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Associations among Health Literacy Levels and Health Outcomes in Pregnant Women with Pregestational and Gestational Diabetes in an Urban Setting

Rosemary Ann McLaughlin
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Associations among Health Literacy Levels and Health Outcomes in Pregnant Women with Pregestational and Gestational Diabetes in an Urban Setting

Abstract

Purpose/Objectives: Poor health literacy is a problem for over 45% of American adults and is associated with a variety of adverse health outcomes. Low health literacy has been associated with poor prenatal care utilization and a higher likelihood of poorer glycemic control. Poor glycemic control can lead to poor birth outcomes for both the mother and infant. Health literacy levels of pregnant women with diabetes can influence these outcomes and need to be known early in the pregnancy. Interventions can influence tighter glycemic control and lessen the impact of diabetes for the mother and infant. Therefore, the purpose of this study was to explore the associations among health literacy levels and health outcomes in pregnant women with pregestational and gestational diabetes.

Methods: With a sample of 32 pregnant women in an urban, safety-net clinic in the South we measured health literacy using the Rapid Estimate of Adult Literacy in Medicine (REALM), the Literacy Assessment for Diabetes (LAD), and the Rapid Estimate of Adult Literacy in Genetics (REAL-G) and determined glycemic control. In addition, we evaluated three questions from the Short Test of Functional Health Literacy in Adults (S-TOFHLA) as a potential health literacy screening instrument in this sample. Outcome measures included birth outcomes for the mother of hypertension, premature birth, delivery method, polyhydramnios, and vaginal laceration, and for the infant, gestational age at birth, birth weight, respiratory distress, congenital anomalies, and fetal demise. The sample was characterized with descriptive statistics. Parametric and non-parametric tests were conducted to compare levels of health literacy and birth outcomes between groups.

Results: Over 81% of the participants in this study were African American with 56.3% of the women demonstrating high health literacy as determined by the REALM. Glycemic control, measured by glucose self-report, demonstrated that women with high health literacy recorded more glucose readings ($p = .02$) than women with low health literacy scores. Mothers with high health literacy experienced more spontaneous labor at term ($p = .10$), a higher cesarean section rate and more normal weight infants than the mothers with low health literacy. While not statistically significant, women with low health literacy experienced more adverse birth outcomes. Women with pregestational diabetes trended toward higher health literacy than did women with gestational diabetes on all three instruments. In fact, those with gestational diabetes initiated prenatal care later than those with pregestational diabetes. The 3 questions from the S-TOFHLA did not show high enough correlation to the REALM ($r = -.25$) and thus were not considered as an effective as a screening tool for health literacy in this study.

Conclusions: In our small sample, higher health literacy was associated with more glucose readings by maternal self-report and more spontaneous labor at term. A better understanding of health literacy and its' role in maintaining health, specifically in relation to the health of pregnant women with diabetes, is needed by health providers as this knowledge may improve birth outcomes. These results need to be interpreted cautiously because of the small sample size and further research is needed.

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**ASSOCIATIONS AMONG HEALTH LITERACY LEVELS AND HEALTH
OUTCOMES IN PREGNANT WOMEN WITH PREGESTATIONAL AND
GESTATIONAL DIABETES IN AN URBAN SETTING**

A Dissertation
Presented for
The Graduate Studies Council
The University of Tennessee
Health Science Center

In Partial Fulfillment
Of the Requirements for the Degree
Doctor of Philosophy
From The University of Tennessee

By
Rosemary A. McLaughlin
May 2009

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DEDICATION

This dissertation is dedicated to my husband, Bobby, and my children, Lauren, Haley, and McKenna for their love, continuous support, and encouragement. Thank you for keeping me swimming and sane.

I Corinthians 2:9: “No eye has seen, no ear has heard, and no mind has imagined the things that God has prepared for those who love him.”

“To God be the glory.”

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
AMA	American Medical Association
ANA	American Nurses Association
BMI	Body Mass Index
BSAIT	Basic Skills Agency Initial Assessment Test
CDC	Centers for Disease Control
GDM	Gestational Diabetes Mellitus
GDMA1	Gestational Diabetes Mellitus Controlled with Diet
GDMA2	Gestational Diabetes Mellitus Controlled with Insulin
GED	General Education Development
HALS	Health Activities Literacy Scale
HbA1c	Glycated Hemoglobin
HIV	Human Immunodeficiency Virus
IDM	Infant of a Diabetic Mother
IMCHB	Interaction Model of Client Health Behavior
IOM	Institute of Medicine
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LAD	Literacy Assessment of Diabetes
LBW	Low Birth Weight
LEP	Low English Proficiency
LGA	Large for Gestational Age
MDI	Metered Dose Inhaler
NALS	National Adult Literacy Survey
NVS	Newest Vital Sign
PAIT-R	Peabody Individual Achievement Test-Recognition Scale

PASS®	Power Analysis and Sample Size Software
PKU	Phenylketonuria
RDS	Respiratory Distress Syndrome
REAL-G	Rapid Estimate of Adult Literacy in Genetics
REALM	Rapid Estimate of Adult Literacy in Medicine
SES	Socioeconomic Status
SGA	Small for Gestational Age
SORT-R	Slosson Oral Reading Test-Revised
SPSS®	Statistical Package for the Social Sciences
S-TOFHLA	Shortened Test of Functional Health Literacy in Adults
S-TOFHLA-3	Three Screening Questions from the Shortened Test of Functional Health Literacy in Adults
TOFHLA	Test of Functional Health Literacy in Adults
WRAT	Wide Range Achievement Test
WRAT-R	Wide Range Achievement Test-Revised

CHAPTER 1: INTRODUCTION

Overview

With a cost of \$73 billion dollars [1] and reports couched in terms of patient safety, health disparity, and poor health outcomes, health literacy is coming into sharper focus within the healthcare community. Health literacy is a multifaceted concept that enables consumers of health care to understand their health and how to take care of themselves and their families. In the United States health literacy has been defined as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions, according to *Healthy People 2010* [2,3]. The Joint Commission underscores that for patient safety a person has a fundamental right to receive information about their health, both in written and oral form, in a way that they can understand [4]. The importance of health literacy as a factor in health care is borne out in a report from the American Medical Association (AMA), which states that poor health literacy is a stronger predictor of health than age, income, employment status, education level, and race [5]. Health literacy is a global issue, and the World Health Organization has issued a statement that health literacy has a central role in determining inequities in health in both rich and poor countries. Poor health literacy has been associated with increased mortality [6-8], increased risk of hospital admission [9,10], poorer glycemic control, and higher rates of retinopathy [11] and also health behaviors including under use of preventative services [12-15], mismanagement of medication administration [16-19], and less understanding of personal illness and treatment options [20,21].

Health literacy as a skill set has been recognized by healthcare professionals for at least two decades. Health literacy consists of an array of skills that a person needs to enhance health promotion and disease prevention. To be health literate, a person is required to understand, interpret, and analyze health information from many sources such as the physician's office appointment slip, printed materials (like food labels), and other media (such as the World Wide Web). Health literacy, according to Speros in 2005, includes reading and numeracy skills, comprehension, the capacity to use the information in health care decision making, and successful functioning in the role of healthcare consumer [22].

When people are health literate, they can apply health information in a variety of life events and situations to improve their health outcomes. For example, they are more likely to take medication safely and operate medical devices, such as a glucometer or a peak flow meter, properly. They can also navigate the healthcare system and actively engage healthcare professionals during medical encounters to understand, give informed consent, and advocate for their rights [23].

Ninety million people, the equivalent to 50% of the U.S. adult population in 2003, have poor to inadequate health literacy skills [24]. This means they are unable to understand health information needed to function within the healthcare system, and healthcare providers are often not aware of the patient's health literacy abilities [25]. In

2004, the Institute of Medicine (IOM) published the first report to examine this topic. *Health Literacy: A Prescription to End Confusion*, is a multidisciplinary report designed to address the origins, consequences, and solutions of health literacy [26]. At the core of health literacy is clear communication between the individual and the healthcare provider. Little attention is given to enabling individuals to comprehend their condition and treatment. This is a neglected pathway to high-quality health care. It is important that health literacy be assessed in every person to empower them to become active participants in their personal health care to improve health outcomes.

Health literacy has a direct impact on pregnancy for both the mother and her child. If pregnancy is the first contact with the healthcare system, her health literacy level will affect how she navigates the system. It influences how she obtains, processes, and understands basic health information. It also mediates how appropriate health decisions for her and her child are made and will directly influence her future response in seeking health care for herself and family [27]. In fact, the Centers for Disease Control and Prevention (CDC) reported that the infant mortality rate of mothers who completed fewer than 12 years of school was 49% higher than that of mothers who completed 16 years or more [28]. While low educational attainment is a complex issue and is associated with poverty and inadequate access to health care, the mother's health literacy level may be a factor in the risk of losing her child. If her health literacy level is not assessed and intervened upon, the mother's inability to understand may be mistaken for non-compliance, and an opportunity to assist her and her child will be missed.

Low health literacy has been associated with poor prenatal care utilization [12] and a higher likelihood of poorer glycemic control. Poor glycemic control can lead, for example, to poor birth outcomes for both the mother and infant in the form of miscarriage, stillbirth, preterm birth, or congenital anomaly. Health literacy levels of pregnant women with diabetes can influence these outcomes [29] and need to be known early in the pregnancy. Interventions can influence tighter glycemic control and lessen the impact of diabetes for the mother and baby [11,30,31].

Diabetes is increasing in prevalence in the U.S. from 5.1% in 1988-1994 to 6.5% in 1999-2002 of the total population [32]. In fact, in 2008, Yogeve and Visser estimated a 40% increase in diabetes before pregnancy, also known as pregestational diabetes, worldwide [33]. Lawrence et al. identified an increase in pregestational diabetes from 0.81 per 100 in 1999 to 1.82 per 100 in 2005, while rates of gestational diabetes, or diabetes first seen during pregnancy, remained constant [34]. Pregnant women with pregestational and gestational diabetes are at high risk for complications during pregnancy and birth.

Complications for the mother with diabetes can include perinatal morbidity from cesarean section, vaginal lacerations [35-37], and a higher incidence of preeclampsia and prematurity than pregnancies without diabetes [38,39]. For the infant, complications can include a higher incidence of congenital anomalies [40], increased miscarriages and stillbirth [41]; macrosomia, or birth weight greater than 4500 grams [36] that can result in birth trauma [42]; plus various metabolic abnormalities. A significant reduction in these complications has been seen when blood sugar levels were kept as close as possible to normal levels [43-45]. To have a positive impact on these delivery outcomes, health

literacy levels need to be assessed and intervened upon early in pregnancy by health care providers.

Genetic considerations for the pregnant individual with diabetes are necessary, as there is a higher incidence of congenital anomalies in this population [40,46]. If pregnant women are to be given the benefit of genetic counseling, understanding this counseling is paramount to an informed decision on the part of the mothers [47,48]. Counseling is important not only for the present pregnancy but for subsequent obstetrical decisions such as a subsequent pregnancy or even pre-implantation genetic diagnosis. Genetic health literacy is a relatively new concept, affecting healthcare providers and recipients alike. With the rapid advances in genetic research findings linking to health as a cause of disease or potential cure, together with the availability of this genetic knowledge on the World Wide Web, genetic concepts and vocabulary have become a necessity for health literacy [49]. Health literacy needs to be assessed and acted upon for the best patient outcomes to be accomplished.

The complex nature of health literacy has proven a challenge to measure. This is because many characteristics make up one individual and the health care systems offering medical care. These characteristics include, but are not limited to, cognitive reading and reasoning ability, language, culture and religion, the physical environment, poverty, access to medical care, and previous medical experience. The healthcare system has complex medical terminology, and patient reading materials are often written at reading levels too high for the individual to understand.

Instruments to measure health literacy were first published in the early 1990s. The purpose of these instruments was to assess “patient literacy.” Two of the primary instruments were the Rapid Estimate of Adult Health Literacy in Medicine (REALM) in 1991 [50], and the Test of Functional Health Literacy in Adults (TOFHLA) in 1995 [51]. While these instruments were created to assess literacy levels by measuring word recognition and pronunciation and some comprehension, the scope of the instruments is narrow; more instruments are needed to encompass the comprehensive nature of health literacy [26,52]. In an effort to encourage the development of valid and reliable instruments that can be used across diverse populations, the IOM has recommended that support be given to the development, testing, and use of new measures of health literacy that are culturally appropriate [26]. With the assessment limitations of a non-Spanish-speaking investigator in mind, this study has utilized the Rapid Estimate of Adult Literacy in Medicine (REALM), the Literacy Assessment for Diabetes (LAD), and the Rapid Estimate of Adult Literacy in Genetics (REAL-G), plus the three questions from the Shortened Test of Functional Health Literacy in Adults (S-TOFHLA).

Purpose of the Study

The purpose of this research project is to determine if a three question screening tool could be used to assess health literacy levels in pregnant women with diabetes as well as to explore the association of the health literacy level of the pregnant woman with birth outcomes for the infant and pregnancy outcomes for the mother in a sample of pregnant women with pregestational and gestational diabetes.

Specific Aims

The specific aims of this study are designed to identify possible screening tools for health literacy in this population and to add to the body of literature concerning this vulnerable population of pregnant women with diabetes. Associated research questions follow each study aim.

Specific Aim One

Determine if three questions from the Short Test of Functional Health Literacy in Adults (S-TOFHLA) can be used to assess low health literacy in pregnant women with pregestational and gestational diabetes.

- 1.a. Are the three questions from the S-TOFHLA associated with the REALM?
- 1.b. Are the three questions from the S-TOFHLA associated with the LAD?
- 1.c. Are the three questions from the S-TOFHLA associated with the REAL-G?

Specific Aim Two

Determine health literacy levels of pregnant women with pregestational diabetes and pregnant women with gestational diabetes using three health literacy instruments.

- 2.a. Is there a difference in general health literacy using the Rapid Estimate of Adult Health Literacy in Medicine (REALM) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?
- 2.b. Is there a difference in diabetic health literacy using the Literacy Assessment for Diabetes (LAD) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?
- 2.c. Is there a difference in genetic health literacy using the Rapid Estimate of Adult Literacy in Genetics (REAL-G) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?
- 2.d. Is there a difference in genetic health literacy using the three questions from the S-TOFHLA tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

Specific Aim Three

Determine if health literacy is associated with maternal glycemic control during the pregnancy.

- 3.a. Is the REALM associated with maternal glycemic control?
- 3.b. Is the LAD associated with maternal glycemic control?
- 3.c. Is the REAL-G associated with maternal glycemic control?

- 3.d. Are the three questions from the S-TOFHLA associated with maternal glycemic control?

Specific Aim Four

Determine if there are associations between health literacy levels and birth outcomes for both the mother (hypertension, premature labor, premature birth, delivery method, polyhydramnios, and vaginal laceration), and infant (gestational age at birth, birth weight, respiratory distress, congenital anomalies, and fetal demise).

- 4.a. Is there an association between the REALM and birth outcomes?
- 4.b. Is there an association between the LAD and birth outcomes?
- 4.c. Is there an association between the REAL-G and birth outcomes?
- 4.d. Is there an association between the three questions from the S-TOFHLA associated and birth outcomes?

Significance of the Study

The health literacy skills of an individual directly affect that individual's health care and quality of life as well as that of the person's family. Health literacy deficits are a significant barrier to health care [26]. Without the ability to understand healthcare information, an individual cannot make informed decisions regarding their healthcare options, which can also influence the efficiency of seeking and receiving medical treatment. Low health literacy is a major source of economic inefficiency within the healthcare system because of associations with poorer health status, diminished use of preventive care [26], increased hospitalization [53], and decreased compliance with prescribed treatment and self-care regimes [54]. The cost of inadequate health literacy is enormous. The cost of low literacy skills for the U.S. was estimated in 2003 at \$50-\$73 billion dollars annually [55]. In 2007, the cost estimate more than doubled (to \$106-\$238 billion annually) based on the 2003 National Assessment of Adult Literacy survey [56]. This same report states that 75% of the low literacy population is insured. If persons understand and act upon medical instructions and engage in self-care, unnecessary emergency room visits and hospitalizations can be reduced, which in turn lowers overall medical costs. Low health literacy is beginning to be addressed as part of the national agenda, where policy changes can be implemented to effect positive health outcomes and lower overall costs.

Despite the prevalence of low health literacy and knowledge of its associated healthcare risks, in general, healthcare providers generally do not assess health literacy and are unaware of patients' reading abilities [9,25,57,58]. Much medical literature for the general public is written at a reading level that exceeds the average reading ability of U.S. adults, thus making the problem of low health literacy even more complex [59,60]. Health literacy may be part of the solution for positive patient outcomes and needs to be addressed with each patient. A former U.S. Surgeon General noted that improving the nation's health literacy should be a national health and public priority [61]. Providing

healthcare information that is understandable to patients enables them to make informed decisions regarding their health care and is considered by some to be an ethical responsibility of healthcare providers [62]. If pregnant women with diabetes understand their disease and what they can do to ameliorate the effects of the diabetes on themselves and their infant, better maternal and infant outcomes may become apparent.

Conceptual Model

The Interaction Model of Client Health Behavior (IMCHB) [63] was selected as the conceptual model because of its ability to address the demographic makeup of individuals as well as the interaction of the individual with the healthcare provider. In 1982 the IMCHB model was created by Cox to address research and practice in a framework that would “recognize the client’s individuality and uniqueness,” thus allowing for therapies to be “individually tailored.” Client health behavior could then be influenced by the healthcare provider through the provision of health information, emotional support, and assistance in decision-making [63]. The model is depicted in **Figure 1.1**.

Current health literacy issues highlight the fact that client care is not tailored enough to influence, for example, the desired health outcomes of medication adherence and use of preventive care. Health illiteracy is a liability for the individual and needs to be corrected by improving health communication and increasing provider awareness. However when viewed from a broader perspective, health literacy can be seen as an outcome or an asset in and of itself—thus becoming a goal which can be improved upon through intervention to improve health outcomes [64]. If health literacy levels are improved, a more health literate individual evolves and becomes more comfortable with caring for self. This individual can then reduce the cost of care by circumventing the complications that go along with chronic disease. For instance, if the blood sugar levels continue to be elevated, a visit to the healthcare provider could change insulin dosage before hyperglycemia demands a trip to the emergency department. This change in health outcome by increasing health literacy can decrease the cost of low health literacy upon society.

The IMHCB can identify the components that make up the person, the health information needed by the person, as well as the elements of the person-provider interaction, and point to healthcare outcomes that can be achieved through mutual agreement. Tailored therapies would encourage people to seek care and encourage behavior change as well as encourage health care to change the way health information is delivered. The IMHCB model has a comprehensive scope for health behavior. This study proposes the identification of another outcome variable—that of health literacy, in addition to maternal and infant birth outcomes. Thus the IMHCB model has been adapted to look specifically at the assessment of health literacy as it is associated with diabetes in pregnancy.

The IMHCB model considers three components or elements. *Client Singularity* addresses what the client brings to the interaction, *Client-Professional Interaction*

Figure 1.1 Adaptation for This Study of Cox's Interactive Model of Client Health Behavior

Bold indicates our study elements. Modified with permission. Cox, C.L., *Online exclusive: a model of health behavior to guide studies of childhood cancer survivors*. *Oncol Nurs Forum*, 2003. **30**(5): p. E92-9 [75].

addresses what the healthcare provider offers, and *Health Outcome* addresses the goals and end results of the interaction that the client has with the healthcare system.

Each element influences the other through various feedback mechanisms. Each client is different, and the healthcare provider should treat each one according to their needs. For instance, if the client is in need of health information regarding pregnancy and diabetes and has very little knowledge of self-care, then the healthcare provider would supply the knowledge base and assist in decision-making. If the client comes with adequate health literacy and has adequate decision-making skills, then the provider would take on a more supportive role as a teacher, counselor, and technician. The model has been adapted to highlight the areas in bold that this researcher emphasized.

Client Singularity is the element that consists of the background variables of demographic characteristics such as age, race, education, and household income; the social influence of culture and religion; previous healthcare experiences; and environmental resources of the client. These background variables interact with each other to produce a specific health behavior, such as seeking prenatal care early. This study explored the demographic variables of age, race, education, and household income to describe the sample. The other pieces of client singularity such as culture and religion, previous healthcare experiences, socioeconomic status, and environmental resources were not explored. Also included in client singularity are the internal emotional responses of motivation, cognitive appraisal (self efficacy, goals and aspirations, self competence), and affective response (worries over the pregnancy, diabetes and its outcomes) [63]. This study did not investigate these areas.

The *Client-Professional Interaction* element incorporates those things that the client needs from the healthcare provider, such as emotional support, health information, decisional control, and professional and technical competencies, with those background variables from the individual. The model recognizes that this interaction has a major influence on healthcare behavior. The health professional tailors the delivery of health information about a diagnosis, risks, and treatment of the problem to the client, offering technical competencies such as a physical assessment, as well as assisting with decision making and emotional support, to assist the individual with coping. The healthcare professional takes into account the background variables of the individual in order to tailor these interventions. Based on this approach, the provider can motivate individuals to take better care of their health, which will result in positive health outcomes. This professional interaction is one that involves teaching and trust and moves the individual to have the maximum amount of control feasible [65]. We used the technical competency piece of the model to identify the level of health literacy.

Health Outcome addresses the utilization of health services, health behaviors, and health status that results from those behaviors, satisfaction with care, and adherence to the recommended care regime [63]. Issues that require persistent individual self-care management—in contrast to direct provider management—such as diabetes and asthma, continue to be of major concern to health care. Individuals must become more active determiners of their health outcomes [66].

The model recognizes that only one health outcome is needed per investigation. For this study, we were concerned with health status that resulted from health behavior. This was the maternal and infant outcomes that resulted from the level of glycemic control on the part of the mother.

This study explored the demographic variables of age, race, education, and household income within the element of *Client Singularity*; however, these variables were used solely to describe the study sample. We added the outcome variable of health literacy. The assessment of health literacy levels within the element of *Client-Professional Interaction* was done by this researcher as a professional or technical competency. This health literacy assessment must be done for pregnant women with diabetes so that interventions are tailored to her level of understanding to change health behaviors and ultimately health outcomes. Outcomes for the mother and infant as well as blood sugar control during pregnancy were also explored, as seen in the element of *Health Outcome*, to ascertain any associations between diabetes in pregnancy and levels of health literacy.

Definition of Terms

For purposes of this study, the following key terms were defined as follows:

- Diabetes—A disorder of carbohydrate metabolism, usually occurring in genetically predisposed individuals, characterized by inadequate production or utilization of insulin and resulting in excessive amounts of glucose in the blood and urine, excessive thirst, and weight loss.
- Genetic health literacy—General knowledge of genetics principles and vocabulary to allow informed decision-making for the well-being of self and family [67].
- Gestational diabetes—Diabetes diagnosed during a pregnancy. It appears during pregnancy because of the general insulin resistant state of pregnancy. Gestational diabetes can be controlled with diet alone or with the use of insulin [68].
- Grade level or reading level—The average reading skills expected after each year of school in the U.S. public school system or the written material that we expect students at each level to understand. [69]
- Health disparity—The difference in access to care, treatment, health status, health outcome, and the like between individuals or groups[70].
- Health literacy—The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions [2].
- Health outcome—The consequence or end result of an action or intervention. These outcomes may be positive, as in a healthy mother and baby after delivery, or negative, as in fetal demise.
- Maternal health literacy—Knowledge and understanding about pregnancy and childbirth information to enable the mother to make informed decisions during pregnancy and childbirth [71].

- Pregestational diabetes—The presence of diabetes diagnosed before a pregnancy [34].
- Safety net hospital—A safety net hospital provides health care to low-income, uninsured, and vulnerable populations because of a commitment to provide access to care for people with limited or no access to health care due to their financial circumstances, insurance status, or health condition.

Assumptions

The following assumptions were made for this study:

- Health literacy is assumed to be measurable.
- Because health literacy is highly individual, the participants will answer the questions honestly and will accurately record blood sugar levels.
- Health literacy levels of individuals and communities can be changed with tailored interventions.
- Because glycemic control varies according to the individual, patients who develop pregestational or gestational diabetes can influence the birth outcomes of their offspring with close attention to glycemic control.

