

8-1-2011

The effectiveness of Diabetes Mellitus education for managing hemoglobin A1c levels in adults

Amy Rebekah Farnsworth

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THE EFFECTIVENESS OF DIABETES MELLITUS EDUCATION FOR MANAGING
HEMOGLOBIN A1C LEVELS IN ADULTS

By

Amy Rebekah Farnsworth

A Thesis
Submitted to the Faculty of
Mississippi State University
in Partial Fulfillment of the Requirements
for the Degree of Master of Science
in Nutrition
in the Department of Food Science, Nutrition, and Health Promotion

Mississippi State, Mississippi

August 2011

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FOR MANAGING HEMOGLOBIN A1C LEVELS IN ADULTS

Pages in Study: 61

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Hemoglobin A1c (HbA1c) levels are indicators for managing Diabetes Mellitus. This study investigated the effectiveness of Diabetes Mellitus education classes based on participants' HbA1c levels. The HbA1c and body mass index (BMI) values were analyzed using *t*-tests to determine significant ($P \leq 0.05$) differences between baseline ($N = 46$) levels compared to three months, six months, and 12 months after class participation and reported as means \pm standard deviations. The study was not able to track all participants as some did not attend all follow-up sessions. Mean HbA1c levels were lower at three months ($8.1\% \pm 2.1$, $P = 0.002$, $n = 31$), six months ($8.11\% \pm 2.6$, $P = 0.001$, $n = 39$), and 12 months ($8.7\% \pm 2.3$, $P = 0.050$, $n = 29$) compared to baseline ($9.5\% \pm 2.4$). The baseline BMI was $36.7\text{kg/m}^2 \pm 9.7$ with similar ($P > 0.05$) values after class attendance.

ACKNOWLEDGMENTS

It is truly a pleasure to thank the many people that have made this thesis possible. Dr. Diane Tidwell has shown enthusiasm, inspiration and has gone to great lengths to make this thesis a reality. She has helped make this thesis enjoyable and encouraged me as I continue to pursue avenues in diabetes education. Without her help and guidance I would have been lost in the process.

I would like to thank Dr. Michelle Lee who served as Dietetic Internship Director during my first year at Mississippi State University. It was through her encouragement that I continued to pursue my Master of Science in Nutrition. She has been a source of wisdom both professionally and personally. To Dr. Chiquita Briley, thank you for serving as a preceptor while I was a Dietetic Intern. Your passion for community nutrition education is contagious.

Lastly, I am grateful to have a wonderful family, fiancé and friends who believed in me and encouraged me to pursue my dreams. They provided me with a loving environment and support system that I knew would always be there. My parents instilled in me from a young age to set high goals and never give up no matter the circumstances.

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CHAPTER I

INTRODUCTION

Nationally, Diabetes Mellitus affected 25.8 million Americans in 2010 (Centers for Disease Control and Prevention, 2011). Approximately 18.8 million people were diagnosed and seven million were undiagnosed with Diabetes Mellitus in the United States during 2010 (Centers for Disease Control and Prevention, 2011). While the national prevalence of Diabetes Mellitus was 8.4% for adults aged 30 to 59 years and 23.6% for those aged 60 years and older, Mississippi had a higher prevalence rate of 11.4% in adults aged 30 to 59 years and 27.7% for those aged 60 years and older (Danaei, Friedman, Oza, Murray, & Ezzati, 2009).

Diabetes Mellitus is a metabolic disease characterized by high blood glucose concentrations, or hyperglycemia, resulting from defects in insulin secretion, insulin action, or both (American Diabetes Association, 2011a). This disease is manifested as Type 1 Diabetes Mellitus, Type 2 Diabetes Mellitus, or Gestational Diabetes Mellitus. Type 2 Diabetes Mellitus accounts for 90 to 95 percent of diagnosed cases and is associated with insulin resistance in the target tissues, mainly muscle, liver, and adipose cells (Franz, 2008). As Type 2 Diabetes Mellitus progresses, production of insulin from the pancreas decreases. Approximately 40% of people with Type 2 Diabetes Mellitus eventually require insulin therapy for adequate blood glucose control (Franz, 2008).

Medical nutrition therapy is paramount for managing Diabetes Mellitus. There is not a specific diet that best manages Diabetes Mellitus; instead the focus should be on an individualized nutrition prescription that considers the patient's culture, lifestyle preferences, and overall quality of life. For medical nutrition therapy to be effectively administered, it should be a team approach with doctors, nurses, pharmacists, and dietitians all working together to provide optimal care for people with Diabetes Mellitus. When medical nutrition therapy is provided in combination with self management, a decrease in glycosylated hemoglobin A1c (HbA1c) occurs by one to two percentage points in people with Type 2 Diabetes Mellitus (Lemon et al., 2004; Pastors, Franz, Warshaw, Daly, & Arnold. 2003). The goals of medical nutrition therapy are to (1) achieve HbA1c levels below seven percent, (2) achieve blood pressure levels within the normal range, and (3) achieve lipid profiles in healthy ranges to reduce the risk of cardiovascular disease (American Diabetes Association, 2007a). People with Diabetes Mellitus are encouraged to adjust their lifestyle and intake of foods and beverages to prevent the development of chronic diseases (American Diabetes Association, 2007a).

With the number of cases of Diabetes Mellitus expected to increase by 165% by the year 2050 in the United States (Diabetes Foundation of Mississippi, 2010), it is important to deliver programs that help people with Diabetes Mellitus effectively manage their disease, especially in Mississippi. Over 200,000 Mississippians have been diagnosed with Diabetes Mellitus; for every 100 Mississippians, approximately 8.9 are living with Diabetes Mellitus (Kaiser Family Foundation, 2011). Mississippi has the second highest prevalence of Diabetes Mellitus in the United States (Kaiser Family Foundation, 2011) and effective Diabetes Mellitus education is needed to assist people in

controlling their Diabetes Mellitus and preventing long-term diabetic complications such as kidney disease, neuropathy, and retinopathy which can lead to blindness (Franz, 2008).

This study evaluated the effectiveness of Diabetes Mellitus education provided by the interdisciplinary team at the Diabetes Mellitus Education Class at North Mississippi Medical Center-Eupora (NMMC-Eupora). The purpose of the study was to compare HbA1c levels prior to participants attending Diabetes Mellitus Education Class and again at three months, six months, and 12 months after attending the class. The objective was to compare the outcomes between each of the HbA1c levels to determine the effectiveness of Diabetes Mellitus education as related to HbA1c levels. Body mass index (BMI) values were evaluated at baseline, three months, six months, and 12 months to determine if participants were experiencing changes in weight as they managed their Diabetes Mellitus.

CHAPTER II

REVIEW OF LITERATURE

National Prevalence of Diabetes Mellitus

Although Diabetes Mellitus is diagnosed in approximately 18.8 million Americans, there are an estimated seven million Americans who have diabetes and are undiagnosed (Centers for Disease Control and Prevention, 2011). There are 25.6 million cases of Diabetes Mellitus in people over the age of 20 years, which is 11.3% of the United States population (Centers for Disease Control and Prevention, 2011). Much of what is considered to be the Southeastern region of the United States has a large prevalence of Diabetes Mellitus (Figure 1).

The likelihood of developing Diabetes Mellitus increases with age. Among the American population over the age of 65 years, there are approximately 10.9 million people living with Diabetes Mellitus, which accounts for approximately 26.9% of the total population and just over one-fourth of the senior citizen population (Centers for Disease Control and Prevention, 2011). For people over the age of 20 years, Diabetes Mellitus is more prevalent in the male population with 13 million cases compared to 12.6 million cases of Diabetes Mellitus in females (Centers for Disease Control and Prevention, 2011). Approximately 11.8% of all males and 10.8% of all females have

Diabetes Mellitus in the United States (Centers for Disease Control and Prevention, 2011).

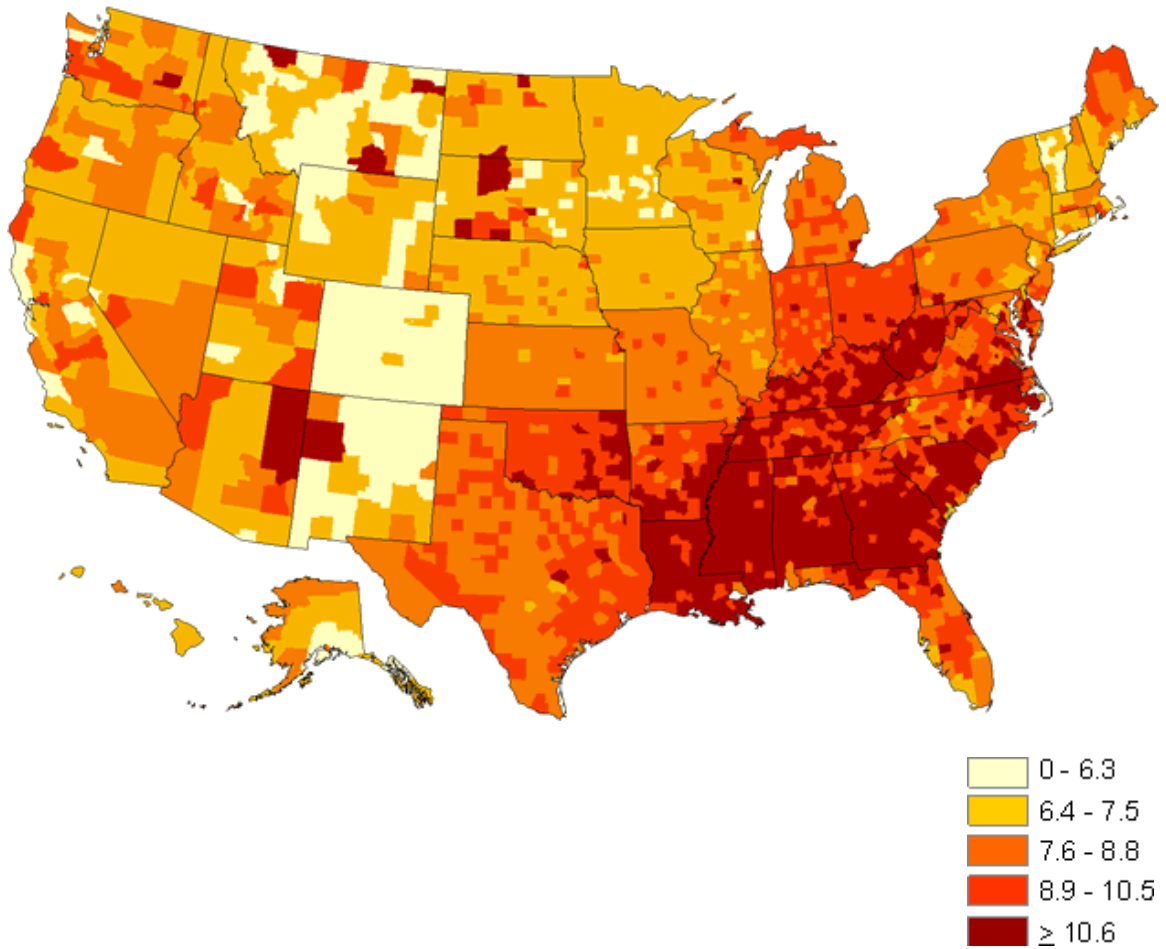


Figure 1. Percentage Estimates of Adults Diagnosed with Diabetes Mellitus.

