THE INFLUENCE OF PATIENT ACTIVATION ON EXERCISE, MEAL PLANNING KNOWLEDGE, AND POLYPHARMACY IN PATIENTS WITH TYPE 2 DIABETES

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THE INFLUENCE OF PATIENT ACTIVATION ON EXERCISE, MEAL PLANNING KNOWLEDGE, AND POLYPHARMACY IN PATIENTS WITH TYPE 2 DIABETES (74)

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Type 2 Diabetes is a chronic illness associated with multiple medical complications. Successful self-management of type 2 diabetes requires active participation on the part of the patient that includes therapeutic lifestyle interventions in the form of meal planning and exercise. The purpose of this study was to understand and quantify relationships and differences between a measurement of patient activation, physical activity level, meal planning knowledge, and polypharmacy in patients with type 2 diabetes and a hemoglobin A1C (A1C) > 6.5 %. A total of 19 participants were evaluated for the study. Statistical analysis included one-way ANOVA and Pearsons Product Moment Correlation. No significant differences between the level of participant activation and level of physical activity, meal planning knowledge, or medications was found ($p < 0.05$). A significant negative correlation between number of medications and meal planning for diabetes knowledge test was found ($r < 0.01$). Additional research addressing specific characteristics of patient activation in the management of type 2 diabetes prior to participation in a self-management program is warranted.

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CHAPTER I

INTRODUCTION

Currently in the United States, seven percent of the population has diabetes of which 14.6 million children and adults have been diagnosed with diabetes mellitus and another 6.2 million individuals with symptoms remaining undiagnosed (National Diabetes Fact Sheet, 2005, ACP Diabetes Care Guide, 2007). The rise in adult obesity is a contributing factor to the 800,000 plus new cases of type 2 diabetes diagnosed each year. Approximately 21% of individuals over 60 years of age have diabetes. Complications stemming from poorly controlled diabetes include heart disease, retinopathy, nephropathy, neuropathy, hypertension and dental caries (National Diabetes Fact Sheet, 2005, American Diabetes Association, 1994, American Diabetes Association, 2001). In 2005, the estimated total diabetes healthcare cost in the United States was $132 billion including direct medical costs, as well as costs related to disability, work loss and premature mortality (American Diabetes Association, 2006).

The first line of defense in the treatment of type 2 diabetes includes a lifestyle change in nutrition and exercise (Pan, 1997; American Diabetes Association, 2002). Lifestyle interventions in the form of meal planning and exercise play an important role in a Diabetes Self Management Education (DSME) program (Parchman, Pugh, & Wang, 2007). Hemoglobin A1C (A1C) is a recognized marker for glycemic control over a 3-month period of time (ADA, 2004). Elevated levels of A1C are strongly associated with complications of diabetes (Cagliero, 1999; American Diabetes Association, 2006).

Patient education regarding the effects of food, exercise, medication, stress, illness, and diabetes complications are part of the DSME programs recognized by the American Diabetes Association (ADA) (American Diabetes Association, 1994). Therapeutic lifestyle changes may be effectively addressed in comprehensive Medical Nutrition Therapy (MNT) programs. MNT can improve health and reduce medical costs commonly associated with poor glycemic control (Franz, Bantle, & Beebe, 2002).

In order to better manage blood glucose levels incorporating changes in lifestyle such as diet and nutrition, it is important for patients with type 2 diabetes to increase their level of activation. Increased activation on the part of the patient requires a set of skills, knowledge, beliefs and behaviors relevant to managing their diabetes. The Patient Activation Measure (PAM) developed by Hibbard (Hibbard, Stockard, & Mahoney, 2004) is a valid and reliable 13-item instrument used to assess a patient's progress through four stages of activation. PAM can be used by physicians to individualize a care plan for the patient based on the patient's level of activation. Patients who are informed, active participants in their own chronic disease care have improved cost-effective outcomes (Wagner, 1998; Wagner, Glasgow, & Davis, 2001).

While long-term adherence to a patient activated program of nutrition and exercise are essential in the management of type 2 diabetes, initiating an exercise program requires self-activation on the patient's part. Factors that may influence a patient's ability to initiate an exercise program include varying degrees of knowledge regarding the influence of nutrition and exercise in the management of type 2 diabetes, a low level of patient activation regarding the management of their disease, and

polypharmacy, specifically ≥ 2 oral hypoglycemic medications (Bayliss, Steiner, & Fernald, 2003).

The percentage of diabetic patients that continue an exercise regimen beyond 1-year is not known. However, the relationship between fitness level and mortality among diabetic patients is currently being studied. After adjusting for confounding variables, low-fit diabetic men had a 2.2-fold greater mortality risk compared with men with moderate or high fitness. Also, mortality in diabetic men reporting no physical activity participation in the previous 3 months was 1.8-fold higher than in those reporting any participation in such activity (Wei, Gibbons, & Kampert, 2000). Although a program in DSME is available to newly diagnosed type 2 diabetics through the Center for Medicaid and Medicare Services (CMS); the actual percentage of patients who participate is not known. Among adults with type 2 diabetes, only 52.2% reportedly take a self-management class. In addition, more males than females take a diabetes self-management class (56.9% vs. 47.0%)

Problem Statement

Type 2 Diabetes is a chronic illness associated with multiple medical complications particularly when blood glucose level is poorly controlled over a prolonged period of time. Patients with a chronic illness such as diabetes have improved health outcomes (i.e. shorter length of stay and fewer complications during hospitalization) when they take a more active role in the self-management of their disease.