Potential Limitations

During this study several limitations were noted. Because the data were collected during one period of time, they do not reflect all of the mother's experiences with glycemic control or with health literacy over time and cannot be used to infer a causal effect. Most of the study participants were from the urban area surrounding the clinic; therefore, the results of the study may not be reflective of the experiences reported by those who live in a rural area, other areas of the city, or other regional areas. Another concern was that since the sample size was small, the findings may not be generalized to all pregnant patients with diabetes. Because the researcher was Caucasian and most of the study participants were African American, the researcher's presence may have influenced the study. Because the assessment tools for health literacy were designed for English speaking participants, individuals who could not read or speak English were not represented in this study.

CHAPTER 2: REVIEW OF LITERATURE

Introduction

The ability of an individual to take care of their health depends on their understanding of their health needs and if they can get the resources to care for those needs. In order for an individual to care for a medical condition, such as diabetes, an understanding of the disease, its treatment, and how to access medical care is required. Also required is the ability, for example, to fill out medical forms, calculate medicine dosages, operate a glucometer, and accomplish other tasks needed to achieve a positive health outcome. This set of cognitive and psychomotor skills comprises health literacy. Health literacy or the ability to understand and act upon medical information is what each individual needs, regardless of their educational level, to care for their health. Responsibility for health is shared between the individuals, their healthcare practitioners, and the greater healthcare system. For an individual to understand how to care for themselves and their family, practitioners and healthcare agencies must give medical information to the individual in such a way that it is understood by that individual. Interventions offered or performed by the system or the practitioner may be inadequate if the individual does not understand how to use the information to help themselves and their family. This mismatch in understanding can lead to confusion and may be a barrier to a positive health outcome. The question that this investigator tried to answer was, “What effect does health literacy have on birth outcomes in pregnant women with diabetes in an urban area?” This chapter will focus on the concept of health literacy, diabetes in pregnancy, and how the two influence each other in regard to birth outcomes for the mother and infant.

Health Literacy

Health literacy is a multi-factorial construct with many interpretations. One uniform definition has been adopted by the U.S. 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 [2,72]. *Health literacy* is the term used to describe an individual’s capacity to engage in health promotion and disease prevention activities. Health literacy involves understanding, interpretation, and analyzing health information gained from sources such as medical personnel, the internet, and other media as well as family and the community. This information is applied by the individual over many situations in life. The individual uses health literacy skills to navigate within the healthcare system to find a healthcare center that fits their needs and medical personnel with whom they can communicate. The individual is unique and processes information in a unique way. This unique perspective poses a challenge for healthcare professionals who must communicate with the individual in a way that has understanding and meaning for the individual. Health literacy cannot be equated with educational attainment alone, because people often read at a level several grades below the last grade of school completed [73,74]; nor can it be correlated with intelligence or lack of motivation [75]. Health literacy levels can be changed and

improved upon with improved methods of teaching and communication between the individual and healthcare providers at all levels. It is this tailoring of interventions that will improve health literacy. With improved health literacy this investigator believes that improved health outcomes can be attained.

Literacy and Health Literacy

In order to understand, interpret, and analyze health information, an individual should draw upon their basic education experience for general literacy skills—the ability to read and write plus other skills, such as functional literacy (being able to perform), numeracy, culture, and language. These are all unique to the individual. Basic print literacy (the ability to read, write and understand printed language) is necessary for the individual to fill out medical forms, read up on health issues, and understand what to do to for their health. Oral literacy, which uses listening and speaking skills, is needed to be able to tell a healthcare provider the individual's history and symptomatology and to communicate healthcare needs. Numeracy skills, or the ability to use numbers, in daily life [76] are needed to understand time, logic, and multistep operations such as sliding scale insulin requirements or the calculation of prescription drug dosages. Functional literacy, or the use of literacy to perform a particular task, is required to calibrate of a piece of medical equipment, such as a glucose meter. Since literacy is a part of health literacy, it also involves an intricate network of individual factors such as culture and language, which cannot be separated from the individual, and so must be incorporated into the care of that individual for health information to be meaningful, understood, and acted upon [60]. While it can be seen that literacy is a part of health literacy, health literacy is a more complex construct influenced by many factors.

Genetic Health Literacy

Genetic health literacy is a relatively new concept affecting healthcare providers and recipients alike. With the rapid advances in genetic research findings linking to health as a cause of disease or potential cure, together with the availability of this genetic knowledge on the World Wide Web, genetic concepts and vocabulary have become necessary for health literacy [49]. In the early 1960s, screening tests were developed for phenylketonuria (PKU) because it is widely recognized that early detection and treatment of PKU can ameliorate the effects of the disease and allow the child to live a relatively normal life. Today, newborn screening tests are obtained for all live births in the U.S. to identify newborns at risk for various genetic and metabolic diseases [77]. These screening tests vary by state mandate but require informed consent by the mother as well as follow up for further testing if the test is positive. Most states require this screening and fund the cost of the screening and operation of the program. This is an early example of genetic testing and requires a certain amount of health literacy in the area of genetics to understand. This PKU model of screening that is relatively familiar to the population can be expanded to the concept of genetic testing in the future for all ages.

Genetic considerations for the pregnant diabetic are necessary, because not only will she need to understand the newborn screening, but there is a higher incidence of congenital anomalies in this population [40,46]. Pregnant women have limited knowledge of genetic screening in regards to congenital anomalies [78]. If pregnant women are to be given the benefit of genetic counseling, understanding this counseling is paramount to an informed decision by the mother [47,48]. Counseling is important not only for the present pregnancy but for subsequent obstetrical decisions such as a subsequent pregnancy or even pre-implantation genetic diagnosis. All genetic screening and testing require individual understanding, which begins with assessing the individual's level of genetic health literacy.

The Rapid Estimate of Adult Literacy in Medicine (REALM) was used to determine health literacy level and a modified Maternal Serum Screening Knowledge Questionnaire was used to measure understanding of prenatal screening tests in 101 pregnant women in a prenatal clinic [79]. Thirty-eight percent of the women had low literacy levels. The two findings that came from this study were that health literacy was a more sensitive predictor of inadequate understanding than education level and that those with low health literacy levels were more likely to demonstrate inadequate understanding of the prenatal screening tests [79]. Cancer risk, it found, can be ascribed through genomic testing. Brewer et al. (2008) found that women with low health literacy, as determined by the REALM, gave higher mean estimates of recurrence of breast cancer in a hypothetical model than did women of higher health literacy [80]. No studies used the Rapid Estimate of Adult Literacy in Genetics (REAL-G) instrument.

Significance

Health literacy has been termed a “silent epidemic” because, until recently, it has not been actively addressed by the healthcare system, including healthcare providers. Instead, terms such as “decreased compliance” and “non-adherence” have been used to describe the individual's inability to follow the medical regime outlined by healthcare providers. The scope of the problem was brought to light in 1993 during the National Adult Literacy Survey (NALS) which found that one quarter of the population, about 44 million, in the United States (U.S.) were functionally illiterate and another 40 million (36%) had marginal literacy skills [26,81]. This means that almost half the population of the U.S. have trouble reading and are unable to perform simple mathematical computations [22]. Taking into account the way the healthcare system functions today, health literacy presents itself as a barrier to health care for the general public. Noting the volume of people affected by poor health literacy, issues such as cost, patient safety and racial disparity begin to emerge.

Realizing the enormous scope of the problem of low health literacy, or the lowered ability to understand basic health information and services, research studies have centered on who is at risk. Low health literacy has been identified in groups with demographic traits of age, race, ethnicity, education and economic level who are the most vulnerable to the impact of low health literacy [82]. Those who are at risk are older than age 60 years [83-86] and African American [47,86,87] or Latino [9,84], with lower

economic income [88]. The level of education is also implicated in health literacy. Individuals with less than a high school diploma or GED have lower literacy levels than those who have graduated high school [89]. Gender and the type of data collection instrument did not show a difference in health literacy levels [82]. In 2007, Vernon et al., explained that while ethnic minority groups are disproportionately affected by low health literacy, the majority of those with low health literacy skills in the US are white, native-born Americans, as the latter group represents the largest segment of the population [56]. All of this information will be of assistance when forming national health policies to address this health issue.

The Cost of Health Literacy

The U.S. economy will have to pay for health literacy concerns. Higher healthcare costs have been associated with low health literacy [10,90,91]. The ability of the individual to seek health care and receive treatment is largely dependent on that individual's level of health literacy ability. If the individual has a low level of health literacy, the efficiency of seeking care is diminished—that is, health promotion and disease prevention may be sought at the more expensive emergency rooms rather than at a primary care provider's office. Lack of health literacy is a major source of “economic inefficiency” in the healthcare system and in 2008 was estimated to cost the U.S. economy \$236 billion annually [56].

In 2004, Weiss et al. studied 74 Medicaid enrollees and found that the mean charges for lower than third grade literacy level were \$10,688 per year as opposed to \$2,981 per year for those above a fourth grade literacy level [90]. Those with lower literacy had higher hospitalization rates and were 1.7 times more likely to be hospitalized; the risk increased to 3.1 times more likely if they had been hospitalized the year preceding the study [53]. Low literacy levels are also attributed to a lower knowledge of discharge instructions [92,93], such as use of a metered dose inhaler (MDI), which can lead to readmission and increased emergency department use [94]. Later in 2005, a study by Howard et al. found low health literacy was strongly associated with the use of emergency care in 3,260 elderly people in a Medicare-managed health plan [95]. If persons cannot understand and act upon medical instructions and self-care necessary to protect themselves, emergency room visits and hospitalizations will continue to increase. If, however, understanding and adherence to the plan of care can be enhanced, emergency room visits can be reduced because the individuals will be better able to take care of themselves and not need to return to the emergency room. This will lower the overall medical costs of emergency room use and improve health outcomes for the individual.

Patient Safety

Patient safety has always been at the core of health care. The Joint Commission states that the safety of patients cannot be assured without reducing the negative effects of low health literacy and ineffective communications regarding patient care [4]. Low health literacy places patients at risk for adverse events. Research has shown that

communication between healthcare providers and patients is one of the most common causes for adverse events [96] and that communication is the key to positive health outcomes, including patient safety [97,98]. In fact, The Joint Commission found that over 3,000 sentinel events (i.e., unexpected deaths and catastrophic injuries) from January 1995 to December 2007 involved communication factors [99]. Individuals need to be able to locate, understand health information, and evaluate its importance to their situation, and apply it to their lives if they are to self-manage their own health care.

Individuals with low English proficiency or those who do not have English as their primary language are particularly vulnerable. A study conducted by the Joint Commission regarding low English proficiency and English-speaking patients found some degree of physical harm occurred to 49.2% of patients with low English proficiency that reported adverse events compared to 29.5% of proficient English speakers [99]. Of those that did suffer harm, permanent or severe harm or death occurred 3.7% of the time in LEP patients and 1.4% in English-speaking patients. In addition, informed consent is oftentimes poorly communicated and may leave patients vulnerable to adverse events [97,100].

Patient safety impacts all who are a part of health care, from patients to policy makers. Efforts to counteract low health literacy must occur at the local, regional, and national levels to make clear communication a right, not a privilege [101]. The Joint Commission is developing health literacy standards as part of its hospital accreditation process. By modifying the healthcare system, specifically the regulatory and reimbursement infrastructure, more time, attention, and education for individuals would be allowed and hopefully attenuate the effects of low health literacy on patient outcomes [4].

Health Disparity

Health literacy may be a factor in health disparity. Health disparity is evident when looking at racial and socioeconomic characteristics in our society. Poor communication between the individual and healthcare provider likely contributes to the health literacy-related disparities in understanding disease, health status, and utilization of services [11,53,102-104]. Enhancing health literacy may be an important avenue to reducing health disparities, as some researchers found that disparities were attenuated and even eliminated after accounting for literacy [105-107]. In fact, the American Medical Association states that poor health literacy is a stronger predictor of health than age, income, employment status, education level, and race [5]. In 2006, Sudore and colleagues found that African Americans with adequate literacy skills had mortality rates similar to whites [6].

One can observe racial health disparity in the arena of pregnancy and diabetes. Studies have shown a disproportionate increase of diabetes in pregnancy among African Americans. One study from Southern California showed prevalence of pregestational diabetes among racially or ethnically diverse women to have increased from 10% to 21% over a 6 year period (1999-2005). The gestational diabetes mellitus prevalence, however,

remained constant [34]. In the U.S. gestational diabetes mellitus has increased from 1.9% in 1989-1990 to 4.2% in 2003-2004—an overall relative increase of 122%. What is interesting to note is that while the increase for Caucasians was 94%, the African American increase totaled 260% [108]. This reveals a widening black-white disparity and deserves further investigation.

One possible factor in this equation is that initiation of prenatal care was found to be different for non-Hispanic whites and women of color [109]. Park et al. found that of 439 participants, non-Hispanic white women visited prenatal clinics more often and earlier in the pregnancy than did non-white women. Women who were high school or college graduates visited prenatal clinics more often than those with less than a high school education. This disparity in prenatal care rates leads to a discrepancy in birth outcomes between the non-Hispanic white and non-white women [109]. A study by Bennett et al. in only African American pregnant women found that regardless of health literacy, they had high rates of poor prenatal care utilization, suggesting that improved physician communication could be of help [12]. Black versus white disparities were also seen in Wisconsin when infant mortality rates were studied in an attempt to understand the impact of specific risk factors. Black infants who had the same risk profile as white infants still had a two-fold excess risk of death. Significant differences between the black and white mothers were maternal age, higher levels of education, and adequate prenatal care. Byrd et al., concluded that even if access to prenatal were improved, low health literacy would influence how the health messages were received [110]. More studies need to be conducted as to the reasons for this occurrence.

For Latino Medicare beneficiaries with diabetes and healthcare providers alike, a multifaceted educational program was used to decrease disparity evidenced by decreasing HbA1c levels. This program, which was bilingual, designed with low literacy education materials and tools, and included mass media, succeeded in reducing the HbA1c levels in this population. This culturally appropriate program shows promise in assisting those with low health literacy get the health information they need to have a positive health outcome.

Health disparity widens the gap in healthcare outcomes and health behaviors. Reasons for this are not apparent. Health literacy seems to be a factor in these disparities. What is promising is that although race is a fixed variable, health literacy level is not and can be manipulated with interventions that may prove to help decrease health disparity and ultimately lead to positive health outcomes for everyone.

Health Literacy and Health Outcomes

Research has shown several associations between health literacy, health behaviors, and health outcomes. Adequate health literacy is essential to empowerment of the person to change behaviors and lifestyles, to access health systems, and to improve their health. Low health literacy also influences people's quality of life and is pervasive in all segments of society [22]. Studies have looked at low health literacy levels in relation to health knowledge of disease and its treatment, such as medication adherence

[19,30,94,111,112]. Others have looked at use of preventive care services [113], emergency room and hospital use [53,94,102], and mortality risk [6,114]. Understanding one's medical condition is central to self care in areas such as adherence to medical instructions and preventive health. Various studies have shown that low health literacy correlates to low knowledge of the disease process in mammography [15,88,115], cervical cancer screening [9,115-117], HIV and HIV medication knowledge [19,20,118], emergency department discharge instructions [53,94], knowledge about asthma [94,111,112,119,120], hypertension [30,112,121], diabetes [11,122-125], reproductive health [21,29,126], informed consent [127], and heart health [112,121,123].

Studies looking at knowledge of disease and treatment and have found that individuals with lower literacy levels have lower knowledge of their disease and treatment. Since low health literacy can mean lower knowledge of the disease and its care, the individual may not know to access medical care in a timely fashion [128]. For instance, Dolan et al. studied male veterans and their attitudes toward and knowledge about colorectal cancer screening and found that while most had heard of colorectal cancer screening. They found that while most of these veterans had heard of colorectal cancer, were more likely not to have heard about colorectal cancer screening tests. The veterans with low health literacy also indicated that they would not use a fecal occult blood test because they felt it was messy and inconvenient [14]. Low literacy also influenced how early men sought care for prostate cancer. Low literacy also influenced how early men sought care for prostate cancer. Those with poorer reading ability being more likely to present with late-stage prostate cancer than those with better reading ability [87]. Other preventive care studies report similar findings [9,14,15,113,117]. Other studies have investigated the effects of low health literacy on lower physical health status [84,111], poorer mental health status (including depression) [84,129,130], lower quality of life [94], and less satisfaction with health care [10,20,84,103,131,132].

Medication self-administration is a fundamental part of health care and a major factor in health outcomes. Studies have shown that people with low literacy levels have been associated with poorer adherence to medication regimes, such as with anticoagulant therapy [16-19,30], less ability to identify their medications [133], misunderstanding of instructions on prescription drug labels [134], and an increase in medication error rate [16,133]. With antiretroviral medication adherence, Golin et al. found no difference in patients with HIV and literacy levels, after adjusting for race, income, social support, and education [135]. What has been missing from these studies is a more comprehensive approach to health behavior change.

Low health literacy has been significantly associated with all-cause mortality in a group of 3,260 Medicare elderly patients [95]. Sudore et al. in 2006 studied 2,512 older adults in a longitudinal study of 4.2 years and found 24% with low health literacy skills. A two times higher risk of death was found to be present in those with lower literacy levels after adjusting for demographics and socioeconomic status, co-morbid conditions, self-rated health status, and health-related behaviors.

There were some areas where low literacy was not associated with poorer outcomes. Parental literacy level did not correlate with use of preventive services or

parental understanding of or the ability to follow medical instructions for their children [47] nor were differences found in heart failure after adjusting for education level [123].

Health Literacy Barriers

Two main health literacy barriers face individuals when accessing and using the healthcare system. They include difficulty reading materials that are offered and difficulty in communicating with the healthcare provider. Health literacy materials are helpful to individuals who can read and understand the information, but most health materials are written at reading grade levels of 10th grade or higher [136]. The average adult reads at the 8th- and 9th-grade level, and 20% of the population reads at or below the 5th-grade level [137]. This is why patient education materials are recommended to be written at the 5th-grade level [138]. In 2009, Wilson examined the patient education materials used in a community healthcare setting serving low-income populations and found that the materials were written at a level too high for the average adult [138]. The same outcome was found in the patient education materials on the World Wide Web (WWW), which were written at a 12th-grade reading level, too high for the average adult according to D'Alessandro et al. [139]. Written patient education materials need to be revisited and written at a 5th-grade reading level in order to ensure that individuals with low health literacy can understand them. Another concern for individuals is the oral form of communication with their healthcare providers.

While client comprehension, recall, satisfaction with care, and improved health outcomes have been linked to effective healthcare provider-client communication [140-143], the terminology or “language” used by healthcare providers is not understood and is confusing for people with inadequate health literacy [144,145]. In 2007, Castro et al. found medical terminology to be unclear to individuals when physicians assessed symptoms (10%), delivered test results (24%), recommended treatment (37%), and when health education (29%) was given to individuals [58]. Moreover, healthcare providers were unaware that they were contributing to the difficulties experienced by individuals with low literacy [146,147]. Healthcare providers tend to underestimate the health literacy levels of their patients, which leads to lack of tailored communication for the individuals’ understanding, which can then result in non-adherence to the treatment plan [12,25,58,148]. One study showed that clients who have recently left their physician’s offices are able to recall 50% or less of important information given to them [149]. Individuals also have a skewed understanding of their own literacy levels. Of interest to note is that while the individual’s level of health literacy was low, their perception of their reading level is high, as shown by their self-reported reading level as “well or very well” [150]. Individuals may also hide or mask limited literacy, which may be a source of embarrassment for these patients by saying that they have left their glasses at home and cannot read the materials [151-153]. The ability of the individuals to describe their symptoms and recall the history of the illness can directly affect how healthcare providers are able to diagnose the illness [154]. In order for effective provider-client communication to happen, a common language needs to be shared so that the individual and healthcare provider understand each other and what must happen to effect a positive health outcome.

This gap in communication can also be seen during transition of care from one healthcare provider to another or from one venue to another [99,155]. This gap can place the patient at risk for adverse events. Forster et al. found that 49% of hospitalized patients experienced at least one medical error following discharge, most commonly involving medication use, and most errors could have been prevented through better communication [155,156]. The effort required by the individual to understand can be overwhelming and lead to less desire to participate in medical decision-making [48,157]. Effort must be made by individuals and providers to narrow the communication gap that is required to comprehend healthcare information [99]. Therefore, it stands to reason that the more involved a patient is in their care, the less likely errors will occur, leading to a decrease in adverse events and ultimately a decrease in the cost of care.

Health Literacy and Diabetes Outcomes

The literature concerning health literacy and diabetes focuses on diabetes knowledge, glycemic control, self-efficacy, and interventions to correct some of the problems. Diabetes is a complicated medical condition requiring knowledge of the disease and complex self-management activities, such as self-monitoring of blood glucose, foot care, and eye examinations on a regular basis to help prevent adverse outcomes [158,159]. It has been estimated that one in three individuals with diabetes has limited health literacy [11]. Studies to date have shown that low health literacy is associated with lower knowledge about diabetes and higher HbA_{1c} levels.

Studies in health literacy among diabetic patients have yielded conflicting reports concerning glycemic control. There are conflicting results as to literacy levels and glycemic control, with some studies showing a higher likelihood of poorer glycemic control [11,30,122,160] with two other studies reporting good glycemic control and lower literacy [124]. In 2002, Schillinger et al. investigated health literacy levels and diabetes outcomes in 408 Spanish- and English-speaking patients with type 2 diabetes. The study found that inadequate health literacy was independently associated with poor diabetes knowledge, worse glycemic control (HbA_{1c} level), and higher rates of retinopathy [11]. In 2006, Schillinger et al. found that literacy levels mediated between education and health outcome, showing that even after taking educational level into account, low health literacy levels were associated with low glycemic control [161]. Williams et al. found that only 38% of individuals with low health literacy knew the signs and symptoms of low blood sugar as compared to 73% of individuals with adequate health literacy [30]. In 2007, Powell et al. investigated 68 patients with type 2 diabetes and the relationship between health literacy and diabetes knowledge. The study found that both patient knowledge and the most recent hemoglobin A_{1c} level were found to be significantly associated with patient literacy ($P = .004$ and $P = .02$, respectively)—that is low health literacy was significantly associated with poorer glycemic control and poorer disease knowledge in patients with type 2 diabetes [122].

On the other hand, one recent cross-sectional study by Morris et al. studied 1,002 older, Caucasian (97%), female (58%), and high school graduates or above (75%) with diabetes. They found no association between literacy levels and glycemic control

(HbA1c) or report of diabetes complications [124]. The majority of patients in this study (81%) were treated with diet or oral hypoglycemic alone. There were no other studies to date that replicated this outcome.

Empowerment behaviors of self-advocacy and participation in decision-making have not been associated with low health literacy. Powell et al. and others found that while individuals with lower literacy skills are still willing to take action in the management of their diabetes [122,157,162], there is also less desire to participate in medical decision-making and advocating for their rights as well as understanding and giving informed consent [26,157]. The impact of having low health literacy on those without diabetes, as estimated by Volandes, is along the same magnitude as actually having diabetes [163]. Therefore, those with both low health literacy and diabetes have a double dose of health barriers to overcome.

Positive outcomes occur when individuals with low literacy are given individual instruction. Rothman et al. studied 193 predominately African American patients and found that those with low literacy benefitted from the teaching to a greater degree than those with higher literacy [164]. Kleinbeck also found that tailoring interventions, such as communication and patient education materials, allowed people to succeed in managing their disease and keep their glucose levels (HbA1c) closer to normal range [165].

Health Literacy and Diabetes in Pregnancy

There is a paucity of published information about health literacy in pregnant women with diabetes. Health literacy on the part of the mother is important because it has a direct impact on her child as well as the well-being of her family in general [27]. For the pregnant woman with diabetes, health literacy is directly related to maternal and infant outcome. Low literacy is common in patients with diabetes and is associated with poor disease-specific knowledge [30,166,167]. This low literacy may be one factor that can be manipulated to influence the pregnancy outcome. Low literacy has been associated with poor knowledge about diabetes [11,30,122] in non-pregnant diabetics and poor prenatal care utilization in those who are pregnant [12]. Low health literacy has also been associated with unreliable self-report of glycemic control [168].

Low literacy is associated with poor participation in preventive health care and has been identified as a barrier for patients seeking health care [164]. While it is well known that high serum glucose levels pre-pregnancy has great consequences for both the mother and infant in pregnancies complicated by diabetes, early counseling of diabetic women for preconception care [169,170] is strongly encouraged. In 2004, Endres et al. examined 74 pregnant women with pregestational diabetes. Twenty-two percent had low health literacy levels, as measured by the TOFHLA, and were significantly more likely to have an unplanned pregnancy. Furthermore, they were more likely to not have even discussed pregnancy ahead of time with an endocrinologist or obstetrician [29]. Bennett et al. investigated prenatal care utilization in African American women and health literacy. Their study found that pregnant African American women of both low and high

health literacy had high rates of poor prenatal care utilization [12]. Studies of pregnant women with diabetes have shown that those with adequate health literacy are more likely to seek prenatal care earlier, be Caucasian, and have longer average duration of diabetes, while those patients with low literacy levels, have higher likelihood of lower SES, not having a high school education, greater likelihood of hospitalization, and significantly higher infant birth weights [29].