Source: Centers for Disease Control and Prevention, 2008a.

Diabetes Mellitus is a disease that discriminates against specific racial/ethnic populations (Franz, 2008). After adjusting for population age differences, a national survey from 2007-2009 indicated that 12.6% of non-Hispanic blacks, 11.8% of Hispanics, 8.4% of Asian Americans, and 7.1% of non-Hispanic whites were diagnosed

with Diabetes Mellitus (Centers for Disease Control and Prevention, 2011). Sufficient data were not available to determine the ratio of diagnosed to undiagnosed cases of Diabetes Mellitus for all minority groups. When compared to non-Hispanic white adults, the minority groups were at increased risk of developing Diabetes Mellitus by 77% among non-Hispanic blacks, 66% in Hispanics, and 18% in Asian Americans (Centers for Disease Control and Prevention, 2011). Signorello et al. (2007) noted that while there are many reasons that have been stated for racial disparities in Diabetes Mellitus prevalence including environmental, socioeconomic, physiological, and genetic contributors, scientific evidence does not support race alone as a risk factor. They concluded that analyses of 34,331 African American and 9,491 Caucasian adults suggested differences in Diabetes Mellitus prevalence between African Americans and Caucasians may simply reflect differences in socioeconomic status (Signorello et al., 2007).

The cost of Diabetes Mellitus care is expensive and a strain on the United States health care system, and is expected to add more of a strain to an already overburdened health care system (Huang, Basu, O'Grady, & Capretta, 2009). The total estimated cost of Diabetes Mellitus in the United States in 2007 was 174 billion dollars (Centers for Disease Control and Prevention, 2011). Health care costs of treating Diabetes Mellitus are expected to at least double in the next 25 years to an annual spending rate of approximately 336 billion dollars (in constant 2007 U.S. dollars) (Huang et al., 2009).

Mississippi Prevalence of Diabetes Mellitus

Mississippi has a high prevalence of Diabetes Mellitus (Figure 2). Of the 2,844,658 Mississippi residents, approximately 11.6% (206,000 Mississippians) have

been diagnosed with Diabetes Mellitus (Kaiser Family Foundation, 2011).

Approximately 9.7 in 100 people in Mississippi have Diabetes Mellitus (Kaiser Family Foundation, 2011). The largest age group of Mississippians diagnosed with Diabetes Mellitus is between the ages of 45 and 64 years, with approximately 90,000 confirmed cases. Mississippians aged 65 and older account for approximately 74,000 cases of Diabetes Mellitus. Diabetes Mellitus is beginning to affect younger generations, with 41,000 people under the age of 44 years having Diabetes Mellitus in Mississippi (Kaiser Family Foundation, 2011).

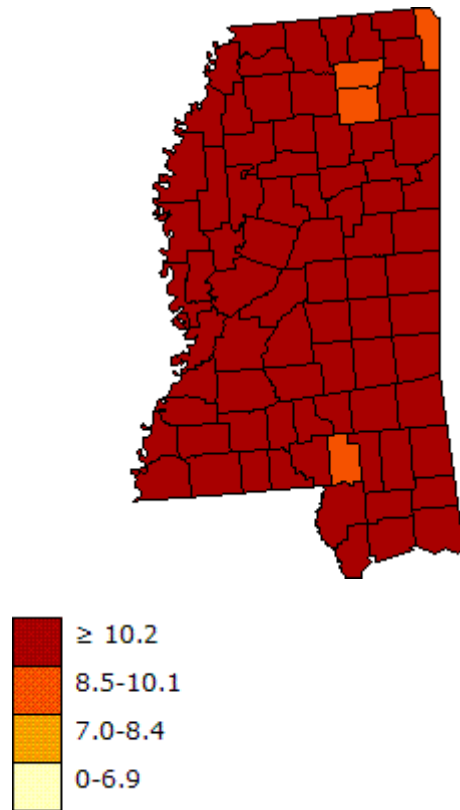


Figure 2. Percentage Estimates of Adults Diagnosed with Diabetes Mellitus in Mississippi.

Source: Centers for Disease Control and Prevention, 2008b.

Diabetes Mellitus was the seventh leading cause of death among Americans in 2007 (Centers for Disease Control and Prevention, 2011). In Mississippi, approximately 21.8 deaths per 100,000 were related to diabetic complications in Mississippi in 2007, and the incidence of death of the African American population was 38.2 per 100,000 as compared to 15.4 for the Caucasian population (Kaiser Family Foundation, 2011). The risk of dying from a diabetic complication is twice as likely when compared to a healthy individual of the same age that does not have Diabetes Mellitus (Centers for Disease Control and Prevention, 2011). Signorello et al. (2007) stated that African American adults are 50 to 100% more likely to have Diabetes Mellitus than Caucasians.

In Mississippi, only four of the 82 counties reported a 10 percent or less prevalence of Diabetes Mellitus (Centers for Disease Control and Prevention, 2008a). Specifically in Webster County, Mississippi, which has a population of 9,887 people, 11.1% of its residents are living with Diabetes Mellitus (Mississippi State Department of Health, 2007). Diabetes Mellitus has been shown to affect the non-Caucasian population more severely, causing 55.2 deaths per 100,000 as compared to 12 per 100,000 in the Caucasian population in Webster County (Mississippi State Department of Health, 2007). It is evident that Mississippi is experiencing an epidemic in Diabetes Mellitus. Aggressive forms of treatment and prevention are needed throughout the state due to this rising number of diabetic cases both diagnosed and undiagnosed.

Diabetes Mellitus

Diabetes Mellitus is a group of metabolic diseases characterized by a defect in insulin secretion and/or insulin action (American Diabetes Association, 2011a). Diabetes

Mellitus is manifested as Type 1 Diabetes Mellitus, Type 2 Diabetes Mellitus, or Gestational Diabetes Mellitus occurring during pregnancy. Type 2 Diabetes Mellitus is much more common than Type 1 or Gestational and accounts for 90 to 95 percent of all diagnosed cases (Franz, 2008). The focus of this thesis is on Type 2 Diabetes Mellitus.

Diabetes Mellitus affects how the body uses blood glucose, commonly known as blood sugar; the body is unable to metabolize glucose properly (Franz, 2008). Glucose is vital to a person's health as one of the most important sources of energy used by muscle cells and other tissues, and glucose is the brain's main source of fuel (American Diabetes Association, 2011a). A person diagnosed with Diabetes Mellitus, regardless of the type, indicates there is too much glucose in the bloodstream and it is not being delivered into the cells properly.

Glucose comes from the food we eat and is also naturally produced in the liver. The liver acts as a glucose storage and manufacturing center when there is a lack of food being ingested (American Diabetes Association, 2011a). During digestion and absorption, glucose is absorbed into the bloodstream and glucose is able to enter the cells with the aid of insulin. Specialized endocrine cells in the pancreas, the Islets of Langerhans, produce hormones; the alpha cells produce glucagon, and the beta cells produce insulin which decreases glucose levels in the blood. When a person eats, the pancreas secretes the hormone insulin and it circulates throughout the bloodstream. Insulin acts like a key which unlocks the doors to the cells that allow glucose to enter into the cells, and lowers the amount of glucose in the bloodstream.

In most cases, Type 2 Diabetes Mellitus results from progressive defection in insulin secretion that is coupled with insulin resistance and beta cell failure. The extent to

which insulin resistance and beta cell failure contribute to the development of Diabetes Mellitus is still unclear (Franz, 2008). The cells of the body become resistant to the action of insulin, and the pancreas is unable to produce enough insulin to overcome this resistance. Glucose builds up in the bloodstream leading to hyperglycemia. While endogenous insulin levels may be normal, depressed insulin levels are not able to adequately overcome the insulin resistance of the cells (Franz, 2008). Increased hepatic glucose production coupled with diminished glucose uptake and utilization, results in insulin resistance occurring mainly in muscle, liver, and adipose cells (Chan & Abrahamson, 2003).

Experimental evidence suggests that insulin resistance may be due to the compromised synthesis or mobilization of the cells' glucose transporters (Garvey et al., 1991). Insulin resistance in the cells of skeletal muscle is caused by a reduction in glucose transporter activity, specifically the failure of the vesicles to translocate the response to insulin (Garvey et al., 1991). This can be thought of as a short circuit in the insulin signal that typically initiates the glucose uptake process (Garvey et al., 1991). Due to the defect of the binding insulin receptors, there is a decrease in the number of insulin receptors, which reduces the action of the insulin receptors and decreases the uptake of glucose (Franz, 2008). In the beginning stages of the disease, there are compensatory increases in insulin secretion which aids in maintaining normal glucose concentrations but with disease progression, insulin production gradually decreases (Franz, 2008).

Hyperglycemia first exhibits signs of being elevated in the post-prandial (after meal) blood glucose, which is caused by a resistance to insulin at the cellular level and then is followed by an elevation of fasting glucose concentrations (Franz, 2008). As the

disease progresses, insulin secretion decreases and the hepatic glucose production increases, which cause elevated pre-prandial blood glucose levels prior to a meal (Franz, 2008).

Insulin resistance also occurs at the adipocyte level which leads to an increased number of free fatty acids (Bergman & Adler, 2000). There is a depletion of mRNA encoding the GLUT 4 transporter which results in a depletion of intracellular stores of protein (Garvey et al., 1991). Protein synthesis is interfered with in the translocation process leading to an inadequate number of surface receptors to uptake insulin, which leads to lipolysis and an elevation in free circulating free fatty acids (Bergman & Adler, 2000). When there is an excess accumulation of visceral fat, intrabdominal obesity occurs around the abdominal organs and leads to an increased flux of free fatty acids to the liver, and insulin resistance (Bergman & Adler, 2000). Due to an increased number of fatty acids, this can lead to a further decrease in insulin secretion and hepatic glucose production known as lipotoxicity (Bergman & Adler, 2000). Obesity leads to insulin resistance by reducing the GLUT 4 mRNA, which results in a decrease in the de nova synthesis of the transporter (Garvey et al., 1991). The extent of mRNA suppression is directly related to increased adiposity (Garvey et al., 1991).

