate health literacy were less likely to name any of their medications. Health literacy was assessed with the Short Test of Functional Health Literacy. Medical records were used to identify the number and name of patient medications.

Morris, MacLean and Littenberg (2006) conducted a cross sectional study of 1002 English speaking adults with diabetes to determine if there was a relationship between health literacy, physiological control and diabetes complications. A cross sectional study of 1,002 English-speaking adults with diabetes were randomly selected to participate in this study. The finding suggest that literacy, as measured by The Short Test of Functional Health Literacy in Adults, was not associated with glyated hemoglobin, blood pressure, lipid levels or self-reported diabetes complications. These findings do not support other literature that suggests literacy levels are associated with poorer knowledge of disease. The authors suggests that they way health

literacy is assessed may need to be further researched. This point is key to understanding the health literacy assessment tools and the reliability and validity in various populations. This will be discussed at length in the discussion section of this document.

Despite the availability of valid health literacy assessments tools, many of the instruments are time consuming and not practical to use in busy clinical settings (Chew, *et al*, 2007). While the long and short versions of the Test of Functional Health Literacy in Adults and the REALM are the most widely used test to measure health literacy, other tests have been developed to measure health literacy more effectively.

Chew and associates (2004) created a brief questionnaire to identify patients with inadequate health literacy. The purpose of their research was to identify a clinically appropriate use of questions that might be effective in identifying patients with marginal or inadequate health literacy. The sixteen questions were developed based on five domains: 1) navigating the health system, 2) completing medical forms, 3) following medication instructions, 4) interacting with providers and 5) reading appointment slips. To ensure that patients did not underreport reading difficulties, questions were phrased to ask "how often" or "how confident", they were in each of the themes. They also scaled the responses for each question on a likert scale of zero to four. They found that these questions were effective for identifying patients with inadequate or marginal health literacy. However, to further identify patients

with inadequate health literacy, the tool was narrowed down to three questions using the Area under the Receiver Operating Characteristics Curve (Chew, Bradley & Boyko). Because of the effectiveness in the use of these questions, the Prenatal Care Test of Functional Health Literacy Assessment was modeled after this health literacy method.

While each test has been extensively used in the literature to measure health literacy, discussions have begun around the need for a more comprehensive, context-based measure of health literacy.

Disease specific measures of health literacy

While the TOFHLA, STOFHLA and the REALM are the most documented health literacy measurement tools identified in the literature, other researchers have begun to develop disease specific health literacy measurement tools (Gong, Lee, Rozier, Pahel, Richman & Vann, 2007). This allows the assessing of participants to on content that may be familiar to them.

Gong and associates (2007) developed a dental test of functional health literacy. Using the original Test of Functional Health Literacy Assessment, the researchers used patient education materials used in a pediatric dental clinic to create the Test of Functional Health Literacy in Dentistry (TOFHLiD). The TOFHLiD was reviewed by an expert panel to establish construct validity. Additionally, predictive validity was determined by testing three established hypotheses regarding health literacy and dental

health outcomes. Finally, internal reliability was established by using Cronbach's alpha (0.82).

Diamond (2007) developed a reliable measure of nutritional literacy in adults using The Short Test of Functional Health Literacy in Adults (STOFHLA). The content for the nutritional health literacy assessment was derived from declarative sentences found in nutritional related websites. The assessment tool was piloted with 132 adult patients. Content validity and construct validity was established. Similarly, internal consistency was established using Cronbach's alpha (0.84).

Agre, Stieglitz and Milstein (2006), reviewed the need for reading assessment tools for patients with cancer and analyzed existing reading assessment tools to determine if a new tool specific measure was needed for cancer patients. They argued that word-recognition tests are quick and easy to administer but may not capture information about understanding. While the TOFHLA is an improvement it also has limitations. First, it feels too much like a test and may intimidate participants. Second, results place participants into one of three categories based on a three sample passages in a wide range of reading levels. Lastly, the content of the instrument is narrow. The outcome provided the argument for the development of a new test of health literacy for cancer populations. The proposed assessment tool, while only being used in research is modeled after an informal reading inventory, which is based on participant's individual comprehension level. The assessment has following

content: 1) a graded words-in-isolation test, 2) a series of graded reading passages based on cancer topics, 3) a set of five questions for each passage to assess comprehension of the text and 4) a procedure to determine reader familiarity with the content of each selection. The final outcome of this measure would prove helpful in identifying cancer patients with limited health literacy. This supports the development of disease or content specific health literacy assessments.

Jeppesen, Colye & Miser (2009) developed screening questions to predict limited health literacy in patients with diabetes. They wanted to determine which screening questions and demographic information independently predict limited health literacy. Two hundred and twenty five (225) patients being treated for diabetes were asked several questions regarding their reading ability. The Short Test of Functional Health Literacy in Adults was administered to measure health literacy level. They found that self-reported reading ability coupled with education level, sex and race independently predicted whether a patient has limited literacy.

Chew and colleagues (2004) created a practical method for identifying patients with low health literacy. They developed screening questions based on five domains: 1) navigating the healthcare system, 2) completing medical forms, 3) following medication instructions, 4) interacting with providers and 5) reading appointment slips. The domains were selected based on poor health literacy outcomes found in the literature. Sixteen questions were developed,

pilot tested, revised to increase clarity and reduced to three questions that identified individuals with inadequate health literacy. The Short Test of Functional Health Literacy in Adults was used for comparison standards. Because the questions used in this measurement tool are more closely linked to the variables indicated in the definition of health literacy: obtain, process and understand; this tool was used as the model for the development of the Prenatal Care Test of Functional Health Literacy created for this dissertation study. Most of the disease specific measures of health literacy have used the STOFHLA or the TOFHLA to develop their instruments. However, as the literature has shown, both measures have limitations. Additionally, they do not, on the surface, seem to address understanding and processing health related information as the definition of health literacy suggest. Therefore, the use of Chew and associates method of directly asking level of comfort or confidence in each of the domains of the health literacy definition, obtain, process and understand, were used in the development of the Prenatal Care Test of Functional Health Literacy assessment. The knowledge section established some basic level of understanding prenatal care content and the attitude section assessed the comfort and confidence in the specific area of prenatal care.

Each instrument discussed herein has strengths and limitations in measuring health literacy. The limitations range from not being comprehensive to the length of time it takes to administer. Ultimately,

understanding and measuring patients' understanding or comprehension could improve health outcomes, specifically in maternal and child health.

As indicated, there is an increasing body of research that shows that literacy is linked to health status. In fact, a positive association between health literacy and physical health has been widely documented in the literature (Arthur, Geiser, Jacob-Arriola & Kripalani, 2009; Scott, Gazmararian, Williams & Baker, 2002; Wolf, Gazmararian & Baker, 2005). However, this literature concentrated on specific populations, such as the elderly. These findings however, indicate that there may be a relationship between health literacy and health in the general population.

In order to assess health literacy in a prenatal care context, a prenatal care health literacy assessment tool has been developed and reviewed by an expert panel for the purpose of this study. A copy of the prenatal care test of functional health literacy created by the Principal Investigator specifically for use in this dissertation research project is included in the Appendix.

Health Literacy assessment and health

DeWalt and colleagues (2004) assessed the relationship of literacy and health outcomes. Several studies document the prevalence of limited health literacy skills as measured by the REALM or TOFHLA among patients in general medicine and pediatric clinics, specialty care clinics including those for asthma, HIV, family planning, obstetrics and oncology (Gazmararian et al, 1999; Williams et. al, 1995; Dolan et al., 2004; Davis et al, 1996). Studies

were conducted at healthcare facilities, community based- sites including retirement homes and social service agencies.

Health literacy and physician-patient communication

Effective communication between patient and provider may be able to improve health literacy. Researchers have begun to explore and report the relationship between health literacy and physician-patient communication (Arthur, Geiser, Arriola, Kripalani, 2009). Patients with low health literacy have difficulty communicating during the medical encounter (Powell, 2009. Schwartzberg, VanGeest & Wang, 2004). Similarly, physicians do not accurately estimate patients' health literacy skills and subsequently do not address all of patients' needs (Bass, Willson, Griffith, 2002). Communication skills required to perform tasks important to healthcare include skills that allow a person to narrate, comment, explain, request, respond, inform within a specific context (Hester, 2009). This can be challenging for many members of the population. Thus, fewer questions are asked and physicians are not certain if patients understand important health related information or instructions. While communication is critical in all areas of health, understanding if this is affected during the prenatal care experience is important to pregnancy and birth outcomes.

Patients with inadequate health literacy may be at risk for poor physician-patient communication. Arthur, Geiser, Jacob Arriola & Kripalani (2009) conducted a study to determine the effects of the physician-patient

relationship in patients with inadequate health literacy skills. They analyzed 31 transcribed patient visits between African American patients with diabetes and their physicians. They used the Rapid Estimate of Adult Literacy in Medicine (REALM) to test for health literacy. They used the Roter and Hall styles of physician-patient interaction to demonstrate the level of control within the patient encounter. The levels described by Roter and Hall are: Paternalism, where the physician exercised greater control and patients are passive; Consumerism, where patient has the dominant role and the physician is passive and finally; Mutuality, where there is shared control between patient and physicians. They found that patients with inadequate health literacy were more likely to have paternalistic interactions with their physicians. This supports findings by Hester (2009) that patients with lower health literacy are more likely to have a non-autonomous patient-physician relationship. This concept is discussed in more detail in the discussion section of this document.

Health Literacy and demographic and socioeconomic factors

Health literacy is associated with many demographic and socioeconomic factors. Education, occupation and income are markers of socioeconomic status (SES) and health (Paasche-Orlow & Wolf, 2007). The United States Government tracked health statistics related to SES and found that each increase in social position, measured either by income or education, improved the likelihood of being in good health. This SES gradient was

observed for persons of every race and ethnic group examined (USDHHS, 2006). A relationship between low socioeconomic level and fewer years of education and a relationship of both variables to low literacy have been established (Rudd, 2002). For example, a study examining health literacy in an underserved ethnic-minority group seeking community-based treatment services for HIV infection found that years of education were associated with understanding HIV terms and accurately reading and understanding instructions on prescription bottles. Fewer years of education predicted poor understanding (Van Servellen, Brown, Lombardi & Herrera, 2003). Similarly, Farmer and Ferraro (2005) found significant interactions between race and education as well as race and employment status on health outcomes such that when education levels increased for Blacks it was found that they did not have the same improvement in self-rated overall health as Caucasians over time. This suggests that those individuals with lower education and in a lower socioeconomic level are more susceptible to low health literacy.

In other studies, fewer years of schooling or lower educational status was associated with limited health literacy in Black primary care patients. Association with race remained significant when stratified by educational level (Beers et. al, 2003). Low education, but not poverty, was significantly correlated in a study of family planning knowledge of low income women in a Medicaid managed care plan (Gazmararian, Parker & Baker, 1999). This also

suggests that a relationship exists between low education and low health literacy.

As disparities continue to persist in health conditions such as diabetes, hypertension, birth outcomes, HIV/AIDS and cancer, the burden of low health literacy is apparent in various racial and ethnic populations (World Health Organization, 1998). Health literacy concerns affect people from all backgrounds. According to the Center for Healthcare Strategies, 50% of Hispanic Americans and 40% of Blacks have reading problems (Potter & Martin, 2005). The Center for Healthcare Strategies asserts that literacy skills are a stronger predictor of an individual's health status than age, income, employment status, education level or racial/ethnic group (Potter & Martin, 2003). Health literacy empowers individuals to act appropriately in health related circumstances (Speros, 2004). Therefore, understanding the barrier that health literacy plays in engagement in preventive health services is greatly important to improving the health of the nation.

Additionally, medical literature links socioeconomic status factors such as income, education, profession or a combination of the three with health outcomes. Illiterate individuals are more likely to live in poverty, have less years of education, have more health problems or be older or imprisoned (Fouk, Carroll & Wood, 2001). Similarly, various demographic factors such as race and age are of great interest in this area of research because health literacy is highly correlated with these factors.

Black, American Indian/Alaskan Native, Hispanic, and Asian/Pacific Islander adults are more likely than Caucasian adults to perform in the two lowest literacy levels according to the NALS (Kirsch, 2001). Up to 20 percent of Spanish-speaking patients do not seek medical advice because of language difficulties. Two-thirds of US adults over age 60 have difficulty with literacy skills, while over 80 percent of patients at a public hospital could not read prescription labels (Kirsch). The average proficiency of Caucasian adults is significantly higher than the average proficiency of Black, Hispanic and other adults living in the United States. With the exception of Caucasian Americans, more than 10% of each of the other racial/ethnic groups is estimated to be below level 1, which is below basic (Kirsch, 2001). Thirty percent of all adults performed in this level, suggesting that individuals with low health literacy find themselves working through a system that is difficult to navigate. Individuals who are in a lower socioeconomic status and have fewer years of schooling will find themselves in similar situations (Williams et al, 1995). Sudore and colleagues (2006) found after analyzing the relationship between health literacy, demographics and access to healthcare, that after adjusting for socio-demographics, an association remained between limited health literacy, being male, Black and having low income and education.

The NALS found that the functionally illiterate were more likely to be poor, unemployed, and working in jobs subject to seasonal and general

economic fluctuations (Potter & Marin, 2005). Individuals living in poverty have lower health literacy scores on the NALS than those with higher incomes. On average, people across all populations with incomes below 125% of the federal poverty guidelines have health literacy scores in the basic range, while individuals with higher income or 175% of the guidelines or higher, usually fall into average health literacy scores, which place them at an intermediate level (Potter & Marin).

Literacy, health literacy and health outcomes

As indicated, there is an increasing body of research that shows that literacy is linked to health status. In fact, a positive association between health literacy and physical health has been widely documented in the literature. However, this literature concentrated on specific populations, such as the elderly (Baker, Gazmararian, Williams et al, 2002; Gazmararian, Baker, Williams Parker, Scott, Green et al., 1999; Scott, Gazmararian, Williams & Baker, 2002). These findings however, indicate that there may be a relationship between health literacy and health in the general population.

Weiss (1992) investigated 193 adults in a basic education class to determine if there was a relationship between literacy and health. He found that subjects with the lowest reading skills had poorer self-reported physical health. This relationship was consistent even after adjusting for poverty, age, education and ethnic background. Similarly, in a study of 483 asthma patients, an association was found between reading ability and asthma

knowledge. Among the patients who were reading below the third grade level, 89% had poor metered-dosed inhaler technique compared to 48% of patients reading at high school level (Williams, Baker, Hoing, Lee & Nowlan, 1998). Similarly, low parental literacy was found to be associated with worse asthma care measures in children (Dewalt, Dilling, Rosenthal & Pignone, 2007). Additionally, Wolf, Davis, Cross and Marin (2004) interviewed 157 HIV infected individuals receiving care at a community-based clinic. Additionally, a 50-item structured interview was conducted to assess demographic information, drug history, HIV care history, HIV-related knowledge, sources of HIV information, and the name of patients' HIV medication and recommended regimen. The REALM analysis indicated that 23% of participants read at or below the 6th grade level, 25% read at the 7-8th grade level and 52% read at the 9th grade level or higher. One-third of participants could not name their HIV medications, which was significantly related to low literacy ($P < 0.01$). Two-thirds of those reading below the 9th grade level did not know how to take their medications correctly and 75% did not know the meaning of CD4 count or viral load ($P < 0.001$), both indicators of the state of their disease management. Similarly, another study (Davis et. al., 2006) found that 39% of women reading below fourth grade level did not know why women are given mammograms, compared with 12% of those reading at or above a ninth grade level. Patients who had inadequate reading skills were not aware that mammograms are associated with cancer, looking

for abnormalities or an examination of the breast. However, women with adequate literacy skills were knowledgeable about mammograms and their purpose (Davis et al.). This supports the research mentioned earlier that suggest literacy plays an important part in receiving adequate healthcare as well as engaging in preventive health services (Speros, 2005).

In another study of 2,659 public health patients seeking emergency care at two public health hospitals (Baker, 1997) participated in this research. Patients, who were identified as having inadequate health literacy on the Test of Functional Health Literacy (TOFHLA), were twice as likely to have poor self-reported health status than adults with adequate literacy. In fact, literacy was more highly correlated with health status than were educational level and other sociodemographic factors (Baker, 1997). Schillinger et al., (2002), also using the TOFLHA, found that health literacy was associated with poorer diabetes care outcomes among 408 patients with type-2 diabetes in a public hospital, even after adjusting for sociodemographics, diabetes education, treatment regimen, and diabetes duration. In another study of low income Black adults with low literacy, as measured by a three level literacy screening instrument created by the researchers, participants were more likely to have heart conditions and diabetes, even after controlling for age and sex (TenHave et al. 1997).

So to summarize briefly, the key discussion points in the literature regarding the concepts of literacy and health literacy, it is known from the

literature that there is a difference between general literacy and health literacy. Health literacy plays a part in health and health outcomes. Health literacy skills are also important during the medical encounter because as Hester explained, patients and physicians are expected to have good communication with each other during the medical encounter to benefit and have good outcomes. (Hester, 2009) However, as Arthur and colleagues indicated, when a patient has poor health literacy levels, they often sacrifice their autonomy and allow the physician to exercise control over their care. (Arthur et. al., 2009). Further, as Kalichman and colleagues and Williams and colleagues would remind, patients with lower health literacy levels would likely not be able to understand well their treatment options or adhere to their treatment regimens. (Williams et. al., 1995; Williams et. al., 1998).

Additionally from the literature, there are several ways to test general health literacy. Recall that general health literacy is defined as the basic literacy needed in a healthcare environment (United States Department of Health and Human Services, 2001, p. 16). However, recall that when one is facing a special disease or condition, it might be helpful when there is more health knowledge and understanding specific to that disease condition or circumstance available while navigating through the healthcare system. However, this is where knowing whether the level of disease or content specific health literacy is adequate enough or not to understand and communicate effectively to make appropriate decisions for oneself or their

loved ones becomes essential. If one follows the current literature, tools available to assess general health literacy, such as the STOFHLA (Baker et. al., 199), do not really exist for determining disease or content specific health literacy on any appreciable level.

Further, it is also critical to have a basic level of understanding disease or condition specific concepts because of the importance of seeking and accessing healthcare screenings and preventive care services, as explained by Fortenberry (2001) and Lindau (2002). Of particular interest to me in this regard is prenatal care during pregnancy. That is, the condition specific literacy that will be discussed further in this chapter.

As is also clear from the literature, healthcare takes on many shapes and fashions, and is built of various components. There are various disciplines of health, structural foundations and navigational systems, financial systems and auxiliary services that make up the current health system. Further review of the literature reveals that in order to succeed in healthcare, it is necessary to have an understanding of, at minimum, the most basic concepts in healthcare. However, at what point is this level inadequate? It becomes inadequate when one needs to understand other components, because the healthcare being discussed is highly technical, such as in cancer care. Based on this generalized discussion in the literature, one specific healthcare area is of particular interest to this author, and is the subject of this dissertation research: prenatal care.

Prenatal Care

Prenatal care is a central component of maternity care (Taylor, Alexander, Hepworth, 2005, Hack, Taylor, Klein, Eiben, Schatschneider, Mercuri-Minich, 1994). Prenatal care is defined as pregnancy related healthcare services provided to women between conception and delivery (USDHHS, 2000). Seeking and participating in consistent prenatal care is an important health promoting behavior contributing to beneficial pregnancy outcomes including, but not limited to, an increase in maternal and infant well being, a reduction in maternal morbidity and mortality, a reduction in maternal risk and a reduction in preterm birth (USDHHS, 1999). Early initiation of and adherence to prenatal care are important aspects of a healthy pregnancy for mother and child (US Government Printing Office, 2000).

The American College of Obstetrics and Gynecology (2007) suggests that prenatal care should begin in the first trimester, occur every four weeks until week twenty-eight, then every two weeks until week thirty-five and then weekly until birth. Prenatal care involves a series of visits with one or more medical providers and includes components such as blood pressure measurement, weighing, urinalysis, abdominal exam, and some basic health education (Kramer, Seguin, Lydon & Goulet, 2000). Prenatal care visits provide an opportunity for physicians to identify risk factors for low birth weight and preterm labor and delivery (Berhman & Stith-Butler 2006;

USDHHS, 2002). In addition to medical care, prenatal care programs often include comprehensive educational, social, and nutritional services.

The *ante partum* experience, or the period prior to birth, predicts not only immediate neonatal outcomes, but also long term outcomes including post neonatal mortality, school performance, behavior problems and intelligence (Hack, Taylor, Klein, Eiben, Schatschneider, Mercuri-Minich 1994; Sanders-Phillips & Davis, 1998). Although the issue of school performance, behavior problems and intelligence will not be discussed in this paper, it is important to note the long term problems that may exacerbate health related problems such as low or high health literacy and health outcomes later in a person's life.

Etiology

Prenatal care has been recognized as the cornerstone of healthcare for pregnant women since the beginning of the twentieth century (Keily & Kogan, 2003). The idea of organized prenatal care has been attributed to earlier concepts generated by Ballantyne in the early 1900s. Ballantyne's initial interest in prenatal care stemmed from the prevention of fetal abnormalities. His research observed connections between eclampsia and albumin in the urine and high blood pressure in pregnant women. He later discovered that prenatal care might also reduce maternal, fetal and neonatal deaths (as cited in Alexander and Kotelchuck, 2001).

Reducing maternal morbidity and mortality were among the earliest outcomes targeted as a benefit of prenatal care. Originally, the core components of prenatal care were implemented as a result of eclampsia and toxemia in pregnancy. These concepts shaped the content of prenatal care and played an important role in establishing the timing and frequency of visits (Alexander and Kotelchuck, 2001). During the early 1900s, the hypothesis that prenatal care could reduce the risk of low birth weight and preterm births and resulting mortality, gained much respect. In 1915, J. Whitridge Williams of Johns Hopkins Hospital, championing the potential benefit of prenatal care, asserted that prenatal care and instruction offer great possibilities for the diminution in the number of deaths due to prematurity because of the discovery of and prevention of birth related problems that occur during the pregnancy (as cited in Kiely & Kogan, 2006, p. 105). This began the documented research surrounding prenatal care and birth outcomes.

Prenatal care and birth outcomes

The most common factors contributing to poor birth outcomes are low birth weight and infant mortality. Prenatal care is critical in ensuring successful birth outcomes through health and education about maternal health. A successful birth outcome is defined as the birth of a healthy baby to a healthy mother (Institute of Medicine, 1985). Although the idea of causal relationships between prenatal care and birth outcomes is controversial, recent literature suggests that engagement in prenatal care and adherence to

recommend schedules positively influence both birth outcomes and lower mortality rates (Groutz & Hagay, 1995; Henderson, 1994; Johnson et. al, 200; Lewis, Matthews & Heuser, 1996). Additionally, poor birth outcomes have been associated with little or no prenatal care (Herbst, Mercer, Beazley, Meyer, & Carr, 2003; Higgins & Murray, 1996).