While glycemic control in diabetes is necessary to prevent organ damage, it is even more important during pregnancy, because hyperglycemia is associated with adverse events for both the mother and child [40,171,172]. Only one study demonstrated that glycemic levels were falsely presented to the healthcare provider by pregnant women with diabetes. In that study by Kendrick in 2005, glucose logs of 85 pregnant women with pregestational and gestational diabetes in an urban teaching hospital were examined. Findings showed that women with type 1 diabetes did not accurately record 36.7% of blood glucose values, as compared to 8.5% of type 2 diabetes and 21.2% of GDMA1 and 23.4% GDMA2 [168]. In 2002, Homko et al. studied 58 women with diet-controlled GDM in regards to self-efficacy and glucose control. While excellent glucose control was achieved, self-efficacy had no effect on this monitoring. The study also found that even though glucose control was achieved, the rates of macrosomia, delivery by cesarean section, and occurrence of birth trauma were similar [173]. This begs the question, Are other reasons at play for these outcomes? Of interest is that these studies were not associated with health literacy at all.

While there are conflicting results regarding low literacy levels and glycemic control, identification of health literacy levels can identify patients with low literacy and predict who will benefit from an intervention program [164]. Intervention has been shown to improve HbA_{1c} values independent of health literacy level [86] and lead to healthier pregnancy outcomes.

In December of 2007, the American College of Obstetricians and Gynecologists published a committee opinion on health literacy that supports health literacy for all and giving practical guidelines for the clinician [174]. For women with diabetes who may become pregnant, improved methods of communication need to be in place to encourage pre-conception counseling. Because low health literacy has been associated with poor prenatal care utilization [12] and a higher likelihood of poorer glycemic control among people with diabetes [11,30], health literacy levels of pregnant women with diabetes need to be known early in the pregnancy. Interventions may then be put into action to keep glycemic levels in better control and lessen the impact of diabetes for the mother and baby.

Diabetes in Pregnancy

Before insulin was discovered by Frederick Banting in 1921 [175], women with diabetes who became pregnant, albeit few in number, faced a deadly combination of diabetes and pregnancy, leading to bleak pregnancy outcomes including maternal and fetal death [176]. Since this discovery and other medical advancements, the pregnancy

outcomes for women with diabetes and their infants are much more positive [177,178]. While these improved outcomes have resulted in a decline in the perinatal mortality, there still remains significant morbidity for the mother and infant [179]. It is imperative that mothers take an active role in the management of their health during this time to ensure a positive outcome for themselves and their child. Diabetes is a complex disorder that requires understanding of the disease and medical regime, such as diet therapy and medication management, and glycemic control, and the consequences of poor glycemic control.

Adequate health literacy is needed for the individual to be able to navigate the healthcare system and be capable of self-management of diabetes. Diabetic patients who become pregnant also are faced with the complexities of managing diabetes plus the new state of pregnancy. Diabetes complicates 3-5% of all pregnancies. While the etiology is unknown, pregnancy is normally characterized by increased insulin resistance and a 50% to 70% reduction in sensitivity to insulin action resulting from the influences of placental hormones [180-182]. This can result in exaggerated levels of glucose that adversely affect the mother and infant.

Of the two types of diabetes in pregnancy, gestational diabetes, or diabetes first seen in pregnancy, is the more prevalent—affecting 2% to 7% of all pregnancies (depending on the population to be screened), or approximately 135,000 cases annually. The prevalence of gestational diabetes in the United States has increased dramatically—a relative increase of 122% between 1999 and 2004 [108]. Pregestational diabetes, or pre-existing diabetes, accounts for 19,000 pregnancies annually in the U.S. [29]. Gestational diabetes (GDM) occurs when the diabetogenic environment of pregnancy is too great for the woman's pancreatic function. This intolerance was not detected before pregnancy—hence its diagnosis [183]. The amount of GDM varies in direct proportion to the prevalence of type 2 diabetes [108]. It is detected through an initial 50-g 1-hour glucose challenge test between 24-28 weeks of gestation. If the result is over 130mg/dL, the patient undergoes a 100g 3-hour glucose tolerance test. Two or more abnormal values are considered positive for GDM [183]. It is necessary to explain that 50% of women with GDM are not diagnosed with the risk factors alone. The two methods of classification of diabetes in pregnancy are from Priscilla White, M.D. (**Table 2.1**) and the American Diabetes Association (ADA). In 1949, Priscilla White introduced a diabetes classification system designed to evaluate the effects of diabetes on the mother, fetus, and neonate [184]. It has undergone several modifications. With the recognition of different causes of diabetes, the American Diabetic Association (ADA) presented a classification of diabetes based on pathogenesis of the hyperglycemia [185]. Published in 1994, the ADA's classification divides the types of diabetes into type 1 (immune-mediated diabetes), type 2 (insulin resistance as well as a relative insulin deficiency), plus a third division, gestational diabetes (GDM), which is any degree of glucose intolerance with onset or first recognition during pregnancy [186].

Risk factors for GDM include being older than 25 years, having a family or personal history of type 2 diabetes, or previous gestational diabetes; increased pregravid body mass index (BMI) [187,188]; African American, American Indian, or Hispanic race

Table 2.1 Modified White Classification of Diabetes in Pregnancy

Class	Diabetes Onset Age	Duration (yr)	Vascular Disease	Insulin Needed
Gestational				
A ₁	Any	Any	0	0
A ₂	Any	Any	0	+
Pre-Gestational				
B	Diabetes developed after age 20, have had the disease less than 10 years, no vascular complications.	< 10	0	+
C	Diabetes developed between age 10 and 19 or have had the disease for 10-19 years; no vascular complications.	OR 10-19	0	+
D	Diabetes developed before age 10, have had the disease more than 20 years, vascular complications are present.	OR > 20	+	+
F = Renal	Any age: Diabetic women with kidney disease called nephropathy.	Any	+	+
R = Retinopathy	Any age: Diabetic women with retinopathy (retinal damage)	Any	+	+
T = Renal Transplant	Any age: Diabetic women who have undergone kidney transplant.	Any	+	+
H = Cardiovascular	Any age: Diabetic women with coronary artery or other heart disease	Any	+	+

[189-191]; and an unexplained stillbirth or large for gestational-age infant in previous pregnancies [190]; polycystic ovaries; essential hypertension; or pre-pregnancy overweight or obesity [192,193]. Studies have suggested that there is a genetic similarity between type 2 diabetes and GDM. A recent study by Lauenborg et al. examined the association between GDM and 11 gene variants or proven risk alleles for type 2 diabetes. Two-hundred and eight-three women with previous GDM were compared to 2,446 glucose tolerant women. The study found that the prevalence of several proven type 2 diabetes risk alleles equals the findings from association studies on type 2 diabetes. This supports the hypothesis that GDM and type 2 diabetes are two of the same entity [194-197].

A healthier pregnancy begins before conception with a discussion with the healthcare practitioner in order to have optimal glycemic control before the pregnancy, along with adequate folic acid supplementation to enhance a positive birth outcome. Mothers with low literacy are significantly more likely to have unplanned pregnancy and less likely to have discussed pregnancy with their physician [29]. Treatment usually is in the form of dietary control and physical activity for Class A1, and for Class A2 insulin is required as well as diet and physical activity. Treatment for pregestational diabetes (Classes B through T) includes increasing insulin dosages, diet, and physical exercise. A significant reduction in both fetal and maternal risk of complications has been seen when glycemic control was kept within normal HbA_{1C} limits (3.3 to 7.8% for one study) during the pregnancy [43-45]. Because the placenta undergoes changes, toward the end of gestation in women with diabetes the fetus can experience fetal hypoxia and possibly fetal death [198]. Early delivery is performed, usually by cesarean section, to prevent these adverse events; however, delivery at 38-40 weeks is not considered controversial in spite of the risk to the fetus of an immature respiratory and gastrointestinal system.

Maternal Birth Outcomes

The normal pregnant state is characterized by insulin resistance, oxidative stress, and mild systemic inflammation [199] which is usually tolerated and returns to normal after the pregnancy. In the pregnant woman with diabetes, the hyperglycemia can be detrimental to the fetus resulting in congenital anomalies and fetal loss [200-202]. Women with diabetes tend to be highly motivated to improve their glucose control to maximize their chances of having a healthy baby [203] and having adequate health literacy to accomplish this is a positive health outcome.

Complications of gestational diabetes include a risk of preterm birth [204], higher possibility of a cesarean section [205] related to the large size of the infant. Delivery of a large infant by the vaginal route may result in third and fourth degree lacerations [35-39,108,193,206]. These mothers are also at risk for cardiovascular problems after pregnancy especially if hypertension and preeclampsia were present [38,207]. It is documented that some seventy percent of mothers identified with gestational diabetes are at risk for type 2 diabetes within 10 years of the current pregnancy [208] and are at seven times the risk for cancer of the pancreas later in her life [209]. Adequate health literacy

would help the mother to take care of herself in regards to diet, exercise and glycemic control to help reduce these adverse effects.

Mothers with pregestational diabetes also have increased miscarriage, stillbirth, and congenital anomaly rates [210]. Preterm birth, in the presence of previous vascular complications from diabetes [211], can result in a small for a gestational age infant because of the dysfunction incurred by the placenta [212]. Other problems include a risk of delayed wound healing from a cesarean section delivery [213,214], and because of previous damage to the kidney and eye before pregnancy, retinopathy and nephropathy frequently worsens during pregnancy [215]. The pregnant mother is also at risk for hypertension, preeclampsia, preterm birth and complications from worsening diabetes [180,216]. Recent literature has also documented that type 2 diabetes is associated with even greater perinatal mortality than type 1 diabetes [202,217]. While some of the complications from diabetes are beyond the control of the mother, her health behaviors which are linked to her health literacy level, can help reduce these complications.

Delivery Method

Cesarean delivery is one of the most common surgical procedures in the U.S. and currently is performed at a rate of 31.1% [218,219]. Morbidity and mortality rates from cesarean deliveries are difficult to tease out because women who need this type of intervention have chronic conditions such as diabetes that influence these rates. In births that involve infants of mothers with diabetes, cesarean delivery rates are tripled, as the healthcare provider seeks to avoid birth trauma to the mother and infant related to the large size of the infant [205,220,221]. Fetal macrosomia may result in fetal birth injuries such as brachial plexus, shoulder dystocia, birth asphyxia, and neurological damage [180,205,221-224]. Cesarean delivery is indicated for the mother in cases of failure to progress, preeclampsia, hypertension, preterm birth, and severity of diabetes [38,206,207,223,225-227]. Cesarean section deliveries and third to fourth degree vaginal tearing related to the delivery of an infant with macrosomia thus place the mother with diabetes at risk for delayed wound healing [214].

Preeclampsia and Hypertension

Pre-eclampsia is a disorder characterized by the presence of hypertension and proteinuria [228] manifesting in the latter half of pregnancy [229,230]. Preeclampsia can occur in up to 10% of all pregnancies and is a major cause of neonatal morbidity and maternal mortality [231,232]. Complications include seizures, stroke, and coma for the mother and fetal distress, intrauterine growth retardation, premature delivery, and death for the fetus [232,233]. Preeclampsia is associated with both gestational and pregestational diabetes [234] at rates that are two to four times higher in pregnancies complicated by diabetes than in pregnancies not complicated by diabetes [235]. This may be because insulin resistance, chronic inflammation, and endothelial dysfunction share common pathophysiology [234,236-238]. Gestational diabetes is associated with increased risk for preeclampsia and gestational hypertension [236,239]. The only cure

for this disorder is removal of the placenta [229,232]. While the exact cause is still under investigation, it is related to placental oxidative stress from lack of oxygen supply and the maternal response to this occurrence is probably related to chronic inflammation [237,240,241].

The association of hypertension and vascular disease to gestational diabetes mellitus has been studied [205,239]. Studies have shown that the incidence of gestational diabetes is significantly higher among women with chronic hypertension than in the general population [242,243]. Ray et al. found a higher rate of chronic hypertension in pregestational diabetes than in the gestational group, which correlated to the pathophysiology of organ damage in diabetes [205]. These individuals also have increased insulin resistance, which affects birth outcomes with an increased risk for cesarean delivery and for delivering a large-for-gestational-age infant [207,244]. Others have found increased rates of low birth weight and preterm infants in this population [205,242,243,245]. Preexisting conditions of diabetes, obesity, and hypertension were associated with 22.3% of preeclampsia cases in a Danish cohort study [245,246].

Preterm Birth

The American College of Obstetricians and Gynecologists has re-defined spontaneous preterm birth to include preterm birth, preterm labor, premature rupture of membranes (PROM), and/or cervical incompetence resulting in delivery before 37 gestation weeks [247]. Preterm birth complicates 12.8% of all deliveries in the U.S. and is the most important cause of perinatal mortality and infant morbidity, and these rates have continued to increase in the U.S. for the past 20 years [248]. Both gestational and pregestational diabetes have been associated with preterm birth and are increasing in incidence [187,205,249]. The preterm birth is related to diabetes end-organ damage from vasculopathy in pregnant women with diabetes that is likely to decrease uterine blood flow and result in the birth of a low-birth-weight infant [211,212,250,251]. One of the leading causes for preterm birth is preeclampsia [229].

Infant Birth Outcomes

Infants of diabetic mothers, numbering between 50,000 and 150,000 each year in the U.S. [252], face a hostile uterine environment from the beginning of conception through delivery and beyond. The infant faces a myriad of problems such as complications with organogenesis resulting in congenital anomalies—usually from maternal hyperglycemia experienced early in the pregnancy. Later in the pregnancy the infant responds to maternal hyperglycemia with its own hyperinsulinemia, which can lead to macrosomia, premature birth, cesarean section, and fetal demise. In childhood, issues relating to obesity and learning problems may also be seen. Health literacy and preterm birth has not been studied, yet low levels of education, African American race [253], and poverty have been associated with preterm birth [254]. Pre-conception care and early prenatal care, is of great importance in regulating glycemic control early in pregnancy as they help to ameliorate the effects of maternal hyperglycemia during gestation and reduce

preterm birth. Thus, the health literacy level of the mother is important, since it may influence how she cares for herself and her infant as she navigates through the health-care system.

Perinatal Mortality

Although perinatal mortality for infants born to diabetic mothers has declined from over 30% to 2-4% over the past 50 years [255-257], it still is three to six times higher than in the general population [216,258]. Reasons cited for this include congenital anomalies, spontaneous abortions, and stillbirth [259]. All of these conditions are influenced greatly by poor glycemic control during the pregnancy [220].

Congenital Anomalies

Congenital anomalies are the leading cause of perinatal mortality [180], especially if there is poor glycemic control during the time of organogenesis, the 3rd through the 8th weeks after the last menstrual cycle [169,200,216,260,261]. This results in higher perinatal mortality[180,259,262], spontaneous abortions, and birth anomalies[263]. The frequency of congenital malformations are estimated at 6-18% in pregestational pregnancies complicated by diabetes, which represents a two-fold to five-fold increase compared to the rate seen in the general population [40,264-266]. Congenital anomalies are one of the main causes of spontaneous abortion. In an attempt to control for preterm birth, known fetal anomalies were ineligible for this study. The relationship between health literacy and congenital anomaly have not been studied, although a significant reduction in these complications has been seen when blood sugar levels were kept as close as possible to normal levels [43-45]. To have a positive impact on these delivery outcomes, health literacy levels need to be assessed and intervened upon early in pregnancy by health care providers.

Spontaneous Abortion

Spontaneous abortion rates rise in the population of pregnant women with diabetes, depending on the level of glucose control in early pregnancy. The rate of spontaneous abortion in a group of control women was 16% and in a group of women with diabetes was 9% when glucose control was within normal range, but it exceeded 45% when glucose control was markedly elevated [267]. When compared to normal pregnancies, women with pregestational diabetes have five times the risk of stillbirth [268], and it appears to be more prevalent in Asian women with diabetes [269]. Reasons for this mortality are linked to fetal asphyxia [270,271] and chronic fetal hypoxemia[271], suboptimal glycemic control, and placental insufficiency. Chronic fetal hypoxemia and fetal asphyxia, demonstrated by increased fetal erythropoietin levels [272], could be a result of hyperinsulinemia and hyperglycemia [216]. Lauenborg et al. in 2003 found suboptimal glycemic control later in pregnancy, as evidenced by higher HbA_{1C} levels in 67% of their 22 cases of stillbirth [259]. The placenta is influenced by

fetal hyperinsulinemia and has a role to play with glycemic control and stillbirth; studies are ongoing in this area [212,216]. Infection has also been implicated in the cause of stillbirth with chorioamnionitis and has been implicated in type 2 diabetic pregnancy [262]. Lack of understanding on the mother's part about good glycemic control early in the pregnancy may have an effect on these outcomes.

Neonatal Morbidity

Infants who have been exposed to the environment of the womb of a diabetic mother have morbidities during the neonatal period. Neonatal morbidity is manifested in many ways including congenital anomalies, respiratory distress syndrome (RDS), macrosomia and birth injury, hypoglycemia, metabolic concerns of hypocalcemia and hypomagnesemia, as well as polycythemia and hyperbilirubinemia. Later in the child's life the long-term effects of the pregnancy influenced by diabetes include obesity by age seven and one half [256,273], and delayed motor and cognitive development are seen [274,275].

Fetal Demise

When compared to normal pregnancies, women with pregestational diabetes have five times the risk of stillbirth or fetal demise [220,268,276]. Reasons for this mortality are linked to intrauterine asphyxia [271,277,278], suboptimal glycemic control [259], placental insufficiency [212,216], and infection [262]. Lack of understanding on the mother's part about good glycemic control early in the pregnancy may have an effect on these outcomes. Infection has also been implicated in the cause of stillbirth, with chorioamnionitis implicated in type 2 diabetic pregnancy [262]. While type 2 diabetes is usually considered a less detrimental type of diabetes, there is mounting evidence that type 2 diabetes consequences are no less significant than those associated with type 1 [205,217].

Congenital Malformation

The frequency of congenital malformations are estimated at 6-18% in pregestational pregnancies complicated by diabetes, which represents a two-fold to five-fold increase compared to the rate seen in the general population [40,264-266]. Anomalies associated with diabetic pregnancies include cardiovascular, central nervous system, genitourinary, gastrointestinal, and skeletal disorders [279]. Congenital anomalies are also present in women with gestational diabetes, suggesting that these women may have undiagnosed type 2 diabetes mellitus [217,280,281]. In either case, there is a strong relationship between first trimester glucose levels and the incidence of malformations [40,171,172]. Furhmann and colleagues found a significant reduction in the rate of birth anomalies (7.5% vs. 0.8%) in the offspring of pregnant, diabetic women who received information on the intensive preconception glycemic control as opposed to those who did not [263]. The genetic connection is that hyperglycemia alters the

expression of regulating genes resulting in altered cellular mitosis and normal programmed cell death which can result in fetal anomalies [256,260,282].

Respiratory Distress Syndrome

The risk of respiratory distress syndrome (RDS) is 5.6 times higher in the infant of a diabetic mother (IDM) than in infants of mothers without diabetes [283]. In vivo studies suggest that hyperglycemia may be the cause of altered lung maturation in an IDM [284]. Maturation of surfactant synthesis occurs at the same time glycogen is normally depleted from the lungs and liver in utero. In IDMs, hyperglycemia interferes with this glycogen depletion thereby delaying this surfactant synthesis maturation. The infant also contends with hyperinsulinemia which is also implicated as to the cause of RDS. Fetal hyperinsulinemia contributes to RDS by decreasing surfactant synthesis through interference of phosphatidylcholine (PC) production which is a necessary precursor to surfactant development and alters the natural anatomic changes that occur with glycogen depletion [285,286]. These IDMs tend to be large for gestational age and may have immature respiratory systems because of the effect of hyperglycemia and insulin on the fetus. This risk of lung immaturity complicates attempts to reduce risk of a stillborn fetus by elective early delivery [180]. Because of this the neonate needs closer scrutiny and interventions similar to a preterm infant. Preconception care for the mothers with diabetes would greatly enhance their level of health literacy allowing them to take care of their glycemic control and decrease the impact of hyperglycemia on the fetal lung.

Birth Weight

Birth weights for IDMs vary from being low (LBW) or small-for-gestational-age (SGA), which is less than 2,500 grams, to being large-for-gestational-age (LGA) or macrosomia, which is a weight of more than 4,000 grams. Low birth weight usually occurs in women who have pregestational diabetes with vascular complications such as hypertension and nephropathy [205]. Preterm birth usually results in a LBW infant who is SGA because of the decrease in uterine blood flow [211,212,250,251].

Macrosomia of the infant occurs in up to 45% of diabetic pregnancies [287] because the fetus produces its own insulin in response to maternal hyperglycemia [288], leading to excessive fetal growth [180]. This growth includes increased body fat, muscle mass, and organomegaly as well as hypertrophic cardiomyopathy [289-291]. The large-for-gestational-age infant (LGA) has a birth weight greater than 4000 grams, brought on from macrosomia in utero, which poses problems during delivery for both the mother and infant [221,271,277,292,293]. These birth injuries include shoulder dystocia that can result in brachial plexus injuries, which may cause permanent arm impairment in the newborn in 5-10% of cases [216], and Erb's palsy [224,270]. Compared to fetuses of the same weight, fetuses of mothers with diabetes have an increased the risk for shoulder dystocia by three to four times that of non-diabetic mothers. Birth weight has a direct influence, with infants less than 4,000 grams having a 9% occurrence of shoulder dystocia and infants greater than 4,500 grams having a 26% occurrence [292,294]. Even

though these infants are large and healthy looking, they have immature respiratory and gastrointestinal systems. In addition to the early cesarean delivery to avoid the birth injuries associated with macrosomia, these infants run the risk of respiratory distress syndrome (RDS) from immature lungs, which are related to the early influences of hyperglycemia.

Infant Metabolic Response

Another infant response to maternal hyperglycemia is fetal hyperinsulinemia. This leads to an increase in catabolism and an increase in energy use, which decreases fetal oxygen stores, leading to fetal hypoxia (which stimulates erythropoietin) and an increase in red cell production (polycythemia). The breakdown of the extra red blood cells may account for the increased rate of hyperbilirubinemia seen more in the IDM than the normal infant because of the breakdown of the excess red cells caused by the polycythemia [179,295,296].

Neonatal hypoglycemia (blood glucose levels < 40 mg/dl), is manifested by the infant shortly after birth. This most prominent problem is caused by maternal hyperglycemia and fetal hyperinsulinemia and a decreased glucagon response, along with decreased hepatic responsiveness to glucose [297-299]. Maternal hyperglycemia stimulates the fetal pancreas, resulting in fetal B-cell hypertrophy and hyperplasia [255]. After birth, the maternal glucose source is removed, yet the neonatal hyperinsulinemia remains resulting in neonatal hypoglycemia [216,260,300,301]. The effect of hypoglycemia on the infant includes lethargy, poor feeding, irritability, high-pitched cry, and seizures [260]. Infants who have hypoglycemia and seizures are reported to have had later neurologic impairment [302].

As many as 50% of infants born to IDM mothers have hypocalcemia, and 33% have hypomagnesemia; both are manifested in the neonate and are thought to be related to the severity of the diabetes during gestation [303,304]. The proposed reason for this is that along with the hyperphosphatemia that is present during the first 48 hours after birth, hypomagnesemia may suppress parathyroid activity and produce hypocalcemia [216].

Summary

The infant of a diabetic mother faces many adverse events after delivery. Though these infants appear healthy, they have immature organ systems and need to be monitored as would a premature infant to decrease these effects of these adverse events. Pre-conceptual care and early prenatal care are of great importance in regulating glycemic control early in pregnancy. Health literacy and glycemic control would help to ameliorate the effects of maternal hyperglycemia during fetal organogenesis.