Unfortunately, the traditional and current standard of practice for outpatient diabetes patient care is based on a highly regimented primary care physician-patient

model, which does not support patient activation or a patient's ability to play a more active role in the self-management of their diabetes. While current diabetic self-management programs focus on newly diagnosed diabetics; pertinent and timely education concerning recent medical advances in diabetic management is important for all patients.

Historically, dietitians have not been instructed on methods for incorporating the patient activation measurement model in their practice. In an effort to understand patient adherence to the recommended lifestyle changes for managing type 2 diabetes, it is important to understand the relationship between a patient's level of self-activation and their knowledge regarding nutrition and exercise. Also, the influence of polypharmacy on lifestyle modifications such as nutrition and exercise is not well understood (Good, 2002).

Currently, no studies to date have explored the multiple relationships and differences between patient activation and variables commonly included by dietitians in MNT for patients with type 2 diabetes.

Purpose Statement

The purpose of this study is to understand and quantify relationships and differences between a measurement of patient activation, physical activity level, meal planning, and polypharmacy in patients with type 2 diabetes and a A1C > 6.5 %.

Operational Definition of Terms

- Diabetes Meal Planning Questionnaire (Level of knowledge) - The meal planning questionnaire consists of 10 multiple choice questions used to test a patient's knowledge regarding the role of nutrition and type 2 diabetes. Participants were

asked to identify the answer that best completes the statement or answers the question pertaining to food choices, carbohydrate timing, and diabetes.

- Polypharmacy - The total use of different medications used concomitantly for a single patient. Not to be confused with the prescription, administration, or use of more medications than are clinically indicated (Montamat, 1992).
- Type 2 diabetes - According to the American Diabetes Association (ADA), Impaired Fasting Glucose refers to an individual with a fasting plasma glucose (FPG) level between 110 and 125 mg/dl. Normal blood glucose levels are between 70 and 110 mg/dl and therefore this laboratory value has been used to diagnose individuals as prediabetic. Type 2 diabetes is diagnosed when an individual has a FPG greater than 126 mg/dl on two different days (Mensing, 2002).
- Medical Nutrition Therapy (MNT) - Introduced by the American Dietetic Association in the early 1990s to describe the nutrition therapy assessment, goal setting, intervention and evaluation. This term is defined in the statute and Federal Register (Part B Medicare Benefits for Medical Nutrition Therapy, 2001; American Diabetes Association, 2004).
- Summa Family Practice Center Diabetes Self Management Patient Interview: Diabetes Care Profile (DCP) Physical Activity (Q28, Q30) - A self-administered questionnaire that assesses the social and psychological factors related to diabetes and its treatment. The DCP also contains questions concerning demographic information and self-care practices. Questions 28 and 30 are specific to exercise.

    28. Do you have an activity or exercise program that you follow?

30. How often do you exercise?

- Diabetes Self-Management Education (DSME) - An essential element of diabetes care and National Standards for DSME are based on evidence of health outcome benefits. Optimal DSME utilizes a skill-based approach focused on helping those with diabetes make informed self-management choices. In addition to improved self-care behavior and improved clinical outcomes, studies have shown DSME is associated with improved diabetes knowledge. Following the standard medical care for diabetes, individuals with type 2 diabetes should receive DSME upon diagnosis and as needed thereafter. Components of the National Standards for DSME include recommendations for meal planning as part of the MNT process and physical activity (Mensing, Boucher, & Cypress, 2002).
- The Patient Activation Measure (PAM) - Developed by Hibbard et al., (2004) is a valid and reliable 13-item instrument used to assess a patient's progress through four stages of activation. PAM can be used to establish a patient's level of self-activation prior to participating in a MNT program (i.e. type 2 diabetes). PAM can be used by physicians to individualize a care plan for the patient based on the patient's level of activation. PAM is the first instrument for measuring the essential components of an activated patient and is a valid and reliable tool to both quantify and understand patient activation, and also to evaluate interventions (Hibbard et al., 2004). The four levels of the PAM include level 1) patient's belief in the importance of taking an active role in their own care, 2) knowledge and confidence to act on their own behalf, 3) act to improve and maintain health, and

4) continued activation in managing their health even in times of stress (Hibbard et al., 2004).

- The Chronic Care Model -The chronic care model (CCM) developed by Wagner et al., 2001)focuses on delivery of health care that encourages productive interactions between an informed patient who takes an active part in their diabetes management, and a prepared proactive practice team with resources and expertise in the treatment of diabetes.

Research Hypothesis

1. There is a difference between low, moderate, and high level of activity/exercise and stage of PAM in patients with type 2 diabetes with an A1C > 6.5%.
2. There is a difference between Meal Planning for Diabetes Questionnaire and stage of PAM in patients with type 2 diabetes with an A1C > 6.5%.
3. There is a relationship between number of medications and stage of PAM in patients with type 2 diabetes with an A1C > 6.5%.
4. There is a difference between level of activity (low, moderate, high) and score on the Meal Planning Questionnaire in patients with type 2 diabetes with an A1C c > 6.5%.
4. There is a relationship between number of medications and Meal Planning for Diabetes Questionnaire in patients with type 2 diabetes with an A1C > 6.5%.