Taylor, Alexander and Hepworth (2005) studied the differences in pregnancy outcomes among Black, Caucasian and Hispanic women receiving no prenatal care. In a no-care sample of 126,200 women, they found that not only are women who receive no prenatal care characteristically different from women who receive any care, but also that birth outcomes varied among the groups but were always worse for no care in comparison to women in the any care group.

The total population studied for this analysis was over 10 million, and of that, only 126 thousand had no care. Women in the “no care” group were clustered into six distinct categories based on socio-demographic and medical risk factors. Women receiving no care were more likely to be Black or Hispanic, unmarried, younger, less educated, foreign born, multiparous and urban dwelling. Aligning their findings with the findings discussed herein on literacy and health literacy among populations reveals that individuals in lower socio-economic, socio-demographic, educational and literacy populations are not taking advantage of healthcare, wellness and preventive care services and have poorer health outcomes in general, again suggesting

a need to further investigate the impact of health literacy and health-specific literacy in pregnancy preventive care.

Interestingly, in reviewing the literature, there does not seem to be any newly developed content specific tools designed yet to measure prenatal care based health literacy levels, although this is not wholly unexpected. Recall that only two disease or content specific tools are discussed in the literature, developed by Gong and colleagues and Diamond, both in 2007, respectively, and those only addressed dental and nutrition. So one element not yet known or discussed in the literature is whether or not health literacy plays a part in any of these outcomes.

Prenatal Care and Literacy

There is a relationship between educational attainment and prenatal health. Women with lower educational levels engage in prenatal care later in pregnancy. Similarly, as a woman's literacy level increases, infant mortality decreases (Zarcdoolas, Pleasant & Greer, 2006). Health literacy in pregnant women in the literature is limited. However, a few articles were found to be important to the issue of health literacy and prenatal care.

Endres (2004) conducted a pilot study of 74 women to determine if there was a relationship between health literacy and pregnancy preparedness in women with pregestational diabetes. About 19,000 women with pregestational diabetes become pregnant each year (Endres). Appropriate planning and pre-pregnancy counseling for these women can decrease the

risk of poor birth outcomes. In the Endres study, women with pregestational diabetes completed the TOFHLA. Additionally, another survey that included socioeconomic questions as well as questions regarding overall health, diabetes control and basic conception information was administered. Significant differences were ($p < 0.05$) found between the low and adequate literacy groups for factors related to pregnancy preparedness. The researchers found that women with low functional health literacy were more likely to have an unplanned pregnancy than women with intermediate or adequate health literacy levels. These same women were also found to be less likely to have discussed becoming pregnant with the healthcare provider who managed their diabetes (Endres).

More recently, Bennett et al. (2007) examined whether low health literacy was associated with depressive symptomatology in pregnant Latinas with limited English proficiency. Ninety-nine Latina women participated in this study. The women were recruited from a larger study on maternal stress and birth outcomes. All of the women completed the original study interviews in Spanish, thus making them eligible for this study. Women were identified as either Mexican or Non-Mexican. Health literacy was assessed using the STOFHLA, the short version of the Test of Functional Health Literacy in Adults. Depressive symptomatology was assessed using the Spanish version of the Center for Epidemiological Studies Depression Scale (CES-D), a 20-item instrument widely used to assess depressive symptomatology (Bennett,

Culhan, McCollumn, Mathew & Elho). They found that women in prenatal care who had limited English proficiencies were more likely to have inadequate literacy and had a greater chance of having maternal depressive symptomatology. This study was consistent with other studies that found that Latina immigrants have higher rates of depressive symptomatology than other populations. Additionally, the women who were identified as having inadequate health literacy were also found to be at greater risk for depressive symptomatology. They suggested an association between literacy and depressive symptomatology that may be prevalent in English speaking populations as well (Bennett). This study could be important for further explaining the role that health literacy plays in engagement in prenatal care. The study supports the need for further research in the area of health literacy and prenatal care engagement. Although the variables and populations included in these research studies are different, it is reasonable to assume that similar results could be found in different population of women regarding prenatal care engagement.

A year earlier, Bennett et al., (2006) looked at patient-clinical communication and prenatal care among black women of low and high literacy. A grade level was assigned to each woman based on results of their REALM score. Two hundred two women were recruited from an urban Medicaid obstetrics practice within the University of Pennsylvania. Women were recruited within 48 hours of giving birth. Thirty-three women were

determined to have low literacy based on having less than a sixth grade reading level. This overall small sample size and an extremely smaller literacy sample size is a major limitation of this study. Prenatal care was defined by the Adequacy of Prenatal Care Utilization index (APNCU). Adequate care was assigned if the woman initiated prenatal care during the first trimester and inadequate care was assigned to women who initiated care in the third trimester or not at all. The Cultural Domain Analysis, a combination of a free listing and cultural consensus analysis, was used to determine how members of the group defined a particular domain of understanding. The free listing is a qualitative method used in this study to explore various topics of prenatal care. The cultural consensus yields a numerical value for the items listed in the free listing. The cultural consensus is a function of Anthropac®, a software package (Bennett, Switzer, Aguirre, Evans & Barg). Focus groups were conducted to confirm the information obtained from the Cultural Domain Analysis. The women in the study all had extremely high levels of poor prenatal care.

Although the researchers were surprised by their results, within the sample of 202 women they did not find a difference in prenatal care utilization among individuals of low and high literacy. However, they found that communication with clinicians influenced these women's decision to engage in prenatal care (Bennett, Switzer, Aguirre, Evans & Barg, 2006). The ability of a clinician to clearly communicate by breaking down important concepts

and provide continuous prenatal care, being trusted by the patient, and having close patient-clinical relationship were all important factors to the patient when deciding to engage or not engage in prenatal care (Bennett et al.). This study is important because it stresses the importance of the communication and the understanding that occurs during the medical encounter. Therefore, it is important to look at both utilization and at the patient's level of understanding regarding their specific disease or condition.

Similarly, Iranian researchers (Kohan, Ghasemi & Dodangeh, 2007) conducted a study among 150 randomly selected women from a hospital in Isfahan. This descriptive study included 150 postpartum women who were recruited from a hospital in Beheshti, Isfahan. These women had completed a gestational period of 28 weeks or more and had a general literacy as defined by guidance school level. Women who had either a dangerous pregnancy period including pre-eclampsia, twins, severe vomiting or had graduated in the medical sciences were excluded from the study. The women completed a questionnaire that included demographic information, outcome of the pregnancy and evaluation of the mother's literacy level through the mother's perception and ability of pregnancy care, diagnosis of dangerous symptoms, having a suitable diet and the quality of a healthy life during the pregnancy. They scored the questions according to the total number of answers. Although the article notes the questions were valid and reliable and mentioned the validity and reliability methods used, there were no

factors of reliability or validity provided. The researchers concluded that 68% of the sample were housewives, 61% had high school diploma or higher, 54% were in the average socioeconomic status and 58% were between 20-28 years old. (Kohan et al.). Eighteen percent of the women had good maternal health literacy, 48% had average health literacy and 34% had weak health literacy. All of the women with good health literacy began prenatal care during the first trimester and received sufficient care, while more than 60% of the women with weak health literacy had insufficient prenatal care. The researchers concluded that there was an association between maternal health literacy, prenatal care and pregnancy outcomes (Kohan et al.). Even though the variables included in this study are categorically important to the prenatal care research, the methods used in assessing health literacy do not include recognized reliable and/or valid measures. However, this study's findings are certainly in line with the research that is needed to understand health literacy and prenatal care literacy.

As stated before, health literacy is critical to have during the medical encounter and better health literacy leads to better health outcomes. It is also known that prenatal care is a preventive health service that reduces poor birth outcomes. Additionally, it is known that disparities exist in birth outcomes, specifically in minority communities (Johnson et al., 2007; Groutz & Hagay, 1995) and that several researchers between 1995 and 2007 (Johnson et al., Krueger & Scholl, 2000; Lewis and colleagues, 1996; Taylor et al., 2005)

have all shown a direct relationship between prenatal care and improved birth outcomes. It has also been shown that women with higher health literacy generally engage in prenatal care more than women of lower health literacy. (Bennett, 2006; Kohan, Ghasemi & Dodangeh, 2007).

Despite these facts there are still several unknowns surrounding health literacy and prenatal care in the literature. For example, considering the fact previously stated that health literacy assessment among patients, currently measured by one of three widely accepted tools (the REALM, TOFHLA/STOFHLA or WRAT-R) may not be sufficiently adequate today given the technical nature of healthcare, disease or content specific healthcare assessment tools are beginning to be developed, initially in the areas of dentistry and nutrition. (Gong et al, 2007, Diamond, 2007). Also, while there are some findings reported, most notably by Endres (2004) and by Bennett et al(2006) and again by Bennett et al (2007), all centering on pregnancy/prenatal care and health literacy, a health literacy assessment tool specific to prenatal care has not been identified in the literature. Further, it is still unclear if there is a relationship between general health literacy and prenatal care health literacy. These areas of uncertainty in the literature made it possible to pursue the area of prenatal care and health literacy reported in this research dissertation.

Summary

While most of the studies discussed have suggested a strong association between literacy and health in specific populations, especially in populations in which low literacy is common, such as among the elderly and the poor, research is sparse when searching for studies of the general population. There are many confounding factors affecting functional health literacy. Anyone may be likely to require assistance when seeking healthcare (USDHHS, 2000). When looking at literacy, health literacy and outcomes, other variables such as socioeconomic status and race and ethnicity must be considered. Included in socioeconomic status are education, income and occupation. Certain populations such as the elderly, minorities, immigrants and individuals with low socioeconomic status are disproportionately affected by the negative outcomes of low health literacy skills (Kirsch, Jungleblut, Jenkins, & Kolstad, 1993).

This review includes an extensive review of general literacy, health literacy and prenatal care research. The current research includes important advances in the areas of health literacy. While much has been learned from the existing research, there is a paucity of information on content specific literacy in the healthcare arena, specifically regarding prenatal care. Recall that prenatal care is the care a woman gets while she is pregnant (American College of Obstetrics and Gynecology, 1997). A doctor, midwife or other healthcare professional can provide this care. The goal of prenatal care is to

monitor the progress of pregnancy and to identify potential problems before they become serious for either the mother or the unborn child. It is clear from the literature that women who see a healthcare provider regularly during pregnancy have healthier babies and are less likely to have poor birth outcomes (Lewis, Matthews & Heuser, 1996). It is also clear that effective language and communication skills are integral to patient-provider communication (Hester, 2009). Therefore, ensuring that women in prenatal care understand the content and context of that care is critical to successful pregnancy outcomes. Because of the importance of prenatal care to on birth outcomes, it is critical to understand if there is a relationship between general health literacy levels and prenatal care health literacy levels.

Chapter Three

METHODOLOGY

Introduction

The goal of this study was to determine if a predictive relationship existed between general health literacy and prenatal care health literacy and whether the inclusion of demographic variables enhanced the predictive relationship between these literacy measures. Three survey instruments were used to assess the variables included in this research project. Chapter three explains the overall research design, the sampling, the instrumentation, the data collection procedure and analysis.

Research Design

This study utilized a cross-sectional, descriptive and correlational research design. A cross-sectional study was employed as data was collected at one point in time to prevent testing or history effects from influencing differences among the participants. (Polit & Hungler, 1995). In this case, data was collected from first time pregnant women representing several educational levels and ethnic groups who were seeking services at prenatal care clinics at one point in time. According to Polit & Hungler (1995), the purpose of a descriptive, correlational design is to describe variables and examine relationships among them. No attempt is made to control or

manipulate the variables. A correlational design was used to determine: 1) if a predictable (linear) and significant relationship existed between the participants' levels of general health literacy and their prenatal care health literacy; and 2) if general health literacy levels correlate linearly (predictably) with prenatal care health literacy levels, in pregnant females. Additionally, demographic characteristics of the sample will be organized and summarized through a descriptive design. The decision to use a descriptive and correlational design is supported by Portney & Watkins (2000), who state that a descriptive design is appropriate to use when documenting phenomena of individuals or groups of individuals under study, while correlational designs are generally suitable for describing the nature of existing relationships among variables.

Incidentally, most empirical research belongs clearly to one of two general categories: correlational or experimental. (Portney & Watkins, 2000) In correlational research such as in this study, there is a conscious attempt made not to influence any variables but to only measure them and look for relationships (correlations) between some set of variables (e.g. general literacy and prenatal health literacy levels). In this study, no such manipulation is occurring and hence no causation may be implied in the results obtained. Here, the data obtained from correlational research can only be "interpreted" in causal terms based on identified theories, but the

correlational data cannot conclusively prove causality. (Portney & Watkins, 2000).

Sampling Procedure

Statistical hypotheses, such as those accompanying the research questions forming the basis of this study, are statements of observed generalizability, or statements about the study's population parameters, where this study's population is defined as a complete set of individuals, objects, or measurements having some common observable characteristic. Here, the target population for this project was a convenience sample of first time pregnant women presenting for prenatal care at either of two locations in the State of New Jersey: Newark Community Health Centers (North Jersey) and the School of Osteopathic Medicine Women's Health Center (South Jersey). Both are community based health centers catering to the needs of a diverse population. Statistical hypotheses can be evaluated by statistical tests.

In a perfect world, it would be desirable to run a true post hoc power analysis after the pilot study in order to determine the optimal sample size, which would provide the best opportunity to attain significant results during analysis of the data collected. However, because a large enough sample size sufficient enough to approach a significant result in the pilot study was not obtained, a post hoc analysis was not possible. Also, the pilot was intended

to test methodology, thereby not necessitating a particularly large sample population greater than the 11 sample participants used in the pilot study.

Usually when conducting a statistical analysis, more often than not, one does not have access to an entire statistical population of interest, for one of several reasons: the population is too large, is unwilling to be measured, or the assessment process is too expensive or time-consuming to allow observation of more than just a small segment of the population. (Hill & Lewicki, 2007) Consequently, important decisions about a statistical population are made based on a relatively small amount of sample data. In this case, what normally happens is that a pilot sample is considered and a quantity is calculated, called a "statistic; this is done so that some characteristic about a population maybe estimated, called a "parameter." The purpose of conducting a power analysis and sample size estimation is to provide the statistical means to determine how precise the parameter estimates will be if a particular sample size is selected and how big a sample must be to attain a desirable level of precision. (Hill & Lewicki, 2007).

Properly selecting a study's sample population improves the probability of detecting differences or associations, therefore researchers are increasingly asked to provide information regarding their respective sample size(s) in their human respondent protocols (IRB applications) and publishable manuscripts (including discussions on power calculations and effect size). Strong recommendations by both the American Psychological

Association (6th edition, Results section) (APA, 2010), and the Task Force on Statistical Inference (VanVoorhis & Morgan, 2007, Wilkinson, 1999), are the forces driving this level of justification today. Therefore, when determining that a reasonable sample size is not possible by post hoc analysis of pilot study data, such as occurred in this study, sample size is often calculated based on assumptions made about three factors: 1) what constitutes a reasonable minimum effect that can be detected; 2) the minimum power needed to detect that effect; and 3) the sample size that will achieve that desired level of power (Hill & Lewicki, 2007).

In determining sample size in this study particularly, and in general, power analysis and sample size estimation involves steps that are fundamentally the same, as follows: 1) the type of analysis and null hypothesis are specified; 2) power and required sample size for a reasonable range of effects are investigated knowing that researchers can manipulate power with sample size; and 3) the sample size required to detect a reasonable experimental effect, or departure from the null hypothesis, with a reasonable level of power, is calculated, while allowing for a reasonable margin of error, which means that power has a relationship with Type I and Type II errors. (Hill & Lewicki, 2007).

The term "effect size" refers to the magnitude of the effect under an alternate hypothesis. The nature of the effect size will vary from one statistical procedure to the next (for example, a difference in cure rates, a standardized

mean difference, or a correlation coefficient), but how effect size functions in power analysis never changes, and it represents the smallest effect of clinical or substantive significance (Hill & Lewicki, 2007). Similarly, power analysis gives power for a specific effect size. Selecting an effect size requires balancing the size of the effect that is detectable and the resources available for the study, which means that small effects will require a larger investment of resources than large effects. These concepts being discussed herein are components of statistical hypotheses testing was also considered as part of the sampling rationale.

There are two types of statistical hypotheses: the Null Hypothesis and an Alternative Hypothesis. The null hypothesis is a hypothesis of no difference; in this study a null hypothesis would be stated as: "The Short Test of Functional Health Literacy Scores do not predict prenatal care health literacy." The alternative hypothesis is simply the opposite: "The Short Test of Functional Health Literacy Scores predict prenatal care health literacy." These are two mutually exclusive hypotheses and both must be stated (or clearly implied) prior to analyzing data; in this study, the null hypothesis is implied and not stated. (Polit & Hungler, 1995; Portney & Watkins, 2000). It is important to qualify here that all statistical analyses only assign a probability level to the null hypothesis or predict how likely it is that the null hypothesis is true.

However, there was a risk with hypothesis testing that needed to be clarified after the pilot study results were obtained because, certain hypotheses were suggesting probabilities, which led to the possibility of making two types of errors, called Type I or Type II. A Type I or alpha-I (α) error is one in which the null hypothesis is rejected when it is really true, which means that a difference is declared when it really does not exist. Conversely, a Type II error occurs when the null hypothesis is not rejected when it is really false, which means that there is a failure to detect a difference when one exists. Type I errors are very concerning and should be minimized whenever possible. (Portney & Watkins, 2000)

To minimize the risk of making a Type-I error in this study, the probability level for rejecting the null hypothesis was set at a relatively low value, which is called the α -level or level of significance. This level is usually set at 0.05 for no other reason than it is generally accepted to be a reasonable level of risk. Here, the α -level of 0.05 means that there is a 5% chance (or 1 in 20, expressed as $1/20$) that the null hypothesis is correct, or conversely, that there is a 95% chance that it is wrong. The rationale for this decision is simple: if statistical analysis yields a probability level less than 0.05, the null hypothesis is rejected and the alternative hypothesis is accepted which is termed a significant difference ($p < 0.05$). Similarly, if the alpha level, or p-value, is greater than 0.05, the null hypothesis is not rejected (recognizing that it is not really appropriate to "accept" the null hypothesis by

scientific convention) (Polit & Hungler, 1995; Portney & Watkins, 2000).

Simply, in this study, such probabilities reflect that there is a less than 1 in 20 chance that any sample will fall outside of the ± 2 SD (95% CI, $p=0.05$) and less than a 1 in 100 chance of any sample falling outside ± 3 SD (99% CI, $p = 0.01$). Alpha is the significance level used to calculate the confidence level, such that $\alpha = 0.05$ indicates a 95% confidence level (CI).

Applying this statistical theory to practicality in this study, this means that the p-value represents a decreasing index of the reliability of the result according to Portney & Watkins (2000). This means that the higher the p-value, the less likely that the observed relationship between variables in the sample N is a reliable indication of the relationship between the respective variables in the population. This means that the p-value represents the probability of error that must be accepted when accepting the observed result as valid or representative of the population. So, in the study herein, the p-value of 0.05 (1 in every 20 survey result packages collected or 5%), represents that, assuming that there is no relationship between the identified variables to begin in the identified population N, there would be one survey package of data returned in which the relationship between the variables found in sample N would be equal to or stronger than what is predicted, and the probability of replicating this 1 in 20 result over and over again across the sample population N is related to the statistical power of the design (Portney & Watkins, 2000).

Additionally, by scientific convention, in this study, the Type I error rate was kept at or below 0.05, and β , representing the Type II error rate, was kept low as well. The corresponding statistical power of 80% or 0.80 in this study, defined as $1-\beta$, where β equals .20, was kept correspondingly high, and ideally, the power was rationalized to be at least 0.80 to detect a reasonable departure from the null hypothesis. In this study, therefore, the corresponding sample size N was estimated to achieve a reasonable minimum effect that should be detected (here, a median effect), a minimum power to detect that effect (here, a power of 0.80 for various values of p), when the null hypothesis is $p = 0.05$, and the sample size N needed to achieve the desired level of power. The package used to calculate the corresponding sample size of 88 first-time pregnant females was G*Power 3.1 by Faul, Erdfelder, Buchner & Lang (2009) and is adequate when providing a power of .80 with a medium effect size. Rationalizing the selection of the key criteria of 0.05 alpha, 0.80 power and 0.3 median effect is as follows. For a power of 0.80 in this study, the asserted p -value of 0.05 assigned is referred to as having a median effect size of .30, in a two-tailed test at .05 alpha, based on a power of .80. Similarly, to reduce the probability of making a Type 2 error or rejecting a true null hypothesis, power was set at .80. Finally, a medium effect size of .30 was set based on criteria established by Cohen (1988), when no previous analysis is available to calculate a true effect size. Cohen's criteria are that a large effect is 0.8 or more, reflecting a standard deviation of 0.8, 0.5 is median or medium

effect and 0.2 is small effect (Cohen, 1988; Cohen, 1998). Further, in this study, the effect size was estimated according to its definition as the degree to which a phenomenon is present in a population (here, regarding health literacy and prenatal health knowledge and attitude levels in first-time pregnant females); it is reflecting an index of how much difference there is between groups and is based on means if the outcome is numerical, proportions if nominal or correlations if association-based (Cohen, 1988). Under all circumstances, an underlying assumption of a normally distributed population was made when a sample size of greater than 30 participants exists, allowing for parametric statistical data analysis which is more rigorous (rather than using nonparametric statistical analysis), which will be discussed subsequently (Polit & Hungler, 1995). All of this translates into an acceptable error rate to avoid error.

Inclusion/Exclusion Criteria

The subjects for this study were invited to participate based on the inclusion/exclusion criteria established for this research. First, second and third trimester pregnant women attending prenatal care visits were included in this study, while postpartum women and men were excluded.

Third trimester pregnant women were not included in the pilot project but subsequently included in this study because, according to the United State Department of Health and Human Services (2010), women enter prenatal care at all stages of pregnancy, with about 17% of pregnant women entering

during the 2nd and 3rd trimesters. Additionally, women in the third trimester of pregnancy were added to the inclusion criteria post-pilot in order to establish if prenatal care knowledge increases as a women progresses through the pregnancy.

The National Institutes of Health (2010) suggests that every pregnancy has some risk. However, women over age 35 at the time of gestation, those who are pregnant with more than one baby or who have had previous pregnancy problems increase the risk during subsequent pregnancy (Blondel et al, 2002; Milner, Barry-Kinsella, Unwin & Harrison, 1992).