Measuring Health Literacy

Health literacy is a complex construct because it involves many variables, ranging from the individual's capacities and environment to the healthcare provider and the

environment of the greater healthcare system itself. To date, there is not one instrument that measures the total construct. Measuring health literacy has most often been done with the Rapid Estimate of Adult Health Literacy in Medicine (REALM), the Test of Functional Health Literacy in Adults (TOFHLA), or the Wide Range Achievement Test (WRAT) [7]. The REALM and S-TOFHLA are primarily word recognition and pronunciation instruments and measure basic print literacy. Health literacy is more than just print literacy, however, since it involves numeracy and psychomotor skills as well as culture. There are no current instruments that measure health literacy in light of culture or ethnicity. The TOFHLA does have a Spanish version, and the three screening questions from the TOFHLA have been used in a Spanish-speaking population with the same effectiveness [305].

Two other instruments have been developed and added to the measurement toolbox of health literacy. The Newest Vital Sign (NVS) is a nutrition label from a pint of ice-cream. Six questions are asked about how the individual would interpret the answers based on the label. It is clinically applicable because it takes about 3 minutes to administer. It is able to detect limited literacy but is not associated with health outcomes [306]. The Health Activities Literacy Scale (HALS) is a comprehensive, large scale literacy survey that is linked to the National Adult Literacy Survey. The HALS includes prose, quantitative and document items in five health-related areas of health promotion, health protection, disease prevention, health care and maintenance, and systems navigation. This survey takes over one hour to complete and has not yet proven if it can predict behavior and outcomes [52]. Because of the lack of more comprehensive methods of assessment, the Institute of Medicine (IOM) has called for more expansive measurement instruments [26].

This study looked at word recognition measures of medical information with the REALM, diabetes information with the Literacy Assessment of Diabetes (LAD), and genetic information with the REAL-G. The three literacy screening questions from the TOFHLA were compared with the word recognition test to see if they could be used as a screening test for low health literacy in this population of pregnant women with diabetes [57]. The REALM and the TOFHLA are considered the “gold standard” at this point in the measuring process [52] and they have been shown to predict knowledge, behaviors, and outcomes [8,14,30,112]. The LAD and the REAL-G have been fashioned after the REALM to produce an instrument that is specific to diabetic and genetic health literacy, respectively. The use of these two instruments in this study is to identify their potential use in this population.

Future Interventions for Health Literacy

Health literacy is a construct with many characteristics that can be manipulated to assist the individual to gain information about his health and how to take care of himself. Because this construct is influenced by many factors, many interventions are proposed to help raise an individual’s health literacy level. On the federal level, policy makers such as the American Medical Association, the Joint Commission and various interest groups are calling for research studies to assist in making informed policies that would

encourage increased health literacy levels. Healthy People 2010 have as one of its goals to improve the health literacy of persons with inadequate or marginal literacy skills.

Health literacy of individuals needs to be improved, and several interventions have been proposed to facilitate this change. Standards of care, such as confirming comprehension by the patient, should be brought to the forefront. Teaching confirmation by the healthcare provider of the patient's understanding can be done by the teach-back method. This method allows patients to reiterate what was taught to them. A standard of "universal precautions" in health literacy has also been proposed to ensure comprehension of their healthcare regimes by all patients [60]. This means that everyone is assumed to have lower health literacy and is taught based on this assumption. Efforts to improve providers' communication ability and provide clearer teaching tools, and increase funding for research all work together to encourage a more health literate society. The National Patient Safety Council has recommended "Ask me 3" program—a series of three questions that the patient asks the healthcare provider (What is my main problem? What do I need to do? and Why is it important for me to do this?) in an effort to have clearer communication and understanding between the two. Since medical documents are often written at a 10th-grade level, and verbal communications are fraught with opportunities for misunderstanding [307], education materials should be short, simple, contain culturally sensitive pictures and graphics that encourage the desired behavior [144].

The Joint Commission has identified common factors that lead to patient harm—such as poor communication and poor clinical management [308]. As a result, it has offered many recommendations to help prevent these problems. For the healthcare provider, recommendations include refer patients with low literacy to adult learning centers to assist them with enrollment procedures; broaden reimbursement policies for patient education provided in physician offices; pursue pay-for-performance strategies that provide incentives to foster patient-centered communications and culturally competent care; and expand the number of medical liability insurance companies that provide premium discounts to physicians who receive education on patient-centered communications techniques. For the clinician, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommends the use of clear, concise language, having the patients repeat back what they have learned, limiting teaching to two to three points at one time, and encouraging patients to ask questions [4].

Conclusion

Health literacy can save lives, save money, and improve the health and well-being for millions of Americans, as reported by the Surgeon General's office [309], and needs to be a priority in the care of every patient. Health literacy is a major factor in the effort to improve the health of Americans. Pregnant women with diabetes are at risk for many adverse birth outcomes and need to have adequate health literacy in order to take care of themselves and their infants. Since health literacy is not a fixed characteristic and can be improved, changes in the ways that individuals are included in their health care are

necessary so that they can take a more active role in their healthcare-related decisions and improve their level of health literacy and thus health outcomes.

There are gaps in the literature regarding several characteristics of health literacy. The intangible things that affect health literacy are harder to understand. Mediating factors include, for example, attitude, bias, and ability that both individual and healthcare provider bring to the equation. What has yet to be studied includes the effect that culture, religion, and language have on the meaning of health and how it relates to health literacy. Studies that give a more comprehensive view of the data by examining the extent to which these characteristics influence the outcome of health literacy level would be able to direct further research in a more meaningful way. Other gaps include research into pregnancy and diabetes as it relates to health literacy level. This study helped to answer whether health literacy level has any association with birth outcomes.

CHAPTER 3. METHODOLOGY

This section will present the methodology used to address the research questions in this study. The research design, sample and setting, instrument, procedures, statistical analysis, and protection of human subjects will be described.

Research Design

This study, which was approved by the Institutional Review Board at The University of Tennessee Health Science Center and the Regional Medical Center, Memphis (**Appendixes A, B, and C**), used a descriptive, correlational, longitudinal research design to study 32 pregnant women with a medical diagnosis of pregestational or gestational diabetes. The study examined the medical status of the mother and type of diabetes during pregnancy. Birth outcomes for both the mother and infant were also examined. Levels of medical, diabetic, and genetic health literacy were evaluated to examine attributes within this pregnant population with diabetes that might contribute to or protect against adverse health outcomes for both mother and infant.

The International Conference on Harmonization good clinical practices (GCPs) were followed in the current research study. Federal regulations 45 CFR part 46 that require informed consent from a prospective study subject were followed [310]. Subject recruitment for this research project was in compliance with inclusion/exclusion criteria in IRB-approved protocol. This researcher complied with NIH & FDA requirements in areas of subject recruitment. This researcher has read and understood the “NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research” [311] and the “NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects” [312].

The study sample was drawn from individuals who presented to the high risk obstetric outpatient clinics with a diagnosis of either pregestational or gestational diabetes. It was conducted in an urban setting at a safety-net hospital that has a maternal delivery rate of 4,700 babies per year. Written consent was obtained prior to subject participation in the study (**Appendix D**). The sample consisted of a final tally of 32 participants.

Sample and Setting

The patient population comprised eligible pregnant women between 16 and 40 years of age. All obstetric patients were identified in The University of Tennessee Medical Group prenatal care clinic in the Regional Medical Center, Memphis (The MED), and the Institutional Review Board at the MED approved the study. A breakdown of participants in the study is shown in **Figure 3.1**. This investigator screened 105 pregnant women with diabetes at this urban clinic in a safety-net hospital. The participants were screened to identify the variables that would influence the chance of a preterm birth. Of the 105 screened, 68 women did not meet eligibility requirements for

Figure 3.1 Breakdown of Participants in the Study

several reasons. Three refused to participate, 18 had chronic hypertension and were taking medication for it, and 12 had other conditions such as thyroid disease, lupus, and sickle cell anemia. Nine had a diagnosed fetal anomaly, 9 had already delivered, and 8 had a late delivery due date. Three were found to have a normal glucose tolerance test and thus no gestational diabetes, and there were two sets of twins. Because this investigator did not speak Spanish, reading and speaking English was necessary, which meant that 7 women were not eligible. The sample numbered 34 participants, with two delivering at another hospital; because their birth data were not available, they were not included in the study. The makeup of the patient population consisted of 75% African American, 11% Caucasian, 10% Hispanic, and 4% other. For each participant it took approximately 30 minutes to complete the one-time data collection of their demographic and health literacy data. This included an interview for the consent and completion of the three health literacy assessment tools. Additional data were collected post delivery. All data were collected between June 1, 2007 and December 31, 2007.

Many variables are present in the relationship between diabetes and pregnancy. Since health literacy is unique to each individual, variables need to be controlled for as much as possible. By utilizing one prenatal clinic location, the variation in diabetic teaching practices, physician treatment of the pregnancy and diabetes, and the labor and delivery environment is lowered for each subject. The following criteria were used to help control other variables:

Inclusion Criteria

Participation for this study was open to all who met the inclusion/exclusion criteria. Inclusion criteria for this study consisted of the following:

- Pregnant women with pregestational or gestational diabetes determined by diagnosis.
- 16 to 40 years of age. (Graviditas < 18 years of age were offered inclusion provided both they and their legally authorized representative agreed to participate and sign the consent.)
- Ability to read, speak, and understand English.

Exclusion Criteria

The following exclusion criteria were chosen because of their association with birth complications. In an effort to decrease the number of variables that might influence the outcome, several risk factors for prematurity were included in the exclusion criteria. Exclusion criteria for this study consisted of the following:

- Multiple gestation in the current pregnancy.
- Delivery outside of the study hospital (The Med).
- Clinical conditions that could affect pregnancy or birth outcomes not related to this study were also excluded, including:

- Chronic hypertension or vascular disease requiring therapy
- Maternal red cell alloimmunization
- Hemoglobinopathy including sickle cell trait and severe iron deficiency anemia (hemoglobin <9)
- Prolapsed or ruptured membranes
- Oligohydramnios
- Complete placenta previa
- Endocrine disease other than diabetes
- Collagen disease (lupus erythematosus, scleroderma, etc.)
- Active or chronic hepatitis
- Pulmonary or heart disease requiring therapeutic medication or limitation of physical activity (except for mitral valve prolapse or asthma requiring only occasional medication)
- Major fetal anomaly discovered during the pregnancy
- Infection with the human immunodeficiency virus (HIV)

Materials and Methods

This investigator selected a sample of convenience from a list of pregnant individuals who had appointments at the prenatal clinics located in an urban safety net hospital. This selection was further refined by comparing these potential participants against a list of individuals who had an appointment with either the clinical diabetic educator or nutritionist. Once a potential participant was found to have gestational or pregestational diabetes by either diagnosis or an appointment with the diabetic educator, the medical record was examined to determine if the inclusion and exclusion criteria applied.

After the diabetic educator and dietician had met with the potential participants about their pregnancy needs for that visit, those who met the inclusion criteria were approached by the investigator and asked to participate in the study. Those who agreed to participate were moved to a private room where the consent form was discussed and signed; questions about the study were answered by the investigator, and a copy of the consent form was given to the participant. The participants were then asked to read aloud between 60-66 words on each of three literacy tools; the Rapid Estimate of Adult Health Literacy in Medicine (REALM) (**Appendix E**), the Literacy Assessment for Diabetes, and the Rapid Estimate of Adult Literacy in Genetics (REAL-G) (**Appendix F**) as well as answer the short questionnaire composed of the three questions from TOFHLA. At this time, demographic data were obtained from the mother's chart. Data included the mother's age, date prenatal care was sought, highest grade completed in school, and monthly household income. Information was recorded on the Health Literacy Data Collection form (**Appendix G**).

To collect information for glycemic control, glucose readings that the mother reported to the diabetic educators were collected. These data were found in the chart on either the glucose record logs that the mother brought in to the clinic or in the diabetic

educator's notes. The high and low values as well as total number of values were collected.

After the birth of the infant, a review of the mother's chart was conducted to ascertain the pregnancy outcomes for both mother and infant. These outcomes included for the mother hypertension, premature labor, premature birth, delivery method, polyhydramnios, and vaginal laceration and for the infant, gestational age at birth, birth weight, respiratory distress, congenital anomalies, and fetal demise. Congenital anomalies, stillbirth, or miscarriages were also recorded. This information was recorded on the health literacy data collection form.

Instrumentation

While there is no comprehensive method to identify the level of health literacy for an individual, instruments measuring health literacy have been in common use since 1991 [50]. These instruments measure either reading comprehension or word recognition, and the S-TOFHLA measures comprehension. The resulting challenge is the applicability and feasibility of measuring health literacy in the clinical setting because of time constraints and the complexity of the construct. While educational attainment is often used as a proxy for the patient's ability to understand healthcare materials, it is not an accurate predictor of health literacy since patients often read several grade levels below the highest grade completed in school and thus it cannot be used to accurately predict health literacy [73,74]. One factor that the individual may bring to the clinical encounter is shame of their lack of understanding, which they attempt to conceal from the healthcare provider by such things as not asking questions or stating that they have left their glasses at home [146,152].

The instruments selected for this study included the Rapid Estimate of Adult Health Literacy in Medicine (REALM), the Literacy Assessment of Diabetes (LAD) (**Appendix H**), the Rapid Assessment of Adult Health literacy in Genetics (REAL-G), and the three questions from the TOFHLA. They were chosen because of their ease of administration in regard to time and their applicability to the sample studied. The reliability and validity of the REALM has been demonstrated [313,314] and the measurement used in many studies [6,9,14,79,104,117,157,315]. It has been called the "gold standard" for measuring health literacy, allowing for comparisons of this study to other studies [52]. The LAD and the REAL-G were fashioned after the REALM and have not been used in other studies. This study used these two measures plus the three questions from the TOFHLA, to validate them in this population. The time needed to administer the tools was no more than 10 minutes because the participant was able to go from one tool straight into the next, which was convenient because the participant was able to finish the tools in a timely manner and not interrupt the clinic site's day-to-day operation.

Rapid Estimate of Adult Literacy in Medicine (REALM)

The Rapid Estimate of Adult Health Literacy in Medicine (REALM) is a screening tool designed to assess health literacy through word pronunciation from a 3rd-through 12th-grade level [314]. It was specifically designed to identify patients who read at levels below 9th grade [50]. It consists of 66 medical words arranged in 3 columns, each containing 22 words arranged by number of syllables and difficulty and printed in 18 font for easy readability. This tool is administered by a health professional who scores each word as the patient reads it out loud. It takes 3-5 minutes to perform. Points are awarded for correct pronunciation of the words and are converted to grade equivalents. Scoring ranges are: 0–18 equal to < 4th grade; 19–44 equal to the 4th–6th grade; 45–60 equal to the 7th–8th grades; and 61–66 equal to high school grade.

The reliability and validity of the REALM has been confirmed through other standardized reading tests. In one study, the SORT-R (Slosson Oral Reading Test-Revised), PAIT-R (Peabody Individual Achievement Test-Recognition Section) and WRAT-R (Wide Range Achievement Test-Revised) were administered to 207 patients along with the REALM. The SORT-R, designed to assess the subject's level of oral word recognition and the REALM correlated at 0.96 ($p < 0.01$); the PIAT-R, a norm-referenced academic achievement test, that measured 1) mathematics, 2) reading recognition, 3) reading comprehension, 4) spelling, and 5) general information, correlated with the REALM at 0.97 ($p < 0.01$); and the WRAT-R, a brief achievement test measuring reading recognition, spelling, and arithmetic computation, correlated at 0.88 ($p < 0.01$) with the REALM [314]. The co-relation of the REALM to the other standardized reading tests gives credence to the validity of the REALM to assess the same parameters. Test-retest reliability is reported at 0.99 ($p < 0.01$) and inter-rater reliability as 0.99 based on 20 cases. The REALM tool was further validated in a United Kingdom population with coronary heart disease with the Basic Skills Agency Initial Assessment Test (BSAIT), with a correlation of $r = 0.70$; $P < 0.001$ [313].

In similar obstetrical populations, individuals seeking prenatal care were assessed using the REALM in regards to their understanding of prenatal testing. It was found that of the 125 patients recruited, 38% demonstrated low health literacy, as measured by the REALM. These patients with low literacy were more likely to demonstrate inadequate understanding of prenatal screening tests for fetal aneuploidy or an abnormal number of chromosomes as well as neural tube defects [79]. Another study assessed health literacy levels with the REALM in regards to knowledge of the effects of tobacco during pregnancy in low-income, pregnant women. The study found that higher literacy levels and higher reading levels had more knowledge and greater concern for their babies but still smoked during the pregnancy [132]. After pregnancy, exclusive breast-feeding is considered the ideal way to feed an infant for the first six months as per the recommendation of the American Academy of Pediatrics [316]. In 2001, Kaufman et al. utilized the REALM to assess health literacy levels with regard to breast-feeding practices in new mothers with infants 2-12 months of age in the New Mexico region. They found 23% of the lower literacy group (grades 7-8) and 54% of the higher literacy group (high-school) breast fed their infant exclusively for the first two months of the baby's life [21].

Among low-income African American women, health literacy was found to be a better predictor of knowledge and behavior than race in regard to cervical cancer screenings and anxiety. In 2002, Sharp et al. studied cervical cancer risk factors and health literacy in low income African American women. They found that 25% of women with cervical abnormalities experience severe distress, a level consistent with prior published reports on predominately white or mixed race populations [117]. Later, in 2008, Lindau et al. found health literacy was a better predictor of cervical cancer screening knowledge than ethnicity or education in a study that was dominated by 58% African American women [9].

Literacy Assessment for Diabetes (LAD)

The Literacy Assessment for Diabetes (LAD) tool was developed as a word recognition test designed after the REALM. It has three columns of 60 words that increase in difficulty as the reader nears the end of the list. This diabetes-specific literacy test measures a patient's ability to pronounce terms they would encounter during clinic visits pertaining to self-care and diet management. Most of the words are on a 4th-grade reading level and the rest ranged from the 6th-16th-grade levels. To assess its reliability and validity, the LAD was compared to the Wide Range Achievement Test (WRAT3) and the REALM, which were all given to 203 participants in a test-retest study design [317]. The reliability shows correlation coefficients of 0.96 for the REALM, 0.86 for the LAD, and 0.92 for the WRAT3. Face validity, content and criterion validity, and concurrent validity were all verified by experts in the field of literacy and diabetes [317]. Studies that have used this assessment tool are not in the literature.

Rapid Estimate of Adult Literacy in Genetics (REAL-G)

Pregnant women with diabetes face the real concern of congenital anomalies and may face genetic issues as a result of the pregnancy. An assessment tool that was patterned after the REALM is the Rapid Estimate of Adult Literacy in Genetics (REAL-G), which is a 63-item pronunciation tool designed to assess the level of genetic health literacy in patients receiving genetic services. It is grounded in the clinical practice of over 150 genetic counselors, lending content validity to the tool. The REAL-G was strongly correlated with the REALM ($r = 0.83$ ($p < 0.0001$)) and has a 95.4% sensitivity and an 88.5% specificity [49]. Time of administration took 3-4 minutes. A score of 0-21 was equated to less than 4th grade; 22-50 equal to the 4th-6th grade; 51-60 equal to the 7th-8th grade; and 61-63 equal to high school grade. This assessment tool has been available since 2008, but studies utilizing it have not been published to date.

Short Test of Functional Health Literacy in Adults (S-TOFHLA) Screening Questions

Chew et al. (2004) studied the 16 questions from the Short Test of Functional Health Literacy in Adults STOFHLA and found three specific questions to be effective in

detecting inadequate health literacy [57]. The study was conducted on 1,796 predominately white, male, Veteran's Administration outpatients. The three questions were, "How often do you have someone help you read hospital materials?" "How confident are you filling out medical forms by yourself?" and "How often do you have problems learning about your medical condition because of difficulty understanding written information" [57]. The questions were ineffective for identifying marginal health literacy. These three questions were also utilized on 116 Spanish-speaking individuals in the Rio Grande Valley. The results were similar, leading the author to conclude that the screening questions were equally as effective in this population [305]. Wallace et al. in 2006 used these same screening questions on 305 predominately female, Caucasian, English-speaking adults attending a university-based primary care clinic [318]. They found that only one screening question predicted low health literacy; that was, "How confident are you filling out medical forms by yourself?" The three screening questions "How often do you have someone help you read hospital materials?" "How confident are you filling out medical forms by yourself?" and "How often do you have problems learning about your medical condition because of difficulty understanding written information?" were used by this researcher to explore if they could be used as a viable screening test in this group of predominately African American women.

Measurement Standards

The following measurement standards regarding health literacy were used in the study:

- Low health literacy was measured using the REALM instrument. A score below the 6th-grade level or a score < 45 was used to determine this level.
- Marginal health literacy was measured using the REALM instrument. A score below 7th- to 8th-grade level, i.e., a score of 45 to 60, was used to determine this level.
- Adequate health literacy was measured using the REALM instrument. A score above the 9th-grade level, or a score of 61-66, was used to determine this level.

Operational Definitions

The following definitions, which also tell measurement methods, were used during the study:

- *Birth weight*, measured in grams, is the weight of the infant immediately after birth. This information was recorded on the infant's birth certificate.
- *Congenital anomaly* is any physical defect that is present at birth in the infant. It was measured as "yes" or "no." The type of defect was also recorded. If a fetal congenital anomaly was known during pregnancy, the participant was not eligible for the study.

- *Delivery method* referred to the type of delivery, either vaginal or cesarean section, experienced by the mother and child. This information was found on the birth certificate on the medical record.
- *Fetal demise* refers to the death of the fetus in utero. It was measured as “yes” or “no” and was recorded in the medical record.
- *Gestational age at birth* recorded in weeks refers to the number of weeks of intrauterine growth at birth. This information is recorded on the infant’s birth certificate.
- *Glycemic control* refers to the number of blood sugar levels within normal limits given by self-report from the mother. It is recognized that this measure depends on maternal self documentation. The measures were taken from glucose logs brought in to the clinic by the mother or recorded by the diabetic educator in the medical record. Because each mother had a different number of recordings, a percentage of the total number of glucose readings recorded, the total number of abnormal glucose readings, and the percentage of this was analyzed to detect any associations.
- *Gestational diabetes* refers to diabetes that is discovered during pregnancy diagnosed after a 100 gram, 3-hour glucose tolerance test. A positive result is any two criteria above the following values: Fasting = 95 milligrams per deciliter (mg/dL); 1 hour > 190 mg/dL; 2 hour > 155 mg /dL; and 3 hour > 140 mg / dL. It was recorded according to the modified White Classification of Diabetes in Pregnancy as A₁ (controlled by diet only) or A₂ (requiring insulin during pregnancy). This information was documented in the medical record.
- *Hypertension* was measured as “yes” or “no” based on medical diagnosis present on the medical record. Those taking medication for this were not eligible for the study.
- *Polyhydramnios* is a condition of excess amniotic fluid present in the uterus of the mother and was measured as “yes” or “no.” This finding was located on the mother’s medical record.
- *Premature birth* was measured as “yes” or “no” based on the birth of the fetus before 37 weeks of gestation. This measure was found on the birth certificate on the medical record.
- *Premature labor* was regarded as the mother having regular contractions before 37 weeks of gestation and was measured as “yes” or “no.” Premature labor may or may not result in the delivery of the infant. This indicator was located on the medical record.
- *Respiratory distress* is the difficulty that the infant has with breathing after delivery. It was measured as “yes” or “no” and is recorded in the medical record.
- *Pregestational diabetes* refers to diabetes that is pre-existing to this pregnancy. It was recorded according to the modified White Classification of Diabetes in Pregnancy (B through D). It is documented by a medical diagnosis in the medical record.
- *Vaginal laceration* was measured as “yes” or “no,” along with the degree of tearing of the vaginal opening after delivery of the infant. This was documented on the mother’s medical record.

Data Analysis

Statistical analysis of the data was performed using the Statistical Package for the Social Sciences (SPSS) version 16.0. Descriptive statistics including means, standard deviations, and frequencies were calculated on demographic variables and the health literacy levels of the pregestational and gestational diabetic women.

Overview of the Data Analysis

Data analysis began by examining frequency distributions for nominal and ordinal level data and measures of central tendency for interval/ratio level data. Normality assessment was conducted and interval/ratio level data were determined to be non-normally distributed, appropriate data transformations, such as log transformations, was performed or non-parametric statistics were conducted. Alpha was set at $p < .05$. A power analysis was done post hoc and is reported in Chapter 4.

Specific Aim One

Determine if three questions from the Short Test of Functional Health Literacy in Adults (S-TOFHLA) can be used to assess low health literacy in pregnant women with pregestational and gestational diabetes.