CHAPTER II

REVIEW OF RELATED LITERATURE

Type 2 Diabetes

Epidemiology

Currently in the United States, 7% of the population has diabetes of which 14.6 million children and adults have been diagnosed with diabetes mellitus and another 6.2 million individuals with symptoms remaining undiagnosed. The two primary forms of diabetes are type 1 and type 2. Approximately 800,000 new cases of diabetes are diagnosed each year; rising proportionally to the obesity epidemic in the United States. The etiology of obesity stems from a combination of genetic and lifestyle influences such as poor nutrition and inactivity. Obesity is known to cause or exacerbate many co-morbid conditions such as diabetes, hypertension, dyslipidemia, coronary heart disease, stroke, certain cancers, arthritis and obstructive sleep apnea (Ness-Abramof, Nabriski, & Apovian, 2004). Twenty one percent of individuals 60 years of age and older have diabetes. While diabetes is the sixth leading cause of death in the United States, it is often the most underreported cause of death. The death rate among middle aged diabetics is twice as high compared to their healthy middle aged counterpart. Type 2 diabetes accounts for 90-95% of all cases of diabetes and is more prevalent with advancing age, obesity, family history of diabetes, history of gestational diabetes, physical inactivity, impaired glucose metabolism, and race/ethnicity (National Diabetes Fact Sheet, 2005).

Complications stemming from diabetes include heart disease, retinopathy, nephropathy, neuropathy, hypertension and dental caries (Chau, Shumaker, & Plodkowski, 2003). Heart disease is the leading cause of diabetes-related deaths. Adults

with diabetes have heart disease death rates about 2 to 4 times as high as those of adults without diabetes (Saydah, Fradkin, & Cowie, 2004). The risk of stroke is 2 to 4 times higher in people with diabetes. An estimated 60 to 65 percent of people with diabetes have high blood pressure (L'Abbate, 2005). Diabetes is the leading cause of new cases of blindness in adults 20 to 74 years old. Diabetic retinopathy causes from 12,000 to 24,000 new cases of blindness each year. Diabetes is the leading cause of end-stage renal disease, accounting for about 40 percent of new cases. About 60 to 70 percent of people with diabetes have mild to severe forms of nervous system damage (which often includes impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, and other nerve problems). Severe forms of diabetic nerve disease are a major contributing cause of lower extremity amputations. More than half of lower limb amputations in the United States occur among people with diabetes. Periodontal disease (a type of gum disease that can lead to tooth loss) occurs with greater frequency and severity among people with diabetes. Periodontal disease has been reported to occur among 30 percent of people age 19 years or older with type 1 diabetes (Chau et al., 2003).

In 2005, the estimated total diabetes healthcare cost in the United States was $132 billion including direct medical costs, as well as costs related to disability, work loss and premature mortality. In fact, one out of every ten healthcare dollars spent in the United States goes toward the treatment of diabetes (American Diabetes Association, 2006).

Risk Factors for Diabetes

Genetic and environmental risk factors related to type 2 diabetes include an intake of excessive calories leading to a body weight greater than 120% of ideal body weight,

intra-abdominal obesity, hypertension, HDL cholesterol less 35mg/dl, triglyceride levels greater than 250 mg/dl, history of gestational diabetes, a first-degree relative with type 2 diabetes, physical inactivity, advancing age, and a high risk ethnic group background. Changes caused by disease include abnormal pattern of insulin secretion and action, decreased cellular uptake of glucose, increased postprandial glucose, and increased gluconeogenesis in the early morning. (Mahan & Escott-Stump, 2004).

Disease Course

Insulin is an anabolic hormone that plays a key role in the metabolism of carbohydrates, fats and protein. Type 2 diabetes results from a combination of impaired biologic response to both exogenous or endogenous insulin (i.e. insulin resistance) and β-cell failure in the pancreas. Although type 2 diabetes is the most common form of diabetes; the role of exogenous vs. endogenous insulin in the progression of diabetes is not well understood. A complex interaction of genes, environment, and abnormalities in insulin production and secretion, glucose production and fatty acid metabolism all play a contributing role in type 2 diabetes (Buchanan, Xiang, & Peters, 2002; Mahan et al., 2004).

Insulin resistance is the first stage in type 2 diabetes. Skeletal muscle and the liver are target tissues for insulin resistance. Insulin attaches normally to receptor sites on the hepatic and muscle cells, but is unable to move glucose out of the blood stream and into the cell. During this stage the patient continues to produce normal or even high amounts of insulin sufficient to overcome the resistance, however, the patient will experience postprandial hyperglycemia (Hu, Lindstrom, &Valle, 2004; Mahan et al., 2004).

Elevated blood glucose levels postprandial caused by insulin resistance at the cellular level result in an elevation of fasting glucose concentrations. Fasting blood glucose levels are further elevated as insulin secretion decreases thereby stimulating an increase in hepatic glucose production (American Diabetes Association, 2001).

Diagnosis

Screening for diabetes should be considered in all individuals older than 45 years of age. Diagnostic criteria for type 2 diabetes include one of the following: fasting plasma glucose (FPG) ≥ 126 mg/dl, casual plasma glucose (CPG) ≥ 200 mg/dl, and 2-hour plasma glucose ≥ 200 mg/dl (Mahan et al., 2004; American Diabetes Association, 2006). According to the American Diabetes Association (ADA), Impaired Fasting Glucose refers to an individual with a fasting plasma glucose (FPG) level between 110 and 125 mg/dl. Normal blood glucose levels are between 70 and 110 mg/dl and therefore this laboratory value has been used to diagnose individuals as prediabetic. Type 2 diabetes is diagnosed when an individual has a FPG greater than 126 mg/dl on two different days (American Diabetes Association, 2006).