Therefore, women under the age of 18 and over the age of 36 at the time of conception were excluded from this study. Additionally, to avoid history biases from women who have been pregnant before, only women who were pregnant with their first child carried to term were included (Portney & Watkins, 1995). Finally, research materials have not been translated into the languages spoken by women represented at the clinics. Therefore, only English-speaking women were included in the study.

Settings

This study focused on a convenience sample of first time pregnant women presenting for prenatal care at either of two locations in the State of New Jersey: Newark Community Health Centers (North Jersey), and the School of Osteopathic Medicine Women's Health Center (South Jersey).

Both are community based health centers catering to the needs of a diverse population.

Newark Community Health Centers (NCHC)

Newark Community Health Centers is a Federally Qualified Health Center (FQHC) with locations in Newark, East Orange, Orange and Irvington. Serving more than 19,000 patients annually, NCHC is one of the largest providers of healthcare for the uninsured and underinsured population in Essex County. It provides primary and specialty care to a diverse population of residents throughout the county.

School of Osteopathic Medicine (SOM)

The School of Osteopathic Medicine is New Jersey's only school conferring a Doctor of Osteopathic degree. The University Doctors, the medical component of the medical school, offers healthcare throughout southern, NJ. Staffing over 200 physicians in 60 clinical offices, services are provided in all components of primary and specialty care.

Instrumentation

Survey research is a data-gathering tool used to collect information about a specific population. It is frequently used to describe the attitudes, beliefs, values, demographics, behaviors, opinions, habits, desires and ideas of a target population (Alreck & Settle, 2004). Three instruments were used in this research study. One survey used in this study was created by another investigator and was used with permission, entitled the Short Test of

Functional Health Literacy in Adults (STOFHLA). The second survey, entitled the Prenatal Care Test of Functional Health Literacy, and the demographic questionnaire, were both created by the Principal Investigator. Constructing clear questions that measure the intended construct(s) is an essential part of developing a valid survey (Ary et al., 2006; Gall et al., 2005). Each tool is discussed further below.

Demographic Questionnaire

According to Alreck & Settle (2004), demographic surveys usually include variables such as age, sex, marital status, family status, education and employment, each of which is used to identify and/or differentiate the typical member of this group to create a mental picture of this hypothetical aggregate, first to determine what segments or subgroups exist in the overall population; and second, to create a clear and complete picture of the characteristics of a typical member of each of these segments. To that end, a demographic survey was compiled using questions from the Center for the Study of Elections and Democracy at Brigham Young University (2010). The demographic questions, as presented in Appendix K, solicited information about the participant's age, race, socioeconomic status, trimester of pregnancy, education and employment status.

Age was important because, according to Milner, Barry-Kinsell, Unwin and Harrison (1992), older women are more likely to suffer poorer birth outcomes and birth defects than women who are younger. Additionally,

according to Famer and Ferraro (2005), minorities are affected by poorer birth outcomes and lower health literacy, and so race becomes an important demographic characteristic to capture. Similarly, Beers et al, (2003) and Gazmararian, Parker and Baker (1999), both suggest that individuals of lower educational levels are affected by lower health literacy, hence why educational level became important to capture as well. Socioeconomic status and employment status were considered to be somewhat overlapping demographically in order to capture these elements in this study. In regard to these two demographic factors, in 2001, Kirsch reported that individuals who are impoverished are more likely to present with lower health literacy skills. Poverty may also be represented in employment and household income. Kirsch also reported that immigrants or those who do not speak English as their primary language may suffer from lower health literacy. In this case, if the participant indicated that they did not speak English as their primary language, this demographic variable actually served as an exclusion criteria in this study. Finally, trimester of pregnancy was included in the demographic survey because, according to the USDHHS (2010), women enter prenatal care at all stages of pregnancy.

Short Test of Functional Health Literacy in Adults - (STOFHLA)

The Short Test of Functional Health Literacy in Adults (STOFHLA) is a health literacy assessment modified from the longer Test of Functional Health Literacy Assessment (TOFHLA) (Baker, Williams, Parker, Gazmararian &

Nurss, 1999). The STOFHLA is comprised of two prose passages: (1) instructions for an upper gastrointestinal tract radiographic procedure (written at grade level 4.3) and (2) the Medicaid patients' "Rights and Responsibilities" passage (written at grade level 10.4). Each passage is followed by several fill-in-the blank questions in which a word in a sentence is omitted and must be chosen from a multiple-choice list, a technique referred to as the Cloze procedure. A total of 36 items comprise the STOFHLA, and one point is assigned for each correct responses.

Possible scores on the STOFHLA range from 0 - 36. Using established conventions (Chew, Bradley & Boyko, 2004), these scores have been used in two ways: 1) as a total score or 2) as a category of health literacy. Used as a *total score*, a higher STFHHLA scores suggests greater health literacy levels.

Used as a *measure of health literacy*, established conventions categorize patients into three mutually exclusive groups: as individuals having inadequate, marginal or adequate health literacy, where:

Individuals with scores of 0 – 16 often misread the simplest materials, including prescription bottles and appointment slips and would be categorized as having inadequate health literacy.

Individuals scoring 17 – 22 perform better on the simplest tasks but have difficulty comprehending more complicated passages such as instructions for a radiographic procedure or understanding educational

brochures and would be categorized as having marginal health literacy.

Individuals who score 23 – 36 successfully complete most tasks required to function in the healthcare setting and would be categorized as having adequate health literacy (Chew, Bradley & Boyko, 2004).

Typically, as evident, STOFHLA scores divide health literacy into three criterion levels: inadequate, marginal, or adequate health literacy. Inadequate health literacy (*scores totaling 0 to 16*) describes individuals who often misread basic materials such as an appointment slip. Marginal health literacy (*scores totaling 17 to 22*) refers to persons who often have difficulty comprehending more complicated information such as that found in health educational pamphlets. Adequate health literacy (*scores totaling 23 to 36*) denotes individuals who typically are able to understand most printed health material. (Chew, Bradley & Boyko, 2004)

The STOFHLA has good internal consistency (Cronbach's alpha = 0.98 for all items combined) and concurrent validity compared to the long version of the TOFHLA ($r = 0.91$) and a medical-word recognition and pronunciation test, the Rapid Estimate of Adult Literacy in Medicine (REALM) ($r = 0.80$) (Davis et al., 1993). As the STOFHLA is repeatedly deemed an accurate measure of health literacy in various clinical populations in current literature (Nurss, Parker, Williams & Baker, 1995), it was considered an appropriate tool to assess the health literacy of first time pregnant females for

purposes of assessment in this study. A copy of The Short Test of Functional Health Literacy in Adults (STOFHLA) is included in the Appendix (*with permission*).

Prenatal Care Test of Functional Health Literacy

The Prenatal Care Test of Functional Health Literacy is an author-developed, content specific health literacy assessment, created by modifying the brief health literacy assessment tool (Chew, 2004). Both face and content validity were established by review of an expert panel using the Delphi procedure described by Baker, Lovell and Harris (2006). As the definition of an expert is controversial in the literature, for this study, an expert was defined as knowledgeable in a specific area (Soanes & Stevenson, 2003). To establish face and content validity for the Prenatal Care Test of Functional Health Literacy, six experts (two health literacy experts, two OB/GYN experts, one nurse and one educational professional) were invited to participate in the review, and all 6 invitees accepted and agreed to participate. All expert panelists had a masters and/or an MD degree, and all were working actively in their fields of expertise. While they were not qualified prior to participation, all of the panelists had over 20 years in their field of expertise. All six of the panelist completed the first round. Five of the six panelists completed the second round. Each panelist received the first draft of the survey and was asked to review the questions for clarity, sequence, importance, and appropriateness. These four categories were selected based on content from

Patel, Koegel, Booker, Jones & Wells (2006) on establishing criteria for a modified Delphi. Clarity was defined for the reviewers as achieved when to determine if the survey questions and answers were easy to understand. Sequence was explained as the determination of whether or not the questions and answers were presented in a logical order. Importance addressed whether or not the questions were important to the area of content. Finally, appropriateness was defined as the determination of whether or not the questions and answers were suitable for this study. The Principal Investigator revised the survey once they were returned. The questions were revised if three or more of the panelists commented on the same question with the same or similar concern. Several changes were made to the content and sequence of the initial draft of the survey. The revised survey was sent back to the panelists for a second review according to the same criteria defined and explained above, within three days of the close of the first review. The results from the first round of reviews were included in the instructions for the second round. The second round met the required consensus needed to finalize the survey. Therefore, no additional rounds of review were required. The final version of the Prenatal Care Test of Functional Health Literacy is presented in the Appendix.

Data Collection

In order to remove any effects to internal validity (Portney & Watkins, 2000) research assistants were secured to collect data from study participants at both locations. This also allowed for data to be collected simultaneously at both locations. Upon receipt of location approval and Institutional Review Board approval from the site location (Appendix N) and Seton Hall University (Appendix O), the Principal Investigator trained the research assistants (RA) on the appropriate procedures needed to complete the entire data collection process (Appendix D). As the first step in their training, the RAs completed the National Institutes of Health Protection of Human Subjects Training Module. Then, the PI familiarized the RAs with a script (Appendix I) and checklist of actions and steps that were carried out during the entire recruitment and data collection process (Appendices D & E). The checklist served as a memory aid and quality control measure to ensure consistency and completeness in the data collection process from beginning to end, from participant to participant. Once the training of the research assistants was completed, the participant recruitment process was initiated. A sample of the training guide is located in Appendix F.

Prior to the start of data collection, the PI prepared each survey packet and envelope with a matching site identifier and participant ID number in order to keep track of the data being distributed and returned. Each site identifier began with a different ID code (School of Osteopathic Medicine –

100, Newark Community Health Centers – 200) in order to determine the location where surveys were completed. Each survey envelope contained one of each of the following documents: a letter of solicitation (Appendix J), the demographic survey (Appendix K), the STOFHLA (Appendix L) and the Prenatal Care Test of Functional Health Literacy (Appendix M). These envelopes were arranged in ascending numerical order in boxes, which were given to each RA on the mornings of the data collection to take to their assigned facility, along with stationery items (including pencils, checklists, scripts, withdraw/incomplete stickers, tape and other materials) any day that participants were going to be recruited.

Before going to the data collection site, the RA ensured that each survey envelope contained the data collection documents, in the prescribed order, and that both the surveys and the envelopes were identically numbered with the site and participant identifiers. This was done for quality control and to ensure that the participants did not experience any unnecessary delays once they qualified for and agreed to participate in the study. This also ensured that the materials that were distributed to a participant were returned. At no time was there an intention to use the participant and site identifiers to link any particular response to the participant, as anonymity was assured as part of the implied informed consent.

Prior to patient recruitment commencing, the RA advised the office staff about study and prepared for the recruitment as part of the

organization's procedure once permission was granted for research to be conducted on site. The Principal Investigator spoke with the office staff at the School of Osteopathic Medicine's Women's Health Center and Newark Community Health Centers prior to the start of recruitment to determine the best days and hours for recruitment, and requested their assistance in identifying possible participants for her study. Once the days and times were established and communicated to the PI, the PI introduced the Research Assistants, two registered nurses, to the office staff prior to the beginning of each data collection session.

The office staff initially identified potential participants. After the patient completed their appointment registration process, the office staff quietly informed each individual of an opportunity to participate in, if interested, a survey regarding prenatal care. If the patient indicated interest in participating, the office staff introduced the patient to the RA, who was located in an area near to but separate from the waiting room area, to avoid the appearance of coercion.

As mentioned, the RAs were trained in conducting research for this project, and used the script provided to them during the research assistants' training to invite pregnant women to participate in the research survey. As part of the process, the RAs explained to each interested participant that the study involved completing surveys to reveal information about general health and prenatal care health knowledge, and beliefs, experiences and utilization

of a health service. Participants were informed of the purpose of the informed consent and were asked to review the letter of solicitation (Appendix C). Consent was implied by their participation and completion of the survey documents. Participants were also informed that the entire survey process should take no longer than 15 minutes to complete. The RAs escorted interested participants to a private, quiet location assigned by the office staff for the determination of eligibility to participate and actual completion of the surveys. The recruitment location consisted of a table and two chairs, one for the participant and one for the RA. Eligibility was determined using the previously explained inclusion and exclusion criteria.

The research assistants gave each eligible participant one of the pre-coded envelopes labeled with an ID number. As noted, all materials included in the packet had the same ID number as the coded envelope. Upon handing a qualified participant a survey envelope, the RA instructed the participant to open the envelope and to remove the materials contained within the envelope. The RA then reviewed all materials with the participant prior to the participant completing the surveys and demographic questionnaire. This served the dual purpose of not only familiarizing the participant with the materials and what needs to be completed, but also as a secondary check for completeness of each package of information, to ensure that all survey ID material codes match each other and the envelope ID, that the surveys and demographic questionnaires were in the prescribed order, that the envelope

and survey identifiers matched, and that all materials are included in the packet. If a packet was found to be incomplete, an incomplete label was placed on the envelope and the participant was given another. The RA repeated the entire review process again with the participant.

When the package was reviewed satisfactorily, the participant was told that they may begin completing the survey documents, and may take as much time as needed. The RA reminded the participants that they were free to withdraw from the study at any point in time during the process without penalty. If a participant informed the research assistant or office staff that she wanted to withdraw from the study, all materials were collected and returned to the original coded envelope. A "withdraw" label was attached to that envelope and the envelope was sealed. The sealed envelope was returned to the data collection box so all materials were kept together safely under the control of the RAs.

If a participant was called to her medical appointment before completing the survey package, the participant was instructed to attend the appointment and was told that the survey packet would be available to complete at the end of the appointment. In such cases, the RA gathered the materials into the corresponding coded envelope and the envelope was placed in a secured location. The RA notified the office staff that the participant had not completed the research packet before the prenatal appointment, so that the participant was gently reminded by the office staff to

return to the RA, if the participant desired to complete the packet. If the participant did not return by the end of business on that day, the RA sealed the envelope and marked it with a “withdrawn” sticker.

Materials completed by a participant were returned to their coded envelope. At the end of each day, the RA verified each package for completeness and utilized the checklist to ensure that all documentation was completed and returned as they were trained. Additionally, they perused each document to ensure that each survey was filled in. Incomplete surveys were returned to the corresponding coded envelopes and the envelopes were marked with an “incomplete” label, thereby indicating that they are incomplete. At the end of the each day, the RAs verified that all envelopes and materials brought to the facility were returned to the box, and that the location used was left neat and clean. The RAs returned all materials to the PI at the end of each recruitment day and refreshed all supplies required for use in the next data collection day.

This process, outlined in Figure 2, was adhered to throughout subsequent data collection periods at both facilities, until complete surveys were obtained from 88 qualified participants. By adhering to this rigorous methodology, the PI ensured complete consistency and quality in the process.

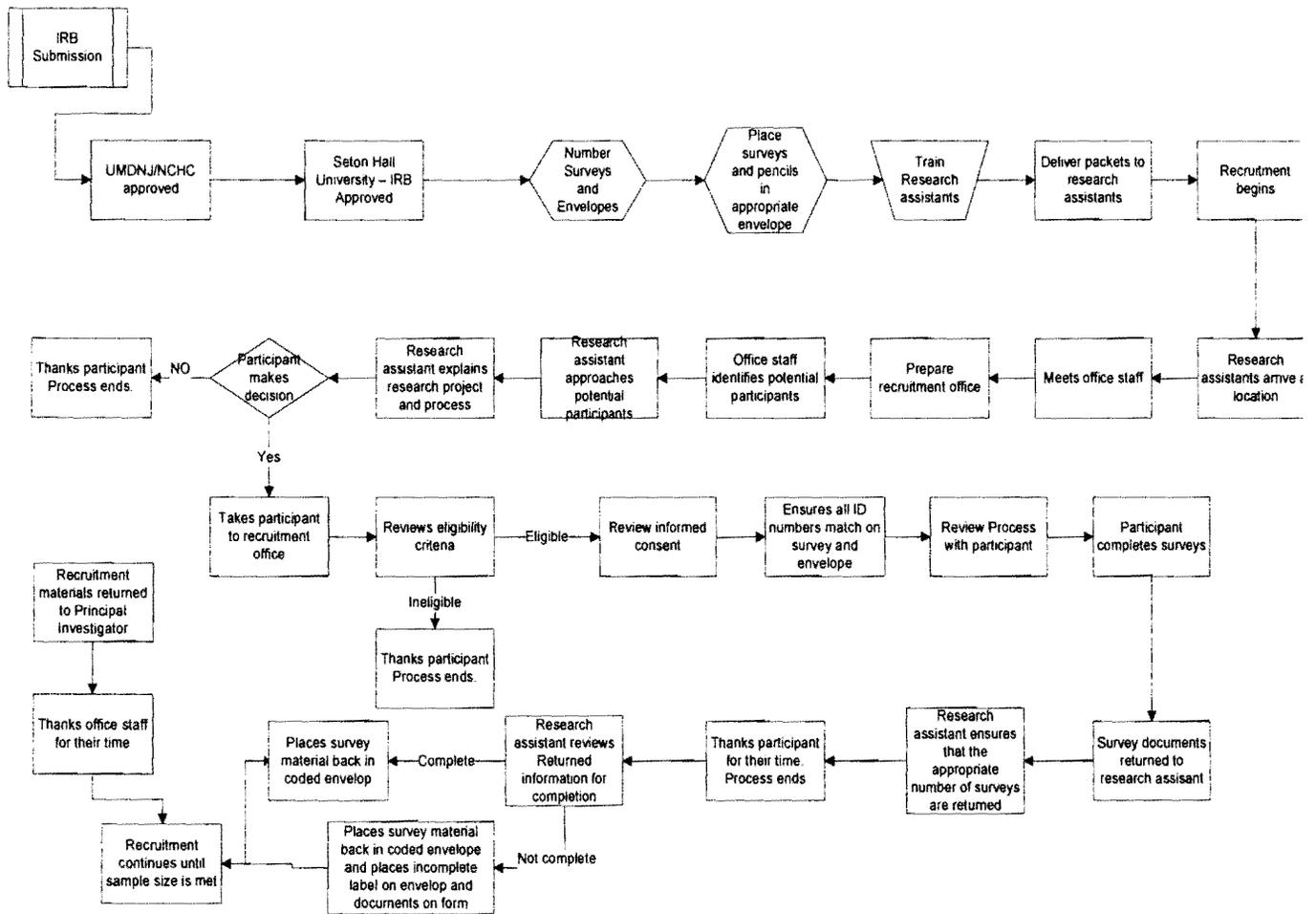


Figure 2. Description of data collection process

Data Analysis

As soon as the PI collected the envelopes with the completed questionnaires, she screened the survey instruments for missing responses. Usable data was entered into PASW Statistics (formerly, SPSS) Version 18.0 (SPSS, 2007) and was stored on a memory key. If any participant's survey was missing any responses and was not previously captured as "incomplete or withdrawn" by the RA, that data was not included in the analysis; further, the entire package of information corresponding to the code on that incomplete survey was not used in the analysis, and was segregated and marked as such prior to storage. The PI securely locked the completed surveys and the memory key in a filing cabinet in her home office.

The data was analyzed using both descriptive and inferential statistics. Demographic characteristics will be presented in tabular form using descriptive statistics. Non-parametric statistical analyses are appropriate when the level of data is nominal or ordinal, sample size is small or unequal, or data cannot be presumed to be normally distributed (Polit & Hungler, 1995; Portney & Watkins, 2000). If the data can be shown to be normally distributed, or non-normal data can be transformed appropriately, the more rigorous parametric analyses may be employed. (Polit & Hungler, 1995; Portney & Watkins, 2000).

For the demographic characteristics collected, the following descriptive statistics will be reported: means, standard deviation, frequencies, and percentages. The research hypotheses will be tested using inferential statistical analysis, particularly, a variety of parametric and non-parametric statistics.

Prior to addressing the research questions and corresponding hypotheses, the collected demographic, STOFHLA and Prenatal Health Literacy data was summarized using various descriptive procedures and was examined both graphically and numerically. These procedures, referred to as exploratory data analyses, confirmed that there was no missing data. The data was then examined to see if there were any patterns existing, which would reveal any major anomalies (scores or means are outside their anticipated range of values suggesting an error in data entry), whether outliers were present and whether the data supported the three general assumptions (normality, linearity and homogeneity) of parametric inferential tests. If these assumptions were violated, it could be concluded that the results of the analyses may be biased (Field, 2009). Fortunately this was not the case.

According to the central limit theorem as described by Munro (2005), a sample of 30 is enough to estimate the population mean with reasonable accuracy. (Munro, 2005) Therefore, with a viable sample of 90 participants, the data is assumed normal, allowing the use of parametric inferential

analyses. However, rather than just rely on the central limit theorem, the data was transformed to verify that parametric analyses were possible and that the data could be normalized. However, rather than rely strictly on theories to justify decisions made regarding data analyses performed, the outliers and the parametric assumptions are discussed below.

Outliers

Prior to addressing the research questions and corresponding hypothesis, the collected demographic, STOFHLA and Prenatal Care Test of Functional Health Literacy data was summarized using various descriptive analyses, which is referred to as exploratory data analysis (Field, 2009), and confirmed that there was no missing data.

A careful review of the data further confirmed that there were no major anomalies or outliers. Cases with unusual or extreme values at one or both ends of a sample distribution are known as outliers (Portney & Watkins, 2000). The problem with outliers is that they can distort the results of a statistical test, both comparisons of mean values and the value of correlation coefficients. It is vital that the results of statistical analyses represent the majority of data and are not largely influenced by one, or a few, extreme observations. Analysis of the data for outliers revealed nothing unusual or concerning in this study.

Satisfied General Assumptions of Parametric Analysis

Because it is preferable to use the more rigorous parametric analyses for the collected health literacy data, the data had to be examined to ensure that it met the 3 general assumptions of normality, linearity and homogeneity of variance. (Field, 2009; Munro, 2005). Briefly, these assumptions were met allowing the parametric analyses to proceed.

Normality

There are both graphical and statistical techniques to assess normality of the collected health literacy data. (Field, 2009). Graphically, the data was inspected using a histogram (Figure 3). If normality is defensible, the plot resembles a straight line. These graphical techniques were complemented with statistical permutations such as skewness and kurtosis. If a negative or unacceptable level of kurtosis or skewness is found, the data will also be transformed to determine if the assumptions have been satisfied as suggested by Tabachnick & Fidell (2007) when working with skewed data.

The raw health literacy data was not normal and therefore the data was transformed revealing normalized data. The results of the assessment for normality and the transformed data are presented in Figures 4. All Figures mentioned herein are presented in the Results section of this document.