Diagnosis of Diabetes Mellitus

Diagnosis of Diabetes Mellitus is based on blood glucose levels, which can be measured by several tests. A fasting plasma glucose test measures the blood glucose of a person who has fasted for at least eight hours; if the blood glucose level meets or exceeds 126 ml/dL on at least two separate occasions, then the diagnosis of Diabetes Mellitus is

made (Franz, 2008). This is the preferred test for diagnosing Diabetes Mellitus as it is easy and cost efficient (Franz, 2008).

An oral glucose tolerance test measures the blood glucose levels of a person fasting for at least eight hours. Blood glucose is measured two hours after consuming a glucose-containing beverage. If the blood glucose level meets or exceeds 200 ml/dL, Diabetes Mellitus is diagnosed (Franz, 2008). A random plasma glucose test measures the blood glucose at any point during the day; if the blood glucose is 200 ml/dL or greater, along with an assessment of diabetic symptoms such as excessive thirst (polydipsia), frequent urination, weight loss, or excessive food intake/hunger (polyphagia), this indicates a diagnosis of Diabetes Mellitus (Franz, 2008).

Any of these tests can suggest Diabetes Mellitus, but a positive test must be confirmed by performing a second test on a later date (Franz, 2008). The American Diabetes Association accepted the use of HbA1c as a diagnosis for Diabetes Mellitus in 2010 (American Diabetes Association, 2011b). When an HbA1c value, that is performed in a laboratory certified by the National Glycohemoglobin Standardization Program, is 6.5% or greater, this indicates a diagnosis of Diabetes Mellitus (American Diabetes Association, 2011b).

Hemoglobin A1c

Hemoglobin is a protein that links with sugar molecules inside red blood cells. The HbA1c blood test reflects the blood glucose concentration over the life span of red blood cells, which is approximately 120 days. The measure of HbA1c reflects a weighted average of plasma glucose concentrations of red blood cells. This is expressed as a

percentage of total hemoglobin with glucose (American Diabetes Association, 2006). When Diabetes Mellitus is uncontrolled, too much glucose is in the bloodstream and is reflected by abnormally high HbA1c levels.

The normal HbA1c for people without Diabetes Mellitus is four to six percent (Franz, 2008). Each one percent increase in HbA1c reflects an average increase of approximately 30mg/dL in blood glucose (Table 1). Higher glycated hemoglobin correlates with higher levels of glucose in the blood (American Diabetes Association, 2006). Elevated HbA1c levels indicate that blood glucose levels have been above normal over a period of weeks or months. It is important for people with Diabetes Mellitus to maintain HbA1c levels below seven percent to reduce the risk of complications associated with Diabetes Mellitus such as eye disease, heart disease, kidney disease, nerve damage and stroke (American Diabetes Association, 2006). Fasting blood glucose levels should not exceed 130 mg/dL and the goal for post-prandial blood glucose is less than 180 mg/dL (Table 2) (American Diabetes Association, 2007b).

Table 1. HbA1c Levels and Corresponding Mean Blood Glucose Levels

HbA1c (%)	Mean Blood Glucose (mg/dL)
5.0	100
6.0	120
7.0	150
8.0	180
9.0	210
10.0	240
11.0	270

Source: Franz, 2008.

Table 2. Recommendations for Glycemic Control for Adults with Diabetes Mellitus

Glucose Control	Normal Values
HbA1c	< 7.0%
Pre-prandial plasma glucose	90 – 130 mg/dL
Post-prandial plasma glucose	< 180 mg/dL

Source: American Diabetes Association, 2007b.

Risk Factors for Diabetes Mellitus

Type 2 Diabetes Mellitus has distinguishing characteristics that make some people more at risk for developing Diabetes Mellitus compared to other people. A person with a history of impaired fasting glucose or impaired glucose tolerance has an increased risk of developing Type 2 Diabetes Mellitus (Escott-Stump, 2008).

Age and Gender

Most people, male and female, are over the age of 45 when they develop Type 2 Diabetes Mellitus, although it is now occurring frequently in young adults and even in children (Escott-Stump, 2008). This may be attributed to the fact that as one ages, there is a tendency to exercise less, lose muscle mass, and gain weight (American Diabetes Association, 2011a). A family history that includes parents or siblings with Diabetes Mellitus will increase a person's likelihood of developing Type 2 Diabetes Mellitus (Escott-Stump, 2008).

Overweight and Obesity

An increase in adipose tissue results in cells becoming more resistant to insulin (American Diabetes Association, 2011a). People that are classified as overweight with a BMI of at least 25.0 kg/m² but less than 30.0 kg/m², or obese with a BMI of 30.0 kg/m² or higher, are at greater risk for developing Type 2 Diabetes Mellitus (Escott-Stump, 2008). Physical activity helps control body weight, uses glucose as energy, and makes the cells more sensitive to insulin; thus, inactivity may lead to Diabetes Mellitus (American Diabetes Association, 2011a). A high-density lipoprotein (HDL) cholesterol value of less than 35 mg/dL, a low-density lipoprotein (LDL) value greater than 100 mg/dL, a triglyceride level greater than 250 mg/dL, and hypertensive blood pressure of 140/90 mm Hg or higher are all associated with an increased risk for developing Type 2 Diabetes Mellitus (Table 3) (Escott-Stump, 2008).

Table 3. Recommendations for Lipid and Blood Pressure Levels for Adults with Diabetes Mellitus

High-Density Lipoprotein Cholesterol	> 35 mg/dl
Low-Density Lipoprotein Cholesterol	< 100 mg/dl
Triglycerides	< 250 mg/dl
Blood Pressure	< 140/90 mm Hg

Source: American Diabetes Association, 2007b.

Racial/Ethnic Minorities

It is unclear why certain racial/ethnic groups (African Americans, Hispanic Americans, Native Americans, Asian Americans, and Pacific Islanders) historically are at a higher risk for developing Type 2 Diabetes Mellitus compared to Caucasians (Escott-Stump, 2008). Signorello et al. (2007) suggested that differences in racial/ethnic prevalence of diabetes may occur due to differences in socioeconomic status.

Gestational Diabetes Mellitus

Women that experienced Gestational Diabetes Mellitus during pregnancy or delivered a baby weighing greater than nine pounds have an increased likelihood of developing Type 2 Diabetes Mellitus later in life (Escott-Stump, 2008).

Complications of Diabetes Mellitus

Uncontrolled or untreated Diabetes Mellitus will affect every organ system within the body and may lead to damaging complications such as blindness, kidney damage, heart disease, hypertension, and limb amputations. Long-term complications of poorly managed Diabetes Mellitus include macrovascular diseases, which are diseases of the

large blood vessels, and microvascular diseases that involve the small blood vessels causing nephropathy and retinopathy. Diabetes Mellitus is the leading cause of kidney disease and new cases of blindness among adults aged 20 to 74 years (Centers for Disease Control and Prevention, 2011). Data from 2004 indicated that heart disease was reported in 68 percent of all Diabetes Mellitus-related deaths in people over the age of 65 years, and stroke was the major cause of death for people over 65 years of age with Diabetes Mellitus (Centers for Disease Control and Prevention, 2011).

Approximately 67 percent of people with Diabetes Mellitus have hypertension with blood pressure values that equals or exceeds 140/90 mm Hg (Centers for Disease Control and Prevention, 2011). The treatment for hypertension in persons with Diabetes Mellitus should be proactive to reduce the risk of macrovascular and microvascular complications. Being hypertensive can decrease insulin release which will lead to higher blood glucose levels (Franz et al., 2002). If intense medical nutrition therapy for three months does not reduce the systolic and diastolic blood pressures, then pharmacologic agents should be implemented (American Diabetes Association, 2006).

Controlling blood pressure can reduce the risk of heart disease and stroke by 33 to 50 percent, and reduce microvascular disease by 33 percent (Escott-Stump, 2008). For every 10-mm Hg decrease in systolic blood pressure, the risk for any complication related to Diabetes Mellitus is reduced by 12 percent (Escott-Stump, 2008). However, there appears to be no benefit in reducing the systolic blood pressure below 140 mm Hg (Centers for Disease Control and Prevention, 2011). When the diastolic blood pressure is reduced from 90 to 80 mm Hg, this is associated with a 50 percent reduction in the risk of major cardiovascular events (Centers for Disease Control and Prevention, 2011).

More than 28 percent of people with Diabetes Mellitus over the age of 40 have diabetic retinopathy (Centers for Disease Control and Prevention, 2011). Advanced retinopathy may lead to severe loss of vision; there are 655,000 cases of retinopathy in people with Diabetes Mellitus (Centers for Disease Control and Prevention, 2011). There are approximately 12,000 to 24,000 new cases of blindness each year (American Diabetes Association, 2006). Optimal control of blood glucose and blood pressure can substantially reduce the risk and progression of diabetic retinopathy (American Diabetes Association, 2006). Of the people who have Type 2 Diabetes Mellitus for 20 years or more, approximately 60 percent of them have some degree of retinopathy (American Diabetes Association, 2006).

In the United States, diabetic nephropathy has become the most common cause of end-stage renal disease, and accounts for almost 40 percent of new cases of end-stage renal disease (American Diabetes Association, 2004). People with Type 2 Diabetes Mellitus comprise more than half of all people currently on renal dialysis (American Diabetes Association, 2004). In 2008, there were over 48,000 people with Diabetes Mellitus that began receiving treatment for end-stage renal disease (Centers for Disease Control and Prevention, 2011). Over 200,000 patients with Diabetes Mellitus in 2008 were either living with chronic kidney disease receiving dialysis or waiting for a kidney transplant (Centers for Disease Control and Prevention, 2011). When kidney disease is detected early, controlling blood pressure can reduce the decline in kidney function by 30 to 70 percent (Centers for Disease Control and Prevention, 2011).

The earliest evidence of nephropathy is the appearance of low urine albumin levels, or microalbuminuria. The onset of end-stage renal disease is typically about five

years after microalbuminuria is present in the urine (American Diabetes Association, 2006). Although diabetic nephropathy cannot be cured, strict glucose management and reduction in blood pressure will decrease the progression of nephropathy (American Diabetes Association, 2006).

Chronic high levels of blood glucose are associated with 60 to 70 percent of people with Diabetes Mellitus having nerve damage or neuropathy (Pastors, Warshaw, Daly, Franz, & Kulkarni, 2002). Peripheral neuropathy affects the nerves that control the feeling in the hands and feet. Autonomic neuropathy affects the nerve functioning that controls the organ systems (Franz, 2008).

Almost 30 percent of people with Diabetes Mellitus over the age of 40 years have impaired sensation in their feet (Centers for Disease Control and Prevention, 2011), which can lead to amputation of limbs. In 2006, there were over 65,000 non-traumatic lower-limb amputations in people with Diabetes Mellitus, which accounted for more than 60 percent of all lower-limb amputations (Centers for Disease Control and Prevention, 2011). Neuropathy may be delayed with strict blood glucose management (American Diabetes Association, 2006). Neuropathy is most common in obese patients, thus weight management or weight loss is beneficial to delay or prevent the effects of neuropathy (American Diabetes Association, 2006). Being aggressive in treatment and working with healthcare professionals to control levels of blood glucose, blood pressure, hypertension, blood lipids will help decrease complications of the disease.