Another test that examines blood glucose levels is glycosylated hemoglobin, also known as hemoglobin A1C (A1C). Hemoglobin is a protein molecule found in red blood cells. The average lifespan of a red blood cell is 120 days. When glucose binds to red blood cells, the hemoglobin becomes modified in a process called glycosylation. Elevated levels of glycosylated hemoglobin are strongly associated with complications of diabetes (Cagliero, Levina, & Nathan, 1999; American Diabetes Association, 2006).

An A1C level of 1% above normal range identifies diabetes in 98% of patients. Normal A1C levels do not necessarily rule out diabetes, but if diabetes is present and

levels are normal, the risk for complications is low. Measuring A1C is not currently used for an initial diagnosis, but it may be useful for determining the severity of diabetes as well as providing a clinical picture of blood glucose control over a 3-month time period. Some experts think it should be used to help predict complications in people who have FPG levels between 110 and 139, which are above normal but do not indicate full-blown diabetes. Normal A1C levels should be below 7%. A1C levels between 11% and 12% indicate poor glycemic control. High A1C levels are also markers for kidney complications secondary to poor glucose control (Stratton, Adler, & Neil, 2000; American Diabetes Association, 2006).

Patient Activation Measurement – A Component of the Chronic Care Model

The Chronic Care Model (CCM)

Numerous studies support a direct relationship between the diabetes epidemic and obesity, sedentary lifestyle, and high-fat, high-calorie diets (ACSM, 1998; Albright, Franz, & Hornsby, 2000; Expert Panel on Direction, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2005). Twenty-two academic sites across the country are studying the cost-effective changes in clinical markers for treatment of diabetes. The Chronic Care Model (CCM) as outlined by Dr. Edward Wagner from the Robert Woods Johnson Foundation (RWJF) is an innovative program for health care delivery and management of chronic disease (Wagner, 1998; Wagner, Sandhu, & Newton, 2001). The CCM is currently being used to collect data and analyze innovative programs in 22 academic sites in the United States. The RWJF funded the MacColl Institute to test the model nationally across varied health care settings: the national program being

"Improving Chronic Illness Care" (ICIC) (Siminerio, 2004; Wagner, Grothaus, & Sandhu, 2001).

In an effort to promote high-quality chronic disease care for diabetics in the U.S., critical elements of the CCM in the health care system include community and health system support, delivery design, clinical information systems, self-management and decision support. The informed activated patient together with the expertise and resources of the prepared provider will equate to better chronic disease management while providing a significant financial savings to the health care system (Wagner, Grothaus, & Sandhu, 2001). This concept is supported by The American Dietetic Association position that an evidence–based approach to delivering nutrition assessment, appropriate therapy and counseling services using MNT with the CCM are needed to support improved patient outcomes and to reduce health care costs (American Dietetic Association, 2002).

Medical care for individuals with type 2 diabetes should come from a physician – coordinated team based on a collaborative and integrated model. Additional team members may include nurse practitioners, dietitians, mental health professionals and pharmacists. The chronic care model (CCM) developed by Wagner et al., focuses on delivery of health care that encourages productive interactions between an informed patient who takes an active part in their diabetes management, and a prepared proactive practice team with resources and expertise in the treatment of diabetes (Wagner, 1998; Wagner, Grothaus, & Sandhu, 2001)

Patient Activation Measurement

Patients who are well informed regarding the specifics of their disease and actively participate in their healthcare decisions have better health outcomes and generally have fewer healthcare costs compared to those who are not inactive counterpart. (Wagner, Sandhu, & Newton, 2001). The Patient Activation Measure (PAM) developed by Hibbard et al, 2004, is a valid and reliable 13-item instrument used to assess a patient's progress through four stages of activation (Hibbard et al., 2004).

PAM can be used by physicians to individualize a care plan for the patient based on the patient's level of activation. The Patient Activated Measure (PAM) is the first instrument for measuring the essential components of an activated patient (skills, knowledge, beliefs and behaviors). As a valid and reliable tool, the PAM measures the four progressive stages to becoming an activated patient. Initially, a patient believes their role in their own care is important. Secondly, they learn and develop the skills and confidence to make decisions regarding their health. Thirdly, they carry out the decisions they make and finally, they are able to make these decisions even under stress.

PAM may be a valid and useful tool to both quantify and understand patient activation, and also to evaluate interventions (Hibbard et al., 2004). Achieving both cost effective and improved patient care and outcomes requires "activated" patients that have the skills, knowledge, and motivation to manage their chronic disease. The Patient Activation Measure (PAM), developed by Hibbard et al. (2004), has been utilized to assess patient activation base level and change over time. Individualized care plans are most effective when a physician develops an appropriate plan based on the PAM level of their patient (Fitzgerald, Anderson, & Funnell, 1997; Fitzgerald, Funnell, & Hess, 1998).

Understanding the relationship between PAM and health behaviors such as meal planning and diabetes and active participation in exercise may help develop a more effective patient-centered glycemic management program (Anderson, Fitzgerald, & Wisdom, 1997. The 13-item instrument is included in appendix B (Hibbard et al., 2004).

Diabetes Self-Management Education and Medical Nutrition Therapy

Diabetes Self-Management Education Programs (DSME)

Type 2 diabetes care begins with a complete medical evaluation, including laboratory tests to classify the patient, determine if complications exist, and devise a management plan and basis for appropriate care. The first line of defense in the treatment of type 2 diabetes includes a lifestyle change in nutrition and exercise (Pate, Pratt, & Blair, 1995; Franz et al., 2002). Lifestyle interventions in the form of meal planning and exercise play an important role in Diabetes Self Management Education (DSME).