Linearity

Linear relationships among pairs of measured variables (e.g., the score on the STOFHLA and the score on the Prenatal Health Literacy tool)

were evaluated through visual inspection of bivariate scatter plots. The linearity requirement was met without consequence.

Homogeneity of variance

Homogeneity of variance means that the variance within each of the populations is equal or that an assumption is made that the dependent variable exhibits similar amounts of variance across the range of values for an independent variable. Since this test was met after transformation of the data was completed, the three assumptions were met and parametric analyses, ANOVA and factorial analyses for the collected health literacy data could proceed.

Once this initial review of the data was completed, the initial data analysis to answer each of the attendant research questions began. Here, as the three instruments the demographic questions, the STOFHLA and the Prenatal Care Test of Functional Health Literacy yielded both nominal and interval data, this information was summarized using appropriate descriptive statistics such as means, medians, frequencies, percentages, and standard deviations (SD). Further, given the descriptive nature of Research Questions 1 and 2, only descriptive statistics were used to answer these two research questions.

However, Research Questions 3 through 5 evaluated relationships or posed comparisons among groups of participants, and accordingly mandated appropriate parametric inferential analyses. In order to conduct further

analysis using parametric statistics, three general assumptions must be supported: normality, linearity and homogeneity of variance.

To determine the relationship between the Short Test of Functional Health Literacy and Prenatal Care Health Literacy, several statistical methods were employed. As well documented in the literature, the Short Test of Functional Health Literacy can be reported as a score, as a level or as a reading proficiency. The Prenatal Care Test of Functional Health Literacy is reported as a score. Therefore, the initial intention was to employ a statistical method with each as such: (1) Score vs. Score – Pearson's r correlation coefficient; (2) Level vs. Score – Cohen's f index; (3) Reading proficiency vs. Score – biserial correlation. Pearson's r is more appropriately used when there is one independent and one dependent variable and data is on the interval scale. Cohen's f was supposed to be used if study data yielded three health literacy levels (adequate, inadequate or marginal). However, in anticipation of the data collected being more representative of the results obtained from the pilot study, only two levels will be seen (inadequate and marginal), so the biserial correlation was used for this category as well as the reading proficiency category.

So as stated and given the nature of the data yielded by the STOFHLA and the Prenatal Care Test, the Pearson product moment correlation coefficient (r) was used to establish the relationship between the two variables (Munro, 2005). This correlation coefficient measures the degree

and direction of the relationship that exists between two interval-scaled variables. In this case, the bivariate regression predicted a dependent variable from an independent one. Correlation coefficients range from -1.00 for a perfect negative relationship between independent and dependent variable, to 0.00 for no correlation between independent and dependent variable, to +1.00 for a perfect positive relationship between independent and dependent variable, or that you only need to measure 1 variable to know the value of the other. For example, a positive correlation suggests that an individual scores at roughly the same level on both measures. Thus, a pregnant woman with high general health literacy would have a similarly high level of Prenatal Care Test Health Literacy. On the other hand, a correlation that is negative implies that individuals typically score at opposite levels on the two measures. Thus, a pregnant woman with an adequate (high) health literacy score (STOFHLA) might have a low Prenatal Care Test score or vice versa. Anticipating the possibility that the relationship between the STOFHLA and the Prenatal Care Test was significant ($p < 0.05$, or 95% CI, occurs by chance, less than 5 chances in 100), regression analyses (simple and step-wise multiple regression) would have been used to determine how well the STOFHLA score predicted the pregnant woman's score on the Prenatal Care Test and whether including other demographic variables would clarify or enhance the predictive relationship between the STOFHLA and the Prenatal Care Test. However, since it is nearly impossible to find perfect correlations,

predictions between variables are made to try to minimize deviations from the closest straight line fit (Portney & Watkins, 2000, Polit & Hungler, 1995).

In addition to determining the strength and direction of the relationship between the STOFHLA and the Prenatal Care Test, this study was also directed at comparing the participants' scores on each of these measures when the pregnant women were grouped by one demographic variable. For example, when the pregnant women were grouped by the trimester of pregnancy, a one-way Analysis of Variance (ANOVA) would have been used to compare the average general health literacy scores (STOFHLA) for the first, second and third trimester women. A second one-way ANOVA would have compared the average Prenatal Care Test scores for these three groups. The one-way ANOVA was appropriate for these comparisons, as this analysis is based on one independent variable with two or more groups and one interval scaled dependent variable (Portney & Watkins, 2000, Polit & Hungler, 1995).

Significant differences from each one-way ANOVA were to be further explored using the Tukey's HSD test. Tukey's Honestly Significant Difference test is applicable for pairwise comparisons, and allows one to compare all pairs of means. It is the most accurate and powerful procedure to use, as it is based on power, which is the ability to detect a difference if one actually exists. In this case, a high power would mean that a null hypothesis will be correctly rejected more often than not. Tukey's uses a multiplier which is

based on the number of treatment levels and degrees of freedom for error mean square and takes into account the sample size of each group being compared. Significance is declared when the HSD calculated is exceeded. This also allows for one to make statements of confidence intervals between low and moderate groups (Polit & Hungler, 1995). Simply, in this study, the HSD test quantifies the smallest difference that must exist for two group means to be considered significantly different. Thus this post hoc comparison would determine which trimester groups differed significantly on the STOFHLA and which trimester groups differed significantly on the Prenatal Care Test.

Justification for this statistical approach taken is as follows. Tests for significance between groups is important and was planned for in this study. In this statistical test, a significant result is achieved if the calculated value of H is equal or more positive than the critical χ^2 , or the significance level for the relationship between variables that must be exceeded to be greater than that which would be expected by chance. If the result is found to be significant (meaning $> \chi^2$), Portney and Watkins (2000) suggest that a multiple comparison procedure has to be performed to determine which specific groups are different from each other. In this case, a multiple comparison for the ANOVA is conducted to test the significance of pairwise differences between the means of the ranks for each group. Each pairwise comparison is tested against a minimum significant difference (the lowest distinguishable

difference that is statistically meaningful), which is based on the degree of variance within groups (between subjects).

Since Type 1 errors are common in multiple comparison testing, the alpha level for the comparisons will be based on the familywise error rate (α_{FW}), to control for the risk of Type 1 errors occurring. Familywise error rate is the sum of the error rates per comparison (Portney & Watkins, 2000). A significant result is declared if the absolute difference between a pair of means is equal to or greater than the minimum significant difference. This means that the groups being compared are different from each other. All the data in this study will be analyzed at $\alpha = 0.05$, $\beta = 0.20$ with a corresponding power of 80% which Portney and Watkins (2000) suggest is a reasonable protection against Type II error. These comparisons will be made until all demographic data influences on the variables are analyzed.

A final goal of this study was to compare the average Prenatal Care Test scores of the pregnant women grouped by the combination of the three demographic variables of educational level, ethnicity, and age. As it was unlikely that sufficient cell sizes would be obtained if these three demographic variables were combined as originally conceptualized, modifications to the number of levels or categories within each variable were anticipated. For example, it was expected that the educational variable might need to be reduced to three levels: (1) high school, (2) some college and (3) bachelor's and beyond, instead of using it in the originally contemplated four-cell

grouping of (1) high school, (2) some college, (3) graduate and (4) post graduate. Likewise, it was anticipated that the ethnicity variable might need to be re-conceptualized as two levels: (1) minorities versus (2) whites, instead of retaining the original categorical levels of White, Black, Hispanic, Asian, Native American and Other. Finally, it was expected that the age variable might require categorization using a median split – with one age group below the median age value and the other at or above the median age, instead of retaining the original breakout of 4 groups, ages 18-21, 22-25, 26-29, 30-34. Conceptualized in this way, instead of using a 4 x 4 x 5 Factorial ANOVA Analysis, a 3 X 2 X 2 Factorial ANOVA was planned to compare the average Prenatal Care Test score for the 12 groups formed by the combination of these three demographic variables. This parametric analysis would not only permit the identification of significant main effects but would also identify significant two and three-way interactions among the independent variables. Nonparametric tests in this case simply do not exist, so this parametric test is the right choice to use because the criteria test is met: when three or more independent groups are involved in a study; when the groups are not of the same size and the level of data is ordinal. So as stated, this statistical test compares whether the mean value of the test variable (e. g. such as social support) for one group differs significantly from the mean values of the same test variable for the other groups.

As with the one-way ANOVA, significant main effects and interactions resulting from the three-way ANOVA would be followed by post hoc comparisons.

A Comment on Testing the Reliability of an Instrument

As Research Questions 1 and 2 were purely descriptive in nature, but Research Questions 3 through 5 required the use of inferential statistical procedures, the PI deemed it essential to calculate the reliability of both instruments, the STOFHLA and the Prenatal Care Test, for this sample of first time pregnant women. Polit and Hungler (1995) advise researchers to calculate the reliability of each instrument or survey that is used in a study, claiming that the reliability of an instrument is a major criterion for evaluating the quality and adequacy of the instrument (p. 411-412). The reliability of an instrument determines the degree of consistency with which the survey measures what it was intended to measure. If an instrument lacks internal consistency, that instrument should not be used in subsequent analyses, as the findings may provide misleading statistical results, perhaps suggesting relationships among variables that do not exist (Field, 2009). However, analysis may provide insight into clinical or theoretical relevance. Therefore, this study conducted all analyses and on all findings for statistical, clinical or theoretical relevance. Extending Polit & Hungler's (1995) perspective, it is reasonable to assume that an instrument with documented internal consistency in one clinical population at one point in time may not have the

same degree of internal consistency with a different targeted group at another point in time. Hence, there is the need to compute the internal consistency of each instrument, each time a new population is targeted.

The most stringent measure of internal consistency is Cronbach's alpha (as cited in Portney & Watkins, 2000, p. 575). Coefficient alpha ranges from 0, indicating the scale is not at all consistent, to 1, suggesting perfect consistency. Researchers are not in strict agreement regarding the minimum acceptable level of internal consistency that should be tolerated in a study. For example, Kline (1999) notes that although the generally accepted Cronbach value of 0.8 is appropriate for cognitive tests such as intelligence tests, he argues that for ability tests a cut-off of 0.7 is more suitable. Also representing a social science research perspective, Petersen (1994) suggests a Cronbach alpha greater than .70 is acceptable. Thus, for both the STOFHLA and the Prenatal Care Test of Functional Health Literacy, a Cronbach alpha of 0.70 was designated as the minimum level tolerable in this study for reporting statistical significance. However, as stated before, all analysis will be performed and discussed for clinical or theoretical relevance.

Chapter IV

RESULTS

Introduction

This study assessed two types of health literacy in a convenience sample of first-time pregnant women to determine if there was a predictive relationship between general health literacy, as measured by the Short Test of Functional Health Literacy in Adults (STOFHLA), and the Prenatal Care Test of Functional Health Literacy, and whether the inclusion of demographic characteristics clarified the relationship between these two health literacy measures. This chapter presents a profile of the first time pregnant women based on the description of the demographic characteristics, followed by a detailed presentation of the general and prenatal care literacy scores for this sample of 90 females, including the reliability of the two health literacy measures.

Characteristics of the Sample

The targeted group in this study consisted of women who were pregnant with their first child who were engaging in prenatal care at one of two sites in the state of New Jersey. The research assistants returned ninety-six (96) completed survey packets to the Principal Investigator. Of these packets, four included incomplete data and two others were discarded

because they did not meet the inclusion criteria. The final sample of 90 surveys represents a 96% return rate and this sample was used in all data analyses.

Demographic Characteristics

The 90 complete packets included 40 participants from Newark Community Health Centers (North Jersey) and 50 from The School of Osteopathic Medicine (South Jersey). As presented in Table 1, the pregnant women seeking prenatal care at these two sites did not differ significantly in any of the demographic characteristics. Accordingly, the profile of the typical participant in this study was based on the combined data from the two sites.

The typical participant averaged 24.9 years of age (SD = 4.17) with a similar mean age at conception (M = 24.5; SD = 4.22). Approximately 75% of the women participants were either in their first (35.6%) or second trimester (38.9%) of pregnancy. The remaining quarter of the participants was in their third trimester of pregnancy. More than half of the participants reported that they were employed (N=61, 67.8%), compared to being unemployed (N = 29, 32.2%). Similarly, a little more than half of the women (N = 47, 52.2%) were married, compared to being_unmarried (N = 43, 47.8%).

A variety of ethnic groups were represented in this study. African Americans (N = 38, 42.2%) comprised the largest ethnic group, followed by Caucasians (N = 31, 34.4%). The Hispanic or Latino women (N = 15, 16.7%)

were the third largest group to participate while a small percentage of the participants were Asian (N = 6, 6.7%).

In terms of their education, 40% (N = 36) of the pregnant women reported that they earned at least a high school diploma or equivalent. A smaller but nearly equal number of participants indicated that they held an associate's degree (N = 15, 16.7%), had some college (N = 17, 18.9%) or earned a bachelor's degree (N = 17, 18.9%). An even fewer number of the women (N=4, 4.4%) had a master's degree and only 1 participant had a professional degree (1%).

The final descriptive characteristic reported was income level. A small percentage (N = 5, 5.6%) had a household income of less than \$10,000. Twenty-one (23.3%) of the women had a household income of \$10,000 to \$29,000. Most of the women (N = 26, 28.9%) had a household income of \$30,000 to \$49,000. Sixteen (17.8%) had a household income of \$50,000 - \$69,000. A smaller group (N = 10, 11.1%) had an income of \$70,000 to \$89,000. Nine women (10%) had an income of \$90,000 to \$109,000 and only three (3.3%) had an income exceeding \$110,000.

The variables on Table 1 are represented together as a reminder of the literature reported on who is affected by low health literacy. The literature by Farmer and Ferraro (2005) suggests that minorities are highly affected by low health literacy. Sixty-five percent of the sample was comprised of minorities. Beers et al. (2003) and Gazmararian, Parker and Baker (1999) all suggest

that those with lower educational levels were affected by low health literacy, with 40% of the sample having at least a high school diploma. Kirsch (2002) also stated that individuals living in poverty were affected more frequently by low health literacy. The poverty level is based on number of household members. A specific question regarding the number of individuals being supported in the household by the primary wage earner was not included in the demographic questionnaire, so it was not possible to ascertain the answer to this particular question. However, about 29% of the sample had a household income of less than \$30,000, which would be considered below the poverty level for a family of three.

As previously mentioned, this study focused on prenatal care women in two locations in the State of New Jersey: Newark Community Health Centers (North Jersey), and the School of Osteopathic Medicine Women's Health Center (South Jersey). Both are community based health centers catering to the needs of a diverse population.

Table 1 provides a breakdown of the demographic characteristics by individual location as well as the aggregate data.

Table 1

Demographic Characteristics of study participants

	UMDNJ		NCHC		Total	
	Total	%	Total	%	Total	%
Trimester						
First	21	42	11	27.5	32	35.6
Second	16	32	19	47.5	35	38.9
Third	13	26	10	25	23	25.6
TOTAL	50	100	40	100	90	100
Employment Status						
Employed	34	68	27	67.5	61	67.8
Not Employed	16	32	13	32.5	29	32.2
TOTAL	50	100	40	100	90	100
Marital Status						
Married	26	52	21	52.5	47	52.2
Not Married	24	48	19	47.5	43	47.8
TOTAL	50	100	40	100	90	100
Ethnicity						
African America	20	40	18	45	38	42
Asian	3	6	3	7.5	6	6.7
Hispanic	6	12	9	22.5	15	16.7
Non-Hispanic White	21	42	10	25	31	34.4
TOTAL	50	100	40	100	90	100
Education						
High School or GED	18	36	18	45	36	40
Associates/2 yr.	6	12	9	22.5	15	16.7
Some College	12	24	5	12.5	17	18.9
Bachelor's	10	20	7	17.5	17	18.9
Master's	3	6	1	2.5	4	4.4
Professional	1	2	0	0	1	1.1
TOTAL	50	100	40	100	90	100
Income						
Less than 10K	4	8	1	2.5	5	5.6
10K to 29K	8	16	13	32.5	21	23.3
30K to 49K	13	26	13	32.5	26	28.9
50K to 69K	9	18	7	17.5	16	17.8
70K to 89K	7	14	3	7.5	10	11.1
90K to 109K	6	12	3	7.5	9	10.0
Over 100K	3	6	0	0	3	3.3
TOTAL	50	100	40	100	90	100

Findings

No literature has been found on the relationship between general health literacy and prenatal care health literacy in pregnant women engaging in prenatal care. Therefore, this study sought to establish if a predictive relationship existed between general health literacy as measured by the Short Test of Functional Health Literacy and prenatal care health literacy as measured by the Prenatal Care Test of Functional Health Literacy. The results of this study shed some light into the existing body of health literacy knowledge.

Research Question 1: What are the general health literacy scores of pregnant women as measured by the Short Test of Functional Health Literacy in Adults (STOFHLA)?

Health Literacy Scores

To answer this question, the scores from the 36-item STOFHLA were tabulated and categorized as inadequate (0 – 16), marginal (17 – 22) or adequate (23 – 36). Descriptively, the 90 participants comprising the sample scored between 27 and 36 on the STOFHLA, yielding a mean score of 34.9 (SD = 1.34). Additionally, the skewness was -2.41 and the standard error of skewness was .25. The acceptable level of skewness is greater than 2. A second level of verification was examined using the Kolmogorov-Smirnova (K-S) statistic. That also yielded the same level of .241. If the K-S statistic is

non-significant at the 0.05 level ,the distribution of the sample is not significantly different from a normal distribution. In this case, this data is significantly different from a normal distribution. Figure 2 provides a visual representation of the original data scores.

Histogram of Health Literacy Scores

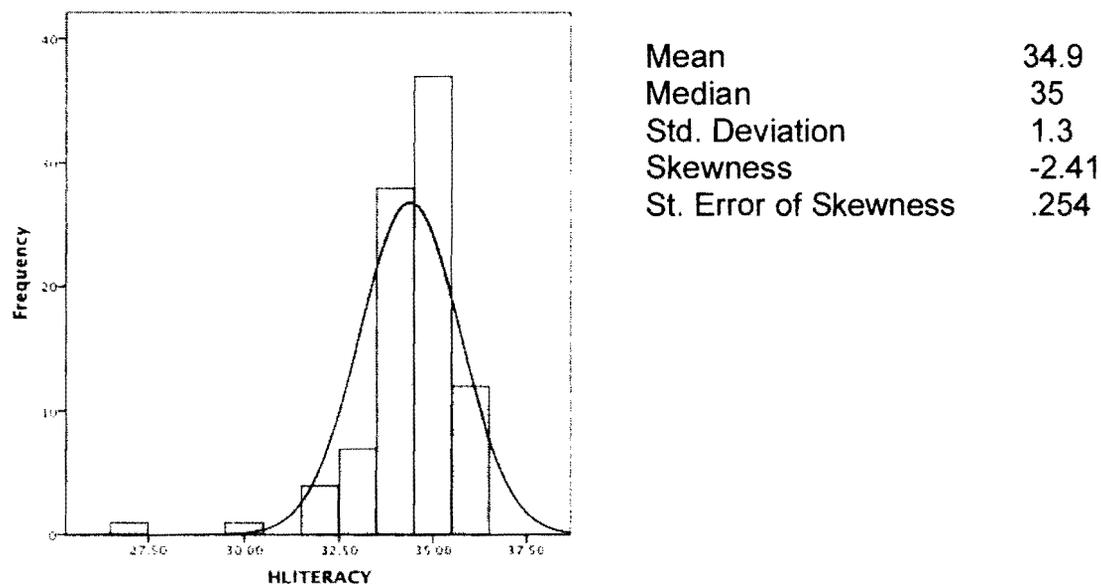


Figure 3. A visual representation of health literacy scores as displayed in a histogram.

The data represents that all 90 participants had an adequate health literacy score. The breakdown of these 90 health literacy scores is provided in Table 2.

Table 2
Health literacy scores

Scores	Frequency	Percent
27	1	1.1
30	1	1.1
32	4	4.4
33	7	7.8
34	28	31.1
35	37	41.1
36	12	13.3
Total	90	100

An attempt was made to normalize the data using a data transformation with reflection as suggested by Tabachnick and Fidell (2007) when severely negatively skewed data exists, if the more rigorous parametric analyses are going to be attempted with the data. Although Munro (2005) states that normalization of the data is assumed when more than 30 usable,

qualified participants respond according to the Theory of Central Tendency, transformation of the data assures that the assumptions necessary for parametric analyses can be met, if normalization is achievable. Figure 4 provides a visual representation of the transformed data. Table 3 represents the transformed health literacy scores.

Histogram of Transformed health literacy scores (Log score)

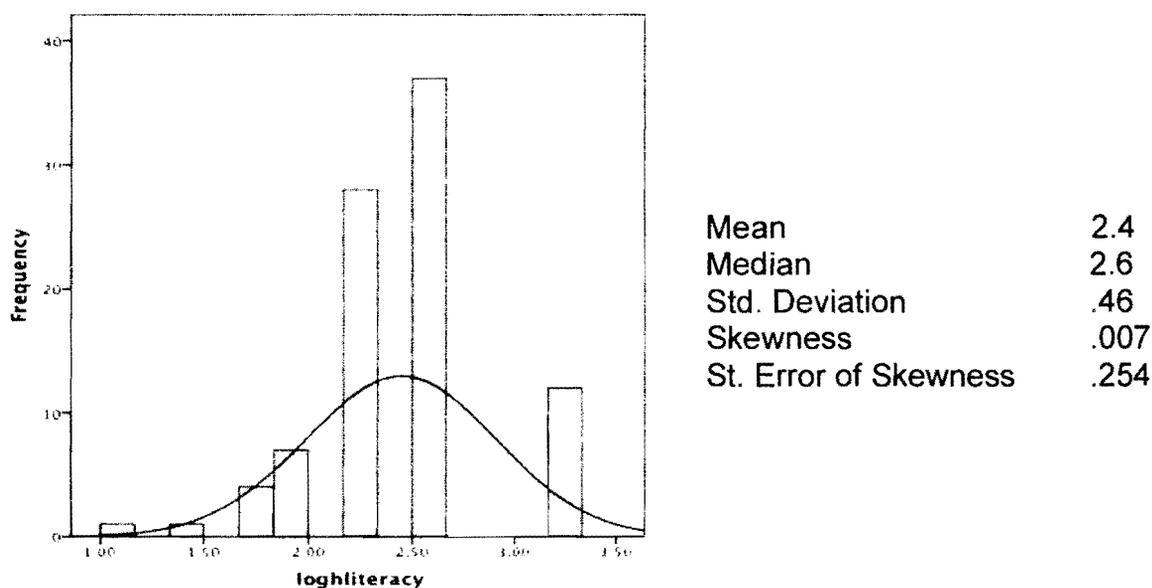


Figure 4. A histogram of the transformed health literacy (log score) after reflection.