United Kingdom Prospective Diabetes Study

The United Kingdom Prospective Diabetes Study Group (1998) was a trial that demonstrated a distinct link between strict glycemetic control and the development of diabetic complications. This study involved more than 5,000 people who were newly diagnosed with Type 2 Diabetes Mellitus and were followed for an average of 10 years. The participants in this study were randomly selected to be in one of two groups: intensive therapy or conventional therapy. The group that received intensive therapy reduced microvascular complications by 25 percent and macrovascular disease by 16 percent (United Kingdom Prospective Diabetes Study Group, 1998).

Nutrition therapy at diagnosis is very important for control of Diabetes Mellitus. Before the participants were randomized in the United Kingdom Prospective Diabetes Study Group (1998), each received individualized nutrition education for three months. During this time, the mean HbA1c dropped by 1.9 percentage points with a modest weight loss of eight pounds. It was concluded that the reduction in energy consumption was just as important in controlling blood glucose levels as the weight loss experienced by most of the participants (United Kingdom Prospective Diabetes Study Group, 1998).

Diabetes Mellitus is a progressive disease and therapy will need to be adjusted and intensified as the disease progresses. Medical nutrition therapy alone will not keep patients' HbA1c levels below seven percent as the disease progresses. It is not the diet that is failing; it is the pancreas' ability to secrete enough insulin to maintain adequate glucose control, and thus, oral medications and/or insulin are needed with strict dietary management (United Kingdom Prospective Diabetes Study Group, 1998). To best manage Diabetes Mellitus, therapies must include medical nutrition therapy, physical

activity, blood glucose monitoring, medications, and self-management education. The overall goal is to equip the person with tools, skills, and knowledge to best achieve glycemic, lipidemia, and blood pressure control to either prevent or delay the onset of microvascular and macrovascular disease complications (United Kingdom Prospective Diabetes Study Group, 1998).

Evidence of Medical Nutrition Therapy in Diabetes Management

The term “medical nutrition therapy” was coined in 1994 by the American Dietetic Association to better communicate the nutrition therapy process (Pastors et al., 2002). Medical nutrition therapy is used to assess the nutritional status of the person and effectively treat the person whether it is with nutrition therapy, counseling, or nutrition supplements (Pastors et al., 2002). When medical nutrition therapy is practiced in accordance with Diabetes Mellitus management, it has four processes:

1. Assessment of the patient’s nutrition and Diabetes Mellitus self-management knowledge and skills
2. Identification and negotiation of individually designed nutrition goals
3. Nutrition intervention involving a careful match of both a meal-planning approach and educational materials to meet the person’s needs, with flexibility in mind so the plan can be implemented by the person
4. Evaluation of outcomes and ongoing monitoring (Pastors et al., 2002)

Medical nutrition therapy plays an integral role in Diabetes Mellitus management. There is not one single diet that can be prescribed for all people with Diabetes Mellitus. In order for medical nutrition therapy to be effectively implemented, it must be a team

approach that includes a registered dietitian that is knowledgeable and skilled at implementing the recommendations and guidelines for Diabetes Mellitus management. When medical nutrition therapy is provided in combination with self-management training, it is associated with a one to two percentage point decrease in HbA1c levels in people with Type 2 Diabetes Mellitus (Lemon et al., 2004; Pastors et al., 2003). The effectiveness of the training will be known three months after HbA1c has been obtained; at that time the registered dietitian may need to assess whether the goals of the therapy will continue to be appropriate for the person. To evaluate the success of medical nutrition therapy, blood glucose monitoring, HbA1c, blood pressure, and lipid panels must all be evaluated.

The goal of medical nutrition therapy with people that have Type 2 Diabetes Mellitus is to achieve blood glucose, lipid, and blood pressure levels within normal limits to reduce the risks of vascular diseases. It is important to slow down, if not prevent, the development of chronic complications of Diabetes Mellitus by modifying food intake and lifestyle (American Diabetes Association, 2007b). Individual nutritional needs, lifestyle, cultural preferences, and willingness to change should be accounted for in a nutrition prescription for Diabetes Mellitus management (American Diabetes Association, 2007b). Food choices should only be limited based on evidence that the foods will increase blood glucose levels, but the overall goal should still be to maintain pleasurable eating. The basis of all nutritional recommendations as related to Diabetes Mellitus is to improve food choices but to continue pleasurable eating experiences (American Diabetes Association, 2007b).

Lemon et al. (2004) conducted a study that examined people with Type 2 Diabetes Mellitus that received nutrition education from a registered dietitian at baseline, and additional nutrition education sessions at the discretion of the dietitian. All subjects received face-to-face counseling according to the facility's policy. It was reported that weight, glycemic control, coronary heart disease risk, and self-management behaviors were all significantly improved from baseline to six months. During the six months, weight loss was 6.2 ± 14.6 pounds, HbA1c reduction was $1.7 \pm 2.0\%$, and reduction in risk of coronary heart disease was $3.5 \pm 6.1\%$ (Lemon et al., 2004).

Banister, Jastrow, Hodges, Loop, and Gillham (2004) composed a group of 70 adults with Type 2 Diabetes Mellitus to study the effect of community clinic education to lower HbA1c levels. The group attended a four-hour education class and attended Diabetes Mellitus support group meetings for at least two months and up to 12 months. The class education consisted of the: definition of Diabetes Mellitus, role of insulin, target ranges for blood glucose and HbA1c levels, symptoms of hypoglycemia and hyperglycemia, nutrition education, exercise, and foot care procedures. The results of the program indicated an average of a one percentage point drop in HbA1c levels in the participants (Banister et al., 2004).

Diabetes Mellitus and Diet

Carbohydrates

The preferred terms for carbohydrates include sugars, starch, and fiber (American Diabetes Association, 2007a). It may seem that a low-carbohydrate diet would be appropriate for managing Diabetes Mellitus but the American Diabetes Association

(2006) states that low-carbohydrate meal plans are not recommended in the management of Diabetes Mellitus. There are numerous factors that will influence a glycemic response to carbohydrates, including the amount of carbohydrates, types of sugars, nature of the starch, food processing, and the blood glucose level prior to consumption of carbohydrates (American Diabetes Association, 2007a). The priority for meal planning should be the total amount of carbohydrate that a person eats for meals and snacks. Carbohydrate counting is a commonly used method for meal planning with Diabetes Mellitus. Carbohydrates are the primary nutrient that affects the postprandial blood glucose and insulin levels. Carbohydrates are measured in grams and servings; one carbohydrate serving is approximately 15 grams of carbohydrate. Carbohydrate intake should comprise approximately 45 to 65 percent of the total daily energy intake (Franz, 2008).

Protein

Protein does not increase the plasma glucose concentration in people with controlled Diabetes Mellitus (American Diabetes Association, 2006). Protein should comprise 15 to 20 percent of daily energy intake of people with Diabetes Mellitus with normal renal function (Sargrad, Homko, Mozzoli, & Boden, 2005). When weight loss is needed, using a slightly higher recommendation of protein may help to enhance insulin sensitivity (Sargrad et al., 2005). High-protein diets are not recommended for people with Diabetes Mellitus (American Diabetes Association, 2006).

Dietary Fat

Due to lack of evidence, the goal of dietary fat consumption for people with Diabetes Mellitus should be the same recommendations as people with a history of cardiovascular disease (American Diabetes Association, 2007a). The total fat intake should not exceed 25 to 35 percent of the total energy consumed daily. The saturated fat intake should be less than seven percent and the intake of trans-fat should either be eliminated or minimized (American Diabetes Association, 2007a). Reducing the amount of fried and creamed foods that a person with Diabetes Mellitus consumes will help decrease the intake of saturated and trans-fat (Escott-Stump, 2008). To reduce total cholesterol and LDL-cholesterol levels, one should reduce the consumption of saturated and trans-fatty acids. Studies indicate that a high-monounsaturated-fat diet seems to have a favorable effect on fasting lipoprotein profiles in people with Diabetes Mellitus (Escott-Stump, 2008).

Alcohol

The same alcohol precautions that apply to the healthy population apply to people with Diabetes Mellitus. Daily alcohol consumption should be limited to one drink for women and two drinks for men. A moderate amount of alcohol consumption has a minimal effect on glucose and insulin levels (Howard, Arnsten, & Gourevitch, 2004). Each alcoholic drink contains approximately 15 grams of carbohydrates. Alcoholic beverages should be consumed as part of a regular meal plan for people with Diabetes Mellitus (American Diabetes Association, 2007a). Food should not be omitted when alcohol is consumed because it may induce alcohol hypoglycemia (Howard et al., 2004).

Alcohol does not require insulin to be present to be metabolized, which may lead to alcohol-induced hypoglycemia (Howard et al., 2004). Light to moderate alcohol consumption (one to two drinks per day) is associated with a decrease in the risk of coronary heart disease in people with Diabetes Mellitus because the alcohol increases HDL-cholesterol levels and improves insulin sensitivity (Howard et al., 2004).

Diabetes Mellitus and Physical Activity and Exercise

Physical activity is movement of the body produced by contraction of the skeletal muscles in which energy expenditure exceeds resting energy expenditure. Exercise is a component of physical activity in which the activity is planned, structured, and repeated to obtain physical fitness (Franz, 2008). Exercise and physical activity are beneficial in people with Type 2 Diabetes Mellitus and those that are insulin resistant (Boule, Haddad, Kenny, Wells, & Sigal, 2001). Regimens of exercise at 50 to 80 percent the maximum amount of oxygen that an individual can utilize during exercise for 30 to 60 minutes three to four times a week has been shown to lower HbA1c levels by one to two percentage points (Sigal, Kenny, Wasserman, Castaneda-Sceppa, & White, 2004).

Blood glucose control can improve with exercise due to a decrease in insulin resistance and an increase in insulin sensitivity in persons with Type 2 Diabetes Mellitus (Boule et al., 2001). This decreased resistance to insulin, and increased sensitivity to insulin, will result in increased peripheral use of glucose not only during exercise, but after exercise (Boule et al., 2001). As the muscles work, this causes insulin levels to decline during exercise while glucagon rises. Exercise enhances insulin sensitivity, which occurs independently of any effect on body weight, and decreases the effects of counter-

regulatory hormones, which in turn reduces the hepatic glucose output leading to improved glucose control (Boule et al., 2001). Exercise also effectively reduces triglyceride levels in people with Type 2 Diabetes Mellitus (Boule et al., 2001).