- 1.a. Are the three questions from the S-TOFHLA associated with the REALM?
- 1.b. Are the three questions from the S-TOFHLA associated with the LAD?
- 1.c. Are the three questions from the S-TOFHLA associated with the REAL-G?

Pearson product moment correlation was used to address this aim. Scores for each of the questions on the S-TOFHLA-3 were correlated with scores from the REALM as well as the total of the sum of the three questions. A correlation of .80 or higher [319] between the S-TOFHLA-3 and the REALM would support the validity of the S-TOFHLA-3 to assess for low literacy and therefore would be used for health literacy assessments in the rest of the specific aims.

Specific Aim Two

Determine health literacy levels of pregnant women with pregestational diabetes and pregnant women with gestational diabetes using three health literacy instruments.

- 2.a. Is there a difference in general health literacy using the Rapid Estimate of Adult Health Literacy in Medicine (REALM) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?
- 2.b. Is there a difference in diabetic health literacy using the Literacy Assessment for Diabetes (LAD) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

- 2.c. Is there a difference in genetic health literacy using the Rapid Estimate of Adult Literacy in Genetics (REAL-G) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?
- 2.d. Is there a difference in genetic health literacy using the three questions from the S-TOFHLA tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

Independent sample t-tests were used to address this aim. The independent variable was group: (pregnant women with pregestational diabetes vs. women with gestational diabetes). Mean scores for diabetic, genetic, and general health literacy were compared between the two groups. It was hypothesized that women with pregestational diabetes would have significantly higher diabetic, genetic, and general health literacy than women with gestational diabetes because of their previous exposure to the medical terminology and treatments required to treat their diabetes.

Specific Aim Three

Determine if health literacy is associated with maternal glycemic control during the pregnancy.

- 3.a. Is the REALM associated with maternal glycemic control?
- 3.b. Is the LAD associated with maternal glycemic control?
- 3.c. Is the REAL-G associated with maternal glycemic control?
- 3.d. Are the three questions from the S-TOFHLA associated with maternal glycemic control?

To conduct the analyses to address Specific Aim Three, the three health literacy measures of the REALM, LAD, and REAL-G were dichotomized into low and high literacy groups. Independent sample t-tests were used to determine any differences. Data were obtained from glucose log recordings that mothers brought to clinical encounters. Two different measures were obtained from these logs: the total number of abnormal glucose readings recorded and the total number of readings recorded overall. Using these two measures, an index of maternal glycemic control was determined by dividing the number of abnormal readings by the total number of readings and multiplying by 100 to obtain a percentage. Women who did not have any glucose readings recorded were not included in the analyses.

Specific Aim Four

Determine if there are associations between health literacy levels and birth outcomes for both the mother (hypertension, premature labor, premature birth, delivery method, polyhydramnios, and vaginal laceration), and infant (gestational age at birth, birth weight, respiratory distress, congenital anomalies, and fetal demise).

- 4.a. Is there an association between the REALM and birth outcomes?

- 4.b. Is there an association between the LAD and birth outcomes?
- 4.c. Is there an association between the REAL-G and birth outcomes?
- 4.d. Is there an association between the three questions from the S-TOFHLA associated and birth outcomes?

To address this aim, multiple birth outcomes for the mother and infant were assessed. The outcomes were coded as 0 “not present” or 1 “present.” Chi square scores were used for categorical variables and t-tests for continuous variables. Because of problems with low cell frequency counts, analyses were conducted on the REALM, LAD, and REAL-G using the low and high literacy grouping.

Consideration of Human Subjects

This study received approval from The University of Tennessee Health Science Center’s Institutional Review Board and the Office of Medical Research at the MED. Good clinical practice was followed in care of the data. Appropriate guidelines were maintained to ensure anonymity and confidentiality for the subjects. A unique identification code was assigned to each subject to facilitate data analysis; however, data collection forms were stored in a separate location. The data were stored in a locked filing cabinet in a locked office in a locked office suite in Jackson, TN, where only this researcher had access. At no time were subject names reported, and all publications and presentations will reflect only aggregate data.

CHAPTER 4: RESULTS

The purpose of this study was to explore the association between health literacy level of the pregnant mother and birth outcomes for the infant and pregnancy outcomes for the mother in a sample of pregnant women with pregestational and gestational diabetes. The aims were to 1) determine if three questions from the Short Test of Functional Health Literacy in Adults (S-TOFHLA) can be used to assess low health literacy in pregnant women with pregestational and gestational diabetes; 2) determine health literacy levels of pregnant women with pregestational diabetes and pregnant women with gestational diabetes using three health literacy instruments; 3) determine if health literacy is associated with maternal glycemic control during the pregnancy, and 4) determine if there are associations between health literacy levels and birth outcomes for both the mother (hypertension, preeclampsia, premature birth, delivery method, polyhydramnios, and vaginal laceration), and infant (gestational age at birth, birth weight, respiratory distress, congenital anomalies, and fetal demise). A post hoc power analysis was conducted and is reported. Data analyses were conducted to address each of the specific aims and associated research questions. The results for each research question will be addressed.

General Sample Description

A summary of the study participants' characteristics is shown in **Table 4.1**. The participants could read and speak English, had a diagnosis of either gestational diabetes or pre-gestational diabetes, and had signed an informed consent. The mean age of the participants was 26.7 ± 5.4 years and had an average education level of 12.0 ± 1.4 years. The majority of the women were African American (81.2%), with the remaining 18.8% Caucasian. The mean monthly household income was $\$1,624.2 \pm \$1,173.0$, and the median income was \$1,225.

Table 4.2 presents the demographic characteristics and prenatal care initiation information, (time from first prenatal visit to delivery date), of the sample by gestational and pregestational diabetes groups. Both groups were similar with those with gestational diabetes slightly older, with more education. There were no significant differences between these groups except in the prenatal initiation days. Prenatal care initiation for all 32 pregnant women ranged from 11 to 224 days with a mean of 142.9 ± 56.8 days. Women with gestational diabetes had significantly fewer days of prenatal care (mean 122.2 ± 61.6 days) compared to women with pregestational diabetes (mean 164.4 ± 45.4 days, $p = 0.028$).

Health Literacy Scores

In this study we found that health literacy scores varied for those who had attained a high school grade level as measured by the REALM (**Table 4.3**). In those who had finished high school, 36.4% had low health literacy and 63.6% had high health literacy.

Table 4.1 Demographic Characteristics of Study Participants (N = 32)

Variable	N (%)	Mean (SD)	Observed Range
Age (years)		26.7 $\pm$ 5.4	18-38
Education level attained (grade)		12.0 $\pm$ 1.4	09-14
Household income (monthly)		1624 $\pm$ 1173	426-5666
Prenatal care initiation (days)		142 $\pm$ 56.8	11-224
Ethnicity			
African American	26 (81.2%)		
Caucasian	6 (18.8%)		
Type of Diabetes			
Gestational	16 (50%)		
Pregestational	16 (50%)		

Table 4.2 Demographic Characteristics and Prenatal Care Initiation by Gestational and Pregestational Diabetes (N = 32)

Variable	Gestational Diabetes n = 16 Mean (SD) or N (%)	Pregestational Diabetes n = 16 Mean(SD) or N (%)	t or Chi- Square Value	P Value
Age (years)	27.4 (5.5)	26.0 (5.5)	.74	.46
Education level attained (grade)	12.1 (1.3)	11.9 (1.6)	.25	.81
Ethnicity				
African American	14 (87.5%)	12 (75.0%)	.82	.37
Caucasian	02 (12.5%)	04 (25.0%)		
Household income (\$ monthly)	1547.9 (961.4)	1700.4 (1380.8)	-.36	.72
Prenatal care initiation (days)	122.2 (61.6)	164.4 (45.4)	-2.21	.035*

*P < .05

Table 4.3 Health Literacy Scores by High School Graduation Attainment

Health Literacy Variable	Non-High School Graduate n = 10(31.2) N (%)	High School Graduate n = 22(68.8) N (%)	Chi- Square Value	P Value
REALM				
Low health literacy	06 (60)	08 (36.4)		
High health literacy	04 (40)	14 (63.6)	0.50	.48
LAD				
Low health literacy	03 (30)	00 (00)		
High health literacy	07 (70)	22 (100)	21.13	.000
REAL-G				
Low health literacy	09 (90)	13 (59)		
High health literacy	01 (10)	09 (41)	4.50	.34

Conversely, of those that did not finish high school, 60% had low health literacy and 40% had high health literacy.

Health literacy scores of study participants are presented in **Table 4.4**. Total health literacy scores are reported in two different ways. In **Table 4.5** they are reported as continuous variables in literacy categories by grade level and categorized as low and high literacy. Upon examination of health literacy, the Rapid Estimate of Adult Health Literacy (REALM) scores had a mean score of 57.2 ± 10.6 . When assessed using literacy groupings, 43.8% had low health literacy and 56.2% had high health literacy, as assessed by the REALM. For the Literacy Assessment for Diabetes (LAD), the mean score was 50.7 ± 6.7 . Study participants who scored in the 5th to 9th grade level, which is considered low literacy, numbered 9.4%. High literacy scores are those 9th grade or higher level and made up 90.6% of the sample. For the Rapid Estimate of Adult Literacy in Genetics (REAL-G), the mean score was 56.0 ± 7.7 . Scores were dichotomized into low and high literacy as well as by grade level, with 68.7% having low health literacy in genetics and 31.3% having high health literacy in genetics using the REAL-G. The S-TOFHLA-3 were examined and found to have internal consistency with a Cronbach alpha of .75. Since these three items are cohesive as a measure of health literacy, both the individual S-TOFHLA items and the summary measure were included in the specific Aim One analysis.

The three questions from the S-TOFHLA (S-TOFHLA-3) were self report items that were scored on a Likert scale ranging from 0 to 4. The results are found in **Table 4.6**. The question “How confident are you in filling out medical forms by yourself?” was answered by 25 (78.1%) women as extremely confident and as “quite a bit confident” by 7 (21.9%). The “How often do you have someone help you read hospital materials?” question was answered by 19 (59.4%) as “never,” 9 (28.1%) as “occasionally,” and 4 (12.5%) as “sometimes.” The last question (“How often do you have problems learning about your medical condition because of difficulty understanding written information?”) was answered by a majority (68.7%) of women as “never,” by 5 (15.6%) as “occasionally,” 3 (9.4%) as “sometimes,” and 2 (6.3%) as “often.” Because the separate items of the S-TOFHLA-3 were also assessed as a group in previous research, the sum of the three questions was also calculated [57]. This was done after reverse scoring the question about filling out medical forms. The mean for the sum of the three items was 4.3(SD 1.6), with higher scores indicating lower health literacy.

Maternal and Infant Birth Outcomes

The birth outcomes for the sample are presented in **Table 4.7**. These births included 22 term infants (68.7%) and 10 preterm infants (31.3%) with gestational ages ranging from 26 to 42 weeks. The mean gestational age was 36.9 (SD 3.3) weeks. Data were unavailable for 9 deliveries. Because the American College of Obstetricians and Gynecologists has re-defined spontaneous preterm birth to include preterm birth, preterm labor, premature rupture of membranes (PROM), and/or cervical incompetence resulting in delivery before 37 gestation weeks, [247], preterm birth was calculated by this grouping. Using these criteria, 10 women (31.3%) had a spontaneous pre-term birth.

Table 4.4 Health Literacy Scores of Study Participants (N = 32)

Health Literacy Variable	Mean (SD)	Observed Range
REALM	57.2 $\pm$ 10.6	23-66
LAD	50.7 $\pm$ 6.7	35-59
REAL-G	56.0 $\pm$ 7.7	37-65
S-TOFHLA – 3	04.3 + 1.6	03-12

Table 4.5 Health Literacy by REALM, LAD, and REAL-G for Study Participants (N = 32)

Health Literacy Variable	Number	Percent	Range
REALM			23-66
Low literacy	14	43.8	
4 th – 6 th grade 19-44	5	15.6	23-43
7 th – 8 th grade 45-60	9	28.2	47-60
High literacy	18	56.2	
High school and above 61-66	18	56.2	61-65
LAD			35-59
Low literacy (5 th to 9 th grade)	3	9.4	35-38
High literacy (9 th grade and higher)	29	90.6	41-59
REALG			37-63
Low literacy	22	68.7	
4 th – 6 th grade 22-50	6	18.7	37-47
7 th – 8 th grade 51-60	16	50.0	52-60
High literacy	10	31.3	
High school and above 61-63	10	31.3	61-63

Table 4.6 Health Literacy by S-TOFHLA-3 for Total Study Participants (N = 32)

S-TOFHLA Questions	Number	Percent
How confident are you in filling out medical forms by yourself?		
Extremely		
Quite a bit		
Somewhat		
A little bit	25	78.1
Not at all	7	21.9
How often do you have someone help you read hospital materials?		
Always		
Often		
Sometimes	4	12.5
Occasionally	9	28.1
Never	19	59.4
How often do you have problems learning about your medical condition because of difficulty understanding written information?		
Always		
Often	2	6.3
Sometimes	3	9.4
Occasionally	5	15.6
Never	22	68.7
S-TOFHLA – 3	Mean (SD) 04.3 + 1.6	Range 03-12

Table 4.7 Birth Outcomes for Total Study Participants (N = 32)

Outcome Variable	Number	Percent
Preterm birth	10	31.3
Hypertension	13	40.6
C-section	20	62.5
Preeclampsia	7	21.9
Spontaneous labor at term	15	46.9
Preeclampsia	7	21.9
Fetal demise	2	6.3
Respiratory distress	7	21.9
Congenital anomalies	1	3.1
Infant birth weight		
< 2500 grams	5	15.6
2500-4000 grams	23	71.9
> 4000 grams	4	12.5

Thirteen mothers (40.6%) had hypertension during pregnancy and 7 (21.9%) had preeclampsia. Those that experienced cesarean section deliveries numbered 20 (62.5%) and 12 (37.5%) delivered vaginally. There were no cases of polyhydramnios. Of the 12 vaginal deliveries, only 2 (16.7%) reported less than third degree tearing of the vaginal wall.

The birth weights ranged from 1,078 grams to 4,107 grams, with 5 (15.6%) low birth weight infants and 4 (12.5%) macrosomic infants. The majority of 15 (71.9%) were of normal birth weight, with a mean weight of 3,157 grams. Data was unavailable on 7 infants. Seven of the infants (21.9%) had respiratory distress. Despite screening out women likely to give birth to infants with congenital anomalies, 1 (3.1%) infant did have a cardiac anomaly. Two infants (6.3%) suffered a fetal demise.

The birth outcomes by gestational and pregestational diabetes group are available in **Table 4.8**. Nine (60%) of the sixteen mothers with gestational diabetes experienced spontaneous labor at term, with 12 (75%) infants having normal birth weights. Maternal complications included 6 (37.5%) with hypertension, 4 (25%) with preeclampsia, and 8 (47.1%) had a cesarean delivery. The infants experienced no fetal demise or congenital anomaly but 2 (12.5%) had respiratory distress syndrome, 1 (6.2%) had low birth weight and 3 (18.8%) had macrosomia. On the other hand, there were 8 (50%) mothers with pregestational diabetes delivering preterm, with 12 (75%) having a cesarean delivery. Maternal complications included 7 (43.8%) with hypertension and 3 (18.8%) with preeclampsia. Two (12.5%) of the infants experienced fetal demise, and 1 (6.7%) had a congenital anomaly. Other infant complications included 5 (33.3%) with respiratory distress, 4 (25%) with low birth weight, and 1 (6.2%) with macrosomia.

Specific Aim One

Specific Aim One was to determine if three questions from the Short Test of Functional Health Literacy in Adults (S-TOFHLA-3) were a useful instrument to assess health literacy in pregnant women with pregestational and gestational diabetes.

To address questions 1a, 1b, and 1c, a correlational analysis was conducted using Pearson's product moment correlations. **Table 4.9** presents the correlations of the REALM, REALM-G, and the LAD with the individual S-TOFHLA items, as well as the sum of the three questions from the S-TOFHLA. The questions were coded as 1 = never through 5 = always. Data are presented in literacy categories by grade level and categorized as low and high literacy.

1.a. Are the three questions from the S-TOFHLA associated with the REALM?

No significant correlation was found between the REALM and the individual items of the S-TOFHLA. Nor were there any significant correlations between the REALM and the total of the 3 questions. The validity of the individual S-TOFHLA items or combination of items was not supported as they did not correlate at a level of 0.80 or higher with the REALM.

Table 4.8 Birth Outcomes by Gestational and Pregestational Diabetes (N = 32)

Outcome Variable	Gestational Diabetes (n = 16) n (%)	Pregestational Diabetes (n = 16) n (%)	Total (n = 32) n (%)	Chi-Square	P Value
Pre-term birth	2 (11.8)	8 (50)	10 (31.3)	5.7	.03*
Hypertension	6 (37.5)	7 (43.8)	13 (40.6)	0.13	.72
C-section	8 (47.1)	12 (75)	20 (60.6)	2.70	.10
Preeclampsia	4 (25)	3 (18.8)	7 (21.9)	0.18	.67
Spontaneous labor at term	9 (60.0)	6 (37.5)	15 (48.4)	1.57	.21
Fetal demise	0 (0.)	2 (12.5)	2 (6.3)	2.13	.14
Respiratory distress	2 (12.5)	5 (33.3)	7 (22.6)	1.92	.22
Congenital anomalies	0 (0.0)	1 (6.7)	1 (3.3)	1.03	1.0
Infant birth weight					
< 2500 grams	1 (6.2)	4 (25.0)	5 (15.2)		
2500-4000 grams	12 (75.0)	11 (68.8)	23 (71.9)		
> 4000 grams	3 (18.8)	1 (6.2)	4 (12.5)	§	

Note: Infant outcomes do not include the data from the 2 infants that died. § Chi-square could not be run because of low cell frequencies. N's may vary slightly due to missing data. *P < 0.05

Table 4.9 Correlations of S-TOFHLA-3 and the REALM, LAD and REALG (N = 32)

Literacy Variable	Medical Forms	Hospital Materials	Written Information	3 Total Questions S-TOFHLA
REALM	-.34	-.19	-.12	-.25
LAD	-.24	-.37*	-.21	-.35*
REALG	-.27	-.25	-.21	-.30

* $p < .05$

1.b. Are the three questions from the S-TOFHLA associated with the LAD?

Significant correlations were noted between the LAD and the combination of the three questions from the S-TOFHLA ($r = -0.35$, $p < .05$). This correlation appeared to be driven by the S-TOFHLA question about “Hospital materials” which was significantly correlated with the LAD ($r = -.37$, $p < .05$). None of the other individual items were significantly correlated with the LAD.

1.c. Are the three questions from the S-TOFHLA associated with the REAL-G?

There was no significant correlation found between the REAL-G and the individual items on the S-TOFHLA. The same was true of the REAL-G and on the combination three item scale of the S-TOFHLA.

In summary, the hospital forms question on the S-TOFHLA was the only item that demonstrated a significant relationship with the other accepted health literacy measures, and this was only with the LAD. The correlations did not support that the S-TOFHLA-3 was a valid measure of health literacy with respect to construct validity, as they did not correlate with any of the health literacy measures at a level of .80 or higher. Because of this, the S-TOFHLA-3 was not used to analyze Aim Three and Aim Four.

Specific Aim Two

Specific Aim Two was to compare the health literacy levels of pregnant women with pregestational diabetes and pregnant women with gestational diabetes using three health literacy instruments. To address Specific Aim Two, Chi-square was used to test for differences in health literacy grouping (low literacy vs. high literacy) by gestational and pregestational diabetes group and these results are presented in **Table 4.10**. Independent samples t-tests were used to compare the mean health literacy levels of pregnant women with gestational diabetes and the women with pregestational diabetes. These test results are depicted in **Table 4.11**. In looking at the data, there is a trend toward the women with pregestational diabetes having higher health literacy scores on all three instruments. Seven women (43.7%) with gestational diabetes scored in the low literacy group on the REALM, 13 (81.2%) on the LAD, and 3 (18.8%) for the REAL-G as having low literacy. For the pregestational group scores were higher on each instrument with 11(68.7%) for the REALM, 16 (100%) for the LAD, and 7 (43.7%) on the REALG with high literacy. Overall, the pregestational diabetes group reported higher health literacy than the gestational diabetes group.

2.a. Is there a difference in general health literacy using the Rapid Estimate of Adult Health Literacy in Medicine (REALM) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

Table 4.10 shows the mean results of the health literacy scores and women with gestational and pregestational diabetes. Chi square scores

Table 4.10 Health Literacy Scores by Gestational and Pregestational Diabetes (N = 32)

Health Literacy Variable	Gestational n = 16 n (%)	Pregestational n = 16 n (%)	Chi-Square	P
REALM			2.03	.15
4 th – 6 th grade 19-44	3 (18.8)	2 (12.5)		
7 th – 8 th grade 45-60	6 (37.5)	3 (18.8)		
High school and above 61-66	7 (43.8)	11 (68.7)		
REALM overall low literacy	9 (56.3)	5 (31.3)		
REALM overall high literacy	7 (43.7)	11 (68.7)		
LAD			3.3	.23
5 th to 9 th grade (low literacy)	3 (18.8)	0		
9 th grade and higher (high literacy)	13 (81.2)	16 (100)		
REALG			2.33	.13
4 th – 6 th grade 22-50	3 (18.8)	3 (18.8)		
7 th – 8 th grade 51-60	10 (62.5)	6 (37.5)		
High school and above 61-63	3 (18.8)	7 (43.8)		
REALG overall low literacy	13 (81.2)	9 (56.3)		
REALG overall high literacy	3 (18.8)	7 (43.7)		

Table 4.11 Mean Results of Health Literacy Scores by Gestational and Pregestational Diabetes (N = 32)

Health Literacy Variable	Gestational Diabetes Mean(SD)	Pregestational Diabetes Mean(SD)	t Value	P
REALM	56.2 ± 9.8	58.3 ± 11.5	-.55	.59
LAD	49.2 ± 7.2	52.3 ± 5.9	-1.31	.20
REALM-G	54.7 ± 7.9	57.3 ± 7.5	-.96	.34

indicated there was no significant difference between women with pregestational diabetes and gestational diabetes on the REALM ($\chi^2 = 2.03$, $p = .15$). Similarly, the independent samples t-test was not significant when comparing the low vs. high REALM literacy by diabetes group ($p = .59$).

- 2.b. Is there a difference in diabetic health literacy using the Literacy Assessment for Diabetes (LAD) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

An independent samples t-test indicated there was no significant difference between women with pregestational diabetes and gestational diabetes on the LAD ($p = .20$). Chi-square analysis comparing LAD low and high literacy by diabetic group could not be conducted due to low cell frequency in the low literacy LAD group.

- 2.c. Is there a difference in genetic health literacy using the Rapid Estimate of Adult Literacy in Genetics (REAL-G) tool in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

An independent samples t-test indicated there was no significant difference between women with pregestational diabetes and gestational diabetes on the REALM-G ($p = .34$). Similarly, the chi-square analysis was not significant when comparing the low vs. high REAL-G by diabetes group.

- 2.d. Is there a difference in genetic health literacy using the three questions from the S-TOFHLA instrument in pregnant women with pregestational diabetes as compared to those with gestational diabetes?

There was no significant difference between women with gestational diabetes and pregestational diabetes on the individual items on the S-TOFHLA. There was no significant difference on the combination three item scale of the S-TOFHLA between the two groups.

In summary, the comparison of the diabetic groups using t-tests did not demonstrate any significant differences. The comparison of the diabetic groups using low and high literacy groupings with chi-square did not demonstrate statistically significant differences. However, overall it appeared that the pregestational diabetic group reported higher health literacy than the gestational diabetic group.