Table 3

Transformed Health literacy scores (Log score)

Log Scores	Frequency	Percent
1	1	1.1
1.36	1	1.1
1.69	4	4.4
1.92	7	7.8
2.20	28	31.1
2.61	37	41.1
3.30	12	13.3
Total	90	100

Research Question 2: What are the prenatal care scores of pregnant women as measured by the Prenatal Care Test of Functional Health Literacy?

Prenatal Care Health Literacy Scores

To answer this question, the participants' responses to the two sections of the Prenatal Care Test of Functional Health Literacy on knowledge and attitudes were calculated and summarized separately. The knowledge section consisted of five multiple-choice items yielding a knowledge score between 0 and 5. As summarized in Table 4, these 90 pregnant women had knowledge scores between 3 and 5, yielding an

average score of 4.8 (SD = .39). With 90% of the sample earning the highest knowledge score possible, it is reasonable to suggest that the knowledge portion of the prenatal care test is characterized by a ceiling effect. According to Polit and Hungler (1995), when data has a clustering of high scores in a sample, it creates a ceiling effect.

Table 4
Prenatal Care Knowledge Scores

Knowledge score	Frequency	Percent
3	2	2.2
4	7	7.8
5	81	90
Total	90	100

The attitude portion of the Prenatal Care Test of Functional Health Literacy consisted of 11 Likert-type questions with each item evaluated on a scale from 1 to 5, to indicate the level of agreement with or endorsement of the item. The possible range of scores on the attitude portion of the Prenatal Care test was from 11 - 55. The 90 pregnant women had attitude scores ranging between 11 and 44. The mean score was 21 and the median was 20.

Recalling the conceptual framework by Baker (2006), an individual's capacity coupled with their attitude contributes to their health literacy and

ultimately their health outcomes. This result clarifies the corresponding component of Baker's conceptual model as it relates to an individual's health literacy.

Table 5 provides a breakdown of general and prenatal care literacy scores for this sample of pregnancy women engaging in prenatal care.

Table 5

Breakdown of Literacy Scores

Variable	Range	M	SD
Short Test of Functional Health Literacy - STOFHLA	27-36	34.39	1.3
Prenatal Care Test of Functional Health Literacy – Knowledge	3-5	4.88	.39
Prenatal Care Test of Functional Health Literacy – Attitudes	11-44	21.11	7.3

The descriptive analyses from Research Question 1 unambiguously show that for all 90 participants in this study, the STOFHLA scores are categorized as "adequate" health literacy. This finding and the fact that the Prenatal Care Test of Functional Health Literacy was an investigator-developed survey, prompted the Principal Investigator to calculate the internal consistency (reliability) of each of these two health literacy measures using the data from the targeted clinical group of first time pregnant women, prior to addressing Research Questions 3 through 5 and their corollary hypotheses.

Reliability

As the reliability of an instrument or survey can serve as a major criterion for evaluating the quality and adequacy of an instrument, the internal consistency, as measured by Cronbach's alpha, was calculated separately for the two measures of health literacy utilized in this study (Table 6).

Using the responses from 90 first time pregnant women, the alpha reliability score for the Short Test of Functional Health Literacy (STOFHLA) was .33. The alpha reliability score for the *knowledge* section of the Prenatal Care Test of Functional Health Literacy was .28. Both reliability estimates were substantially below the accepted social science standard of 0.70 for reporting statistical significance, suggesting that the STOFHLA is not reliable in this population of prenatal care seeking pregnant women. In contrast to these measures, the alpha reliability score for the *attitude* section of the Prenatal Care Test of Functional Health Literacy was .89. This measure was the only survey that was deemed reliable for further analysis in the study.

Putting these findings into context and by way of justification for why all instruments must be checked for reliability when being contemplated for use in a novel population, even when the instrument is considered the "Gold Standard" of the field and has extensive literature substantiating its reliability and validity published, recall that the STOFHLA is well documented in the literature as having great reliability with a Cronbach's alpha of .98 (Baker, Williams, Parker, Gazmararian & Nurss, 1999). The literature also confirms

that participants regularly fall into all three categories of health literacy (inadequate, marginal and adequate). However, since the data analysis herein did not confirm what is found in the literature, reliability of the Principal Investigator-created Prenatal Care Test of Functional Health Literacy instrument becomes automatically questioned. As the creator of the tool, the Principal Investigator therefore pursued reliability testing of the instrument's primary contexts, knowledge and attitudes, as reported herein.

Therefore, from this point forward, the STOFHLA in its entirety and the prenatal care knowledge results will not be discussed in any statistically meaningful way because the measures have not been found to be reliable in this novel population of first time pregnant women seeking prenatal care services. This point will be addressed further in the Discussion section of this document.

Table 6

Scale reliability (Cronbach's Alpha)

Scale	Number of Items	Alpha
Short Test of Functional Health Literacy in Adults (STOFHLA)	36	.330
Prenatal Care – Knowledge	5	.275
Prenatal Care – Attitudes	11	.886

Research Question 3: Is there a significant relationship between general health literacy, as measured by the STOFHLA, and prenatal care health literacy, as measured by the Prenatal Care Test of Health Literacy, in pregnant females?

Hypothesis: There is a relationship between general health literacy and prenatal care health literacy.

Correlation

The Pearson's coefficient correlation was used for this analysis using the transformed data of health literacy. When performed it is possible to see that the hypothesis is partially supported, with a significant relationship evident between the log health literacy score and prenatal care knowledge, as shown in Table 7. No relationship was found between the log health literacy score and prenatal care attitudes.

Table 7.

Correlation of general health literacy and prenatal care literacy

		Prenatal Knowledge	Prenatal Attitudes
Log Health Literacy	Pearson r	.337*	-.140
	N	90	90

* Correlation is significant at the 0.01 level

Research Question 4: Is it possible to predict the level of prenatal care health literacy a pregnant female will have (as measured by the Prenatal Care Test of Functional Health Literacy) if the individual's general health literacy level (as measured by the STOFHLA) is known?

Hypothesis: Short Test of Functional Health Literacy will predict Prenatal Care Health Literacy.

Regression

Because significant differences were found between the log health literacy scores and the prenatal knowledge scores, regression analysis was calculated. A simple regression was conducted with prenatal health literacy as the criterion variable and general health literacy as the predictor. The analysis showed that general health literacy was a significant predictor of prenatal health literacy, $\beta = .34$, $t(89) = 3.36$, $p < .05$ and accounted for 11% of the variance in prenatal health literacy.

Research Question 5a: Is there a difference in the general health literacy levels (as measured by the STOFHLA) between first, second and third trimester pregnant females?

Hypothesis 5a: There is a difference in general health literacy levels between first, second and third trimester pregnant females.

Analysis of Variance

A one-way between groups ANOVA was calculated to determine if there were differences in general health literacy levels between first, second and third trimester pregnant females. The results did not reveal any differences in general health literacy between these groups, $F(2,87) = 2.99$, $MSE = .61$, $p > .05$. These results show that there is no difference in health literacy scores, prenatal knowledge or attitudes scores between women in the first, second or third trimesters of pregnancy. The results are shown in Table 8.

Table 8.

ANOVA general health literacy by trimester of pregnancy

General Health Literacy by trimester	Mean	SD	Sig
First trimester (n = 32)	2.29	.48	
Second trimester (n = 35)	2.54	.47	.06
Third trimester (n = 23)	2.53	.37	

Research Question 5b: Is there a difference in the prenatal care health literacy scores between first, second and third trimester pregnant females?

Hypothesis 5b: There is a difference in prenatal care health literacy scores between first, second and third trimester pregnant females.

Again, to answer this research question and the related hypothesis, a one-way between groups ANOVA compared the average knowledge and attitude scores of the first, second and third trimester pregnant females and did not reveal any significant difference in knowledge: $F(2, 87) = 1.61$, $MSE = .25$, $p > .05$ or attitudes among these groups: $F(2, 87) = 0.43$, $MSE = 23.8$, $p > .05$. Knowledge results are represented in Table 9 while attitudes results are reported in Table 10.

Table 9.

ANOVA prenatal care knowledge by trimester of pregnancy

Prenatal care attitude by trimester	Mean	SD	Sig
First trimester (n = 32)	4.78	.55	
Second trimester (n = 35)	4.91	.28	.21
Third trimester (n = 23)	4.96	.21	

Table 10.

ANOVA prenatal care attitudes by trimester of pregnancy

Prenatal care attitude by trimester	Mean	SD	Sig
First trimester (n = 32)	21.75	8.59	
Second trimester (n = 35)	21.31	6.53	.651
Third trimester (n = 23)	19.91	6.91	

Research Question 6: What are the differences in prenatal care health literacy scores when pregnant women are grouped by educational attainment, ethnicity and age?

Hypothesis: There is a significant difference in prenatal care health literacy scores when pregnant women are grouped by educational attainment, ethnicity and age.

Factorial Analysis

To answer this research question and the related hypothesis, the three demographic variables were combined as originally conceptualized, numerous cells either had no data or insufficient data to execute the planned factorial ANOVA. Thus, modifications were made to the number of categories within the three demographic variables before analyzing the knowledge and attitude scores of the prenatal care test. The educational variable was reduced to three categories: (1) high school, (2) some college and (3) bachelor's and beyond. Next, ethnicity was re-conceptualized as two levels: (1) minorities (consisting of Asians, Hispanics, African Americans, etc) versus (2) whites. Finally, the age variable was broken into two groups based on using a median age split into two groups 18-25 and 26-35 as suggest by Schraedlyey, 2002 for recoding variables into groups. This resulted in two age groups, one below the median age value and the other at or above the

median age. These changes and the “n” within each category of the three demographic variables are presented in Table 11.

Table 11.

Re-conceptualization of the demographic variables

Group	Frequency
Education Group	
High School	36
Associates or some college	32
Bachelor's and beyond	22
Ethnic Group	
Minority	59
White	31
Age Group	
18-25	52
26-35	38

Conceptualized in this way, a 3 X 2 X 2 Factorial ANOVA compared the average knowledge and attitude score on the Prenatal Care Test for the 12 groups formed by the combination of these three demographic variables. This three-way ANOVA between the education group, the ethnicity group and the age group still resulted in several cells without data and is consequently not reported here. As the age group variable still had insufficient size, this

demographic variable was removed from subsequent analyses, and a second ANOVA calculation was performed, a 3 x 2 ANOVA, this time looking only at education and ethnicity.

The 3 X 2 Factorial was executed comparing, the average knowledge and attitude scores on the prenatal care test with education and ethnicity as independent variables. This analysis only identified a significant main effect for educational level and attitudes, $F(2, 84) = 4.06, p < .05, \eta^2 = .09$. No main effect was found between the education group and prenatal care knowledge, $F(2, 84) = 2.42, p < .05, \eta^2 = .05$. As presented in Table 12, there was a significant difference in attitudes toward prenatal care when the pregnant women were grouped by educational level. A Tukey's B post hoc test showed that there was no significant difference in the attitude scores of pregnant women with high school or some college education. However, the attitude score of these two educational groups was significantly better than that of participants with a bachelor's degree or beyond. Thus, participants with more education had significantly poorer attitudes toward prenatal care than first time pregnant females with less education.

The factorial did not reveal a significant main effect of ethnicity, $F(1, 84) = .16, p > .05$, meaning that there were no differences in prenatal knowledge between whites and minorities. Similarly, the factorial did not reveal a significant main effect of ethnicity, $F(1, 84) = 2.93, p > .05$, implying that whites did not differ from minorities in their attitudes toward prenatal care

in this sample of pregnant women. Additionally, no effect was shown in the knowledge of whites and minorities when taking education into account, $F(2, 84) = .63, p > .05$. This suggests that there was no statistical meaning between education level and ethnicity. Likewise, the analysis did not show that the attitudes of white pregnant females differed significantly from that of minorities when taking education into account, $F(2, 84) = 0.41, p > .05$, suggesting that the interaction between educational level and ethnicity was not significant.

Table 12.

3 X 2 Factorial ANOVA

Educational Group	Mean Prenatal Attitude	Sig
High school	23.33	
Associate or some college	21.56	.02
Bachelor's & beyond	16.82	

Chapter V

Discussion

Overview of Findings

The purpose of this dissertation study was to determine if there is a predictive relationship between general health literacy level, as measured by The Short Test of Functional Health Literacy in Adults (STOFHLA), and prenatal care health literacy level, as measured by the, Principal Investigator created, Prenatal Care Test of Functional Health Literacy survey instrument, in pregnant females to determine if indeed, knowing the general health literacy level would predict the level of prenatal care literacy level, thus eliminating the need for disease or health content specific measurement tools.

This study addressed several gaps in the literature by exploring the need for disease or content specific health literacy assessments. Health literacy has moved to the forefront of healthcare. Understanding a patient's health literacy status is important in determining how well a patient can navigate through the healthcare system. The STOFHLA is one of the major tools used to assess an individual's health literacy status. However, does knowing a person's general health literacy status correlate with their knowledge when faced with a disease or another facet of the healthcare

system? Therefore, it seems appropriate to determine if general health literacy knowledge is a predictor of specific health literacy knowledge, in this case, of prenatal care. Nothing in the literature indicates that this question has been adequately explored nor answered yet. Engaging in prenatal care has been shown to improve birth outcomes and reduce the number of low birth weight babies (Groutz & Hagay, 1995; Henderon, 1994; Johnson et al, 2007). It is also intended to reduce infant mortality and morbidity. Improving the health and well-being of mothers, infants and children is one of the US Department of Health and Human Service's (2010) Health People 2020 goals. Within that goal, ensuring that 90% of pregnant woman are engaging in prenatal care is one of the main objectives. While there are no experimental studies conducted in the area of prenatal care, studies have shown that engaging in prenatal care improves birth outcomes (Taylor, Alexander, Hepworth, 2005). However, once engagement occurs, the general health or content specific health literacy of these women should be understood. While there has been some documented research surrounding health literacy and prenatal care utilization, the literature is not clear on the importance of the impact one's general health literacy may have upon an individual's prenatal care health literacy.

The general health literacy scores, as measured by the Short Test of Functional Health Literacy in Adults, of pregnant woman engaging in prenatal care in two health centers in New Jersey, were categorized as having

adequate health literacy. This suggests that a ceiling effect exists in this population. According to Polit and Hungler (1995), when data has a clustering of high scores in a sample, it creates a ceiling effect. This would suggest that, while the literature clearly shows that individuals of lower socioeconomic status, minorities and others are highly affected by lower health literacy, this may not be true for pregnant women engaging in prenatal care. This, in turn, may suggest a confirmation of the conversations that have been occurring in the health literacy field regarding adequate methods of assessing prenatal care, specifically the need for disease specific health literacy tools, only a few of which are currently being developed (Gong and associates, 2007, Diamond, 2007).

No ceiling effect was found during the pilot study, therefore, the reliability of the STOFHLA was not calculated for this larger dissertation study. If the reliability had been calculated, it may have been possible to see the need to determine the reliability prior to data collection. The lesson learned is that just because a tool has been well documented in the literature, reliability should always be calculated when the instrument is being used in a different population, and that reliability of an instrument should never be assumed, even if it is considered the “gold standard” of the field.

Pregnancy is often seen as a positive health experience. Individuals engaging in prenatal care may be more familiar with health. They may have a higher health literacy level than those individuals not engaging in prenatal

care. If this is true, then this may be one of the reasons why the reliability of this tool in this population is questionable and why the conversation in the field since 2007 has been moving in favor of assessing health literacy on a disease or content specific basis, as suggested by both Gong and associates (2007) and Diamond (2007).

The STOFHLA, which well documented in the literature as being a highly reliable instrument (Cronbach's Alpha =.98) (Davis, 1999) for measuring health literacy was found, after a reliability analysis was performed, to be unreliable ($r = .33$) in this population, when comparing it against the industry standard of having a reliability coefficient of .70 or higher (Cohen, 2005). The STFOHLA is one of the most commonly used instruments used for assessing general health literacy in adults. It has been used in various clinical and research settings for over twelve years. However, there has been no literature to date that utilizes the STOFHLA in assessing general health literacy in pregnant women engaging in prenatal care. This could simply suggest that the STOFHLA may not be reliable in pregnant women seeking prenatal care in these locations. While this test has been used extensively, the reliability in various populations has not been explored.

The original goal of this project was to recruit a sample larger than the required calculated sample size of 88. Increasing one's sample size is often the most appropriate way to increase the power of an analysis (Munro, 2005). Thus, a larger sample may have increased the reliability of the STOFHLA.

Regardless, the results of this study reinforce the need to calculate the reliability of an instrument whenever it is being used in a new population.

This finding confirms conversations that have begun throughout the health literacy field around the need for a more comprehensive measure of health literacy. While no one is questioning the validity and reliability of current measures, they have suggested that these instruments may not adequately assess health literacy. In fact, the developer of the Short Test of Functional Health Literacy in Adults also suggests that a more comprehensive test is needed to fully understand the health literacy of the population (Baker, 2006). Understanding the key factors within the healthcare system is needed before adequate understanding of the issues surrounding health literacy and questions that are needed to measure health literacy make cohesive sense. Included in the healthcare system analysis, various demographic characteristics should be analyzed to determine if there is a clinical importance (Baker). The findings of this study are in line with these discussions.

The Prenatal Care Test of Functional Health Literacy measured prenatal care health literacy in terms of knowledge and attitudes. The majority of the participants (90%) scored the top score of five out of three knowledge questions. This measure also had a ceiling effect. Variability was seen in only two of the five questions, Question 3 and Question 5. Question 3 asked the length of pregnancy. However, two of the answer choices provide

the correct number with an incorrect time period. Someone reading the survey quickly may circle the incorrect response by mistake. Question 5 also showed variability, with two of the respondents marking answer choice D, which states that postpartum care is for mother and child. While there was not any literature to support this theory, some women may believe that postpartum care is intended for mother and child.

Recall that the reliability analysis conducted on the knowledge section of prenatal care was .27. In this sample, which means that the prenatal care test of functional health literacy knowledge survey section is not reliable and may not be valuable in evaluating prenatal care knowledge. However, the reliability of this test may be improved by reconstructing the knowledge section of the survey tool by adding more in-depth prenatal care questions, as well as by the addition of terms to the questionnaire, such as procedures or testing done during pregnancy, as well as concerning complications and risks of pregnancy.

It may be possible to improve the reliability of the Prenatal Test of Functional Health Literacy knowledge section by addressing the more difficult concepts of prenatal care. For example, focus groups of women with children may provide insight into content areas for a prenatal care test of health literacy. This population of women would be able to suggest content that one should know during pregnancy. Then, a follow up discussion with other healthcare providers who assist women during pregnancy would benefit a

larger discussion on prenatal content. Following, another Delphi should be conducted to assess the validity of the new questionnaire. Finally, a pilot study should be undertaken with a large sample to assess the reliability of the revised instrument. Irrespective of the reliability of the current measure, the results of this study may still be valid in clinical settings.

It is important to note that the current findings could also be a result of the women that are engaging in prenatal care. While no literature could be found to support this theory, Pregnancy could be viewed as a positive health experience and therefore these women may have higher health literacy than those individuals not engaging in prenatal care. If this true, then this may be one of the reasons why the reliability of this tool is questionable in this population. This could also support the need, as suggested by Gong and associates (2007), to develop disease or content specific health literacy assessments. Pregnant women usually conduct their own research on pregnancy through their familial and social support system as well as through other medical outlets. This may increase their knowledge of basic prenatal care questions, which do not vary significantly from the type of questions that are presented in the knowledge portion of the Prenatal Care Test of Functional Health Literacy.

The Prenatal Care Test of Functional Health Literacy Test attitude component is reliable and could be used in prenatal health centers to educate office staff about ways to improve the attitudes of their patients. This may be

specifically important to those with higher educational levels. Again, this element is important in looking at the need to change patient behavior. Thinking back to the social ecological model (Matson-Koffman, Brownstein, Neiner & Greaney, 2005), changes in health outcomes would be possible if health literacy levels were increased. When health literacy improves, behaviors change, which is what the framework predicts. As applied to health literacy and the health encounter, this means that patients move from a very non-autonomous encounter, as referred to by Arthur, Geiser and colleagues (2009) into the type of health encounter suggested by Hester (2009), where they can clearly articulate their symptoms and engage in meaningful dialogue with their providers, adhere to treatment regimens and have better overall health outcomes, thereby moving toward the patient having more autonomous control in their medical decisionmaking.

On the other hand, the Prenatal Care Test of Functional Health Literacy attitude component had great variability, suggesting that women seeking prenatal care had different attitudes regarding their prenatal care experiences. The reliability analysis of this measure proved to be reliable in accessing prenatal care attitudes in this population. The findings are in line with the conceptual framework (Baker, 2006). An individual's capacity, coupled with their attitude, contributes to their health literacy and ultimately their health outcomes. Thinking back to this model, changes in health outcomes would be possible if health literacy levels were increased. When

health literacy improves, behavior changes, which is what the framework predicts. Referring again to the beneficial shift in the quality of the health encounter that would result, as discussed by Arthur and colleagues (1999) and Hester (2009). These findings could be used in clinical settings to assess the knowledge of women engaging in prenatal care. Understanding the maternal attitudes toward prenatal care could help healthcare providers better care for the mother during pregnancy and ultimately improve the pregnancy experience for mother and child.

The correlation analysis of the transformed health literacy and prenatal care knowledge and attitudes demonstrated concluded that a significant relationship exists between general health literacy and the knowledge of prenatal care ($p < 0.01$). The corresponding regression also shows that if the general health literacy score is known, it is possible to predict the knowledge of prenatal care. While a relationship exists between general health literacy and the knowledge of prenatal care, no relationship was found between the general health literacy and the attitude of prenatal care.

Analyses were conducted to determine if differences exist between prenatal care knowledge and attitudes of women in various trimesters of pregnancy. Analyses showed that no differences exist between women in various trimesters of pregnancy. This hypothesis was not supported. This would suggest that women of all trimesters have the same level of prenatal care knowledge and attitudes. This is interesting to note since, according to

the United States Department of Health and Human Services (2010), women enter prenatal care at different stages of pregnancy. However, this finding could also be supported by an earlier discussion that pregnancy may be viewed as a positive health experience. A woman may conduct her own research on this topic through family, friends and other technological sources upon learning of her pregnancy and prior to entering prenatal care.