Over 30 percent of Mississippi residents are considered to be physically inactive (Centers for Disease Control and Prevention, 2008c). In Webster County, Mississippi, over 31 percent of its residents were reported to be physically inactive. With the high prevalence of Diabetes Mellitus in Webster County, physical activity may lead to better control of HbA1c levels. By being physically active, this can lead to weight loss and improved BMI levels.

Diabetes Mellitus and Obesity

Obesity and Diabetes Mellitus are two of the top public health problems in the United States (Figures 4 and 5) (Centers for Disease Control and Prevention, 2011). Both Diabetes Mellitus and obesity are major causes of morbidity and mortality in the United States (Mokdad et al., 2003). Evidence indicates that obesity and weight gain are associated with increased risk of Diabetes Mellitus, and intentional weight loss reduces the risk of developing Diabetes Mellitus (Mokdad et al., 2003). Overweight and obesity are determined by one's BMI (kg/m^2). An adult that has a BMI of 25.0 to 29.9 is considered overweight, and an adult that has a BMI of 30 or greater is classified as obese (National Heart, Lung, and Blood Institute, 1998). Over the past 20 years, the United States has suffered from a dramatic increase in obesity rates with only Colorado and the District of Columbia having obesity prevalence rates below 20 percent (Centers for Disease Control and Prevention, 2011). There are 33 states with obesity rates of more

than 25 percent, and nine states have greater than 30 percent of their population classified as obese (Centers for Disease Control and Prevention, 2011). Mississippi has a high prevalence of obesity and over 33 percent of adults in Mississippi are considered obese (Trust for America's Health, 2011).

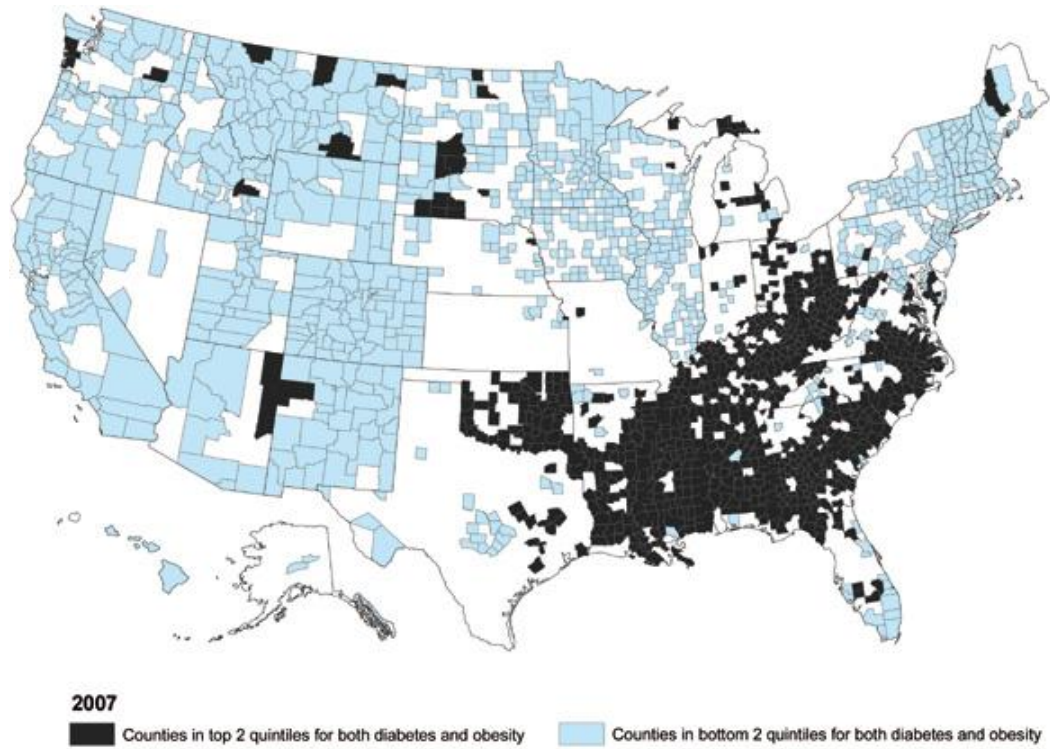


Figure 3. Prevalence Estimates of Obesity and Diabetes Mellitus in the United States.

Source: Centers for Disease Control and Prevention, 2007.

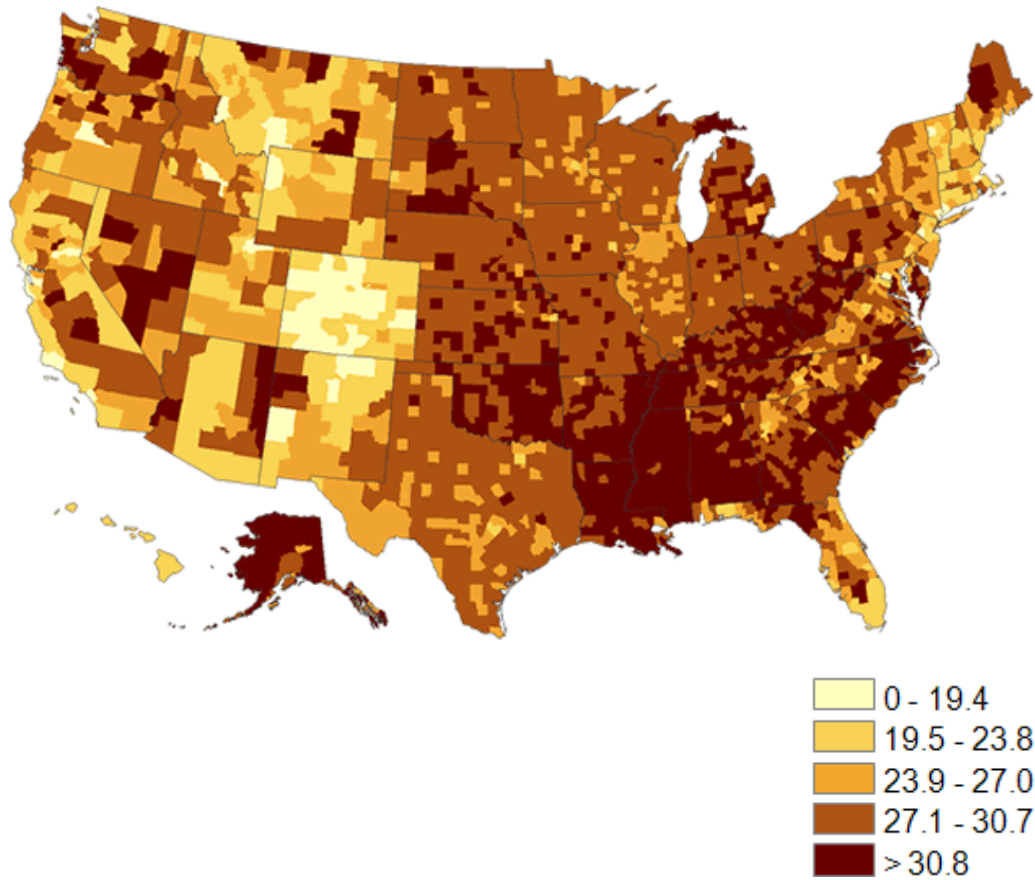


Figure 4. Percentage Estimates of Obesity in the United States.

Source: Centers for Disease Control and Prevention, 2008c.

From 1991 to 2001, there was a 74 percent increase in obesity and a corresponding 61 percent increase in persons diagnosed with Diabetes Mellitus (Mokdad et al., 2003). In 2001, 3.4% of adults in the United States were both obese and diagnosed with Diabetes Mellitus (Mokdad et al., 2003). There are at least 44 million adults (23 million women and 21 million men) classified as obese; and this number is often under-reported (Mokdad et al., 2003). Obesity is an epidemic that needs to be aggressively treated as it can lead to Type 2 Diabetes Mellitus and other serious medical conditions (Franz, 2008). Type 2 Diabetes Mellitus and obesity are often both preventable with

modest lifestyle changes (Mokdad et al., 2003). When changes are made such as increasing physical activity and eating a balanced diet, Diabetes Mellitus and obesity rates can be greatly reduced (Mokdad et al., 2003). Health professionals must continue to stress the importance of consuming a healthy, well balanced diet and regular physical activity as the best ways to promote weight loss (Mokdad et al., 2003).

There must be a team effort to effectively manage Diabetes Mellitus. The person with Diabetes Mellitus needs to be at the center of this relationship because they have the responsibility of managing their day-to-day activities. The nurses, doctors, dietitians, and pharmacists all contribute their knowledge to developing regimens that will help the person achieve metabolic control. The goal is to provide the person with knowledge, skills, and motivation to self-manage their Diabetes Mellitus. Individuals with Diabetes Mellitus should receive individualized medical nutrition therapy as needed to meet their treatment goals (American Diabetes Association, 2011b). In people who are insulin resistant, a modest weight loss of five to seven percent of their current weight has been shown to reduce insulin resistance (American Diabetes Association, 2011b). Medical nutrition therapy is an integral component of Diabetes Mellitus prevention and management. The American Diabetes Association recognizes nutrition as an essential component of Diabetes Mellitus self management and an overall healthy lifestyle (American Diabetes Association, 2011b).

CHAPTER III

METHODOLOGY

Purpose of Study

The purpose of this retrospective study was to investigate the effectiveness of the Diabetes Mellitus Education Class at NMMC-Eupora based on HbA1c levels among class participants. The BMI levels were also documented as this indicates obesity, and obesity is a contributing factor for the prevalence of Diabetes Mellitus. This study evaluated the effectiveness of Diabetes Mellitus education provided at NMMC-Eupora as evidenced by HbA1c levels at three months, six months, and 12 months after attending class. The BMI levels were recorded within one month prior to attending Diabetes Mellitus education class and again at three months, six months, and 12 months after attending class.

Hypotheses

H₀₁: There will not be a significant change in HbA1c levels among people attending Diabetes Mellitus Education Class at three months, six months, or 12 months post class attendance.

H₀₂: There will not be a significant change in BMI levels among people attending Diabetes Mellitus Education Class at three months, six months, or 12 months post class attendance.

H₁: There will be a significant change in HbA1c levels among people attending Diabetes Mellitus Education Class at three months, six months, or 12 months post class attendance.

H₂: There will be a significant change in BMI levels among people attending Diabetes Mellitus Education Class at three months, six months, or 12 months post class attendance.

Participants

The subjects for this study consisted of 46 people diagnosed with Type 2 Diabetes Mellitus who attended Diabetes Mellitus Education Class at NMMC-Eupora. All participants must be referred by their medical doctor to attend the education class. This facility is located at 70 Medical Plaza, Eupora, Mississippi. This study was conducted from participants that attended class between May 2008 and December 2009.