Specific Aim Three

Specific Aim Three was to determine if health literacy is associated with maternal glycemic control during pregnancy. To conduct the analyses to address Specific Aim Three, the three health literacy measures of the REALM, LAD, and REAL-G were dichotomized into low and high literacy groups. Independent sample t-tests were used to determine any differences. Findings can be observed in **Tables 4.12, 4.13, and 4.14.**

Table 4.12 Maternal Glucose Control Outcomes by REALM Literacy Groups (N = 32)

Glycemic Variables	REALM Low Literacy M (SD)	REALM High Literacy M (SD)	t Value	P
Total no. of abnormal glucose readings recorded	14.9 ± 24.5	42.2 ± 53.9	-1.70	.07*
Total no. of glucose readings recorded	42.1 ± 38.6	114.2 ± 113.1	-2.20	.02**

*p = .10 **p < .05

Table 4.13 Maternal Glucose Control Outcomes by LAD Literacy Groups (N = 32)

Glycemic Variables	LAD Low Literacy M (SD)	LAD High Literacy M (SD)	t Value	P
Total no. of abnormal glucose readings recorded	18.3 ± 28.4	32.1 ± 47.1	-0.49	.63
Total no. of glucose readings recorded	46.7 ± 43.8	88.0 ± 99.3	-0.71	.49

Table 4.14 Maternal Glucose Control Outcomes by REALM-G Literacy Groups (N = 32)

Glycemic Variables	REALM-G Low Literacy M (SD)	REALM-G High Literacy M (SD)	t Value	P
Total no. of abnormal glucose readings recorded	26.2 ± 42.8	40.2 ± 51.7	-0.79	.43
Total no. of glucose readings recorded	63.6 ± 68.7	126.7 ± 130.4	-1.44	.17

Data were obtained from glucose log recordings that mothers brought to clinical encounters. Two different measures were obtained from these logs: the total number of abnormal glucose readings recorded and the total number of readings recorded overall. Using these two measures, an index of maternal glycemic control was determined by dividing the number of abnormal readings by the total number of readings and multiplying by 100 to obtain a percentage. This index measure did not measure maternal glycemic control and so was removed from analysis. Women who did not have any glucose readings recorded were not included in the analyses.

3.a. Is the REALM associated with maternal glycemic control?

Table 4.12 compares the low and high literacy REALM groups on the three different maternal glucose control outcomes. Because this was a pilot study and we can loosen the determination of significance to $p \leq .10$ [320,321], there are two statistically significant findings. Data indicate that women in the high REALM literacy group recorded significantly more abnormal glucose readings than women in the low REALM literacy group ($p = .07$). These women also recorded more glucose readings than those in the low literacy group ($p = .02$).

3.b. Is the LAD associated with maternal glycemic control?

Table 4.13 compares the LAD low and high literacy groups on the measures of maternal glycemic control. No significant differences between the groups were noted. However, findings were consistent with the REALM in that women with high health literacy as measured by the LAD recorded more glucose readings as well as abnormal readings than those in the low literacy group.

3.c. Is the REAL-G associated with maternal glycemic control?

Table 4.14 compares the REAL-G low and high literacy groups on the measures of maternal glycemic control. No significant differences between the groups were noted. However, findings were also consistent with the REALM in that women with high literacy, as measured by the REAL-G, recorded more glucose readings as well as abnormal ones than those in the low literacy group.

In summary, literacy grouping on the REALM was significantly associated with the maternal glycemic control outcome of the total number of glucose readings recorded, with women in the high literacy REALM group recording significantly greater number of blood glucose readings than women in the low literacy group. Similar patterns in the data were noted for the LAD and the REAL-G, but the differences between groups were not statistically significant.

Specific Aim Four

Specific Aim Four determined the associations between health literacy levels and birth outcomes for both the mother and infant. For the mother, birth outcomes included the presence of hypertension during pregnancy, preeclampsia, premature birth, delivery method, polyhydramnios, and vaginal laceration. For the infant, birth outcomes included gestational age at birth, birth weight, respiratory distress, congenital anomalies, and fetal demise. Specific Aim Four was analyzed by categorizing each participant into either low health literacy or high health literacy and then conducting Chi Square tests to determine differences among categorical variables. Because there were low cell frequency counts, analyses were conducted on the REALM, LAD, and REAL-G using the low and high literacy grouping, rather than reading level groupings.

4.a. Is there an association between the REALM and birth outcomes?

Table 4.15 depicts the differences between birth outcomes of participants with low health literacy as compared to those with high health literacy using the REALM instrument. Data indicated that there were no statistically significant differences between REALM literacy grouping and birth outcomes. However, two outcomes, preeclampsia and spontaneous labor trended toward significance. The trend may have clinical importance. For example, 11 (61.1%) of the women with high health literacy had spontaneous labor at term compared to only 4 (30.8%) with low health literacy. Women with low health literacy had more preeclampsia (35.7%) than those with high health literacy (1.1%).

4.b. Is there an association between the LAD and birth outcomes?

Table 4.16 depicts the associations between birth outcomes and low and high levels of health literacy in diabetes using the LAD instrument. Significance testing was done with a Fisher's Exact test, which revealed no statistical significant changes between the levels of health literacy in diabetes and birth outcomes. Of clinical importance is that the women with high health literacy in diabetes were all women with pregestational diabetes.

4.c. Is there an association between the REAL-G and birth outcomes?

Table 4.17 shows the associations between birth outcomes and low health literacy and high health literacy levels in genetics using the REAL-G instrument. There were no statistically significant associations found. This instrument is a measure of health literacy in genetics and not of general health literacy, so the birth outcome results are not surprising. Further research is needed using this instrument in an area specifically related to genetic information.

Table 4.15 Birth Outcomes by REALM Literacy Group (N = 32)

Outcome Variables	REALM Low Literacy (n = 14) n (%)	REALM High Literacy (n = 18) n (%)	Total n (%)	Chi-Square	P Value
Pre-term birth	5 (35.7)	5 (26.3)	10 (31.3)	0.34	0.71
Hypertension	6 (42.9)	7 (38.9)	13 (40.6)	.05	0.82
C-section	8 (57.1)	12 (63.2)	20 (60.6)	.12	0.73
Preeclampsia	5 (35.7)	2 (11.1)	7 (21.9)	3.2	.07
Spontaneous labor at term	4 (30.8)	11 (61.1)	15 (48.4)	2.80	.10
Fetal demise	1 (7.1)	1(5.6)	2 (6.3)	0.03	1.0
Birth trauma	0 (0.0)	0 (0.0)	0 (0.0)	§	
Respiratory distress	3 (23.1)	4 (22.2)	7 (22.6)	0.003	1.0
Congenital anomalies	0 (0.0)	1 (5.6)	1(3.3)	0.69	1.0
Infant birth weight					
< 2500 grams	3 (21.4)	2 (11.1)	5 (15.6)		
2500-4000 grams	9 (64.3)	14 (77.8)	23 (71.9)		
> 4000 grams	2 (14.3)	2 (11.1)	4 (12.5)	§	

Note: Infant outcomes do not include the data from the two infants that died. § Chi-square could not be run because of low cell frequencies. N's may vary slightly due to missing data.

Table 4.16 Birth Outcomes by LAD Literacy Group (N = 32)

Outcome Variables	LAD Low Literacy (n=3) n (%)	LAD High Literacy (n=29) n (%)	Total n (%)	P Value
Pre-term birth	0 (0.0)	10 (33.3)	10 (31.3)	.53
Hypertension	1 (33.3)	12 (41.4)	13 (40.6)	1.0
C-section	2 (66.7)	18 (50.0)	20 (60.6)	1.0
Preeclampsia	1 (33.3)	6 (20.7)	07 (21.9)	.54
Spontaneous labor at term	2 (66.7)	13 (46.4)	15 (48.4)	.60
Fetal demise	0 (0.0)	2 (6.9)	2 (6.2)	1.0
Birth trauma	0 (0.0)	0 (0.0)	0 (0.0)	§
Respiratory distress	0 (0.0)	7 (25)	7 (22.6)	1.0
Congenital anomalies	0 (0.0)	1 (3.7)	1 (3.3)	1.0
Infant birth weight				
< 2500 grams.	0 (0.0)	5 (17.2)	5 (15.6)	
2500-4000 grams	2 (66.7)	21 (72.4)	23 (71.9)	
> 4000 grams	1 (33.3)	3 (10.3)	4 (12.5)	§

Note: Infant outcomes do not include the data from the two infants that died. § Chi-square could not be run because of low cell frequencies. N's may vary slightly due to missing data.

Table 4.17 Birth Outcomes by REAL-G Literacy Groups (N = 32)

Outcome Variables	REAL-G Low Literacy (n = 22) n (%)	REAL-G High Literacy (n = 10) n (%)	Total n (%)	Chi-Square	P Value
Pre-term birth	6 (27.3)	4 (36.4)	10 (30.3)	0.29	0.70
Hypertension	10 (45.5)	3 (30.0)	13 (40.6)	0.68	0.45
C-section	13 (59.1)	7 (70.0)	20 (60.6)	0.06	1.00
Preeclampsia	6 (27.3)	1 (10.0)	07 (21.9)	1.2	.27
Spontaneous labor at term	12 (57.1)	3 (30)	15 (48.4)	2.00	0.25
Fetal demise	1 (4.5)	1 (10.0)	2 (6.3)	0.35	0.53
Birth trauma	0 (0.0)	0 (0.0)	0 (0.0)	§	
Respiratory distress	4 (19.0)	3 (30.0)	7 (22.6)	0.47	0.65
Congenital anomalies	1 (5.0)	0 (0.0)	1 (3.3)	0.52	1.00
Infant birth weight					
< 2500 grams	3 (13.6)	2 (20.0)	5 (15.6)		
2500-4000 grams	17 (77.3)	6 (60.0)	23 (71.9)		
> 4000 grams	2 (9.1)	2 (20.0)	4 (12.5)	§	

Note: Infant outcomes do not include the data from the two infants that died. § Chi-square could not be run because of low cell frequencies. N's may vary slightly due to missing data.

4.d. Is there an association between the S-TOFHLA-3 and birth outcomes?

The individual S-TOFHLA-3 items did not demonstrate the ability to assess general health literacy in this sample of pregnant women with diabetes. Therefore, the analysis of this research question was not conducted.

In summary, using the low and high literacy groupings for the REALM, LAD, and REAL-G, no statistically significant associations between literacy and birth outcomes were noted. However, there were differences that may be clinically important and differences may suggest that women with lower literacy may have poorer birth outcomes.

Post-hoc Power Analysis

This study was an exploratory study that assessed health literacy in pregnant women with gestational and pregestational diabetes and examined relationships between health literacy and selected maternal and infant health outcomes. A post-hoc power analysis was performed with respect to preterm birth, a key outcome variable in the study, and health literacy as determined by the REALM. The REALM was used because it is an instrument designed to measure general health literacy. Findings from this study demonstrated that 35.7% of the women in the low literacy group experienced a preterm birth compared to 26.3% of the women in the high literacy group. Given the sample size of $n = 14$ in the low literacy group and $n = 18$ in the high literacy group, a post-hoc power analysis revealed a power of 0.05 to detect a significant difference between these two groups. Using the Power Analysis and Sample Size (PASS)® software, a sample size of 332 in each group would have been necessary to achieve a power of .80 to detect a statistically significant difference between the two groups on preterm birth at an alpha of 0.5 [322]. Therefore with a sample size of 32, this exploratory study was significantly underpowered. While for many of the comparisons made between the groups with gestational and pregestational diabetes, the power was low with respect to detecting statistically significant differences, the results can be interpreted within the context of clinical significance.

CHAPTER 5: DISCUSSION AND IMPLICATIONS

Discussion

Health literacy is a multifaceted construct that enables consumers of health care to understand their health and how to take care of themselves and their family. The relationships between health literacy and birth outcomes in pregnant women with diabetes are grossly understudied. The purpose of this research project was to determine if a three question screening tool could be used to assess health literacy levels in pregnant women with diabetes as well as to explore the association of the health literacy level of the pregnant woman with birth outcomes for the infant and pregnancy outcomes for the mother in a sample of pregnant women with pregestational and gestational diabetes in one safety net hospital in Tennessee. Chapter 5 provides a discussion of the study findings relevant to each research aim and provides implications for theory, practice, and research.

Demographic Findings

The final sample included 32 women with a mean age of 26.5 years, which is slightly older than the national mean age of 25 years for all women giving birth [323] and younger than the reported mean age of 31 years in other studies of pregnant women with DM [29,205,324,325]. The median household income was \$1,225, which means that 50% of the women were below the poverty threshold. The majority of the women were recruited in an urban safety-net hospital and were African American (81.2%) in contrast to studies involving pregnant women with diabetes that reported African American participation from 7.4% to 29% [29,326,327]. As Lawrence et al. documented, there is an increasing prevalence of diabetes mellitus in young, urban, predominately African American women, and our study findings support this [34,328]. Recruitment of this sample was possible because the prenatal clinic conducts research studies often, and most of the women are aware of that fact. These women were asked to read aloud 3 sets of words in 3 columns and answer 5 questions. The interview with these women brought out a few comments such as “Is that all I have to do?” and “That was easy,” which demonstrated that they were comfortable with the tasks that this researcher asked of them. There was also a \$15 gift-card incentive given for participation.

Measuring Health Literacy

Health literacy is a complex construct involving many concepts and, to date, there is not one comprehensive instrument that measures the total construct. In the past, the level of educational attainment was often used as a proxy for the patient’s ability to understand healthcare materials. However, it is not an accurate predictor of health literacy, as patients often read several grade levels below the highest grade completed in school and, thus, grade level attainment has not been found to be a valid way to determine health literacy [73,74]. Even some of the women who were high school

graduates had low health literacy. Upon further analysis of those who completed the 12th grade, our study found 31.3% of high school graduates had low health literacy. Endres et al. also documented that 11.9% of those who completed the 12th grade had low health literacy [29]. This was also the case in Schillinger et al. who found that 66% of those with a high school education had inadequate health literacy in their study of 408 patients with type 2 diabetes [11]. Our study had three times the rate of low health literacy in high school graduates than did Endres and similar rates as Schillinger. Possible reasons may include differences in the demographics of the two studies. In the sample from the Endres et al. study, 80% had completed high school vs. 68.8% in our study, there were 55% vs. 18.8% Caucasian and 19% vs. 81.2% African American and 23% Hispanic plus the study took place in Chicago, Illinois. Confounding factors such as socioeconomic level were not adjusted for in our study. Another reason for this difference was that while this study used the REALM, Endres et al. and Schillinger both used the S-TOFHLA to measure health literacy.

Because level of education attained is inadequate to measure health literacy, there are currently two gold standards for measuring health literacy, the REALM and the Test of Functional Health Literacy in Adults (TOFHLA) [7,52]. The REALM and the TOFHLA have both been shown to predict knowledge, behaviors, and outcomes [8,14,30,112]. The REALM is primarily a word recognition and pronunciation instrument used to measure basic print literacy, while the S-TOFHLA measures reading comprehension and numeracy or functional health literacy using actual pill bottles and appointment slips [329]. The REALM requires 3 minutes to complete, and the S-TOFHLA takes 7 minutes.

Both instruments have served as models on which to fashion other instruments based on either language or knowledge of disease process. The LAD (measure of diabetes health literacy), the REAL-G (measure of genetic health literacy), and the three screening questions from the S-TOFHLA are based on the REALM and TOFHLA [49,57,317,330]. Still, there are several complexities of health literacy that need to be addressed which are not within the scope of all of these instruments. For instance, the influences of culture and role-modeling from family, friends, and healthcare providers need to be addressed. Because of the lack of more comprehensive methods of comprehensive assessment, the Institute of Medicine (IOM) has called for more expansive measurement instruments [26]. At this time, the REALM, LAD, and REAL-G instruments are both reliable and valid, making them the best available for measuring health literacy, health literacy in diabetes, and health literacy in genetics and may serve as a springboard for the development of other health literacy instruments. They will also provide a basis for future research into health literacy and pregnancy complicated by diabetes.

There are few studies in the literature that assessed the health literacy levels of pregnant woman with diabetes. In this study, we found that 43.8% of the participants had low health literacy using the REALM instrument, as compared to Endres et al. who studied 74 women with pregestational diabetes and found that 22% had low health literacy [29]. Cavanaugh et al. studied health literacy and numeracy and found that 31% had low literacy as measured by the REALM [31]. The differences in our study were that

Endres et al. used the S-TOFHLA and we used the REALM to measure health literacy level, that Endres et al. had more high school graduates in their study (80% vs. 69%) and less minorities (42% vs. 82%), which is supported by studies that have shown that low health literacy is associated with non-whites [31,108,331], but these studies did not account for socioeconomic status. We also sampled both gestational and pregestational diabetes, whereas Endres et al. only sampled women with pregestational diabetes who, because of preexisting diabetes, may have more health literacy skill to begin with. Low health literacy has been associated with increased risk of hospital admission [9,10], worse glycemic control, and higher rates of retinopathy in individuals with diabetes [11]. It has also been associated with negative health behaviors including under use of preventative services [12-15], mismanagement of medication administration [16-19], and less understanding of their illness and treatment options [20,21]. Thus it is important to assess for health literacy in order to tailor intervention to influence more positive patient outcomes.

The LAD measured diabetes as a specific content area of health literacy. In our study, 8.8% of the participants had low health literacy and 91.2% of the sample had high health literacy in diabetes. This may suggest that while these women have not learned about health in general, they know a great deal about diabetes. Of interest to note is that all women in the pregestational diabetes group had high health literacy. In our study, each woman received a consultation with a certified diabetic educator and a dietician at their initial visit to this clinic and with a certified diabetic educator with each subsequent visit. Therefore, it is possible that the women have benefitted from education in diabetes received over the course of this pregnancy and from having pre-existing diabetes. The gestational age at recruitment varied among individuals, and the actual number of visits with the diabetic educators that the mother had before recruitment into this study may have affected the results. These results are congruent with those of Morris et al., who found no association between health literacy and diabetes complications in over 1,000 subjects who were 97% Caucasian[124]. Also Schillinger et al. reported low health literacy in 66% in their study with over 86% minority participants.

The REAL-G instrument is a new instrument designed to assess genetic health literacy. Pregnant women with diabetes may need counseling because of the increased rate of congenital anomalies and spontaneous abortions that are affected by poor glycemic control. These women certainly need preconception counseling and may need counseling in pre-implantation genetic options, fetal anomalies, and/or grief counseling. To understand this counseling, the individual needs to understand the vernacular, and the REAL-G instrument is ideal to assess this knowledge [332]. The REAL-G revealed that 67.6% of the participants in this study had low genetic health literacy. This finding is not surprising, as research has suggested that low health literacy in genetics is widespread [333,334].

Discussion of Specific Aims

Correlations of the Three Questions from the Short Test of Functional Health Literacy in Adults (S-TOFHLA) and the REALM, LAD and REAL-G

In 2004, the American Medical Association called for new instruments to measure the construct of health literacy especially in busy clinical practices [26]. In response, Chew et al. studied the 16 questions from the Short Test of Functional Health Literacy in Adults S-TOFHLA. They found three specific questions to be effective in detecting inadequate health literacy and suggested that these three questions could act as a screening tool for low health literacy [57]. Wallace et al., used these same screening questions on a sample of 305 predominately female Caucasian, English-speaking adults attending a university-based primary care clinic [318]. They found that only one screening question predicted low health literacy; that was “How confident are you filling out medical forms by yourself?” These three screening questions used by Chew et al. were used by this investigator to explore their use in this group of predominately African American women. It also appealed to this investigator because the screening was unobtrusive, meaning that it could decrease any anxiety on the part of the patient. The drawback was that the questions required the mother to admit that she could not do a specific action i.e. fill out forms. If the three questions were valid they could alert healthcare providers to use special methods of communication and teaching.

In analyzing the three questions from the S-TOFHLA to ascertain any association with the REALM, no significant correlation was found. A weak correlation was noted between the REALM and the same question that Wallace found to be significant: “How confident are you in filling out medical forms?” ($r = -0.36$ and $p = 0.03$). This question is a subset of the three questions from the S-TOFHLA as a measure of health literacy in our sample. The validity of the three questions from the S-TOFHLA was not supported, as it did not correlate at a level of 0.80 or higher with the REALM. This was also the case when Chew et al. compared the REALM and the three screening questions from the S-TOFHLA in 4,384 Veterans Administration Hospital patients and found that only one question, “How confident are you in filling out medical forms?” correlated with the REALM and S-TOFHLA [330]. Chew et al. thus concluded that this one question could be used as an unobtrusive screening question to detect low literacy levels in patients. We did not find this question to be effective and part of the reason for this result is that the REALM and the S-TOFHLA may be measuring different capabilities since the three questions are a subjective measure and the REALM is a more objective measure [52]. Another possible reason for not finding a correlation is that this study’s small sample size did not have enough power to detect a correlation.

A weak correlation was noted between the LAD and the three question composite from the S-TOFHLA question ($r = -0.36$ and $p = 0.04$). The question “How often do you have someone help you read hospital materials?” was also correlated with the LAD ($r = 0.39$ and $p = 0.02$) which is a subset of the three questions from the S-TOFHLA. However, the validity of the three questions from the S-TOFHLA was not supported, as it did not correlate at a level of 0.80 or higher with the LAD. Again, the two instruments

may be measuring different capabilities of health literacy or the sample size of this study was too small to detect the correlation.

There was no significant correlation found between the REAL-G and the individual items on the S-TOFHLA or the S-TOFHLA-3. Possible reasons are the small sample size or that these two instruments are measuring different capabilities. The S-TOFHLA-3 is measuring general health literacy, and the REAL-G is specifically measuring genetic content. As there were no studies in the literature that had used the REAL-G to assess health literacy (either general or genetic-specific), this investigator could not compare the results.

Overall, the three screening questions from the S-TOFHLA instrument did not detect low health literacy levels in this predominately African American sample of pregnant women with diabetes. Therefore, for this study sample it was not a valid health literacy measurement instrument. One must take into account that the three questions are a screening tool and not a full assessment tool for health literacy plus they did not take into account the subjective nature of the answers by the mother. Further study is needed to validate these findings.

Determination of the Health Literacy Levels of Pregnant Women with Gestational as Compared to Those with Pregestational Diabetes

Diabetes is a chronic disease requiring constant, complex self-care that is managed daily by the individual. Low literacy is common among individuals with diabetes and is associated with poor knowledge about diabetes [11,30,167]. Women with pregestational diabetes would have been exposed to teaching about diabetes and methods to take care of themselves before the pregnancy occurred and should have higher levels of health literacy. In contrast, women with gestational diabetes would not have had this same exposure and thus would have less health literacy in regards to diabetes. Recent research has suggested that gestational diabetes is of the same etiology as type 2 diabetes [195,196] and thus results in poor pregnancy outcomes. Gestational diabetes has been down-played as a benign condition, which Dunne states needs to be dispelled [266]. In specific Aim Two, this investigator determined the health literacy levels of pregnant women with gestational and pregestational diabetes using the three health literacy instruments.

Our sample of pregnant women with gestational diabetes was very similar to our sample of pregnant women with pregestational diabetes in terms of demographics. However, the two groups were different in how early they sought prenatal care, which may be influenced by whether or not the mothers had medical insurance, which was not accounted for in this study. Prenatal care initiation in the group with gestational diabetes was later than in the group with pregestational diabetes. Early prenatal care helps decrease adverse pregnancy and birth outcomes, particularly in gestational diabetes where the risk of poor birth outcomes is thought to be much lower than pregestational diabetes [110,169,335]. Because gestational diabetes is not the benign condition

previously thought, early prenatal care would certainly help to decrease the risks of poor birth outcomes by identifying hyperglycemia.

Comparisons of the health literacy levels between women with gestational diabetes and women with pregestational diabetes revealed no significant statistical differences between the groups, but there were important trends in the data. The gestational diabetes group had lower health literacy mean scores on the REALM, LAD, and REAL-G than did the pregestational diabetes group. In fact, the women with pregestational diabetes showed a trend toward having higher health literacy scores than the women with gestational diabetes on all three instruments. This is of importance because it has been shown that patients with diabetes and low literacy have poor knowledge of their disease [11,30,167], have higher rates of complications from diabetes [11], have fewer self-management behaviors [31], and may have difficulty learning the advanced self-care skills necessary to improve glycemic control [122].

Women with gestational diabetes have been considered to have less acuity than those with pregestational diabetes and their health literacy level may be less than those with pregestational diabetes. Given this information, these women may have the same or higher risk for poorer birth outcomes than women with pregestational diabetes [193,217,262]. Because this study was underpowered, care should be taken when using the findings, but it does show a trend that needs to be explored further.

The Relationship between Health Literacy and Glycemic Control in Pregnant Women with Diabetes

The relationship between health literacy and glycemic control in pregnant women with diabetes has not been studied. Health literacy levels of pregnant women with diabetes can influence birth outcomes [29]. Low health literacy has been associated with a higher likelihood of poorer glycemic control [12], which can lead to poor birth outcomes [33,202,222,262]. Several studies, including a longitudinal study of 12 years, have demonstrated that with good glycemic control the prevalence of birth defects in children of women with diabetes mellitus is similar to that of the general population [216,266]. Thus, monitoring maternal glycemic control is considered crucial to the management of pregnancy complicated with diabetes and can lessen the impact of diabetes for the mother and infant [11,30,31,43].