Diabetes Self Management Education (DSME) is an essential element of diabetes care and National Standards for DSME are based on evidence of health outcome benefits (Mensing et al., 2002). Optimal DSME utilizes a skill-based approach focused on helping those with diabetes make informed self-management choices (Sadur, Moline, & Costa, 1999). In addition to improved self-care behavior and improved clinical outcomes, studies have shown DSME is associated with improved diabetes knowledge (Roter, Stashefsky, & Rudd, 2002; Parchman et al., 2007). Following the standard medical care for diabetes, individuals with type 2 diabetes should receive DSME upon diagnosis and as needed thereafter. Components of the National Standards for DSME include

recommendations for meal planning as part of the MNT process and physical activity (Mensing et al., 2002).

A registered dietitian (RD) and registered nurse (RN) with certified diabetic education or recent experience in diabetes education and management are part of The American Diabetes Association recognized Diabetes Self-Management program staff. The curriculum of ADA recognized DSME programs should cover all areas of diabetes management including meal planning and physical activity specific to type 2 diabetes (Mensing et al., 2002).

Medical Nutrition Therapy

Medical Nutrition Therapy (MNT) was introduced by the American Dietetic Association in the early 1990s to describe the nutrition therapy assessment, goal setting, intervention and evaluation. This term is defined in the statute and Federal Register (42 CFR, Part 410.130, Vol 66, No. 212, November 1, 2001) as "nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes or renal disease." (Part B Medicare Benefits for Medical Nutrition Therapy, 2001). Described as a comprehensive approach to nutrition; MNT can improve health and reduce medical costs commonly associated with poor glycemic control. It has been shown that eating habits can have a significant impact on the incidence and severity of chronic diseases (Saunders et al., 1996).

Management of type 2 diabetes requires the restoration of normal carbohydrate, protein and fat metabolism through medical nutrition therapy (MNT), physical activity, blood glucose monitoring, medications and self-management education (Mahan et al., 2004). The primary goal of MNT is the prevention and treatment of chronic

complications of diabetes by attaining and maintaining optimal metabolic outcomes, including blood glucose and A1C level, low density lipoprotein (LDL), and high density lipoprotein (HDL), cholesterol and triglyceride levels, blood pressure, and body weight. Taking into account cultural, lifestyle and socioeconomic factors; individualized MNT begins with a nutritional assessment to evaluate food intake, metabolic status, lifestyle, readiness to make changes, goal setting, dietary instructions and evaluation. (American Diabetes Association, 2006).

The priority for individuals with type 2 diabetes is to adopt lifestyle strategies that improve the associated metabolic abnormalities of glycemia, dyslipedemia, and hypertension (Albright, Franz, & Hornsby, 2000; Franz et al., 2002). Implementation should occur as soon as possible after the diagnosis has been made, and preferably in the pre-diabetes stage. In addition to reducing energy intake, one significant lifestyle strategy independent of weight loss that can improve glycemia is physical activity (Albright et al., 2000; Jeon, 2007). In addition to attaining and maintaining optimal metabolic outcomes and addressing individual nutritional needs, the American Diabetes Association (ADA) lists modification of lifestyle and increased physical activity as two important goals of MNT for individuals with type 2 diabetes (Part B Medicare Benefits, 2001; American Diabetes Association, 1994).

Short-term studies (< 6-months) determined that small amounts of weight loss, particularly in the intraabdominal region, through a decrease in energy intake as well as an increase in physical activity may improve insulin resistance and glycemia (Markovic, 1998). However, it is well known that long term weight loss is difficult to achieve and therefore it is not clear the extent to which these improvements can be maintained in

individuals with type 2 diabetes. Effective MNT in long term weight loss of 5% to 7% requires frequent, consistent, long-term follow up of patients with type 2 diabetes (The Diabetes Control and Complications Trial Research Group, 1993; Research Group, Mahan et al., 2004).

There are numerous conflicting results from studies regarding HbA1c level and health outcomes. A study by Hussain et al. (2006) found that a sustained reduction 1-2 years after lowering HbA1c level ≤7.7% among adult diabetic patients is associated with significant savings in total healthcare costs, fewer days spent in the hospital, and fewer visits to primary care physicians and specialists (Hussain & Kelton, 2006). However, in a study Wagner et al. (2001), an economic analysis of interventions for diabetes stratified interventions for diabetes according to their economic impact. Eye care and pre-conception care are two known cost saving interventions for patients with type 2 diabetes. While improved glycemic control is clearly cost-effective, is unclear if it is cost-saving in terms of health care dollars spent per year. Self-management training is possibly cost effective, but the economic impact of medical nutrition therapy and exercise are not well known. (Wagner et al., 2001) Certainly understanding a patient's level of activation measure (PAM) may provide insight on appropriate lifestyle programs for glycemic DSME programs.

Type 2 Diabetes and Exercise

A multitude of health benefits are associated with the current physical activity guidelines recommendation of 30-minutes of moderate intensity activity on most days of the week (Pate et al., 1995; American College of Sports Medicine, 1998). Given the appropriate guidelines including consideration of age, interests, fitness level, and general

health; individuals with type 2 diabetes should consider exercise an integral part of their treatment plan. Benefits of regular physical activity include improved insulin sensitivity and weight control, reduction of cardiovascular risk factors, and a healthier mental outlook (Church, Cheng & Ernest, 2004; Mahan, et al., 2004). Blood glucose control can improve with regular exercise in individuals with type 2 diabetes, primarily due to decreased insulin resistance and increased insulin sensitivity. Exercise decreases the effects of counterregulatory hormones such as glucagon, which in turn decreases hepatic glucose output thereby culminating in improved glucose control. Exercise-induced enhancement of insulin sensitivity is independent of weight loss. (American Diabetes Association, 2002; Hu, Lindstrom & Valle, 2004)

It is well known that regular exercise is effective in reducing triglyceride levels and blood pressure in persons with type 2 diabetes (Mahan et al., 2004). In addition, it has been shown that exercise at 50% - 80% VO2max three to four times per week for 30-60 minutes a session can result in a 10%-20% baseline improvement in A1C. The effect of exercise is most beneficial in persons with mild type 2 diabetes as well as individuals most likely to be insulin resistant. (American Diabetes Association, 2002; Mahan et al. 2004, Hu et al., 2001).