Procedure

The Diabetes Mellitus Education Class at NMMC-Eupora offers extensive Diabetes Mellitus education and personalized meal plans to people diagnosed with Diabetes Mellitus. This study focused exclusively on participants with Type 2 Diabetes Mellitus. The staff for the class consists of a Diabetes Nurse Educator and a Registered Dietitian. In order to provide Diabetes Mellitus education, the educators must have at least 15 hours of continuing education in Diabetes Mellitus. The class is under the direction of the medical staff at NMMC-Eupora. This is an 8-hour one day class that focuses on effectively managing Diabetes Mellitus. The class is conducted at NMMC-Eupora in the education facility. Teaching methods include power point lectures, food

models, and personal interaction. A summary of each class is sent to the participant's personal healthcare provider.

The Diabetes Mellitus Education Class is designed for people with newly diagnosed Diabetes Mellitus that would benefit from education on basic Diabetes Mellitus management. Diabetes Mellitus requires comprehensive education to be successfully managed. The Diabetes Mellitus Education Class provides information to allow participants to easily make adaptable changes to their current lifestyle. The class targets specific areas of Diabetes Mellitus management such as blood glucose monitoring and evaluation, recognizing and treating low blood glucose, sick day treatment, meal planning, and foot and eye care recommendations. A Registered Dietitian provides nutrition education and meal plans that are tailored to meet each person's nutritional needs within the guidelines provided by the American Heart Association, the American Dietetic Association, and the American Diabetes Association.

The class is conducted the third Wednesday of each month. In order for the class to meet, there must be at least two physician-referred participants in attendance. The class begins at 8:00 in the morning and lasts approximately eight hours. Class participation averages three to six members; this allows for each participant to receive individualized attention. Upon arrival each participant is asked to complete a 24-hour food recall stating portion sizes and the time of day that foods and beverages are consumed, and to also identify specific areas of nutrition they would like to gain additional knowledge. A pre-test is given by the Diabetes Nurse Educator to identify each participant's understanding of Diabetes Mellitus (Appendix A). Power point lectures consisting of nursing care, complications and sick days, physical activity, pharmacy and medication basics, and

stress/emotions are presented by the Diabetes Nurse Educator. Participants are encouraged to ask questions about any of the topics that are discussed, or other questions about managing Diabetes Mellitus.

Participants have their feet checked for peripheral neuropathy by the Diabetes Nurse Educator. People with uncontrolled Diabetes Mellitus may experience decreased feeling in their feet, which can lead to complications (Franz, 2008). Each participant receives education about the importance of foot care for people with Diabetes Mellitus.

The nurse works with each participant to establish a personalized self glucose monitoring schedule. Each participant is asked to closely monitor their blood glucose levels for a period of time after attending class. The Diabetes Nurse Educator discusses the post class blood glucose values with the participants; if blood glucose levels are not improving, medications are adjusted to aid in achieving blood glucose levels within normal limits. This continued education as provided by the nurse serves as reinforcement to what was taught in the Diabetes Mellitus Education Class.

The Registered Dietitian provides education related to healthy eating and carbohydrate counting. Power point presentations, food models, and group discussions are the teaching methods used by the Registered Dietitian. Copies of the presentations are provided to each participant to take home. Personalized meal plans are provided to the participants prior to discussing carbohydrate counting. Meal plans are developed taking into consideration each participant's gender, height, weight, and personal eating habits. The meal plan is divided into four sections (breakfast, lunch, supper, and snacks). Within each meal and snack there are serving size recommendations for proteins, carbohydrates (which include starch, fruit and milk) and fats. The Registered Dietitian explains in detail

how carbohydrates affect blood glucose levels. Limiting, but not excluding, carbohydrates from the diet is emphasized through portion control of foods containing carbohydrates.

Lunch is provided to each class participant and is served in the hospital cafeteria. All participants are encouraged to follow the new meal plans that have been provided to them by the Registered Dietitian. After the lunch meal, there is class discussion in which each participant identifies the carbohydrates, proteins, and fats that were consumed. The lunch meal is then compared to each individualized meal plan to determine if the participant was able to correctly follow the prescribed meal plan.

A post test is conducted at the end of the Diabetes Mellitus Education Class to determine if participants' knowledge of Diabetes Mellitus improved (Appendix A). Contact information for both the Diabetes Nurse Educator and Registered Dietitian are provided to each participant. Participants are encouraged to call the nurse and dietitian with questions they may have after attending Diabetes Mellitus Education Class.

Continued education is important in the management of Diabetes Mellitus. Participants are referred by their physicians for Diabetes Mellitus Education Class and the cost of this class is covered by most insurance agencies. Because the insurance company pays either the full or partial cost of attending the class, a participant can only attend the class as dictated by their health insurance. For most insurance companies, this means that a patient is allowed to attend Diabetes Mellitus Education Class no more than one time in a calendar year. The Diabetes Mellitus Education Class taught at NMMC-Eupora is recognized by the American Diabetes Association as meeting the standards for Diabetes Mellitus education. When a Diabetes Mellitus Education Class meets the

standards set forth by the national standards of Diabetes Mellitus Self Management Education and is recognized by the American Diabetes Association, the education class is reimbursable as part of Medicare programs (American Diabetes Association, 2011b). Additionally, when medical nutrition therapy for Diabetes Mellitus is delivered by a Registered Dietitian according to the nutrition practice guidelines, it is reimbursable as part of Medicare programs (American Diabetes Association, 2011b).

Institutional Review Board Approval

Project approval was obtained prior to starting this study from the Institutional Review Board (IRB) through the Mississippi State University (MSU) Regulatory Compliance Office, Mississippi State, Mississippi (Appendix B). The IRB of North Mississippi Health Services of Tupelo, Mississippi, also provided IRB approval for the study (Appendix C). Data collection was conducted at NMMC-Eupora in Eupora, Mississippi, which is affiliated with North Mississippi Health Services of Tupelo, Mississippi. Hospital policy requires IRB approval for all research studies including those that use information from medical records.

Data Collection

HbA1c values, weights, heights, age, gender, and race were entered onto an Excel spreadsheet (Microsoft Corp., 2007, Redmond, WA) using medical records of participants who attended Diabetes Education Class at NMMC-Eupora. Participants had follow-up visits where their HbA1c levels and weights were documented. Heights and weights were used to hand calculate BMI values using the equation $BMI = \text{kg}/\text{m}^2$. Weights and heights were converted to metric units (kilograms and meters) since the

weights and heights were recorded in the medical records as pounds and inches. The HbA1c blood values were collected and analyzed in the hospital's laboratory, and recorded in the individual's medical record at three months, six months, and 12 months after the individual attended class; however, sometimes participants did not return for all of their follow-up appointments.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences software, version 18.0 (SPSS, Inc., Chicago, IL). Baseline data for HbA1c and BMI levels were compared using paired *t*-tests for the three follow-up visits at three months, six months, and 12 months post class attendance. Correlation coefficients were examined to investigate relationships between HbA1c and BMI levels. This study was not able to track all participants who attended the Diabetes Mellitus Education Class due to some participants missing follow-up appointments. At least one blood HbA1c value and one BMI value were documented for each participant post class attendance. All available data were used for analysis. A control group was not available. Significance levels were set at $P \leq 0.05$. Continuous variables are reported as means \pm standard deviations (SD).

CHAPTER IV

RESULTS AND DISCUSSION

This retrospective study was conducted with the Diabetes Mellitus Education Class at NMMC-Eupora, Mississippi, to evaluate the effectiveness of Diabetes Mellitus education based on HbA1c levels of 46 participants. Results indicated significant differences ($P \leq 0.05$) in outcomes of HbA1c values at three months, six months, and 12 months post class attendance. This study indicated that the null hypothesis, there will not be a significant change in HbA1c levels among people attending Diabetes Mellitus Education Class at three months, six months, or 12 months post class attendance, can be rejected. There were no significant ($P > 0.05$) differences in outcomes of BMI values at three months, six months, or 12 months post class attendance. Therefore the null hypothesis, there will not be a significant change in BMI levels among people attending Diabetes Mellitus Education Class at three months, six months, or 12 months post class attendance, cannot be rejected.

There were 25 female and 21 male participants (Table 4). Most of the participants were Caucasians ($n = 29$) with 15 Caucasian women who had an age range of 29 to 71 years; Caucasian men ($n = 14$) had an age range of 36 to 84 years; African American women ($n = 10$) had an age range of 40 to 71 years, and the seven African American men had an age range of 32 to 60 years. The mean age of the participants was 54.8 years \pm

13.0 SD (Table 4). Only 3 participants were less than 40 years old, 15 were 40 to 49 years old, 11 were aged 50 to 59 years, and 17 were 60 years and older. The mean weight was 104.4 kg \pm 27.6 SD with a range of 61.8 to 194.5 kg. The height ranged from 152.4 to 198.1 cm with a mean of 168.9 cm \pm 10.8 SD. The mean BMI was 36.7 kg/m² which indicated obesity per BMI classification guidelines of the National Heart, Lung, and Blood Institute (1998). None of the participants were classified as underweight, three had normal BMI values, six were overweight, and 37 were classified as obese with BMI's ranging from 30.1 to 67.1 kg/m² (Table 5).

Table 4. Baseline Characteristics of Participants

Characteristic	Participants (N = 46)
Age (yrs)	54.8 \pm 13.0 (29 – 84) ^a
Weight (kg)	104.4 \pm 27.6 (61.8 – 194.5)
Height (cm)	168.9 \pm 10.8 (152.4 – 198.1)
BMI ^b (kg/m ²)	36.7 \pm 9.7 (22.9 – 67.1)
Gender	25 females 21 males
Race	17 African Americans 29 Caucasians

^aMean \pm standard deviation (range)

^bBody mass index

Table 5. Baseline Body Mass Index Classification of Participants

BMI ^a Category	Males (n=21)	Females (n=25)
Underweight (< 18.5)	0	0
Normal (18.5 – 24.9)	1 African American 1 Caucasian	1 Caucasian
Overweight (25.0 – 29.0)	3 Caucasians	2 African Americans 1 Caucasian
Obese (\geq 30.0)	6 African Americans 10 Caucasians	8 African Americans 13 Caucasians

^aBody mass index, calculated as kg/m²

The HbA1c concentrations allow those in the medical profession to determine if a person is controlling their Diabetes Mellitus. The HbA1c concentration provides a definitive assessment as it measures the overall effectiveness of blood glucose control during an average 3-month period. The HbA1c values for people with Diabetes Mellitus should be less than seven percent (American Diabetes Association, 2007b). The results from this study indicated that the mean HbA1c level at baseline was elevated at 9.5% \pm 2.4 (N = 46). The mean HbA1c level at three months was 8.1% \pm 2.1 and was significantly lower compared to the baseline HbA1c ($P = 0.002$, n = 31). The six-month HbA1c value was also significantly lower compared to the baseline HbA1c value and was 8.1% \pm 2.6 ($P = 0.001$, n = 39). The 12-month HbA1c value, as compared to the baseline HbA1c level, was lower at 8.7% \pm 2.3 ($P = 0.050$, n = 29) (Table 5). Although the three-month, six-month, and 12-month HbA1c levels were lower compared to the baseline level ($P \leq 0.05$), these levels were still higher than the recommended level of less than seven percent for people with Diabetes Mellitus.