The best way to assess glucose control in the individual with diabetes has not been determined. Currently, there are two conventional means available: the use of HbA1c or self-monitoring and self-report of blood glucose (SMBG). Maternal glycemic control was difficult to measure in this population. HbA1c, a common blood test in patients with diabetes, is measured every 3 months to determine the overall state of glycemic control for the preceding months. Women with gestational diabetes are expected to deliver in the next 12 weeks after diagnosis of gestational diabetes and thus do not have a HbA1c done, as it would not be useful in directing patient care. This is supported by Ray et al. in his study regarding diabetes in pregnancy [205]. What is needed, however, is daily feedback of glucose control with self-monitoring of blood

glucose so that the mother can monitor her response to her diet and/or insulin dosages [203]. The problem with this method of monitoring blood glucose is that it is often unreliable since the accuracy of the sample and the reporting of the results are user-dependent [336]. Nevertheless, a log of glucose recordings was used in this study. Some participants in this study chose to record blood glucose levels and bring in their logs, while others explained that they had "left their log at home" on most visits, while still others admitted to not monitoring blood sugar levels at all. This investigator examined the glucose log recordings from all the mothers who brought logs to the clinical encounter.

Analysis for specific Aim Three included dichotomizing the three health literacy measures into low and high literacy categories. Independent t-tests analysis was then conducted to determine differences between health literacy levels and maternal glycemic control. Because this study could be considered a pilot study, the significance level may be loosened to $p = .10$. With this in mind, there were two statistically significant findings. Those women with high health literacy measured by the REALM recorded more glucose readings than did those with lower health literacy ($p = .02$), and they also recorded more abnormal glucose readings ($p = .07$) than women with low health literacy scores. This is of clinical importance because pregnancy is naturally an insulin resistant state. The longer the gestation, the more need for insulin by the mother, which corresponds to more abnormal glucose readings. When the mother brings these readings to the next clinic visit, the certified diabetic educator and physician can clearly see if there is any need to adjust insulin dosages or provide counseling about diet and exercise. This is supported by Schillinger et al., who found that inadequate health literacy was associated with poorer glycemic control and increased rates of complications in older non-pregnant adults who had type 2 diabetes [11]. Other studies have found no significant association between health literacy level and glycemic control [124,337].

Health literacy is a complex construct that involves culture, religion, access to care, and a myriad of other factors that were beyond the scope of this study. Glycemic control is also an individually controlled behavior that is influenced by many factors. Until other factors are studied and accounted for, glycemic control will not be studied effectively. More research is needed to determine if health literacy levels are associated with maternal glycemic control. Since the REAL-G and the LAD have not been studied in pregnancy complicated by diabetes, more research needs to be done using these instruments.

Associations between Health Literacy Levels and Birth Outcomes for Both Mother and Infant

Health literacy in pregnancy complicated by diabetes has been scant, but research has shown that health literacy levels of pregnant women with diabetes can influence birth outcome [29]. Specific Aim Four dealt with the associations between health literacy levels and birth outcomes for both the mother and infant. For the mother, hypertension, preeclampsia, premature birth (which includes premature labor, spontaneous premature rupture of membranes, and early gestational age), delivery method, polyhydramnios, and

vaginal laceration were evaluated. For the infant, birth weight, respiratory distress, congenital anomalies, and fetal demise were evaluated. Specific Aim Four was analyzed with chi-square scores for dichotomous variables.

Health literacy levels of the mothers in our study were 56.3% with high health literacy and 43.7% with low health literacy, as measured by the REALM. Mothers with high health literacy experienced more spontaneous labor at term (61.1%), a higher cesarean section rate (63.2%), and more normal weight infants (77.8%) than the mothers with low health literacy. Using the loosened pilot study significance level, the spontaneous labor at term variable was statistically significant ($p = .10$). More spontaneous labor at term and normal birth weight are positive health outcomes indicating that higher health literacy may be associated with positive birth outcomes.

On the other hand, while not statistically significant, mothers with low health literacy experienced more preterm birth (35.7%), more hypertension (42.9%), more preeclampsia (35.7% ; $p = .07$), more fetal demise (7.1%), and gave birth to infants with more respiratory distress 23.1%), more low birth weight (21.4%), and more infants with macrosomia (14.3%). These findings take into consideration that this safety-net hospital delivers care for a high-risk population with high levels of poverty and drug abuse. This hospital has a preterm birth rate of between 23% and 25% and a consistent level of drug abuse at about 10%. Given the small sample size, this trend toward low health literacy and the association with poorer birth outcomes is an exciting finding because health literacy levels can be improved [98,338-341]. With improved health literacy, the potential to reduce adverse birth outcomes is a possibility. These results need to be interpreted cautiously because of the small sample size, but the results do beg for further research.

This study revealed that low health literacy (measured by the REALM) and preeclampsia were associated ($p = .07$). While preeclampsia usually occurs in 12% of pregnancies, it occurs more often in women with gestational diabetes [342] and pregestational diabetes [199,211,234,343] and increases in frequency and severity in women with chronic hypertension [227,344,345]. Sibai documented rates of 9-66% of preeclampsia in women with pregestational diabetes depending on factors such as increasing severity of diabetes and chronic hypertension. Preeclampsia rose significantly with worsening diabetes, which carried rates of 22% for Class C diabetes and 36% if there was renal involvement [211]. In our study, we found 40.6% of the mothers had hypertension, and 21.9% had preeclampsia. This prevalence is supported by Bryson, who found women with gestational diabetes had more gestational hypertension [236]. In fact, preexisting conditions such as hypertension and diabetes were associated with 22.3% of all preeclampsia cases in nulliparous women and up to 52.2% in multiparous women in a study by Catov et al. [246].

With the LAD instrument, low health literacy was associated with more cesarean deliveries (66%), preeclampsia (33.3%), and macrosomia (33.3%), but care must be taken here because of the small sample size. The REAL-G associated low health literacy level with more hypertension (45.5%) and preeclampsia (27.3%). Two of the assessment tools (REALM and LAD) highlighted that macrosomia is associated with low levels of health

literacy, which is supported by findings from Endres et al., who found 63% of mothers with low health literacy delivered infants with macrosomia [29].

Macrosomia is associated with an increased risk of birth complications for the mother and the infant and is caused by maternal hyperglycemia [38,324,346]. When glucose levels are kept within normal limits, macrosomia is attenuated [216,266]. Early detection of any risk factors for macrosomia, when intervened upon, may reduce the risk of birth complications, may reduce the weight of the infant, or may prevent the macrosomia in the first place [347-349].

Although low education attainment and poverty have been associated with poor birth outcomes, low health literacy partially mediates this relationship and may help explain some health disparities [161]. Low education levels have been found to be associated with adverse pregnancy outcomes such as preeclampsia [350], preterm birth [254,331,351], and low birth weight [331,351]. Those with low educational attainment (less than 12th grade) accounted for 20% of the preeclampsia, yet those with low health literacy in this study had 35.7% of the preeclampsia. This suggests that low health literacy actually is associated with a higher rate of preeclampsia over that of low educational attainment, further solidifying the need for health literacy assessment. Chung et al. also found the risk of macrosomia increases the lower the level of education attained, but this study did not assess for health literacy [352]. On the other hand, Schillinger et al. assessed health literacy and glycemic control behavior in non-pregnant adults and found that after conducting path analysis on education level and health literacy, education level became non-significant [161]. In this study we found higher percentages of macrosomia in women with low literacy levels, but care must be taken not to overemphasize the importance of this because of the sample size.

Summary

In summary, high health literacy levels were associated with the positive birth outcome of spontaneous labor at term ($p = .10$). Women with low health literacy had more complications than women with higher health literacy, including more preeclampsia ($p = .07$). The sample size was small, but the results do lay groundwork for future research.

Strengths and Limitations

Strengths

There were several strengths to this study. The first was the large percentage of African American women with diabetes who were pregnant. Maternal ethnicity is a known factor for the development of both gestational [353] and type 2 diabetes [354]. Previous studies in this area of research have looked at larger proportions of non-Hispanic Caucasian and Hispanic participants. Because the African American population

has a disproportionate amount of diabetes and poor birth outcomes, this study has identified that African American women in this sample had higher percentages of low health literacy than did the Caucasian group. Therefore, if health literacy levels are part of the problem with health disparities, then health literacy levels can be modified to reduce these outcomes, which is encouraging because ethnicity in and of itself is a fixed variable and health literacy is not.

The second strength involved the instruments used to measure health literacy. While they did not measure the total construct of health literacy, they were found to be valid and reliable in individuals with diabetes. Within this study, the use of these tools has been expanded to include a predominately African American sample of pregnant women with diabetes. These instruments were efficient in this busy clinic setting as they only took a total of 5 minutes to administer and were easily scored.

Thirdly, this population of pregnant women with diabetes is understudied especially in regard to health literacy and its association with birth outcomes. This longitudinal, exploratory study attempted to associate health literacy to birth outcomes which is definitely needed in light of patient safety and the need to improve birth outcomes.

Limitations

There were several limitations to our study. The biggest limitation for this study was the small sample size which was under powered to detect differences in the sample which also decreases the generalizability of the findings. While over 100 participants were screened, this investigator felt that it was important not to influence the preterm birth outcome and thus tightened the exclusion criteria, which may have skewed the results in spite of this. This was compounded by the lack of data available on birth outcomes through inefficient documentation on the birth certificate and medical record.

Another limitation experienced in this study included the use of health literacy measures that although are currently the gold standard, still do not measure the total construct. Since the REALM, LAD and REAL-G are only available in English, these instruments required that the participant read and speak English for its use and to experience informed consent. Thus those who could not read or write were not included. While the three screening questions are available in Spanish, this investigator does not speak Spanish and could not administer the consent or the questions.

The amount of drug abuse inherent in this population and the effect that poverty and access to health care had on this study were not accounted for. The recruitment time frame at varying levels of gestation also may have influenced the health literacy rates of the mothers, because some mothers may have had more visits with the certified diabetic educators than others.

One more limitation was that we did not use a control group. A control group would have benefitted this study in two ways. It would have measured health literacy levels in normal, uncomplicated pregnancies that utilize this safety net hospital. Also, it

would have allowed for greater comparisons of birth outcomes between the uncomplicated pregnancy control group and the pregnancy complicated by diabetes group to perhaps tease out the influence of diabetes on the pregnancy.

Lastly, this study took place in only one urban location in the southern US. This may not be reflective of the experiences of the pregnant individual with diabetes who lives in a rural setting or in a different area of the US or who receives care in a private or for-profit health care setting.

Additional Findings

In addition to the above findings, three additional findings were revealed. They included differences in prenatal care initiation based on health literacy level, ethnic differences in birth outcomes, and differences in birth outcomes based on the type of diabetes experienced by the mother.

Prenatal Care Initiation

Health literacy is associated with prenatal care initiation among women who are pregnant with diabetes [12,29]. Prenatal care initiation is a factor in pregnancy as those who receive earlier care tend to have less adverse birth outcomes [355]. In this study, when health literacy levels were examined, only those with higher health literacy were significantly more likely to seek care earlier than those with low health literacy ($p = 0.04$) as measured by the LAD. This was not supported by Bennett et al. who found both low and high health literacy levels had high rates of poor prenatal care utilization in a sample of 202 African American women [12]. Other studies reported prenatal care initiation within the first trimester as early as 9.2 weeks up to 12 weeks [29,348,356]. This may be related to health care access among these women.

Other studies have documented that individuals with low health literacy have more distrust of healthcare providers, pessimism about treatment, lower satisfaction with care, and worry that their limited literacy will be exposed [111,146,153,357]. Given these associations, it is not surprising that individuals with low health literacy do not come to primary care and thus receive less preventive services [87,113,128]. The late prenatal care initiation in mothers with low health literacy may reflect the attitude of non-pregnant people with low health literacy.

Ethnic Differences

Overall the racial differences were not statistically significant. These African American women experienced more hypertension (46.2% vs. 16.7%), more preeclampsia (26.9% vs. 0%), and higher percentages of cesarean delivery (65.4% vs. 50%) than the Caucasian group. The infants of African American women had more fetal demise (7.7% vs. 0%), and more preterm birth (26.9% vs. 15.4%). These outcomes are supported in the

literature [187,253,269,358,359]. Health literacy scores in the African American group showed higher percentages of low health literacy when compared to the Caucasian group. Goodwin and Mercer found African Americans to have more severe hypertension in 45% of their participants and no difference between racial groups for preeclampsia which may help explain our preeclampsia cases [359]. If health literacy levels are part of the problem with health disparities, then interventions can enhance health literacy levels to help ameliorate these poor birth outcomes. Further research is necessary to expand on these findings.

Type of Diabetes

The literature is clear that pregnancy complicated by diabetes is associated with adverse birth outcomes such as preterm birth [205,360], low birth weight infants [187,250], congenital anomalies [40,281,361], preeclampsia and hypertension [205,207,211], macrosomia [193,324], stillbirth and fetal demise [201,362]. This study found these same outcomes. Upon comparison of gestational diabetes to pregestational diabetes, those with gestational diabetes experienced more preeclampsia and macrosomia than did those with pregestational diabetes. The group with pregestational diabetes had a significantly higher rate of preterm birth ($p = 0.03$). This has been demonstrated by Haeri et al. who found that the odds for delivering a low birth weight, small for gestational age infant were significantly increased the worse the vasculopathy experienced by the mother [250]. Catov et al. also found a 5.5-fold increased risk of a small for gestational age infant among women with chronic hypertension [245]. While not significant, those women with pregestational diabetes experienced more hypertension, cesarean delivery, and their infants had more fetal demise, respiratory distress syndrome and low birth weight. These outcomes have been demonstrated by other studies [193,205,207,211,363].

Theoretical Implications

The study was based on Cox's model of The Interaction of Client Health Behavior because health literacy involves behaviors from the individual and the healthcare providers [63]. This model can serve as framework for future research into health literacy because it allows for factors that influence the individual and the healthcare provider to be explored in light of health outcomes. Because clear, understandable communication is needed by the individual and provider alike to affect a positive health outcome in the mother and infant, health literacy needs to be considered an outcome variable changing with increased health information, improving with empowerment and reassessed at the beginning of a client-healthcare provider interface [12].

The provision of healthcare information involves giving knowledge about the health care problem as well as ways to prevent, treat, and live with the disease. This healthcare information must be delivered according to the client's singularity taking into account all of the components that this entails. Because healthcare providers need to be

more aware of health literacy needs of their patients, appropriate measurement instruments need to be created that will allow for a quick, reliable, and valid assessment of health literacy. This model provides framework by which the overall view of health literacy might be viewed from and thus enable evaluation and changes in intervention on the part of the individual to create more positive health outcomes especially in this population. The findings of this study supported the model because the background variables that the client brings to the health encounter influences health literacy. The healthcare provider is also an important factor in the healthcare encounter and when aware of the health literacy needs of the client can tailor the interventions for the client accordingly. While this study explored the demographic variables of age, race, education, and household income to describe the sample, further studies could tease out how much of an impact each one of these variables has on health outcome.

Clinical Practice Implications

This study revealed that low, maternal health literacy levels may lead to poorer maternal and infant birth outcomes. This has practice implications in the arena of increasing health literacy in pregnant mothers.

Health Literacy Awareness

Being aware of our patients' health literacy needs through increased awareness and accurate measurement is to move them to a clearer understanding of their health and healthcare needs—thereby increasing their autonomy and empowerment in their self-care. Basic nursing education teaches assessment of patients' health literacy by assessing for readiness to learn and then adapting our patient education to the patient's need. This assessment is subjective and not entirely accurate. As the acuity level of patients has increased, the amount of time available to work with them has decreased, leading us often to ignore, overlook, or otherwise fail to assess their health literacy level. The REALM instrument is a fast, simple means of ascertaining health literacy levels in patients and needs to be incorporated into patient care. The LAD and REAL-G are instruments that can assess specific areas such as diabetes and genetics respectively.

Implications for the Individual

Low levels of health literacy have been associated with higher utilization of services [53,102,106], fewer preventive services [9,113], poorer glycemic control and more diabetes complications [11,30]. We need to improve our health promotion efforts to empower our patients to take control of their health and their chronic condition such as diabetes and diabetes in pregnancy. A more preventive approach would be potentially more cost efficient, especially if we integrate health education to enhance health literacy in education of children so that they are better prepared to care for themselves for the rest of their lives. Teaching them how to care for themselves and why this is important for their health is part of health literacy. Anderson and Funnell have shared their perspective

about caring for individuals with diabetes in that the individual will make the most important choices of how they will conduct their daily lives—especially in regards to their diet, glucose monitoring, and exercise regime. They have control. Along with this come the consequences of the control and the choices that they have made [336]. In that light, health-care providers can encourage the individual to become more health literate. One way to do this is outlined by Miller et al. in the “Ask me 3” program, which is a series of three questions that the patient needs to ask the health care provider: What is my main problem? What do I need to do?” and “Why is it important for me to do this? [364]. These questions are designed to illicit clearer communication and understanding between the individual and healthcare provider. Kleinman et al. proposed a series of eight questions designed to assess how a person’s culture is reflected in the expression and understanding of the patients disease process [365]. These eight questions allow the nurse insight into how the patient views the illness, what their health literacy level is and allows for more tailored care. With higher health literacy, the individual can make lifestyle changes that will impact health care outcomes in a more positive manner. Nursing has embraced patient teaching in the past but more emphasis needs to be placed in this area today. Assisting the individual in understanding their disease through knowledge acquisition and skills preparation is necessary to enhance the health literacy of that individual and effect positive health outcomes.

Implications for the Healthcare Provider

The U.S. spends more money on healthcare than many nations, yet it has poorer outcomes in terms of general health and average life expectancy [366]. Therefore, awareness of the health literacy levels of our patients needs to be improved. Health literacy needs are being illuminated and brought to the forefront of health care with the use of standards of care, such as confirming that the patient understands his disease and the treatment prescribed. This allows for tailored teaching. Patients would then confirm what they have understood by the patient teaching-back method of reiteration of the material given. Nurses will recognize this “teaching-back” or “reiteration” as the evaluation of teaching as related to the nursing process.

A standard of “universal precautions” in health literacy has been proposed to ensure understanding of their healthcare plan by all patients [60]. This means that every patient is given the benefit of being assessed for their health literacy level. This is much the same as we wear gloves, assuming everyone might have a contagious disease and we need to protect each other from that disease. We should assume that everyone may have low health literacy and be careful to assess if this is so since low health literacy can lead to unsafe practices by the individual.

Since medical documents are often written at a 10th-grade level and verbal communications are fraught with opportunities for misunderstanding [307], educational materials should be written at the 6th-grade level, be short, simple, and contain culturally sensitive pictures and graphics that encourage the desired behavior [144]. Other methods of educating the public, such as by telephone triage, internet access, and community events should be used. Healthcare providers should decrease the amount of “medical

jargon” and explain things in terms that patients can understand. JCAHO recommends the use of clear, concise language, having the patient repeat back what they have learned, limit teaching to two to three points at one time, and encourage patients to ask questions [4].

Implications for the Healthcare System

On the federal level, policy makers and various interest groups such as the American Medical Association and the Joint Commission are sending the call for research studies to assist in making informed policies that would encourage increased health literacy levels. Healthy People 2010 have as one of their goals to improve the health literacy of persons with inadequate or marginal literacy skills. While there is not a specific statement regarding health literacy, The American Nurses Association (ANA) has always advocated for the patient’s right to self-determination. ANA’s Code of Ethics states that patients have the right to be given accurate, complete, and understandable information in a manner that facilitates informed judgment about their health [367].

Building awareness in healthcare executives and healthcare providers and in the public is an important step. The Joint Commission has identified common factors that lead to harm poor communication and thus poor clinical management [308]. As a result, many recommendations are offered by the Joint Commission to help prevent these problems. The recommendations include broadening reimbursement policies for patient education provided in physician offices; pursue pay-for-performance strategies that provide incentives to foster patient-centered communications and culturally competent care; and expand the number of medical liability insurance companies that provide premium discounts to physicians who receive education on patient-centered communications techniques. The need to change the way we as healthcare professionals care for individuals with chronic diseases such as diabetes is great. Chronic diseases such as diabetes are increasing, along with mortality rates, and healthcare costs continue to go up, placing an enormous financial and emotional burden on everyone involved [32,34].

Health literacy, viewed as a continuum, suggests that different levels of literacy progressively allow for greater autonomy in decision-making and personal empowerment, demonstrated through the actions of individuals and communities [71]. There are changes that need to be addressed by individuals, healthcare providers, and healthcare systems for improved health outcomes through increased health literacy. Thus, the empowered individuals can take care of their chronic disease in an efficient manner with accurate medication administration, glucose monitoring, and timely visits to their healthcare provider, which will decrease the overall cost of care.

Pregnancy and Future Health Care

Pregnancy may be a dress rehearsal of sorts whereby the pregnant woman is subjected to the physiologic stressors that may unmask certain diseases that can predict

her health as she gets older [368]. Women who are predisposed to certain diseases are given a “sneak preview” of what their body can accommodate, especially with such diseases as diabetes and hypertension, because these may re-emerge later in their lives [369,370]. A woman with gestational diabetes has a 20-60% chance of developing type 2 diabetes within 5 to 16 years after the pregnancy [225]. Type 2 diabetes is usually considered a lesser form of type 1 diabetes, but research has demonstrated that birth outcomes for these women are just as dangerous, if not worse, than type 1 diabetes [202,217]. Since low health literacy has been associated with poorer health outcomes in diabetes [11,165,371], pregnancy is an excellent opportunity to provide education about lifestyle changes for the future.

Pregnant women with diabetes are also at risk for developing cardiovascular disease later in life and should be advised to adjust their lifestyle after the pregnancy to attenuate this risk [368,369]. Pregnancy is a time when women tend to be motivated about their health and that of their unborn child [180]. With the incidence of type 2 diabetes on the rise and thus pregnancy complicated by diabetes increasing [180,372], efforts must be made to utilize this opportunity to reach and teach these women about their future risks of cardiovascular disease and what they can do now to make lifestyle changes to reduce their risks [369]. Low health literacy is associated with a variety of adverse health outcomes. Low health literacy is common and, if unrecognized, presents as a barrier to effective care [7]. Thus, it is important that we as healthcare providers “catch” these women at this time in their lives to encourage health behavior change in order to lessen the impact of cardiovascular disease later.

Preconception Counseling and Prenatal Care

Given the increase in chronic illnesses that plague our country—such as obesity, diabetes and hypertension—the woman of childbearing age is likely to be affected by these diseases [34,108,373]. The evidence in obstetric literature points to the increased need for pre-conception counseling and early prenatal care [170,335,355,374,375]. Women with diabetes need to have better glycemic control before they conceive in an effort to avoid congenital anomalies and other problems in pregnancy like hypertension, preterm birth, and perinatal mortality [202,324,375]. We as healthcare professionals need to increase awareness of this fact through education of women of childbearing age about this issue. Studies have shown improved birth outcomes, reduced resource utilization, and substantial cost reductions [335,374] when preconception and early prenatal care are used. Relatively few women receive preconception counseling, and major fetal malformations can be the result of poor glucose control before and during early weeks of gestation. This early hyperglycemia has emerged as the major cause of perinatal mortality [180]. Clinical practice should embrace prenatal care as a chance to circumvent adverse pregnancy outcomes as well as to educate women about the future care of themselves. Efforts to reach those with low and high health literacy must be brought to the forefront, and nurses have an excellent opportunity to work toward this aim because of their interactions in multiple healthcare settings.

Recommendations for Future Research

There are seven recommendations for future research regarding health literacy and pregnancy complicated by diabetes suggested by our research. First and foremost, a larger study of pregnancy complicated by diabetes and the associations with health literacy level is sorely needed, especially if it can be framed within the Interaction Model of Client Health Behavior. This would allow for a knowledge base of what needs to be implemented regarding ameliorating any health literacy gaps that these women may face. Next, the other influences on health behavior such as culture, religion and socioeconomic factors (e.g., health care access) need to be explored in relation to health literacy to tease out the significance of these influences. Also, more research into health literacy and its effect on reducing health disparities could be quite promising, as would be more longitudinal studies that tie to health outcomes to make the research more meaningful.

Next, because health literacy is such a broad construct, additional measurement instruments need to be developed to capture all of the influences on health literacy, as supported by the call by the Institute of Medicine for more expansive measurement instruments [26]. A possible composite score of several attributes would be ideal or sensitive and specific tools that could detect improvements in health literacy after implementation of educational programs to enhance health literacy and therefore improve health outcomes. Along with this is the need to have measurement tools that could allow for broader meta-analysis studies.