The standard of medical care in diabetes for physical activity recommendations to improve glycemic control, assist with weight maintenance, and reduce risk of coronary artery disease for individuals with type 2 diabetes are specific: 150-minutes/week of moderate intensity aerobic physical activity (50-70% of maximum heart rate) and/or at least 90 minutes/week of vigorous aerobic exercise (> 70% of maximum heart rate). At a minimum, the physical activity should be distributed over 3 days/week with no more than

two consecutive days without physical activity. In the absence of contraindications, individuals with type 2 diabetes should be encouraged to perform resistance exercise three times/week, targeting all major muscle groups, performing three sets of 8-10 repetitions at a weight that can not be lifted more than 8-10 times (American Diabetes Association, 2006).

A potential barrier to exercise may include insufficient instruction regarding appropriate exercise due to the limited office time for the patient visiting their primary care physician (Leatherman, Berwick, & Iles, 2003). The median time for an outpatient office visit for an elderly patient and their primary care physician is 15.7 minutes. During that time an average of 6 topics are covered ranging in length of 1.1 to 5 minutes per topic. On average 2.7 problems and 8 physician actions occur during an outpatient primary care office visit. Competing demands for time are compounded by patient requests during the visit. Fitting both the physician's and patient's agenda into the time allotted for the outpatient visit has important implications physician productivity and patient outcomes (Tai-Seale, McGuire, & Xhang, 2003; Hussain & Kelton, 2006).

Beyond simply providing patients with medical clearance to exercise and general guidelines, physicians can initiate the educational process of promoting a healthy lifestyle change for their patient by enhancing self-efficacy, promoting social support and influencing the decisional balance regarding participation in physical activity (Pencek, James, & Lacy, 2004; Sigal, Kenny, & Wasserman, 2006). This is especially important for individuals with type 2 diabetes and known coronary risk factors (Expert Panel on Direction, Evaluation and Treatment of High Blood Cholesterol in Adults, 2001). However, the current model of a highly regimented schedule may interfere with a

physician's ability to allow sufficient time for patients with complex medical problems (i.e. type 2 diabetes taking hypertension medications). In fact, it has been suggested that the current views of physician productivity and current methods of billing are poor indicators of the reality of providing primary care (Leatherman et al., 2003).

To date, no studies have examined the relationship between physical activity level and level of activation as measured by PAM.

Meal Planning and Type 2 Diabetes

Meal planning is an integral component for diabetes clinicians and educators. Effective diabetes education in meal planning should consider socioeconomic status, education level and literacy skills (Roter et al., 2002; Brown, 2003). Increasing the knowledge base that pertain to specific food habits of people with diabetes will improve the dialog with clients about dietary self-management and guide the collaborative development of relevant dietary goals (Savoca, Miller, & Ludwig, 2004).

People with type 2 diabetes should receive MNT as needed to achieve treatment goals (American Diabetes Association, 2006). Understanding how the amount (grams) and type of carbohydrate in a food influence blood glucose is the foundation for effective meal planning for patients with type 2 diabetes. Nutritional factors and strategies for achieving glycemic control include understanding the benefit of glycemic load and index, daily protein requirement based on kidney function and saturated and trans fat intake as part of a heart healthy diet. Weight loss is recommended for all adults who are overweight (BMI 25.0-29.9 kg/m2) or obese (BMI >30.0kg/m2) who have type 2 diabetes (American Diabetes Association, 2006). Therapeutic lifestyle change (TLC) as outlined by the American Heart Association includes dietary and physical

recommendations for a healthy approach to weight loss. This program is based on a reduction in energy intake and increase in physical activity (Expert Panel on Direction, Evaluation and Treatment of High Blood Cholesterol in Adults, 2001).

One goal of proper meal planning is optimal blood glucose control. To a certain extent, glycemic control is influenced by proper diet, exercise, and healthy weight maintenance. In addition, a healthy lifestyle that includes healthy nutritional choices and exercise may help control or lower blood pressure and improve lipid profile thereby reducing the risk for heart disease. Proper meal planning includes spacing out smaller meals throughout the day to maintain steady blood sugar levels. Prevent extreme high or low blood glucose levels by avoiding large meals once or twice a day. Understand the effect of exercise on blood glucose levels (Meal Planning, 2007).

It is not clear if patients with type 2 diabetes who exercise on a regular basis are more knowledgeable concerning meal planning and diabetes. However, in a study by Glasgow et al, life style behaviors such as exercise and diet enhance diabetes self-care when strategies to increase regimen-related expectations and diabetes-specific social and problem-solving skills are utilized (Glasgow, Toobert, & Riddle, 1989).

Polypharmacy & Type 2 Diabetes

Polypharmacy is a term often associated with the elderly population and is a reference to the total use of different medications used concomitantly for a single patient. Not to be confused with the prescription, administration, or use of more medications than are clinically indicated (Montamat & Cusack, 1992; Good, 2002).