Although the mean HbA1c level increased from 8.1% at six months to 8.7% at 12 months, it was not a significant increase ($P > 0.05$) (Table 6). Figure 5 presents a time series of the participants' HbA1c levels. It clearly shows a decrease ($P < 0.05$) in HbA1c levels from baseline to three months, and then there is a non-significant increase ($P > 0.05$) from six to 12 months (Figure 5). Brown (1992) reported similar results from a meta-analysis of Diabetes Mellitus education. Individuals with Diabetes Mellitus received education about Diabetes Mellitus self-management skills including weight loss and healthy HbA1c levels; results indicated that HbA1c levels improved between one and six months post education but after six months, the HbA1c levels started to rise. Length of the educational intervention did not appear to affect the outcome (Brown, 1992).

A meta-analysis with 18 randomized controlled trials that evaluated educational and behavioral interventions in participants ($n = 2720$) with Type 2 Diabetes Mellitus with a mean age of 57 years, and follow-up from one to 26 months, reported a reduction in HbA1c of 0.43% ($P = 0.003$) (Gary, Genkinger, Guallar, Peyrot, & Brancati, 2003). The investigators concluded that, "Previous educational and behavioral interventions in type 2 diabetes have produced modest improvements in glycemic control" (Gary et al., 2003, p.488). Results of the present study also showed improvement in glycemic control of the group of 46 participants after attending diabetes education.

Table 6. Mean Hemoglobin A1c (HbA1c) Values for Participants

	Baseline (N = 46)	3 months post class attendance (n = 31)	6 months post class attendance (n = 39)	12 months post class attendance (n = 29)
HbA1c (%)	9.5 ^a	8.1 ^b	8.1 ^b	8.7 ^b

^{ab}Means in a row with different letters are significantly different ($P \leq 0.05$)

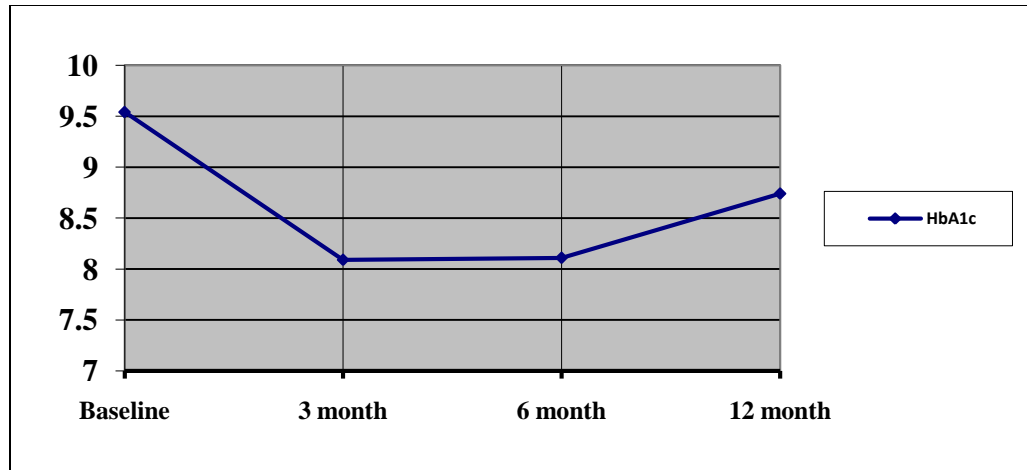


Figure 5. Mean Hemoglobin A1c (HbA1c) Values of Participants from Baseline to 12 months.

The decrease of HbA1c values observed in the present study are similar to results reported by Bannister et al. (2004) who conducted a four-hour Diabetes Mellitus education class to participants (N = 70) followed by individual dietitian consultations and monthly support meetings. After two to 12 months of class participation, they reported a mean HbA1c decrease of 15%, from $9.7\% \pm 2.6$ to $8.2\% \pm 2.0$ (Bannister et al., 2004), which is similar to the 14.7% decrease in HbA1c observed in the present study, from $9.5\% \pm 2.4$ at three months, and $8.1\% \pm 2.6$ at six months. Pastors et al. (2002) review of the United Kingdom Prospective Diabetes Study reported a decrease in HbA1c from approximately 9 to 7% within the first few months in newly diagnosed people with Type 2 Diabetes Mellitus. There was a decrease from 9.5 to 8.1% in the first three months in the present study (Table 6).

Lemon et al. (2004) conducted a study in which HbA1c levels and weight were measured at baseline, three months, and six months. Over the six-month period, there was a weight loss of 6.2 ± 14.6 pounds and a reduction in HbA1c level of $1.7\% \pm 2.0$ (Lemon

et al., 2004). While Lemon et al. (2004) did not report BMI values, a decrease in weight is associated with a decrease in BMI. The present study conducted at NMMC-Eupora revealed non-significant ($P > 0.05$) increases in BMI levels at three months and six months compared to baseline (Table 7). It was only at 12 months that a decrease in BMI was observed; however, it was not a significant decrease ($P > 0.05$) (Table 7). Figure 7 shows the mean BMI value rise from baseline to three months ($P > 0.05$) and then fall from three months to six and 12 months ($P > 0.05$).

Table 7. Mean Body Mass Index Values of Participants

	Baseline (N = 46)	3-months post class attendance (n = 29)	6-months post class attendance (n = 37)	12-months post class attendance (n = 27)
BMI ^a (kg/m ²)	36.7	39.0 ^{ns}	37.2 ^{ns}	36.4 ^{ns}

^aBody Mass Index

^{ns}Not significant, means were not significantly different from one another ($P > 0.05$)

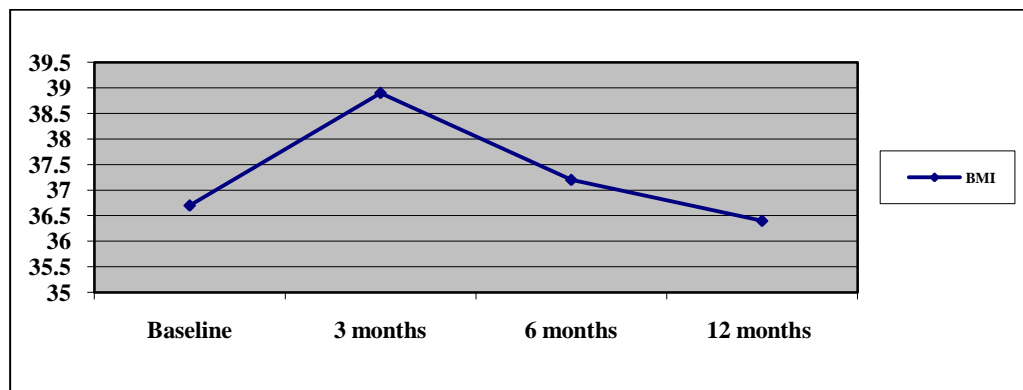


Figure 6. Mean Body Mass Index (BMI) Values of Participants from Baseline to 12 months.

Just over three percent of the United States adult population has been diagnosed with Diabetes Mellitus and classified as obese (Mokdad et al., 2003). In the current study, the mean BMI at baseline for this group of people with Diabetes Mellitus was $36.7 \text{ kg/m}^2 \pm 9.7$ ($N = 46$), which indicated obesity, as did all mean BMI values (Table 7). The three-month BMI was $39.0 \text{ kg/m}^2 \pm 10.4$ ($P = 0.406$, $n = 29$), and the six-month BMI was $37.2 \text{ kg/m}^2 \pm 10.4$ ($P = 0.488$, $n = 37$). The 12-month mean BMI was lower at $36.4 \text{ kg/m}^2 \pm 8.5$, but it was not significant ($P = 0.449$, $n = 27$). None of the values were considered significant at $P > 0.05$ (Table 7).

The BMI levels at three months, six months, and 12 months were not significantly correlated with baseline or other HbA1c values ($P \leq 0.05$). The mean BMI increased just over two points from the baseline BMI to the three-month BMI. From baseline to the six-month BMI, there was half a point increase in the BMI level among participants. It should be noted that only at 12 months post class attendance was there a non-significant ($P > 0.05$) decrease in BMI and this decrease was only three-tenths of a point (Figure 8).

Mississippi has the highest prevalence of obesity in the United States (Trust for America's Health, 2011). The adult obesity rate is 33.8% for the state of Mississippi, and women are the most obese gender in the state with 34.9% falling into this classification (Trust for America's Health, 2011). Among ethnic populations, 42.9% of African Americans and 29.3% of Caucasians are considered obese in Mississippi (Trust for America's Health, 2011). In this study, 43 participants (93.5%) were classified as overweight or obese. Two African Americans were classified as overweight and 14 (30.4%) were obese, as compared to four Caucasians who were overweight and 23

(50.0%) were obese (Table 5). However, all participants in the study were diagnosed with Type 2 Diabetes Mellitus, which is associated with obesity (Escott-Stump, 2008).

It is certainly not the goal of the educators that teach the Diabetes Mellitus Education Class to see an increase in BMI levels. A consensus algorithm determined when oral medications or insulin therapy is initiated in the treatment of Diabetes Mellitus, an association can be made with weight gain in the initial phases of the therapy (Nathan et al., 2009). Numerous Diabetes Mellitus medications, specifically sulfonylureas, thiazolidinediones, and insulin, are associated with weight gain upon initiation (Nathan et al., 2009). A weight gain of approximately two kilograms is associated with the initiation of sulfonylurea therapy and a two- to four-kilogram weight gain upon initiation of insulin therapy (Nathan et al., 2009). Medications are essential in the management of Diabetes Mellitus even if weight gain is an initial side effect. Working with the class participants to achieve a healthy BMI may help manage Diabetes Mellitus more effectively.

Guo, Zeller, Chumlea, and Siervogel (1999) determined that BMI significantly increases with age. Generally there is an age-related increase in BMI for both men and women from the age of 40 to 65 years (Guo et al., 1999). Although there were no significant correlations between gender, HbA1c values, or BMI ($P > 0.05$), there was a significant negative correlation between age and BMI ($r = - 0.355$, $P = 0.016$, $N = 46$) in the current study. However, while only three (6.5%) of the participants were less than 40 years old, 13 participants (28.3%) were older than 65 years in the current study.