The final analysis conducted was a factorial analysis to determine if differences in prenatal care knowledge and attitudes were found when women were grouped by the demographic characteristics of education, ethnicity and age. The first analysis that included a three-way ANOVA could not be conducted because there were not enough individuals in the age cell, and the age demographic was deleted from the analysis, reducing the analysis to a two-way ANOVA. The follow up analysis between education and ethnicity found no interactions between prenatal care knowledge or attitudes. The final analysis was a one-way ANOVA, which was performed to determine if interactions exist between the education group and prenatal care knowledge and attitudes or the ethnicity group and prenatal care knowledge or attitudes. Interactions were only found between the education group and prenatal care attitudes. No interactions were found between the education group and prenatal care knowledge. No interactions were found between the ethnicity group and prenatal care knowledge or attitudes. This hypothesis was partially supported. The analysis showed that those with at least a high

school diploma had better attitudes than those who had a bachelor's degree and beyond. A report by the Robert Wood Johnson Foundation's brief on Education and Health (2009) suggests that higher levels of education have been linked with greater perceptions of personal control, fostering skills and attitudes, such as problem solving, that may contribute to improved health outcomes. Additionally, an article by Armstrong (2007) suggests that racial and ethnic minorities have a higher distrust of the healthcare system and of those who have a higher education.

Recall that Arthur, Geiser and associates in 2009 have shown that patients with low health literacy are more likely to have the physician exercise control over their healthcare needs in the encounter. This means that the patient essentially relinquishes gives up their autonomy during the encounter because they are unable to adequately express their desired healthcare needs because they do not have the requisite level of health literacy needed to take control of their own care, converting what is supposed to be an autonomous patient relationship with the physician into a non-autonomous relationship. So, these results really suggest that, although Arthur and colleagues are correct, Hester's (2009) conclusions that higher health literacy levels lead to better communication and better overall healthcare encounters and outcomes are on point and infer something greater occurring in the provider-patient encounter at this level, when health literacy is higher between the engaging parties. This is because patients with higher health literacy

levels are better able to express their symptoms, understand and explain, clarify and inform the healthcare professional in a certain context, all of which are actions needed for beneficial and effective healthcare encounters. (Arthur, Geiser et al, 2009, Hester, 2009).

Therefore, it would make sense that patients of higher health literacy levels would have a lower attitude about the healthcare system or encounter, perhaps suggesting an interpretation of an element of untrustworthiness. This conclusion would be logical because these individuals have the capability to actually challenge information being given to them rather than acquiesce, which might be occurring among those individuals who have a lower health literacy level, who become almost dependent upon the system for their decisionmaking, as Arthur and colleagues suggest.

Interestingly, the attitude scale and scores are consistent with goals from the United States Department of Health and Human Services Healthy People 2020 goals to increase the proportion of persons who report that their healthcare providers have poor communication skills (USDHHS, 2010). Within these goals are the objectives to increase the proportion of providers that listen to patients carefully, always explaining things so patients can understand, showed respect for what patients have to say and spend enough time understanding their needs.

Finally, understanding both the general health literacy and content specific health literacy, in this case, prenatal care coupled with understanding

patient attitudes, may provide a basis for healthcare providers to work closely with patients to improve their health and health outcomes.

Limitations

As with any research project, this study is not void of limitations. The primary limitation is the generalizability of the results. This study was conducted at two distinct locations in the State of New Jersey. These results cannot be generalized to all pregnant women engaging in prenatal care. Next, this study was a cross-sectional design to investigate relationships between general health literacy and prenatal care health literacy at only one point in time. A longitudinal study design, which involves taking measures over an extended period of time, may have produced different results in the attitude component of the study. A cross-sectional design would not capture changes in patient's attitudes.

Furthermore, data was collected from a convenience sample. These women happened to be attending prenatal care on the days and times when data was being collected. The population of pregnant women seeking treatment at the designated data collection sites may not be reflecting the population of pregnant women and thus may limit the generalization of these findings (Burns & Grove, 2001). Since the sample is not representative of the greater population, the results cannot be generalized to a population beyond that being studied.

Finally, the demographic questionnaire relied on women to self-report their data. Validity and accuracy of self reported data could not be confirmed. For example, respondents may not respond honestly to questions regarding their sociodemographic data; for example, some exaggeration may occur when someone self-reports socioeconomic and educational information. Although this may seem harmless, the problem is that if participants exaggerate or minimize responses, distortions of the results and ultimately the conclusions of the study likely will occur. This must be taken into consideration when interpreting the findings of this study.

Study Implications

The findings of this study provide insight into the health literacy literature. While the Short Test of Functional Health Literacy in Adults (STOFHLA) has been used extensively in assessing general health literacy, it may not be adequate for assessing health literacy levels in pregnant women seeking prenatal care.

There was clearly a difference in the attitudes of prenatal care among women who have a higher education. This provides an educational opportunity for healthcare settings. Training should be provided to providers of prenatal care on the importance of ensuring that patients are confident and comfortable with all components of their care. The Prenatal Care Test of Functional Health Literacy can be used in clinical care settings to measure

the attitudes at the beginning of pregnancy and at the end to determine if attitudes improved.

While this was not a study designed to validate theoretical frameworks, the findings shed some light into understanding the social ecological theory and Baker's (2006) conceptual framework on health literacy. Both theories provided a level of understanding into the impact of knowledge on health literacy and health behaviors. It is critical to understand how intrapersonal, interpersonal and environmental aspects of an individual's life, coupled with their previous knowledge and experiences, helps to shape their attitudes and beliefs and ultimately whether they will improve their health outcomes.

In order for one to really provide a framework for understanding health literacy, the research and clinical communities must come to an agreement on a true definition of health literacy. While the definition provided by the United States Department of Health and Human Services (2000) is most commonly used when defining health literacy, it has been criticized throughout the health literacy literature as not being a comprehensive definition. Therefore, while it provided a great starting point for understanding health literacy, there is still room for further discussion and deeper thought processes about understanding health literacy and all of the components that make up this broad spectrum of ideas.

Recalling Baker's (2006) model, which is the adaptation of SEM to health literacy in the real world, which looks at individuals' capabilities and the

demands of health information messages delivered by the healthcare system as a total product. In this model, the healthcare sector shares responsibility for making sure that individuals can use health information effectively. It looks at individual capacity (reading ability and prior knowledge) and how that translates into ability to understand written materials and communicate effectively orally about health. It also considers other factors such as new knowledge, attitudes, self-efficacy and how all of the pieces correlate into improved health outcomes. Considering the elements of SEM superimposed onto Baker's frame, Baker's frame predicts that the outcome of understanding one's health literacy is understanding what one's health outcomes will be like (Baker). Assuming subsequently, that the goal in healthcare is to have improved health outcomes, then healthy literacy has worked its way to the forefront of healthcare to achieve that goal. The importance piece from Baker's model for this research study understanding the measurement of health literacy as it relates to disease or content specific health literacy and applying that to the idea of pregnant women and the importance of prenatal care. This means that health literacy provides patients and providers with the means by which to improve the healthcare encounter for both patient and provider by giving the provider the proper tools by which to improve communication (Hester, 2009) with the patient. This would enable the patient to process information given by the provider more effectively, in order to make better informed health decisions, thereby regaining personal autonomy in the

health encounter. As Arthur et al., (2009) indicated, autonomy is one of the first things relinquished to the practitioner by patients with lower health literacy. The patient becomes better able to take control of the encounter by better communicating their status as needed. This in turn, would enable the provider to provide better care, which leads to better outcomes for mother and infant (USDHHS, 2010).

This study has implications for further research in the field of health literacy and prenatal care. A comprehensive measure of health literacy is needed that will address individuals across all health related areas in order to determine which individuals need assistance in navigating and comprehending health related services. Since prenatal care is critical to both mother and child, ensuring that all women are engaging and in benefiting from prenatal care is important to birth outcomes. Therefore, accessing the knowledge and attitudes of those women may be helpful in achieving that goal. Finally, understanding and improving the communication that occurs during the physician-patient encounter would allow for an autonomous patient relationship. This would ensure that patients are receiving optimal health care that will ultimately reduce cost and improve health outcomes.

Chapter VI

CONCLUSION

Low literacy, poor health and poor outcomes are strongly correlated around the country (Zarcadoolas, Pleasant & Greer, 2006). The National Adult Literacy Survey (NALS) conducted by the United States Department of Education in 1992 found that 90 million people in the United States have limited literacy (Kirsch, Jungeblunt, Jenkins and Kolstad, 1993). Greater literacy issues were found when the assessment was repeated in 2003. Ninety three million individuals were found to have low literacy (Kirsch, Jungeblunt, Jenkins and Kolstad; United States Department and Human Services, 2006). The limited health literacy found in Americans impede on health and health outcomes. However, we are not clear on the need for understanding general health literacy or disease content specific health literacy in individuals.

There is a distinction between literacy and health literacy. General literacy includes reading, writing, basic math calculations and speech (National Institute of Literacy, 2007) According to the United States Department of Health and Human Services (USDHHS) health literacy is more than obtaining, processing and understanding health related information; it also includes the ability to make decisions based on that information (2010). Being health literate means that one has the ability to understand healthcare

providers regarding health conditions and treatment options and knows where to go and who to seek out if help is needed. It also means being able to understand and take medications correctly. Because of the importance of health literacy on health, the health literacy goal established by the USDHHS is to improve health literacy in 90% of Americans (United States Department of Health and Human Services, 2000, 2010).

Health literacy has moved to the forefront of healthcare because of its relationship to health outcomes. Research has shown that health literacy is directly related to poor health outcomes (Baker, Parker, Williams et al., 1996; Institute of Medicine, 2004). Knowing and improving the general health literacy of individuals is important. However, having a higher level of general health literacy may not equate to a having a higher level of content or disease specific health literacy.

For many, prenatal care is an entry point into the healthcare system. Prenatal care is intended to reduce preterm birth, infant mortality and morbidity and to improve birth outcomes. Therefore, engaging in prenatal care is critical to the health of mother and unborn child. Education and literacy correlate to prenatal health (Zarcadoolas, Pleasant & Greer, 2006). Accessing the prenatal care health literacy of pregnant woman should be just as important as understanding the general health literacy. This is important because the general health literacy may not translate to understanding of specific disease or content specific health information. However, to date

there is no measurement tool available that is validated or reliable for the purpose of assessing prenatal care health literacy. To fill this gap in the literature, an attempt was made by this author to develop a disease or content specific assessment of health literacy for women pursuing prenatal care called the Prenatal Care Test of Functional Health Literacy. This measure combined both knowledge and attitude together to one assessment. The knowledge section captured basic prenatal care content. The attitude section captured ones confidence and comfort level with their ability to obtain, process and understand health related information. However, sections were analyzed separately because the two measures were assessed differently, one multiple choice, the other likert scale. The knowledge section was developed using questions generated from a pregnancy brochure developed by the American College of Obstetrics and Gynecology (2007). The attitude section was modified from a brief assessment to measure health literacy (Chew, Bradley & Boyko, 2004). A modified Delphi was used to establish content and face validity (Baker, Lovell & Harris, 2006), (Appendix P).

This study sought to explore relationships between general health literacy and prenatal care health literacy in pregnant women seeking prenatal care. The findings of this study suggest that further research should be undertaken to explore the reliability of the Short Test of Functional Health Literacy in Adults in pregnant women seeking prenatal care. Because of increasing morbidity and mortality among Americans, developing a

comprehensive assessment of health literacy is critical now more than ever. Furthermore, understanding if general health literacy correlates to content or disease specific health literacy is as important because it will help establish the need for disease or content specific health measures of the need to develop a more comprehensive general assessment of health literacy.

Having a reliable measure of assessing prenatal care knowledge may be important to healthcare providers in managing the care of pregnant women. Therefore, further research is needed to determine if the prenatal care knowledge section can be modified to increase the reliability to acceptable levels. This may be possible for example, by merely adding additional questions.

The goal of Healthy People 2020 is to improve the communication of providers and patients (United States Department of Health and Human Services, 2010). The objectives under this goal clearly suggest that patient attitudes would improve based on changes in provider behavior and understanding of patient feelings and beliefs. Since the Prenatal Care Test of Functional Health Literacy attitude component was reliable in this population, further longitudinal studies should be conducted to determine if participants attitudes scores increase after staff training. This would be conducted using a pre-post test analysis. Attitudes would be assessed prior to staff training (at the beginning of the pregnancy) and again at the end of the pregnancy (after staff training). The measure appears to be a great first step into assessing

and improving the attitudes of pregnant women engaging in prenatal care, especially among women of higher educational levels.

Perhaps the greatest takeaway from these findings could be the concept of clear communication. If healthcare providers worked with each individual, regardless of health literacy level, to ensure that diagnosis, treatment options and medical regimens are clearly articulated and understood, it becomes possible to eliminate the need to create individual general or disease or content specific health literacy assessments. The teach back method, whereby healthcare providers ask patients to repeat in their own words what they understood during a medical encounter, is one way to ensure that patients are comprehending the discussion and possible results of a medical encounter.

Finally, while the results of this study were unable to establish correlations between general health literacy and prenatal care health literacy, the results proved valuable in understanding the measures of health literacy assessment, both general and content specific, in pregnant women engaging in prenatal care in New Jersey.

Future Research

This study was undertaken because there was no literature found that discussed establishing relationships between general health literacy and prenatal care health literacy in pregnant females engaging in prenatal care in New Jersey community based health centers. A major finding of this study

was the identification of differences in prenatal care attitudes between those with a high school diploma and those with a bachelor degree level education and beyond. Women with a bachelor's degree or greater had lower prenatal care attitudes than those with at least a high school education, suggesting that the more education the less likely you were to have positive attitudes regarding your prenatal care experience. It would not be unreasonable to state that based on the findings from the study herein, the higher the education, the lower the attitude. After exploring various sections of the literature, it appears that attitudes equate to distrust in the healthcare system. Attitude includes being comfortable with how much time the provider spends with the patient or how confident they are that the provider explained medical treatments or procedures. The findings from this study supports an article by Armstrong and associates (2006), not only is distrust higher among minority populations, it is also higher among those who have higher than a high school diploma. Additionally, increases the attitude of patients is a goal in the Health People 2020 Initiative, under health communication. (USDHHS, 2010). However, further research is needed with a sample of pregnant women who are not engaging in prenatal care to determine if relationships exist between the study variables and/or differences in trimester of pregnancy and the demographic variables. Further research may also include pregnant women not engaging in prenatal care as a control group to see if there are differences between the groups.

Additional research should also be conducted to determine if there are correlations between general health literacy and other disease or content specific health literacy. This area of research has not fully been explored in the literature. This would provide insight into the need for content or disease specific health literacy measurements going forward not only in prenatal care but also in all disease or medical-content areas. The results of these findings would be valuable in determining if it is even practical to develop disease or content specific assessment tools. It may also provide a basis for determining ways to improve communication between providers and patients during the medical encounter (Hester, 2009).

A longitudinal study could also be conducted using the attitude section of the Prenatal Care Test of Functional Health Literacy to determine if attitude scores increased after training of the healthcare provides. A pre-post analysis could be used at the time of pregnancy and at the time of delivery to determine if a participants attitude scores increase after the office staff participated in training that addressed particular components of a patients' attitudes. A finding of increased health literacy scores would support Hester's (2009) findings that higher scores indicate better encounters and outcomes.

Finally, adding additional demographic characteristics to future research may be valuable in analyzing their effect on the study variables. Characteristics such as marital status may help us understand the support system that may impact health behavior and decision-making.

Characteristics such as employment and insurance status may indicate barriers related to accessing prenatal care and provide clues to how these barriers may be eliminated in the future through improving the understanding of how these barriers affect healthcare as well as how these barriers further impact those individuals with low or limited health literacy skills.

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APPENDICES

- A. Letter to Expert Panel for Modified Delphi
- B. Panel Demographic Questionnaire
- C. Delphi Process Results
- D. Steps in the Research Process for Pilot
- E. Pilot Project Process
- F. Research Assistant Training Guide
- G. Research Assistant Recruitment Preparation Checklist
- H. Research Assistant Recruitment
- I. Research Assistant Script
- J. Participant Letter of Solicitation
- K. Participant Demographic Survey
- L. Short Test of Functional Health Literacy Assessment in Adults
- M. Prenatal Care Test of Functional Health Literacy
- N. UMDNJ IRB Approval
- O. SHU Pilot IRB Approval
- P. Summary of Pilot Results

Appendix A
Letter to Expert Panel

Dear XXXXX:

My name is Rhonda McCathern and I am a doctoral student at Seton Hall University in the School of Health and Medical Sciences. Thank you for agreeing to participate as a member of an expert panel to help establish content and face validity on a survey that will be used in my Ph.D dissertation research project and pilot study on health literacy in a prenatal care population.

Brief background, operational definition & theory

Health literacy, defined by the United States Department of Health and Human Services (USDHHS) is, "the degree to which individuals have the capacity to obtain, process, and understand, basic health information and services needed to make appropriate health decisions"(2001). Health literacy means more than transmitting information or developing skills to be able to read pamphlets or make appointments, it requires the ability to be able to navigate or function within the realm of health care, specifically, functional health literacy. However, the literature will confirm that health literacy extends beyond understanding general health information but being able to obtain, process and understand in the context of health information, that is important or relevant to each individual.

Purpose of tool development

The purpose of my doctoral research is to explore, describe and examine if general health literacy scores as measured by the Short Test of Functional Health

Literacy (STOFHLA) (Baker, Williams, Parker, Gazmararian & Nurss, 1999) predict scores on a prenatal test of functional health literacy. To do this it is necessary to create a modified tool based on the S-TOFHLA as suggested and supported in the literature, so that a clear base of comparison and relation between general health literacy and specific health literacy, if any, can be established (Gong et al., 2007).

The first step of this process is to create and secure face and content validity on the assessment tool for prenatal care health literacy.

Subsequently, this tool will be used for assessment during a pilot study. This pilot study will serve as a catalyst to determine how effectively, if at all, health care organizations and providers communicate with women in prenatal care.

Expert panel instructions

Included in this packet is the created prenatal test of functional health literacy, for which you will be reviewing and providing feedback. The first portion of the tool was modified from the BRIEF test of health literacy that seeks to assess a patient's comfort level with reading and understanding basic health information (Chew, Bradley, Boyko, 2004). The questions have been modified to include questions specific to prenatal care. The second portion assesses knowledge of content specific to prenatal care.

In order to establish face and content validity, I would appreciate your review of the prenatal test of functional health literacy for the appropriateness, clarity, and sequence of the questions. This survey tool will then be modified after responses from the expert panel are received. Based on the panel feedback, a second review may be needed. If that is the case, I kindly ask for your continued participation. After the final version of the survey has been approved and prepared, a sample of women attending prenatal care visits throughout the State of New Jersey will be invited to participate in the study as part of a pilot study to test the process and use of the tool.

You are being asked to review the survey in its entirety, including the cover letter and demographic survey for the participants. Please review the enclosed instructions and questions to the patient. Please provide your responses and comments in the grey box below each question on the enclosed survey. A blank comment section is listed at the end for you to provide any additional feedback. Please also use the following definitions below when providing your feedback:

Appropriate: The survey question and answers are suitable for this study.

Clear: The survey question and answers are easy to understand.

Sequence: The survey questions and answers are presented in a logical order.

Importance - The survey is important to this study.

Additionally, an expert reviewer demographic form is enclosed at the end of the packet for you to complete.

Included in this packet is the following:

- I. Survey content
 - a. Research questions
 - b. Variables
 - c. Operational Definition
- II. Patient Demographic Survey
- III. Prenatal Care Test of Functional Health Literacy Patient Copy
- IV. Prenatal Care Test of Functional Health Literacy Panel Feedback Form
- V. Panel Demographic Form

Should you find that any of these items are missing from your package, please contact me immediately at mccathrh@shu.edu. The missing material will be sent to you immediately.

Privacy and Confidentiality

In order to preserve the anonymity of your response, please return your comments via email to rmverdier@aol.com no later than July 21, 2010. Copies of the feedback and data form will be returned to me without any personal identifiers attached. If a second review is needed, you will receive the revised survey instrument within 5- 7 days after I receive all initially

returned responses. If desired, upon completion of the data analysis, the final results of the study will be provided to you. Thank you for your assistance and expertise in evaluating these survey materials. I look forward to your response and expert review of my survey tool.

Sincerely,

Rhonda M. McCathern

**APPENDIX B
PANEL DEMOGRAPHIC QUESTIONNAIRE**

1. Gender: ___ Male ___ Female
2. Age in years: ___ 30-34 ___ 35-39 ___ 40-44 ___ 45-49
 ___ 50-54 ___ 55 -59 ___ 60 – 64 ___ 65-69 ___ 70+
4. Ethic Background
 ___ African American
 ___ Caucasian
 ___ Native American
 ___ Hispanic
 ___ Other _____
5. Area of Expertise
 OB/GYN
 Health Literacy
 General Health Care
6. Educational Background (Please check degree and specify field)
- Associates Degree - Field: _____
- Bachelor's degree - Field: _____
- Master's degree – Field: _____
- Doctoral degree - Field: _____
- MD - Field _____
- Other: (Please list) _____
7. Years working with surveys and in what capacity? _____
8. Years working in your field and in what capacity? _____

Thank you for taking the time to review this survey and provide feedback. Your time and effort are greatly appreciated.

Appendix C

Modified Delphi Results

The Prenatal Care Test of Functional Health Literacy is a content specific health literacy assessment created by the principal investigator. The Prenatal Care Test of Functional Health Literacy assessment tool, a sixteen question survey, was developed by modifying the BREIF health literacy assessment tool (Chew, 2007). The questions contain either a multiple choice or Likert scale answers. Face and content validity was established by review from an expert panel. A modified Delphi was used to validate the study. Delphi is a technique that uses experts to review and establish consensus on various components used in research. (Baker, Lovell & Harris, 2006). The definition of an expert is controversial in the literature. However, for the purpose of this pilot study an expert is defined as knowledgeable in a specific area (Soanes & Stevenson, 2003). Similarly, experts were selected if they possessed a terminal or master's degree in medicine, education or a related field, with 10 or more years of experience (citation). To establish face and content validity for the Prenatal Care Test of Functional Health Literacy, 7 experts (2 health literacy experts, 2 OB/GYN experts, 2 nurses and 1 educational professional) were invited to participate in the review. Five of the 7 panelist participated in the two rounds of review. Validation of the survey was obtained by emailing seven experts in health

literacy, Obstetrics and Gynecology, education or general health care. Two health literacy experts, two OB/GYN's, two registered nurses and one educator were identified.