Medications used to treat type 2 diabetes are categorized according to mechanism of action and a patient's natural insulin function. The goals of oral agents include

increasing the sensitivity of a patient's own natural insulin stores by stimulating insulin secretion, reducing insulin resistance, or slowing intestinal absorption of carbohydrates (Thornley-Brown, Wang, & Wright, 2005). Oral hypoglycemic medications currently prescribed include sulfonyureas, meglitinides, biguanides, thiazolidinediones, and alpha-glucosidase. Combinations of these agents are often used to increase effectiveness (UKPDS, 1998). Many patients with type 2 diabetes eventually lose natural insulin function thereby requiring insulin replacement. Oral agents and insulin can be used together to achieve optimal blood glucose levels. Insulin analogues for patients with type 2 diabetes include rapid or long lasting insulin derivatives that simulate the normal insulin response (American Diabetes Association, 2006).

Treatment for type 2 diabetes is based on the amount of residual insulin and ability to control blood glucose levels. Initially, a single oral agent that stimulates or preserves any residual insulin is the first choice. While some patients may be able to control their glucose levels with a single drug, over time most patients will need to increase the number of oral hypoglycemic medications to achieve optimal blood glucose levels. In fact, a study by United Kingdom Prospective Diabetes Study (UKPDS) found after three years, 50% of patients with type 2 diabetes require more than one medication for blood glucose control, and at nine years, only 25% could remain on a single drug (UK Prospective Diabetes Study, 1998).

According to a 1999 survey, 90% of diabetes specialists prescribed ≥ 3 medications for their patients. Insulin replacement is introduced as the body's natural insulin fails or for patients with severe hyperglycemia whose blood glucose is not managed with oral medications. Significant adverse effects of insulin include weight gain

and heart complications (i.e. hypertension, hyperlipidemia, coronary heart disease) (ACP Diabetes Care Guide, 2007). A 2001 report found metformin achieved the lowest mortality rates (8%) compared to insulin (28%), a sulfonylurea (16%), and a thiazolidinedione (14%). The two most common adverse drug reactions occur between cholestermine and glycosides, and between non-steroidal anti-inflammatory and oral hypoglycemic medications (ACP Diabetes Care Guide, 2007; Grant, 2003).

The type 2 diabetic patient can be a challenged with adverse drug reactions (ADR), especially when multiple medications are prescribed. Drug action and side effects are referred to as pharmacodynamics and are of particular interest when coupled with pharmacokinetics (drug absorption, distribution, and elimination) and advancing age. The incidence of chronic disease increases with age as does sensitivity to certain drugs. Ten percent or more of elderly patient admissions are due to ADR and 15% of elderly hospitalized patients experience an ADR (Montamat et al., 1992).

In addition to pharmacokinetic and pharmacodynamic changes, ADR may result from homeostatic changes (i.e. baroreceptor responses, thermoregulation, electrolyte and glucose control). Polypharmacy results in an increased likelihood of drug interactions, ADR and changes in drug compliance. In a community survey of drug prescription and compliance among elderly individuals, 88% of the drugs were issued by repeat prescription and only 40% of the group discussed their treatment regimen with their primary care physician in the previous six months.

Noncompliance, whether accidental (i.e. difficulty reading label due to poor vision) or intentional (i.e. ADR, inconvenience of taking medications and differing perceptions between the patient and physician regarding the clinical management of type

2 diabetes) and ADR are particularly common in the elderly population and therefore warrants further study (Hughs, 1998). To date, no study has looked at the relationship between PAM, physical activity, and polypharmacy.

For the patient with type 2 diabetes, compliance with a regimen of multiple medications is imperative for optimal glycemic control. The average number of medications taken by a patient with type 2 diabetes is four. Approximately 78% take medication as directed and less than 40% maintain a consistent diet and exercise program. Many factors may impede medication adherence including side effects specific to the drug, drug interactions, cost of medication, and difficulty comprehending special administration and dosing requirements of certain medications (i.e. insulin regimens) (Funnel, 2006).

In addition to the multiple glycemic medications and insulin, most patients with type 2 diabetes take additional medications for control of hypertension and hyperlipidemia (ACP Diabetes Care Guide, 2007). The risk of drug interactions with comorbidity conditions requiring medication increases significantly with age. When evaluating polypharamcy of the patient with type 2 diabetes, the primary care physician must look at side effects of medication, possible drug-interactions and continued necessity of each medication (Blonde, 2006).

A survey study by Grant et al. (2003) found no correlation between the total number of medications prescribed and medication adherence rate. However, they suggested reduced medication adherence rates may be due to side effects of medications (Grant et al., 2003). While this study provides important insight on one component of DSME (prescribing the adequate number of glycemic control medications) it does not

address the question of possible side effects of polypharmacy and patients' active participation in exercise or adherence to dietary recommendations – each an important component of DSME.

While long-term adherence to a patient activated program of nutrition and exercise are essential in the management of type 2 diabetes, initiating an exercise program requires self-activation on the patient's part. Factors that may influence a patient's ability to initiate an exercise program include securing medical clearance for exercise, patient's level of knowledge regarding nutrition and exercise in the management of type 2 diabetes, and polypharmacy, specifically ≥ 2 oral hypoglycemic medications.