Diabetes Mellitus is common, chronic, and controllable. Good management of Diabetes Mellitus depends on the person's discipline to manage this lifelong disease. Good Diabetes Mellitus management is evidenced by HbA1c levels below seven percent.

Type 2 Diabetes Mellitus is managed through healthy food choices, physical activity, maintaining a healthy weight, and taking medication(s) as prescribed. The treatment for Type 2 Diabetes Mellitus may change over a lifetime. Diabetes Mellitus management will always include continued education, healthy eating, blood glucose monitoring, and physical activity no matter the person's age or duration of Diabetes Mellitus. It is through HbA1c testing that a picture is painted of Diabetes Mellitus control. The HbA1c levels should be checked at least twice a year but good management of Diabetes Mellitus would indicate having an HbA1c checked every three months.

The Diabetes Mellitus Education Class at NMMC-Eupora provides detailed education in all areas of Diabetes Mellitus management. Healthy eating is paramount in the management of Type 2 Diabetes Mellitus. By working with a Registered Dietitian, a proper meal plan can lead to better control as evidenced by HbA1c levels within normal ranges, and may even lead to better weight management. Choosing healthy foods can help keep blood glucose levels within the target range. The Centers for Disease Control and Prevention (2011) reported that 16 percent of adults diagnosed with Type 2 Diabetes Mellitus manage their Diabetes Mellitus through nutrition intake. When a diet is high in fat, this usually leads to weight gain which may result in increased risk of a heart attack and Diabetes Mellitus. By having a modest weight loss, this can lead to major gains in health. Even with a small amount of weight loss, this may lead to lower blood glucose and HbA1c levels. Regular physical activity can help people with Type 2 Diabetes Mellitus lose weight, lower the risk of heart disease, possibly reduce the use of medication, and increase overall health and well being (American Diabetes Association, 2011b).

Participants that attended Diabetes Mellitus Education Class at NMMC-Eupora did not receive education about weight loss. Each participant was provided with a personalized meal plan that indicated a caloric restriction, which was intended for the person to lose weight. Each participant was encouraged to make healthy food choices that included many low-fat food choices. Participants were encouraged to consume fruits and vegetables as part of a healthy meal plan because fruits and vegetables provide fiber and healthy nutrients. Instead of choosing to eat a pastry or other high-calorie snacks that may be within the person's allowed carbohydrate intake, the participants were taught benefits of choosing low-calorie snacks to improve eating habits. These healthy eating tips were not presented as dieting or promoting weight loss, but were incorporated into the person's overall healthful eating plan.

Complications that stem from Diabetes Mellitus were also discussed in the class. Both short- and long-term complications, if not managed properly, can lead to difficulty in managing Diabetes Mellitus. By working together, people with Diabetes Mellitus and their support network can reduce the occurrence of complications resulting from poorly managed Diabetes Mellitus. Nutrition, physical activity, oral medications, and insulin are key tools in the management of Diabetes Mellitus. When oral medications and/or insulin are taken appropriately, it will typically result in better control of Diabetes Mellitus and lowering HbA1c levels. HbA1c is the best test to determine tight control of Diabetes Mellitus. This is a key indicator to a medical professional if the Diabetes Mellitus management tools that were taught during the Diabetes Mellitus Education class are being followed. Continued education is a key ingredient to maintaining or achieving HbA1c levels within normal limits.

CHAPTER V

CONCLUSION

The number of people with Diabetes Mellitus in the United States is increasing and is predicted to continue to increase within the next few decades. Adults over the age of 65 are the largest age group of people diagnosed with Diabetes Mellitus in 2010 (Centers for Disease Control and Prevention, 2011). With the number of cases of Diabetes Mellitus expected to increase by 165% by the year 2050 in the United States (Diabetes Foundation of Mississippi, 2010), it is important to deliver programs that help people with Diabetes Mellitus effectively manage their disease, especially in Mississippi which has a high prevalence of Diabetes Mellitus.

The parameters of the this study established that not all participants were consistent in having their HbA1c checked every three months, although the importance of this was discussed while attending the Diabetes Mellitus Education Class. Having HbA1c levels checked every three months, trends are easier to follow and changes and adjustments to the meal plan and/or medications can be made, which can lead to better control of Diabetes Mellitus. All medical professionals need to encourage people with Diabetes Mellitus to have their HbA1c checked on a routine basis (American Diabetes Association, 2011b).

This study determined that after participants attended the Diabetes Mellitus Education Class, their HbA1c levels were reduced at three months, six months, and 12 months. Although the HbA1c levels remained above the American Diabetes Association recommendation of seven percent or below; there was a significant decrease ($P \leq 0.05$) in HbA1c levels at three months, six months, and 12 months compared to baseline. By attending the Diabetes Mellitus Education Class at NMMC-Eupora, participants and caregivers were provided education about the basics of Diabetes Mellitus management. When food and medication(s) are consumed correctly, this is typically associated with improved HbA1c levels (Franz, 2008). This class provides each person with the tools they need to effectively manage their Diabetes Mellitus whether they are healthy, exercising, or sick.

To improve the Diabetes Mellitus Education Class at NMMC–Eupora, there should be a focus on weight loss. People with Type 2 Diabetes Mellitus can usually benefit from a modest weight loss of five to seven percent of their current weight (American Diabetes Association, 2011b). This small weight loss may lead to the cells being more sensitive to insulin which will lead to overall better control of Diabetes Mellitus (American Diabetes Association, 2011b). Weight loss is recommended for overweight and obese individuals with Type 2 Diabetes Mellitus (American Diabetes Association, 2011b). The Diabetes Mellitus Education Class prepares the participants to manage Diabetes Mellitus through healthy food intake but is lacking in teaching the participants the importance of weight loss, and healthy benefits associated with weight loss.

Continued Diabetes Mellitus education is imperative for any person to successfully manage this disease (Pastors et al., 2003). Comprehensive Diabetes Mellitus education cannot be accomplished in one 8-hour class. Participants need continuous follow-up with the physicians, nurses and dietitians. This study supports the position of the American Diabetes Association (2007a) that nutrition education aids in lowering HbA1c levels. However, the results of this study cannot be generalized to other people with Diabetes Mellitus. There is a need for further research related to Diabetes Mellitus management and nutrition education.

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APPENDIX A

PRE- AND POST-TEST FOR DIABETES MELLITUS EDUCATION CLASS

NAME _____

1. Insulin helps the body
 - a. turn sugar into energy
 - b. get rid of sugar in the blood
 - c. store sugar in the blood
 - d. both a and b

2. Insulin is made in the
 - a. liver
 - b. stomach
 - c. kidneys
 - d. pancreas

3. Complications of diabetes include
 - a. kidney disease
 - b. eye problems
 - c. foot problems
 - d. all of the above

4. Diabetes pills
 - a. lower blood glucose
 - b. increase the release of insulin
 - c. fight insulin resistance
 - d. do all of the above

5. All patients with diabetes follow the same meal plan.
 - a. True
 - b. False

6. For avoidance of hypoglycemia, the best time to exercise is
 - a. anytime you are hungry
 - b. just before dinner
 - c. after meals
 - d. just before breakfast

7. Monitoring should be done more often...
 - a. on sick days
 - b. when traveling
 - c. when meal or exercise plans change
 - d. at all of the above times

8. Regular exercise may
 - a. lower blood glucose
 - b. reduce the amount of insulin needed
 - c. reduce the amount of diabetes pills needed
 - d. do all of the above

9. During illness you should stop taking your medications
 - a. True
 - b. False

10. Which of the following can affect blood sugar control?
 - a. stress
 - b. eating habits
 - c. exercise
 - d. all of the above

11. To decrease dietary fat and cholesterol, which food is the best choice?
 - a. steak
 - b. fried eggs
 - c. broiled chicken without skin
 - d. ham and cheese sandwich

- 12.** Which of the following is a symptom of hypoglycemia?
- a. weakness
 - b. sweating
 - c. shakiness
 - d. all of the above
- 13.** Which of the following foods is a low fat protein source?
- a. broiled flounder
 - b. Swiss cheese
 - c. Carrots
 - d. Saltines
- 14.** If alcohol is allowed, you should drink it
- a. on an empty stomach
 - b. along with food
- 15.** A good source of complex carbohydrates is
- a. eggs
 - b. mayonnaise
 - c. whole-grain bread
 - d. roast beef

APPENDIX B
INSTITUTIONAL REVIEW BOARD APPROVAL
FROM MISSISSIPPI STATE UNIVERSITY

February 18, 2011

Amy Farnsworth
140 Cedar Lane
Starkville, MS 39759

RE: IRB Study #11-046: Effectiveness of Diabetes Education for Managing Hemoglobin A1c Levels in Adults

Dear Ms. Farnsworth:

This email serves as official documentation that the above referenced project was reviewed and approved via administrative review on 2/18/2011 in accordance with 45 CFR 46.101(b)(4). Continuing review is not necessary for this project. However, any modification to the project must be reviewed and approved by the IRB prior to implementation. Any failure to adhere to the approved protocol could result in suspension or termination of your project. The IRB reserves the right, at anytime during the project period, to observe you and the additional researchers on this project.

Please note that the MSU IRB is in the process of seeking accreditation for our human subjects protection program. As a result of these efforts, you will likely notice many changes in the IRB's policies and procedures in the coming months. These changes will be posted online at <http://www.orc.msstate.edu/human/aahrpp.php>.

A signed formal approval letter will only be mailed at your request. Please refer to your IRB number (#11-046) when contacting our office regarding this application.

Thank you for your cooperation and good luck to you in conducting this research project. If you have questions or concerns, please contact me at cwilliams@research.msstate.edu or call 662-325-5220.

Sincerely,

Christine Williams, CIP
IRB Compliance Administrator

cc: Diane Tidwell (Advisor)

APPENDIX C
INSTITUTIONAL REVIEW BOARD APPROVAL FROM NORTH MISSISSIPPI
MEDICAL CENTER



NORTH MISSISSIPPI
HEALTH SERVICES
INSTITUTIONAL REVIEW BOARD

February 2, 2011

Amy Farnsworth
North Mississippi Medical Center - Eupora
70 Medical Plaza
Eupora, MS 39744

Dear Ms. Farnsworth:

The Institutional Review Board received the following:

- IRB submission
- Study description
- Data collection form
- Letter, dated December 2, 2010, from Eupora Hospital Administrator, granting permission to conduct study at Eupora facility

These items were received for the following project:

Title: Effectiveness of Diabetes Education for Managing Hemoglobin A1c Levels in Adults

The IRB approved the above via expedited review, signed by two IRB Members. This study will need to be renewed or terminated before or within one week of February 1, 2012. At the conclusion of the study, please provide the IRB a summary of your study results to be included in the study file. All of the information associated with this study will be kept in the appropriate IRB file.

Sincerely,


Jeannine Peters, PharmD, CIP
IRB Manager

JP/st

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