An introduction letter (Appendix) and demographic questionnaire was included with the copy of the survey. The introduction letter included a brief summary of the purpose of the study, instructions and the investigators contact information in case the expert had questions about the survey. The expert panel was asked to review each question and provide comments on the following criteria:

- a. Appropriateness (Question and answers are suitable for the study)
- b. Clarity (Question and answer choices are clear and easy to understand)
- c. Importance (Question is important to the study)
- d. Sequence (the question is presented in logical order)

To preserve the anonymity of responses, panelist were asked to complete the review and demographic questionnaire and return it to the research assistant in this project. Surveys and demographic questionnaires were printed and hand delivered to the principal investigator. A reminder email was sent to all seven panelist two days prior and one day after the submission date. Analysis was not completed until five responses were received. The survey was revised if three or more of the panelist commented on the same question with the same or similar concern. Additionally, changes

were made if a panelist commented on an area that the investigator felt was important to change. After the first round several changes were required and made to the content and sequence of the survey. The revised survey was sent to panelist within three days of the close of the first review for the second review. The results from the first round were included in the instructions for the second round. The second round met the required consensus needed to finalize the surveys. Therefore, no additional rounds of review were required.

The Prenatal Care Test of Functional Health Literacy has five multiple-choice questions that assess current prenatal care knowledge and eleven questions that assess feelings about various components of prenatal care. Each question of the Prenatal Care Test of Functional Health Literacy will be scored by comparing each screening question to the Short Test of Functional Health Literacy and computing the sensitivity and specificity and positive and negative likelihood ration with a 95% confidence interval. using the Receiver Operating Characteristic (ROC) (Simel, Samsa, & Matchar, 1991).

A description of the results of the Delphi is listed below. A copy of the final Prenatal Care Test of Functional Health Literacy is found in appendix

Results

Analysis

Below are the summaries of the responses per question. Only comments received by three or more experts (30%) were considered for

revision unless the researcher believed that the suggestions would improve clarity.

Question 1

How difficult is it to obtain prenatal care Information?

The purpose of question 1 was to determine how difficult it was for patients to obtain information regarding prenatal care. The experts were asked to review the questions for clarity, importance, importance and sequence. Experts only provided answers for the criteria that they had comments. All five of the experts provided answers for this question. All respondents believed the question was appropriate for the survey. Two experts (40%) felt that question was unclear. One expert felt that prenatal care should be defined and one expert felt that the question should identify which provider (nurse, physician, midwife, etc.) the patient would be receiving information. All of the respondents felt this question was important to the study. Four of the respondents (80%) had concerns with the location of the multiple choice and likert scale questions. Therefore, the multiple-choice questions were moved to the beginning of the survey. The wording of this question was not changed however in round two of the delphi, two of the participants felt that this question should be moved further down in sequence. The question was moved to the third question in the set of likert scale questions.

Question 2

How often do you have to ask for information related to your pregnancy from your health care provider?

The purpose of this question was to determine the difficulty in obtaining information regarding pregnancy. The experts were asked to review the questions for clarity, importance, importance and sequence. All five experts provided responses to this question. Four of the respondents (80%) believed the question was appropriate for the survey. However, one panelist felt the question needed more detail regarding who was being asked for information (physician, nurse, midwife, etc.). One of the respondents felt that this question was inappropriate because patients should always have questions for their providers. Four of the respondents felt the question was clear. One respondent felt that the question was anti-doctor. Four respondents felt that the question was important. One respondent did not respond to the importance of this question. This question was also moved along with the other likert scale questions, based on the respondent feedback. This question was not modified in the final survey.

Question 3

How confident are you asking for information related to your prenatal care from your health care provider.

The purpose of this question was to determine how confident a patient was in obtaining information from their health care provider. All five of the respondents thought this question was appropriate to this study. While all five

of the respondents felt this question was clear, one respondent felt that I should clarify whether I was referring to physician from the practice. All five of the respondents felt this question was important and in the correct sequence. This question was not changed.

Question 4

When I receive prenatal care information, I have someone help me read it.

The purpose of this question was to determine if patients have difficulty reading and understanding prenatal care information. The experts were asked to review the questions for clarity, importance, importance and sequence. All five experts felt this question was appropriate clear and important. However, three of the participants felt that this question should be located before the question asking about written information about prenatal care. This question appropriately relocated to question 13. One respondent in round two felt this question should have written prenatal care information. However, based on the criteria for changing questions, this question was not changed in the final version.

Question 5

How difficult is it for you to make decision about your care based on information from your health care provider?

The purpose of this question is to evaluate a patient's ability to process information and make decision based on that information. Four of the respondent's felt this question was appropriate, clear, important and in the

correct sequence for this study. One respondent felt that the question needed to clarify what decisions were being made. This question was not changed in the final survey.

Question 6

How confident are you making decision alone about your pregnancy?

The purpose of this question was to determine confidence in obtaining and processing information and being able to make decisions regarding their pregnancy.

Four of the respondents felt this question was appropriate, clear, important and in the correct sequence. One respondent felt that patients do not make decisions alone. Their husbands, mothers, friends, etc. usually help a woman make decisions regarding pregnancy. This question was not changed in the final survey.

Question 7

Once I have information regarding prenatal care, I am confident about what I need to do during my pregnancy.

The purpose of this question was to determine if a woman is able to obtain and process information to make decisions regarding pregnancy. Four of the respondents felt this question was appropriate, clear, important and in the right sequence. One respondent felt that the question should clarify whether it was written or verbal information? Based on the criteria for changing questions, this question was not changed in the final version.

Question 8

Based on what I have read about prenatal care, I am comfortable giving consent to my health care provider for care/treatment.

The purpose of this question was to determine if a patient is comfortable making health care decisions based on information they have obtained and processed. Four of the respondents felt that the question was appropriate, clear, important and in the correct sequence. One of the respondents felt that there were not many choices during pregnancy that needs to be determined. Clarity should be provided regarding types of decisions. Based on the criteria for changing questions, this question was not changed in the final version.

Question 9

I have difficulty understanding written information about prenatal care.

The purpose of this question was to determine a patient's difficulty understanding prenatal care information. All of the respondents felt this question was appropriate, clear, important and in the correct sequence for this study. Based on the criteria for changing questions, this question was not changed in the final version.

Question 10

I have difficulty understanding what my health care providers tells me about my pregnancy.

The purpose of this question was to determine if a patient had difficulty understanding what a provider tells them about pregnancy. While all of the respondents felt this question was appropriate, clear, important and in the correct sequence, one respondent felt we needed to ask the reason for the difficulty. Based on the criteria for changing questions, this question was not changed in the final version.

Question 11

How confident do you feel you are able to follow instructions for medication prescribed to you by your health care provider during your pregnancy?

The purpose of this question was to determine if patients were able to understand information provided to them by their provider. While all five of the respondents felt this question was appropriate, clear, important and in the correct sequence, one respondent felt the question should clarify whether it was written or verbal instructions from the physician or the pharmacist. In round two, one respondent felt that the wording should be changed to, "Are you confident or able to follow instructions for medication prescribed to you by your health care provider during your pregnancy?" Based on the criteria for changing questions, this question was not changed in the final version.

Question 12

What is prenatal care?

The purpose of this question was to determine if patients understood the definition of prenatal care. All of the respondents felt that this question

was appropriate, clear and important. Four of the respondents (80%) had concerns with the location of the multiple choice and likert scale questions. Therefore, the multiple-choice questions were moved to the beginning of the survey. While round two of the Delphi had this question located as question 3, three of the respondents felt this question should be moved. Based on the criteria for changing questions, this question was appropriately moved to question 1.

Question 13

What is postpartum care?

The purpose of this question was to determine if patients understood the meaning of postpartum care? All of the respondents felt that this question was appropriate, clear, important and in the correct sequence for this study. Based on the criteria for changing questions, this question was not changed in the final version. Question 14

What is a trimester?

The purpose of this question was to determine if patients understood the meaning of trimester. All of the respondents felt that the question was appropriate, clear, important and in the correct sequence. However, one of the respondents felt that one of the answer choices should be removed. While this comment did not meet the criteria for changing questions, the investigator felt that a clear response could be provided. The answer marathon was changed to every four months. Based on the criteria for

changing questions, no additional changes were made to the final version.

Question 15

You should **ONLY** see your doctor?

The purpose of this question was to determine if patients knew when they should see their doctor. While all of the respondents felt this question was appropriate, important and in the correct sequence, three of the respondents felt that the wording should be consistent with other questions in the survey and clearer. Based on the criteria for changing survey questions, the question was changed to read, "During pregnancy, you should **ONLY** see your health care provider?" However, in round two of the Delphi, the word pregnancy in the question was mistakenly capitalized. One respondent provided a comment on this error. This change was made in the final version.

Question 16

A typical pregnancy lasts for about?

The purpose of this question was to determine if a patient understood the pregnancy length. All of the respondents felt this question was appropriate, clear, important and in the correct sequence. However, one respondent noted a tyop on this question in round two. The question was changed to read, a typical pregnancy lasts (the previous question had last) for about? Based on the criteria for changing the survey, no changes were made to this survey in the final version.

Results Summary

While the location of all of the questions was changed, specifically, the likert scale changed with the multiple choice questions, only three questions were modified based on the input from the experts. The final survey is clear and logically ordered.

Conclusion

The purpose of this paper was to describe the development and validation of a survey to be used to determine confidence in delegation by registered nurses when working with UAPs. The survey was developed after a thorough review of published literature describing issues with confidence in delegation. Validation of the survey was performed by experts in healthcare and research and to ensure that the survey was appropriate, clear and information was presented in the proper sequence. Validating the survey for content validity.

Survey validation allows the researcher to ensure that the survey will adequately capture the appropriate information necessary to conduct the research. Overall the experts believed that the survey was clear and appropriate and the questions were presented in the proper sequence. Only minor changes were made to the final version of the survey and all were made to improve the clarity of the survey. All changes are incorporated into the final survey, Appendix I.

APPENDIX D
Steps in Research Process

Exploring relationships between general health literacy levels and prenatal care health literacy levels.

STEPS in the RESEARCH PROCESS for PILOT

Pre-Recruitment Steps

1. Obtain IRB Approval
 - a. UMDNJ – Appendix P
 - b. Seton Hall University
2. Train research assistant – Appendix E
 - a. Letter of Solicitation/Informed consent
 - b. Administration of survey tools
 - c. Data collection and confidentiality
 - d. Transfer of data to principal investigator
 - e. Recruitment location
 - i. Address
 - ii. Directions
 - iii. Point of contact
 - f. Principal investigator contact information
3. Code surveys & envelopes for Pilot
 - a. Location Code
 - i. UMDNJ – SOM (1)
 - b. Participant code (1-25)
4. Prepare packets in 9 ½ by 11 envelopes
 - a. Sharpened Pencil
 - b. Letter of Solicitation/Informed consent – Appendix K
 - c. Demographic survey – Appendix L
 - d. Short Test of Functional Health Literacy in Adults (S-TOFHLA) – Appendix M
 - e. Prenatal Care Test of Functional Health Literacy – Appendix N
5. Distribute packets to research assistant prior to recruitment

Recruitment Steps

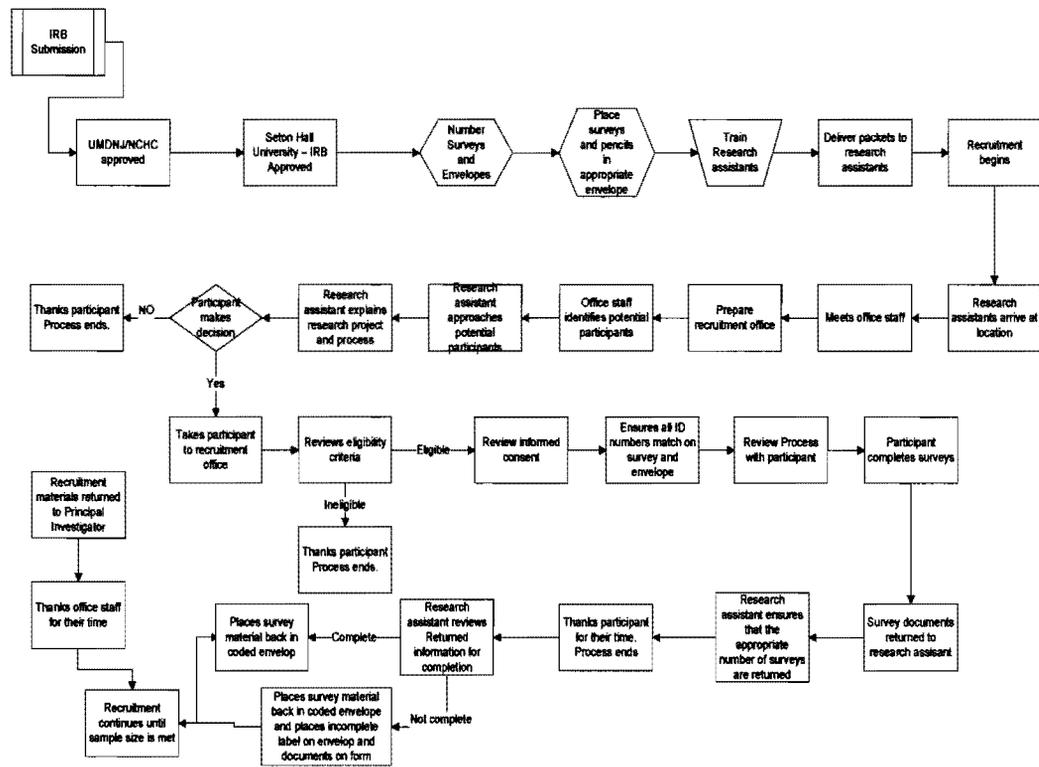
6. Recruitment
 - a. Participant identified by office staff
 - b. Approach participant for participation
 - c. Take potential participant to identified location
 - d. Review inclusion/exclusion criteria
 - e. Review research process with participant
 - f. Ensure appropriate coding on all survey materials

- g. Review informed consent with potential participant
- h. Participant completes demographic questionnaire
- i. Participant completes Short test of functional health literacy
- j. Participant completes Prenatal Care Test of Functional Health Literacy

If participant gets called into their prenatal care appointment, inform participant that you will keep their packet aside until the appointment is completed. Inform the office staff that participant should be gently reminded to complete their survey at the end of the appointment. If participant does not return by the end of the recruitment day, mark the packet with a withdraw label.

- k. Thank participant for participating in the study
 - l. Ensuring appropriate coding on all survey materials upon receipt
 - m. Review surveys for completeness
 - n. Return all materials to envelope and seal
 - o. Mark incomplete packets with withdrawal or incomplete label
 - p. Repeat process until desired number is reached
7. Meet with principal investigator to review the day's activity and deliver participant packet.

APPENDIX E Data Collection Process



APPENDIX F Training Guide

Exploring Relationships between general health literacy levels and prenatal care health literacy levels

Research Assistant Training Guide
Rhonda M. McCathern, MPA

Outline

- Research Outline
 - Purpose
 - Research Questions
- Recruitment Process
 - Sample Size
 - Checklist
 - Preparation
 - Recruitment
 - Research Script
 - Research Steps
 - Inclusion/exclusion criteria
 - Informed Consent
 - Survey Tests
- Recruitment Location Information
 - Location
 - Contact Information
- Principal Investigator Contact Information

Purpose

- To determine if there is a predictive relationship between general health literacy level, as measured by the Short Test of Functional Health Literacy in Adults (S-TOFHLA), and prenatal care health literacy level, as measured by the Prenatal Care Test of Functional Health Literacy, in pregnant females

Research Questions

- RQ1. What are the general health literacy scores of pregnant women as measured by the Short Test of Functional Health Literacy in Adults (STOFHLA)?
- RQ2. What are the prenatal care scores of pregnant women as measured by the Prenatal Care Test of Functional Health Literacy?

Research Question cont.

- RQ3. Is there a significant relationship between general health literacy, as measured by the STOFHLA, and prenatal care health literacy level, as measured by the Prenatal Care Test of Health Literacy, in pregnant females?
- RQ4. Is it possible to predict the level of prenatal care health literacy a pregnant female will have (as measured by the Prenatal Care Test of Health Literacy) if the individual's general health literacy level is known, as measured by the STOFHLA?

Research Question cont.

- RQ5a. Is there a difference in general health levels between first, second and third trimester pregnant females?
- RQ5b. Is there a difference in prenatal care health literacy scores between first, second and third trimester pregnant females?
- RQ6. What are the differences in prenatal care health literacy scores when pregnant women are grouped by educational attainment, ethnicity and age?
- educational attainment, ethnicity and age.

Sample Size

- ▶ Eighty eight (88) women will be recruited from a convenience sample.

Recruitment preparation Checklist

- Review study protocol
- Review inclusion/exclusion criteria
- All research materials received
 - research packets with surveys
 - Pencils
 - Recruitment location
- Directions
 - Recruitment location Contact information
 - Principal investigator contact information
 - Labels for incomplete
 - Labels for withdrawal
 - ID coded sheet for incomplete and withdraw
- Ensure packets have ID code that matches the following
 - Informed consent
 - Demographic Survey
 - Short Test of Functional Health Literacy
 - Prenatal Test of Functional Health Literacy

Recruitment Checklist

- Introduce yourself to staff
- Ensure recruitment office has a table and chair for participant
- Meet with potential participant
- Review research project
 - Eligibility
 - Informed consent
 - Process
- Ensure participant has appropriate number of surveys with same code
 - Demographic survey
 - Short Test of Functional Health Literacy
 - Prenatal Care Test of Functional Health Literacy
- Make sure all materials are returned
- Thank participant for their time
- Make sure all materials match ID number on envelope
- Review participant materials to see if they are complete
- Return all materials to the ID coded envelope
- Mark incomplete packets with an incomplete or withdraw label

Recruitment Script

- ▶ My name is XXX and I am a research assistant with Rhonda M. McCathern, Principal Investigator of this project. The purpose of this project is to explore relationships between general health literacy levels and prenatal care health literacy levels. The research project includes completion of three surveys. It should take about 15 - 20 minutes to complete. Prior to beginning the study, we need to determine if you are eligible to participate. (Review Inclusion/Exclusion Criteria). Informed consent must be reviewed and agreed before you can begin the process. Once you have reviewed the informed consent, we can begin the study.

Inclusion/Exclusion Criteria

Participant inclusion criteria:

- ▶ Pregnant women attending prenatal care visits in their first, second or third trimester
- ▶ Between the ages of 18-35 at time of conception
- ▶ First pregnancy
- ▶ Singleton birth
- ▶ English speaking

Participant exclusion criteria:

- ▶ Postpartum women
- ▶ Males
- ▶ Under 18 years of age or over 35 at time of conception
- ▶ Multiple birth
- ▶ 2nd or more pregnancy carried full term
- ▶ Non-English speaking

Research Process Steps

- Pre-Recruitment Steps
 - Obtain IRB Approval
 - Newark Federally Qualified Health Center
 - UNiDg
 - Seton Hall University
 - Train research assistant
 - Letter of Solicitation/informed consent
 - Administration of survey tools
 - Data collection and confidentiality
 - Transfer of data to principal investigator
 - Recruitment location
 - Address
 - Directions
 - Point of contact
 - Principal investigator contact information
 - Code surveys & envelopes for IRB
 - Location Code
 - UNiDg - SOH 11)
- Newark Community Health Center LT:
 - Participant code
 - Prepare packets in 9 x 11 envelopes
 - Shapovalov Period:
 - Letter of Solicitation/informed consent
 - Demographic survey
 - Short Test of Functional Health Literacy in Adults (S-TFHLEA)
 - Prenatal Care Test of Functional Health Literacy
 - Distribute packets to research assistant prior to recruitment

Research Process Steps cont.

- 1. Recruitment Steps
 - 1. Recruitment
 - Participant identified by office staff
 - Approach participant for participation
 - Take potential participants to identified location
 - Review inclusion/exclusion criteria
 - Review research process with participant
 - Ensure appropriate coding on all survey materials
 - Review informed consent with potential participant
 - Participant completes demographic questionnaire
 - Participant completes Short test of Functional Health Literacy
 - Participant completes Prenatal Care Test of Functional Health Literacy
 - 2. If participant gets called into their prenatal care appointment, inform participants that you will keep their packet aside until the appointment is completed. Inform the office staff that participants should be gently reminded to complete their survey at the end of the appointment. If participant does not return by the end of the recruitment day, mark the packet with a withdrawal label.
 - Thank participant for participating in the study.
 - Ensuring appropriate coding on all survey materials upon receipt
 - Review surveys for completions
 - Return all materials to envelope and seal
 - Mark incomplete packets with withdrawal or incomplete label
 - Repeat process until desired number is reached
 - 3. Meet with principal investigator to review the day's activity and deliver participants back to

Informed Consent

- ▶ Informed consent is an important part of the research process. It requires that prospective participants are aware and fully informed about the purpose of the project, the cost and benefits associated and the process prior to making a decision to engage in the research.

Survey Material

Recruitment Location

School of Osteopathic Medicine
Women's Health Center
Harbor Pavilion
570 Egg Harbor Road, Suite C-2
Sewell, NJ 08080

Newark Community Health Centers
Irvington Location
1150 Springfield Avenue
Irvington, NJ 07111

Contact Information

School of Osteopathic Medicine
Keith Williams, M.D., MBA, DABOG, MBA
Obstetrics and Gynecology
856-566-7099
williamsk@umdnj.edu

Deaf Secretary
Mary Cross
856-566-6938
mccrossm@umdnj.edu

Newark Community Health Center
Janice Anderson, Ph.D., RN
janderson@nchcinc.org
973-483-1300

Principal Investigator Contact

Rhonda M. McCathern
732-425-7729 (mobile)
732-235-3913 (office)
732-805-9292 (home)
mccathern@umdnj.edu (work)
mccathern@shu.edu (school)

Dissertation Advisor

Dr. Deborah Deluca
Seton Hall University
973-275-2842

APPENDIX G
Research Assistant Recruitment preparation Checklist

- Review study protocol
- Review inclusion/exclusion criteria
- All research materials received
 - research packets with surveys
 - Pencils
 - Recruitment location
 - Directions
 - Recruitment location Contact information
 - Principal investigator contact information
 - Labels for incomplete
 - Labels for withdrawal
 - ID coded sheet for incomplete and withdraw
- Ensure packets have ID code that matches the following:
 - Informed consent
 - Demographic Survey
 - Short Test of Functional Health Literacy
 - Prenatal Test of Functional Health Literacy

APPENDIX H

Research Assistant Recruitment Checklist

- Introduce yourself to staff
- Ensure recruitment office has a table and chair for participant
- Meet with potential participant
- Review research project
 - Eligibility
 - Informed consent
 - Process
- Ensure participant has appropriate number of surveys with same code
 - Demographic survey
 - Short Test of Functional Health Literacy
 - Prenatal Care Test of Functional Health Literacy

- Make sure all materials are returned
- Thank participant for their time
- Make sure all materials match ID number on envelope
- Review participant materials to see if they are complete
- Return all materials to the ID coded envelope
- Mark incomplete packets with an incomplete or withdraw label

Appendix I Research Script

My name is XXX and I am a research assistant with Rhonda M. McCathern, Principal Investigator of this project. The purpose of this project is to explore relationships between general health literacy levels and prenatal care health literacy levels. The research project includes completion of three surveys. It should take about 15 - 20 minutes to complete. Prior to beginning the study, we need to determine if you are eligible to participate. (Review Inclusion/Exclusion Criteria). Informed consent must be reviewed and agreed before you can begin the process. Once you have reviewed the informed consent, we can begin the study.