For pregnancy complicated by diabetes, further research also needs to be conducted into the long-term effects of diabetes in pregnancy on the mother with the potential for future cardiovascular disease and on the child as it grows and develops. This is especially needed since studies have shown long-term effects, including memory and inattention problems [275,376]. Lastly, preconception and prenatal care intervention studies need to be increased because they are a cost-effective way to influence birth outcomes and influence the overall health of the nation [170,374].

Conclusions

Health literacy may be the key to changing our ever-increasing statistical rates of increased chronic diseases and poor health outcomes. In the case of diabetes, while health education is a prerequisite for effective self-management of diabetes [377], knowledge does not necessarily predict outcomes. Chronic diseases such as diabetes need to be managed as a team between the individual and the healthcare provider. Because individuals have control over what they will actually do to take care of themselves, the healthcare provider can offer the medical necessities such as health information and medical care to help improve health literacy. This will lead to clearer communication and improved health outcomes. Assessment and intervention concerning an individuals' health literacy level is a pathway to that clear communication. Understanding one's medical condition and how to care for it can empower an individual to make positive health behavior changes. A better understanding of health literacy and

its role in maintaining health, specifically in relation to the health of pregnant women with diabetes, may improve birth outcomes.

With national attention placed on this construct of health literacy, increasing health literacy levels is being recognized as one of the key factors to positively influence patient outcomes and needs to be addressed by every healthcare professional in America. With the increasing prevalence of diabetes and other chronic illnesses, changes to the way health care is conducted are necessary. With the individual, healthcare provider, and healthcare system all working together to improve communication between the recipient and provider of health care, reduction in consequences of chronic disease and increased quality of life can surely be the outcome.

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APPENDIX A: INSTITUTIONAL REVIEW BOARD APPROVAL – UNIVERSITY OF TENNESSEE

May 19, 2008

Rosemary McLaughlin, RN
College of Graduate Health Sciences
Department of Nursing
920 Madison
Suite 507
UTHSC
CAMPUS

Institutional Review Board
910 Madison Avenue, Suite 600
Memphis, TN 38163
Phone: (901) 448-4824

RE: "Comparison of Health Literacy Levels in Indigent, Pregnant Women with Pregestational and Gestational Diabetes in an Urban Setting" (IRB #8803)

Dear Ms. Laughlin,

We are in receipt of your acceptance in response to our e-mail communication dated May 15, 2008 concerning the above referenced Institutional Review Board Project.

The Administrative Section of the UTHSC Institutional Review Board (IRB) determined your application to be consistent with the guidelines for expedited review under categories (5) and (7). Therefore, this application was approved in this regard as complying with proper consideration of the rights and welfare of human subjects, the risk involved, and the potential benefits of the study. This letter constitutes full approval of your application, questionnaire and consent form, stamped approved by the UTHSC IRB on May 19, 2008 for the above referenced study. This project was approved for 12 months with an expiration date of May 19, 2009. The consent form dated May 15, 2008 is also approved from the date of this letter through May 19, 2009.

The IRB has also determined that the informed consent form, incorporating the authorization of subjects to use their protected health information in research, complies with the federal privacy regulations as specified in 45 CFR160 and 45 CFR 164.

In the event that subjects are to be recruited using solicitation materials, such as brochures, posters, website based advertisement, etc., these materials must receive prior approval of the IRB. Any revisions in the approved application must also be submitted to and approved by the IRB prior to implementation. In addition, you are responsible for reporting any unanticipated serious adverse events or other problems involving risks to subjects or others in the manner required by the local IRB policy.

Finally, **reapproval** of your project is required by the IRB in accord with the conditions specified above. You may **not** continue beyond the time or other limits specified unless you obtain prior written approval of the IRB.

Sincerely,

Donna Stallings, CIM
IRB Administrator
Institutional Review Board

Clair E. Cox, M.D.
Institutional Review Board

APPENDIX B: INSTITUTIONAL REVIEW BOARD REAPPROVAL – UNIVERSITY OF TENNESSEE

Institutional Review Board
910 Madison Avenue, Suite 600
Memphis, TN 38163
Phone: (901) 448-4824

July 3, 2008

Rosemary McLaughlin, RN
College of Graduate Health Sciences
Department of Nursing
920 Madison
Suite 507
UTHSC
CAMPUS

Dear Ms. McLaughlin,

The University of Tennessee Health Science Center Institutional Review Board has reviewed your request for the research use of protected health information without subject authorization in your study entitled, "Comparison of Health Literacy Levels in Indigent, Pregnant Women with Pregestational and Gestational Diabetes in an Urban Setting" (IRB #8803). The IRB has approved your request because it has been established, based on the information submitted, that the regulatory requirements for waiver of authorization are satisfied.

Specifically, the IRB has determined that the research using protected health information with a waiver of authorization involves no more than minimal risk to the privacy interests of subjects, could not be practicably carried out without the waiver, and could not practicably be conducted without the use of protected health information. This waiver is being approved to receive and/or collect PHI during the conduct of the study.

This approval applies specifically to the protected health information whose use the IRB has determined to be necessary for the conduct of this research study. This waiver applies to the medical records of patients in the UT Medical Group, Inc., prenatal clinic between the ages of 16 and 40 with the diagnosis of pre-gestational and gestational diabetes.

Your request to use protected health information without subject authorization was approved by the IRB on July 3, 2008.

Sincerely yours,

Donna Stallings, CIM
IRB Administrator
Institutional Review Board

Terrence F. Ackerman, Ph.D.
Chairman
Institutional Review Board

APPENDIX C: INSTITUTIONAL REVIEW BOARD APPROVAL – REGIONAL MEDICAL CENTER AT MEMPHIS

Regional Medical Center at Memphis

June 11, 2008

Rosemary McLaughlin, MSN, RNC
UTHSC - College of Nursing
920 Madison Avenue, Suite 507
Memphis, TN 38163

Dear Ms. McLaughlin:

The project proposal entitled "***Comparison of Health Literacy Level in Indigent, Pregnant Women with Pregestational and Gestational Diabetes in an Urban Setting***" (IRB # 8803) has been reviewed by this office. The goals of the project appear to be consistent with the commitment of the Regional Medical Center to the advancement of medical science and healthcare, and I am pleased to inform you of its approval.

I understand that chart retrieval by the Medical Records Department may be required, and that no other services will be needed from The MED for this study.

For your convenience, the following list will serve as a reminder of some of your responsibilities as the principal investigator at this site. All members of your research team must be aware of these requirements to ensure compliance with the MED's policies for conducting research (items applicable to this study have been listed). Please refer to "Research Policies" in the MED's Administrative Manual for a complete listing. Please note that none of these are new requirements; if you have any questions, please call the Office of Medical Research at 545-7453.

1. Enrollment of the subject must be recorded in the medical record on the day of enrollment.
2. Upon enrollment, a copy of the subject's signed written informed consent must be attached to the medical record. Although these patients will be recruited and consented in the UTMG clinics, a **copy of that signed informed consent must be placed on the hospital medical record after admission to the MED.**
3. The MED is responsible for the care and services provided for our patients. It is therefore paramount that the Office of Medical Research be notified of all patients enrolled in research activity. Please submit the cumulative list as patients are enrolled and terminated using the "**Verification of Patient Enrollment**" form. (Form C enclosed) NOTE: *Due to the time lag from enrollment at the UTMG clinics to delivery at The MED, the names of subjects may be submitted at the time of admission, when MED medical record and account numbers are available for these subjects.*
4. Any revisions in the protocol must be forwarded to the Office of Medical Research.

877 Jefferson Avenue Memphis, TN 38103 901.545.7100

5. Upon completion of the study, the Research Office must be informed of the end date. A copy of IRB Form 7 (Report of Termination of IRB Project) can be submitted to meet this requirement.

I commend you for your research activity and look forward to hearing from you regarding the outcome of this study. If our office may be of help to you in connection with this project or with future endeavors, please let us know.

Sincerely,

Stuart M. Polly, M.D.,
Chief Medical Officer and
Senior Vice President for Clinical Affairs

CC Maria van Werkhoven, Director,
 Office of Medical Research

 Risa Ramsey, PhD, MBA, RN, CCRC
 Rout Center for Women and Newborns
 UTHSC – Department of Obstetrics and Gynecology

APPENDIX D: CONSENT FORM TO PARTICIPATE IN THE RESEARCH STUDY

Comparison of health literacy levels in indigent, pregnant women with pregestational and gestational diabetes in an urban setting

Principal Investigator: Rosemary McLaughlin, PhD candidate, RN
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Co-Investigators: Ann Cashion PhD, RN
Risa Ramsey PhD, RN
Mona Wicks PhD, RN
Bobby Bellflower DNSc, NNP, RN

1. INTRODUCTION.

You are being given the opportunity to participate in a research study. Before you give your consent to volunteer, it is important that you read and understand the following explanation of the proposed procedures. This informed consent describes the procedures and the role that you have as a participant in this research study. Please read this information carefully and do not hesitate to ask the study investigators any questions you may have about this form or about the study. You must sign this informed consent before you enter the study.

There is increasing evidence that poor health literacy can influence how pregnant women who have diabetes understand and follow the treatment plan. Understanding this plan including, diet, exercise can lead to lower complication rates. Any medications orders that occur as well as what interventions during pregnancy can also lead to lower complication rates for the mother and the infant.

This study will evaluate 70 women, between the ages of 16 and 40 years of age, with pre-existing diabetes or gestational (found during pregnancy) diabetes and their understanding of health literacy. The study will be conducted at the Rout Center for Women and Infants, Obstetric Clinics, Regional Medical Center, 853 Jefferson Avenue, Memphis, TN., 38163. The anticipated time for you to complete the study is 30 minutes. The entire study is expected to be completed in one year.

2. PROCEDURES TO BE FOLLOWED.

After agreeing to participate in the study, you will receive instruction on how to read the three lists of words for each measure and answer three questions. You will be in a private

room with the researcher during the reading. The consent and readings should take 25-30 minutes of your time.

3. RISKS ASSOCIATED WITH PARTICIPATION.

There is a potential emotional risk if reading is a problem. This risk may include shame or embarrassment. To decrease this risk, a private room will be used for you to talk with the investigator. There is no health risk associated with collecting information from the questionnaire.

4. BENEFITS ASSOCIATED WITH PARTICIPATION.

While there are no direct benefits to you for participation in this study, other pregnant women with diabetes may benefit in the future. Society may benefit from this study because it could provide information that would help doctors and nurses identify which pregnant women are at risk for not understanding the instructions that the physician or other healthcare provider gives to them about taking care of themselves during pregnancy. Findings from this study could change the way that pregnant women with diabetes are taught about their health care.

5. ALTERNATIVES TO PARTICIPATION.

You may choose not to participate in the study, and therefore not undergo the study procedures. If you choose not to participate in this research study, you may receive standard medical care for pregnancy through your health care provider which may include learning more about diet, exercise, and lifestyle changes to help with diabetes during pregnancy, and/or treatment with medication.

6. CONFIDENTIALITY.

The confidentiality of your medical information collected during the study will be maintained. Your research record will be kept in a separate file, different from your clinical medical record. The research record will be labeled with a code number. The investigator will have access to a master code list, which will tie the code number to each participant. Data from the reports will be copied onto computer worksheets, which will identify you by the code number only. All data will be kept in the investigator's office and stored in a locked file cabinet accessible only to investigators.

No information will be released to any person or entity, other than you, unless requested by you, after signing an authorization for release of information. A copy of the informed consent will be placed in your hospital record at the Regional Medical Center and in the UT Medical Group chart. As a result, this information may be available to third parties such as insurers and/or employers. If results of this study are published or presented at meetings, your identity will be kept confidential. No results from the research records may be placed in your medical record.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "protected health information" or PHI). PHI collected in this study may include your medical history, the results of the literacy tools, as well as basic demographic information. By signing this consent form, you are

authorizing the researchers at the University of Tennessee to have access to your PHI collected in this study. In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including researchers at the University of Tennessee Health Science Center, the Obstetrical Clinics at the Regional Medical Center. The Institutional Review Board (IRB) at the University of Tennessee Health Science Center may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used only for the research purposes described in the Introduction of this consent form. Your PHI will be used until the study is completed.

You may cancel this authorization in writing at any time by contacting the principal investigator listed on the first page of the consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. However, in order to complete the research, your access to this PHI maybe temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

7. COMPENSATION AND TREATMENT FOR INJURY.

I understand that I am not waiving any legal rights or releasing the University of Tennessee, The Regional Medical Center, or the agents of either from liability for negligence. I also understand that in the event of physical injury resulting from the research procedures, neither the University of Tennessee, UT Medical Group, nor The Regional Medical Center has funds budgeted for compensation either for lost wages or for medical treatment. Therefore, neither the University of Tennessee nor The Regional Hospital provides for treatment or reimbursement for such injuries. In the event of a research related injury, Dr. Bringman or the physicians at the Obstetrical clinic at the MED will provide treatment. I understand that I will be billed for any cost of medical treatment in the event of a research related injury.

8. QUESTIONS.

You may ask any questions about the study at any time. If you have any questions related to the study or think that by being in this study you have suffered a problem related to the study you should contact Rosemary McLaughlin PhD candidate, MSN, RN (731) 695-3960. This is a 24-hour telephone number for you, available 7 days a week, in case of a research related injury or if questions may arise.

You may contact Dr. Terrence Ackerman, UTHSC IRB Chairman at (901) 448-4824 if you have any questions about your rights as a participant in this study or your rights as a research subject.

9. PAYMENT FOR PARTICIPATION.

You will receive a \$15.00 gift certificate to Wal-Mart after completing the health literacy assessment tools and answering the short questionnaire.

10. COSTS OF PARTICIPATION.

There are no costs to you for the tests associated with this study. Costs for your regular medical care, which is not related to this study, will be your own responsibility or the responsibility of your insurance carrier. There is no parking cost. Cost associated with transportation to and from the testing sites (The Regional Medical Center Obstetrical Clinic) is your responsibility.

11. PREMATURE TERMINATION.

The study investigator(s) may withdraw you from the study without your consent at any time for any of the following reasons:

- Inability to speak, read or understand the English language
- You do not have diabetes
- You are carrying more than one infant

If you should withdraw from the study or are asked by research staff to leave the study, you must notify Rosemary McLaughlin at (731) 695-3960 (a 24-hour telephone number).

If you desire to withdraw, your usual medical care will not be affected in any way.

Further, in the event that you withdraw from the study, you may request that all collected data be destroyed. The study investigators will send a written notification that the data was destroyed at your request.

12. VOLUNTARY PARTICIPATION.

Your participation in this study is voluntary. You have the right to decide not to participate or you may withdraw from the study at any time. Your refusal to participate in or decision to withdraw from this study will involve no penalty or loss of benefits to which you are otherwise entitled.

13. CONSENT OF SUBJECT.

I have read or have had read to me a description of the study about health literacy in pregnant women with diabetes as outlined above. The investigator or his/her representative has explained the study to me and has answered all the questions I have at this time. I have been told of the potential risks and discomforts, as well as the possible benefits of the study.

I freely volunteer to participate in the study. I understand that I do not have to take part in this study and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I understand that I am free to later withdraw my consent and discontinue participation in this study at any time. I understand that refusing to participate or later withdrawing from the study will not affect my subsequent medical care. I understand that I will receive a copy of the signed consent form for my records.

_____ Signature of Research Subject	_____ Date
_____ Signature of Legally Authorized Representative	_____ Date
_____ Relationship of Legally Authorized Representative	_____ Date
_____ Signature of Person Obtaining Consent	_____ Date
_____ Signature of Witness	_____ Date
_____ Signature of Principal Investigator	_____ Date
_____ Assent of Minor	_____ Date

APPENDIX E: RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM)

RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM)

Terry Davis, PhD, Michael Crouch, MD, Sandy Long, PhD

Chart # _____

Examine date: _____

Name: _____

Birth date: _____

REALM generated reading level: _____

Grade completed: _____

List 1	List 2	List 3
Fat _____	Fatigue _____	Allergic _____
Flu _____	Pelvic _____	Menstrual _____
Pill _____	Jaundice _____	Testicle _____
Dose _____	Infection _____	Colitis _____
Eye _____	Exercise _____	Emergency _____
Stress _____	Behavior _____	Medication _____
Smear _____	Prescription _____	Occupation _____
Nerves _____	Notify _____	Sexually _____
Germs _____	Gallbladder _____	Alcoholism _____
Meals _____	Calories _____	Irritation _____
Disease _____	Depression _____	Constipation _____
Cancer _____	Miscarriage _____	Gonorrhea _____
Caffeine _____	Pregnancy _____	Inflammatory _____
Attack _____	Arthritis _____	Diabetes _____
Kidney _____	Nutrition _____	Hepatitis _____
Hormones _____	Menopause _____	Antibiotics _____
Herpes _____	Appendix _____	Diagnosis _____
Seizure _____	Abnormal _____	Potassium _____
Bowel _____	Syphilis _____	Anemia _____
Asthma _____	Hemorrhoids _____	Obesity _____
Rectal _____	Nausea _____	Osteoporosis _____
Incest _____	Directed _____	Impetigo _____
# of (+) Responses in List 1: _____	# of (+) Responses in List 2: _____	# of (+) Responses in List 3: _____

LEGEND: (+)=Correct (-)=Word not attempted (/)=Mispronounced word

Raw Score: _____

Red Lake Hospital, Red Lake MN 56671
4/98/JMcD

APPENDIX F: RAPID ESTIMATE OF ADULT LITERACY IN GENETICS (REAL-G) WORD LIST

WORD LIST

List 1

test
egg
male
risk
gene
cell
blood
sperm
change
chance
screen
related
trait
odds
pap
result
working
normal
defect
likely
mistake

List 2

detect
lifetime
percent
onset
pattern
sibling
certain
ethnic
severe
needle
sample
fluid
protein
option
cystic
negative
genetic
history
positive
infection
affected

List 3

syndrome
condition
surgery
ultrasound
disorder
carrier
sporadic
uterus
instruction
insurance
mutation
miscarriage
development
variation
chromosome
generation
population
retardation
hereditary
abnormality
susceptibility

SCORE

List 1 _____

List 2 _____

List 3 _____

Raw Score _____

APPENDIX G: HEALTH LITERACY DATA COLLECTION TOOL

Demographics: Information gathered from medical record

Number: _____ Maternal Age: _____ Prenatal Care sought: _____ weeks

Years of school completed:

Less than 3 rd grade: _____	Income: _____
Fourth - eighth grade: _____	< \$20,000 _____
Grades 9-11: _____	\$20,000 – \$39,000 _____
High School or GED: _____	\$40,000 + _____
Some College: _____	Do not know / Refused _____
College Graduate: _____	

Literacy Assessment: (From the mother)

_____ Rapid Estimate of Adult Health Literacy in Medicine (REALM):
Score: 0-18 _____ 19-44 _____ 45-60 _____ 61-66 _____

_____ Literacy assessment of Diabetes (LAD)
Score: 0-18 _____ 19-44 _____ 45-60 _____ 61-66 _____

Rapid Estimate of Adult Literacy in Genetics (REAL-G):
Score: 0-18 _____ 19-44 _____ 45-60 _____ 61-63 _____

_____ Three questions from the Short Test of Functional Health Literacy in Adults:

How confident are you in filling out medical forms by yourself?

Extremely quite a bit somewhat a little bit not at all

How often do you have someone help you read hospital materials?

Always often sometimes occasionally never

How often do you have problems learning about your medical condition because of difficulty understanding written information?

Always often sometimes occasionally never

Maternal outcome: (From the medical record)

Complications of pregnancy:

Preterm labor _____
Threatened preterm labor _____
Hypertension disorder _____
Cesarean section _____
Polyhydramnios _____
Vaginal laceration _____ Degree _____
Spontaneous labor at term _____

Reason for Delivery:

Spontaneous preterm labor _____
PROM leading to spontaneous delivery _____
PROM leading to induced delivery _____
Medically indicated delivery for
maternal indicators _____
fetal indicators _____

admissions to hospital _____ # uses of ER services _____ # evaluation visits _____

Infant Outcome:

Gestational age at birth: _____	Birth Weight: _____ gms	APGAR: 1min _____ 5 min _____
Fetal Demise (stillbirth) : _____	Birth trauma: _____	Type: _____
Blood sugar @ birth: _____	Respiratory distress _____	Congenital anomalies: _____ Type: _____

APPENDIX H: LITERACY ASSESSMENT FOR DIABETES (LAD)

Literacy Assessment for Diabetes (LAD) Shirley Theriot Sylvester, Ph.D., Charlotte Nath, RN, EdD, CDE		
Patient Name/Number _____		Birth date: _____
Date _____	Clinic _____	Examiner _____
List 1	List 2	List 3
cat _____ eet _____ pill _____ pil _____ eye _____ ī _____ fat _____ fat _____ milk _____ milk _____ sugar _____ shoō-gēr _____ lunch _____ lunch _____ meal _____ meel _____ kidney _____ kid-nee _____ drink _____ drink _____ nurse _____ nurs _____ fiber _____ fī-bēr _____ fruit _____ front _____ supper _____ sūp-ēr _____ bread _____ bred _____ heart _____ hart _____ blood _____ bluhd _____ stress _____ stress _____ meat _____ meet _____ doctor _____ dok-tūr _____	thirst _____ thūrst _____ exercise _____ ek-sir-sīz _____ exchange _____ iks-ehānj _____ direction _____ duh-rek-shūn _____ hospital _____ hos-pit-uhl _____ calorie _____ kal-uh-ree _____ colon _____ ko-luhn _____ urination _____ yoor-uh-may-shuū _____ vision _____ vizh-un _____ protein _____ prō-teen _____ vegetable _____ vej-tuh-bul _____ snack _____ snak _____ cereal _____ ser-ee-ul _____ injection _____ in-jek-shun _____ glucose _____ gloo-kōs _____ breakfast _____ brek-fuhst _____ insulin _____ in-suh-lin _____ alcohol _____ al-kuh-hall _____ medication _____ med-ah-kā-shuhn _____ symptom _____ simp-tuhm _____	artery _____ art-tē-ree or ar-tree _____ biosynthetic _____ bī-ō-sin-thet-ik _____ abnormal _____ ab-nor-muhl _____ cholesterol _____ kah-les-tuh-rawl or rol _____ glycogen _____ gli-kuh-jēn _____ nephropathy _____ ni-frap-uh-thē _____ prescription _____ pri-skrip-shuhn _____ pregnancy _____ preg-nuhn-see _____ ketones _____ kee-tōnz _____ ketoacidosis _____ kee-tō-ass-ih-dō-sus _____ pancreas _____ pan-kree-uhs _____ hypoglycemia _____ hī-pō-gli-see-mee-uh _____ atherosclerosis _____ ath-uh-rō-skluh-rō-sīs _____ occupation _____ ok-yoo-pay-shuhn _____ triglycerides _____ trī-glis-uh-rīds _____ emergency _____ ih-mūr-juhn-see _____ communication _____ kuh-mū-nuh-kā-shuhn _____ hemoglobin _____ hē-muh-glo-buhn _____ endocrinologist _____ en duh krīh nawl uh jist _____ retinopathy _____ ret-ehn-op-uh-thē _____
Raw Score 0-20 21-40 41-60	Estimation of Grade Level Fourth Grade and below. (Oral instructions should be given repeatedly with visual assistance.) Fifth-Ninth Grade Level Ninth Grade and Above	Score List 1 _____ List 2 _____ List 3 _____ Raw Score _____
This educational tool was developed and funded through a grant from the West Virginia Diabetes Council Program, West Virginia Bureau of Public Health, West Virginia Department of Health and Human Resources and West Virginia University. © 2000 WVU		

VITA

Rosemary McLaughlin was born in Surrey, England. She received her Bachelor of Science in Nursing degree from Harding University in Searcy, Arkansas, in 1982, and her Master of Nursing Science degree from the University of Arkansas Health Science Campus, Little Rock, Arkansas, in 1988. Her thesis research explored blood collection methods and hemolysis in premature infants. Her areas of expertise lie in neonatal intensive care nursing and nursing education. She has taught pediatric nursing since 1999. She has served on the Editorial Boards for *Neonatal Network* and the *Journal of Pediatric Nursing*, and is a member in the Society of Pediatric Nurses and the International Society of Nurses in Genetics. Her current position is Associate Professor for Nursing at Union University in Jackson, TN.