SETON HALL UNIVERSITY

1 8 5 6

LETTER OF SOLICITATION

Study Title: "Exploring the Relationship between General Health Literacy Levels and Prenatal Care Health Literacy Levels."

Dear Prenatal Care Participant:

Affiliation

My name is Rhonda M. McCathern and I am a doctoral student in the School of Health and Medical Sciences at Seton Hall University. I am conducting a research project that will culminate in my dissertation.

Purpose

You are being invited to participate in this research study because you are a pregnant woman engaging in prenatal care. Studies have shown that health literacy and prenatal care are two important factors in healthcare. However, the relationship between general health literacy and prenatal care literacy has not established. Therefore, this purpose of this study is to explore the predictive relationship between general health literacy and prenatal care health literacy.

Procedure

You will be asked to complete 3 questionnaires found inside this packet.

- (1) Demographic profile – The purpose of this questionnaire is to collect demographic information including, age, ethnicity, years of education, religion, income level
- (2) Short – Test of Functional Health Literacy Assessment – The purpose of this questionnaire is to assess your ability to understand health related information.
- (3) Prenatal care test of functional health literacy – The purpose of this question is to assess your ability to understand prenatal care related information.

It is important that you complete all three questionnaires and return them to the research assistant when you are completed. The process should take about fifteen (15) – twenty minutes (20) of your time.

[973-313-6314]

Seton Hall University
Institutional Review Board

MAR 30 2011

School of Health and Medical Sciences
Department of Graduate Programs in Health Sciences
Tel: 973.275.2076 • Fax: 973.275.2171
400 South Orange Avenue • South Orange, New Jersey 07079 • shms.shu.edu

Approval Date

Voluntary participation

Your participation in the research study is entirely voluntary. You may decide not to participate at any time. If you decide not to participate, you will not be penalized or lose any benefits to which you are otherwise entitled. Consent to participate in this study is indicated by returning the enclosed questionnaire to the research assistant when you are completed.

Anonymity

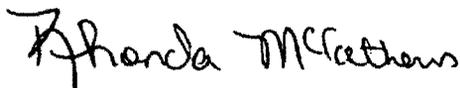
You will not be identified by name or description in any reports or publications about this study. A coding system, through the use of numbers found in the top left hand corner of each questionnaire will be used to maintain complete anonymity at all times.

Confidentiality

All information in this study will be kept strictly confidential. All research data will be stored on a USB memory key in a locked cabinet in the principal investigator's office. The principal investigator, Rhonda McCathern is the only individual who will have access to all of the research data for a period of three years. Thereafter, all research data will be destroyed.

Thank you for your time.

Sincerely,



Rhonda M. McCathern

Doctoral Candidate

[973-313-6314]

Seton Hall University
Institutional Review Board

MAR 30 2011

Approval Date

Appendix K

ID #: _____

Participant Demographic Questionnaire

1. What is your current age _____ 2. What age were you when you became pregnant? _____

3. What is your current trimester? 1st 2nd 3rd

4. Including today, how many prenatal care visits have you had? _____

Race/ethnicity

5. How do you describe yourself? (please check the one option that best describes you)

- American Indian or Alaska Native
- Hawaiian or Other Pacific Islander
- Asian or Asian American
- Black or African American
- Hispanic or Latino
- Non-Hispanic White
- Other: Please list _____

Marital status

6. Are you: Married Not Married

Employment status

7. Are you: Employed Not Employed

7a. If employed, what field, profession or job do you perform? _____

Education completed

8. What is the highest level of education you have completed?

- Grammar school
- High school or equivalent
- Associate/Vocational/technical school (2 year)
- Some college
- Bachelor's degree
- Master's degree
- Doctoral degree
- Professional degree (MD, JD, etc.)
- Other : _____

8a. If degrees issued, what is the discipline or field of study _____

Household Income

9. What is your total household income?

- Less than \$10,000
- \$10,000 to \$29,999
- \$30,000 to \$49,999
- \$50,000 to \$69,999
- \$70,000 to \$89,999
- \$90,000 to \$109,999
- Over \$110,000

Appendix L

PASSAGE A

Your doctor has sent you to have a _____ X-ray.

- a. stomach
- b. diabetes
- c. stitches
- d. germs

You must have an _____ stomach when you come for _____

- a. asthma
 - b. empty
 - c. incest
 - d. anemia
- a. _____
 - b. an _____
 - c. if _____
 - d. it.

The X-ray will _____ from 1 to 3 _____ to do.

- a. take
 - b. view
 - c. talk
 - d. let
- a. beds
 - b. brains
 - c. hours
 - d. diets

DO NOT COPY

THE DAY BEFORE THE X-RAY.

For supper have only a _____ snack of fruit, _____ and jelly,

- | | |
|-----------|-----------|
| a. little | a. roes |
| b. broth | b. throat |
| c. attack | c. toast |
| d. nausea | d. thigh |

with coffee or tea.

After _____, you must not _____ or drink

- | | |
|--------------|---------|
| a. minute, | a. easy |
| b. midnight, | b. are |
| c. during, | c. tank |
| d. before, | d. eat |

anything at _____ until after you have _____ the X-ray.

- | | |
|----------|--------|
| a. ill | a. are |
| b. _____ | b. has |
| c. each | c. had |
| d. any | d. was |

THE DAY OF THE X-RAY.

Do not eat _____.

- a. appointment.
- b. walk-in.
- c. breakfast.
- d. clinic.

Do not _____, even _____.

- | | |
|-----------|------------|
| a. drive, | a. heart. |
| b. drink, | b. breath. |
| c. dress, | c. water. |
| d. dose, | d. cancer. |

If you have any _____ call the X-ray _____ at 616-4500.

- | | |
|---------------|---------------|
| a. answers, | a. Department |
| b. _____, | b. Sprain |
| c. trays, | c. Pharmacy |
| d. questions, | d. Toothache |

Do Not Copy

PASSAGE B

I agree to give correct information to _____ if I can receive Medicaid.

- a. hair
- b. salt
- c. see
- d. ache

I _____ to provide the county information to _____ any

- | | |
|----------|--------------|
| a. agree | a. hide |
| b. probe | b. risk |
| c. send | c. discharge |
| d. gain | d. provide |

statements given in this _____ and hereby give permission to

- a. emphysema
- b. application
- c. gallbladder
- d. relationship

the _____ to get such proof. I _____ that for

- | | |
|-----------------|----------------|
| a. inflammation | a. investigate |
| b. religion | b. entertain |
| c. _____ | c. understand |
| d. county | d. establish |

Medicaid I must report any _____ in my circumstances

- a. changes
- b. hormones
- c. antacids
- d. charges

within _____ (10) days of becoming _____ of the change.

- a. three
- b. one
- c. five
- d. ten

- a. award
- b. aware
- c. away
- d. await

I understand _____ if I DO NOT like the _____ made in my

- a. thus
- b. this
- c. that
- d. than

- a. marital
- b. occupation
- c. adult
- d. decision

case, I have the _____ to a fair hearing. I can _____ a

- a. bright
- b. left
- c. wrong
- d. right

- a. request
- b. refuse
- c. fail
- d. mend

hearing by writing or _____ the county where I applied.

- a. counting
- b. reading
- c. calling
- d. smelling

If you _____ TANF for any family _____, you will have to

- a. wash
- b. want
- c. cover
- d. tape

- a. member,
- b. history,
- c. weight,
- d. seatbelt,

_____ a different application form. _____, we will use

- a. relax
- b. break
- c. inhale
- d. sign

- a. Since,
- b. Whether,
- c. However,
- d. Because,

the _____ on this form to determine your _____.

- a. lung
- b. date
- c. meal
- d. pelvic

- a. hypoglycemia.
- b. eligibility.
- c. osteoporosis.
- d. schizophrenia.

DO NOT COPY

Appendix M**Prenatal Care Test of Functional Health Literacy**

Please read the question below and circle the letter that represents your answer choice

1. What is prenatal care?
 - a. care for mother and child during pregnancy
 - b. care for baby after pregnancy
 - c. care for mother after pregnancy
 - d. care for mother, father and child during pregnancy

2. During pregnancy you should see your health care provider?
 - a. regularly
 - b. when you are sick
 - c. if the doctor's office calls
 - d. at the time of delivery

3. A typical pregnancy lasts for about?
 - a. 40 days
 - b. 20 weeks
 - c. 60 months
 - d. 40 weeks

4. What is a trimester?
 - e. Every other month
 - f. Every three months
 - g. Every four months
 - h. The last month

5. What is postpartum care?
 - a. care for the baby during pregnancy
 - b. care for the mother after pregnancy
 - c. care for the mother, father and child during pregnancy
 - d. care for mother and child during pregnancy

11. Once I have information regarding prenatal care, I am confident about what I need to do during my pregnancy.

<u>Extremely</u>		<u>Somewhat</u>		<u>Not at all</u>
1	2	3	4	5

12. Based on what I have read about prenatal care, I am comfortable giving consent to my health care provider for care/treatment.

<u>Extremely</u>		<u>Somewhat</u>		<u>Not at all</u>
1	2	3	4	5

13. When I receive prenatal care information, I have someone help me read it.

<u>Always</u>		<u>Sometimes</u>		<u>Never</u>
1	2	3	4	5

14. I have difficulty understanding written information about prenatal care.

<u>Always</u>		<u>Sometimes</u>		<u>Never</u>
1	2	3	4	5

15. I have difficulty understanding what my health care providers tells me about my pregnancy.

<u>Always</u>		<u>Sometimes</u>		<u>Never</u>
1	2	3	4	5

16. How confident do you feel you are able to follow instructions for medication prescribed to you by your health care provider during your pregnancy?

<u>Extremely</u>		<u>Somewhat</u>		<u>Not at all</u>
1	2	3	4	5



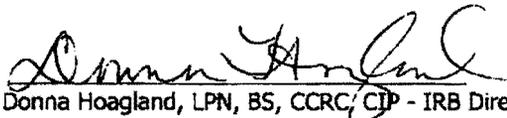
Institutional Review Board (IRB)
New Brunswick / Piscataway Campus

Vulnerable Population Code(s): No Children As Subjects; No Pregnant Women as Subjects; No Prisoners As Subjects

APPROVAL DATE: 3/17/2011
EFFECTIVE DATE: 3/25/2011

EXPIRATION DATE:
N/A – Exempt study

1. **Adverse Events:** Any on-site serious adverse events, or any unanticipated problems involving risk to subjects or others, or any serious or continuing non-compliance that occurs in relation to this study must be reported to the IRB Office (45 CFR 46, 21 CFR 50, 56) as outlined in the investigator instructions for adverse event reporting.
2. **Continuing Review:** Approval is valid until the protocol expiration date shown above. The IRB must review and approve all human subject research studies at intervals appropriate to the degree of risk, but not less than once per year, as required by 45 CFR 46 and 21 CFR 50, 56. In order to avoid lapses in approval of your research and the suspension of subject enrollment, please submit your continuation application at least eight weeks before the study expiration date.
3. **Consent:** Documentation of informed consent has been waived by the IRB for this study in accordance with 45 CFR 46.117 and 45 CFR 164.512.
4. **Subjects: Number of subjects approved at this site: 150**
5. The investigator(s) did not participate in the review, discussion, or vote of this protocol.
6. **Amendments/Modifications/Revisions:** If you wish to change any aspect of this study, including but not limited to study procedures, consent form(s), principal investigator, co-investigator(s), advertisements, the protocol document or procedures, the investigator drug brochure, or accrual goals, you are required to obtain IRB review and approval under 45 CFR 46 and 21 CFR 50, 56. Implementation of these changes may not occur until you receive notice of IRB review and approval.
7. **Completion of Study:** Please notify the IRB when your study has been stopped for any reason. Include the following information in the written notification using a continuing review/final report form: number of subjects enrolled; number of subjects withdrawn from the study; and reason for study termination. Neither study closure by the sponsor or the investigator removes the obligation for timely continuing review or a final report.
8. **Wards of the state: Not applicable**
9. **To increase subject enrollment from 15 to 150. This will allow for adequate data analysis that will determine statistical significance**


Donna Hoagland, LPN, BS, CCRC, CIP - IRB Director

Date: 3/28/11

/fa

DHHS Federal Wide Assurance Identifier: FWA00001861

Appendix O



OFFICE OF INSTITUTIONAL
REVIEW BOARD

SETON HALL UNIVERSITY

March 30, 2011

Rhonda M. McCathern
383 Bowler Court
Piscataway, New Jersey 08854

Dear Ms. McCathern,

The Seton Hall University Institutional Review Board has reviewed your research proposal entitled "Exploring the Relationship Between General Health Literacy Levels and Prenatal Care Health Literacy Levels" and has approved it as submitted under exempt status.

Enclosed for your records are the signed Request for Approval form and the stamped Letter of Solicitation.

Please note that, where applicable, subjects must sign and must be given a copy of the Seton Hall University current stamped Letter of Solicitation before the subjects' participation. All data, as well as the investigator's copies of the signed Consent Forms, must be retained by the principal investigator for a period of at least three years following the termination of the project.

Should you wish to make changes to the IRB approved procedures, the following materials must be submitted for IRB review and be approved by the IRB prior to being instituted:

- Description of proposed revisions;
- *If applicable*, any new or revised materials, such as recruitment fliers, letters to subjects, or consent documents; and
- *If applicable*, updated letters of approval from cooperating institutions and IRBs.

At the present time, there is no need for further action on your part with the IRB.

In harmony with federal regulations, none of the investigators or research staff involved in the study took part in the final decision.

Sincerely,



Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Deborah DeLuca
Presidents Hall • 400 South Orange Avenue • South Orange, New Jersey 07079-2641 • Tel: 973.313.6314 • Fax: 973.275.2361

Appendix P Summary of Pilot Study

Purpose

The purpose of the pilot study was to test the methodology that was to be used for the dissertation process. This included, recruitment, data collection processes and quality control methods as well as to determine if there is a predictive relationship between general health literacy and prenatal care health literacy.

Data Collection Method

The pilot study research design was cross-sectional, descriptive and correlational. Cross-sectional studies are used when data will be collected at one point in time to prevent testing or history effects; in this case data was collected from women in a prenatal care clinic in South Jersey at one point in time. Demographic characteristics of the sample were organized and summarized through a descriptive design. A correlational design was used to explore if a relationship exists between levels of general health literacy and prenatal care health literacy, and if general health literacy levels correlated linearly (predictably) with prenatal care health literacy levels, in pregnant females. According to Polit and Hungler (1995), the purpose of a descriptive, correlational design is to describe variables and examine relationships among them, with no attempt to control or manipulate the variables. The decision to use a descriptive and correlational design is supported by Portney and

Watkins (2000) who suggests that a descriptive design is appropriate for use in documenting phenomena of individuals or groups of individuals under study, while correlational designs are appropriate for use in describing the nature of existing relationships among variables.

Due to the intentionally small sample size indicated for this pilot study, attaining statistically meaningful results was impossible. However, the pilot study was conducted to test the methods and processes used for recruitment and data collection to ensure that they were adequate and appropriate for the subsequent dissertation project.

Sampling Procedure

This pilot study required a convenience sample size of 10 pregnant females, between their first and sixth month of pregnancy (1st and 2nd trimesters). For the purposes of the pilot study, a sample size of 10 was a reasonable number of participants necessary to test the survey tools, the recruitment process, duration of time needed for the completion of the questionnaires, data collection procedure and quality control measures.

With permission from the Department of Obstetrics and Gynecology at the School of Osteopathic Medicine and upon receipt of the pilot study research proposal approval from the Institutional Review Board of Seton Hall University, the Principal Investigator (PI) trained the research assistant (RA) on the appropriate procedures needed to complete the entire data collection process. As part of the research, the RA completed the National Institutes of

Health Protection of Human Subjects Training Module. The PI familiarized the RA with a script and checklist of action/steps to be carried out during the entire recruitment and data collection processes, which was used with each and every participant and as a memory aid and quality control measure to ensure consistency and completeness in performing the process and procedure from participant to participant. Once training of the research assistant was completed, participant recruitment began.

Prior to the first day of the pilot study, the PI prepared each survey package and envelope, each of which had numerical code written on the outside of the envelope and on each document within the envelope. Each survey envelope contained one (1) each of the following documents: a letter of solicitation/implied informed consent, demographic survey, Short Test of Functional Health Literacy Assessment in Adults (STOFHLA and the Prenatal Care Test of Functional Health Literacy. The envelopes were assembled in ascending numerical order in a box and given to the RA to take to the facility. The PI also assembled and included stationery items for the RA to use: pencils, pencil sharpeners, checklists, scripts, withdraw/incomplete stickers, tape and other materials as needed.

Prior to arriving at the facility, the RA ensured that the survey envelopes were coded and that each envelope contained one (1) each of the following documents: a letter of solicitation/implied informed consent, demographic survey, S-TOFHLA and the Prenatal Care Test of Functional

Health Literacy, and that all items were coded with the same identifying code. This was done for quality control and to ensure that the participants will experience no unnecessary delays once they were seated, qualified and ready to complete the surveys.

The research assistant gave each eligible participant one of the pre-coded envelopes labeled with an ID number. The RA reviewed all materials with the participant prior to the participant actually completing the surveys. This served as a dual purpose of not only familiarizing the participant with the materials and what needs to be completed, but also as a secondary check for completeness of each package of information, to ensure that all survey ID material codes match each other and the envelope ID, and that all materials were included in the packet. When the package has been reviewed satisfactorily, the participant will be told that they may begin completing the survey documents. Participants were told that they were free to withdraw from the study at any point in time during the process without penalty.

Materials completed by a participant were returned to the coded envelope. The RA verified each package for completeness and utilized the checklist to ensure that all documentation was completed and returned. Additionally they reviewed each document to ensure that each survey was completely filled in; incomplete surveys were returned to the envelopes, and the envelopes was marked with a sticker indicating that they were incomplete. This process was completed throughout the day of the pilot study until 10

completed packages were attained from 10 qualified participants. Ultimately, data was collected from eleven (11) participants.

Data Analysis

The data collected was nominal and interval and was analyzed using only descriptive statistics due to the extremely small sample size.

Results

Eleven (11) complete packets were returned from the pilot study. The demographic characteristic of age is listed in Table 1. The remaining characteristics of race, primary language, marital status, employment status, education and household income are listed in Table 2.

Table 1

Demographic Characteristics of age

N	Minimum	Maximum	Mean	Std. Dev.
11	19	32	25	3.87

Table 2

Demographic Characteristics of pilot study participants

	Frequency	Percent
Race		
• American Indian	2	18.2
• Black	5	45.5
• Hispanic	1	9.1
• Non-Hispanic White	3	27.3
• Total	11	100
Primary Language		
• English	10	90.9
• Spanish	1	9.1
• Total	11	100
Marital Status		
• Married	5	45.4
• In a Relationship	4	36.4
• Engaged	2	18.2
• Total	11	100
Employment Status		
• Out of work > 1yr	1	9.1
• Out of work < 1yr	2	18.2
• Student	2	18.2
• Employed full-time	5	45.5
• Employed part- time	1	9.1
• Total	11	100

	Frequency	Percent
Education		
• Grade 12 or GED	6	54.5
• Some College (1-3 years)	3	27.2
• College 4 yrs	2	18.2
• Total	11	100
Household Income		
• 10,000-29,000	1	9.1
• 30,000-49,000	5	45.4
• 50,000-69,000	4	36.4
• 70,000-89,000	1	9.1
• Total	11	100

While describing the scores of the participants was not listed as a research question nor was it the primary purpose of the pilot study, it is valuable to view this data. As part of the pilot study participants were asked to complete the Short Test of Functional Health Literacy Assessment in Adults (STOFHLA). This survey was intended to determine the participant score and level of general health literacy. Each of the 36 items on the S-TOFHLA is evaluated as correct or incorrect, yielding a possible total from 0 to 36. Researchers have used the scores from this health literacy test in one of two

ways: (a) total score or (b) a level of functional health literacy. While the mean, median and mode are not always important to show, I thought it was important to see the ranges in scores for this tool. As you see from Table 3 scores ranged from a value of 16 to 36. The breakout of scores and literacy levels are reported in Table 4.

Table 3

Participant STOFHLA scores

Mean	24.36
Median	21
Mode	18 and 21
Min-Max Values	16-36
SD	7.09

Table 4

Participant score and corresponding levels

Score	Level of Functional Health Literacy	N	Percent
0-16	Inadequate	1	9.1
17-22	Marginal	6	63.6
23-36	Adequate	4	36.4

Similarly, participants completed the Prenatal Care Test of Functional Health Literacy to determine the prenatal care literacy. The two sections of the Prenatal Care Test of Functional Health Literacy, Knowledge and attitudes, were calculated and summarized separately. The knowledge section consisted of five multiple-choice items yielding a knowledge score between 0 and 5. As summarized in Table 5 these 11 pregnant women had knowledge scores between 3 and 5, yielding an average score of 4.0 (SD = .79).

Table 5

Total knowledge scores

Knowledge Score Total	N	%
------------------------------	----------	----------

5	5	45.5
4	4	36.4
3	2	18.2

The attitude portion of the Prenatal Care Test of Functional Health Literacy consisted of 11 Likert-type questions with each item evaluated on a scale from 1 to 5, to indicate the level of agreement with or endorsement of the item. The possible range of scores on the attitude portion of the Prenatal Care test was from 11 - 55. As summarized in Table 6, the 11 pregnant women had attitude scores ranging between 27 and 55, with a mean score of 21 (SD = 7.37).

Table 6

Prenatal care Attitude total score

Attitude Total Score	N	%
27	1	9.1
38	2	18.2
41	2	18.2

45	2	18.2
50	1	9.1
55	3	27.3

Discussion/Conclusion

The pilot study provided valuable information into the final dissertation project. As a result of the pilot study and subsequent analysis, I determined that the data collection methods were appropriate for the dissertation. Additionally, the analysis led to the modification of the research questions, inclusion/exclusion criteria and to the demographic survey. A final request for IRB approval was sought from Seton Hall IRB with the changes and the request was approved before the dissertation study began