In summary, increasing numbers of medicines increase nonadherence to the prescribed regimen. Two significant factors influencing adherence to prescribed medication are cost and side-effects (Elliot, Ross-Degnan, & Adams, 2007). Little is known about how older adults manage multiple medicines for type 2 diabetes or the relationship between nonpharmacological factors such as nutrition and exercise and multiple medications. The primary goal of diabetes education include optimal glycemic control through nonpharmacological methods (i.e. diet and exercise), and pharmacological therapy. Adherence to dietary recommendations, exercise, and medication regimens may be compromised by comorbid conditions (i.e. heart disease, obesity), side-effects of medications or socioeconomic variables. To date, no studies have looked at the influence of polypharmacy on patient activation, meal planning knowledge and physical activity (Rosenstock, 2001).

CHAPTER III

METHODOLOGY

Research Design

This study was based on data collected from a survey design as part of a larger pilot study conducted January 2005 – June 2007 (Improving Patient Clinical Outcomes and Healthcare Costs Using Innovative Nutrition Interventions in a Multidisciplinary Chronic Disease Model). The Institutional Review Board (IRB) at Kent State University, University of Akron, and the Medical Review Committee (MRC) at the Summa Family Practice Center granted approval for the pilot study in which the primary goal was to incorporate the elements of the chronic care disease management model into a template for nutrition care that currently does not exist. The current study was designed to understand and quantify relationships and differences between patient activation measurement, medical clearance for exercise, actual participation in an exercise, meal planning knowledge, and polypharmacy in patients with type 2 diabetes and HgBA1c > 6.5%.

Population Data

The Family Practice Center (FPC) of Akron at Summa Health System is a primary care medical practice that provides services to approximately 4,000 patients each year and receives approximately 15,000 patient contacts each year. Recruitment for the study came from the FPC which serves a mixed population of middle class and economically disadvantaged patients. Eleven board-certified family physicians and 33 medical residents staff this urban center. As of May 5, 2006, 137 patients in the FPC met the study criteria. Data for the current study was collected from baseline data on the

patients who met the study criteria (N = 19). Four methods were utilized to recruit patients who met the criteria for the pilot study: a letter was mailed to patients outlining details about the pilot study and contact information regarding participation and a follow-up phone call was placed two weeks after the initial letter was sent by a research member from the Summa Family Practice Center. A poster was displayed in the FPC offering information and contact information for participation in the pilot study, staff members at FPC asked patients coming into the clinic if they would like information on the pilot study.

Kent State University (KSU) utilizes Health Insurance Portability and Accountability Act (HIPAA) standard procedures for protecting all patient records and information. Any identifying information collected is kept in a secure location at KSU Nutrition Department and only the researchers have access to the data. All participants were coded using a random numbering system, which was used for data collection throughout the pilot study.

Participants

All active English-speaking adult patients (≥18 years) with a diagnosis of diabetes in the Family Practice Center at Akron City Hospital with a history of inadequate blood glucose control (A1C > 6.5%) were considered for inclusion in this study. Exclusions included: Axis II psychiatric disorder; pregnancy; chemotherapy/radiation. In addition to A1C, data collected included gender, patient activation level, meal plan knowledge score, activity level, and number of medications. Baseline data: demographic and clinical data was collected on all 19 patients. The 19 participants in the current study completed a

Diabetes Meal Planning MNT Knowledge Test, the PAM questionnaire, and the Diabetes Care Profile.

A written and informed consent was obtained for all 19 participants in the study through the Summa Family Practice Center. Patients were advised that participation was voluntary and that their decision to participate or not would not affect future medical care.

Instruments

Patient Activation Measure (PAM)

Developed by Hibbard et al. (2004), PAM is a valid and reliable 13-item instrument used to assess a patient's progress through four stages of activation. PAM can be used to establish a patient's level of self-activation prior to participating in a MNT program (i.e. type 2 diabetes). PAM can be used by physicians to individualize a care plan for the patient based on the patient's level of activation. PAM is the first instrument for measuring the essential components of an activated patient and is a valid and reliable tool to both quantify and understand patient activation, and also to evaluate interventions. The four levels of the PAM include level 1) patient's belief in the importance of taking an active role in their own care, 2) knowledge and confidence to act on their own behalf, 3) act to improve and maintain health, and 4) continued activation in managing their health even in times of stress (Appendix A: Patient Activation Measurement). The Patient activation measurement (PAM) consists of 13 questions all pertaining to statements about personal health. Four choices based on level of agreement for each question include Disagree strongly: 1, Disagree: 2, Agree: 3, Agree strongly: 4. The raw score is

calculated by adding up all the responses to the 13 questions and the raw score is converted into measure of activation (i.e. divide total raw score by 13).

Summa Family Practice Diabetes Care Profile (DCP) Patient Interview

The DCP is a self-administered questionnaire that assesses the patient's medical, social, and psychological factors related to diabetes and their treatment. The instrument contains 33 questions that assess the patients' social and psychological factors related to diabetes and its treatment. Previous studies have measured the reliability and validity of The Diabetes Care Profile (Fitzgerald, Anderson, & Gruppen, 1998). Using an instrument to assesses the social and psychological factors related to diabetes and its treatment, two studies with separate populations (community and university) and methodologies were conducted. A1C correlated with three DCP scales thereby rendering the questionnaire reliable and valid for measuring psychosocial factors related to diabetes and treatment.

The DCP also contains questions concerning demographic information and self-care practices. Questions 28 and 30 are specific to exercise and were used for this study. Each participant's response to physical activity questions in the patient interview were totaled and converted into a low, moderate or high physical activity scale. Participants were given a score of 0-4 for physical activity based on the response to two questions pertaining to participation and frequency of activity taken from the Summa Family Practice Center Diabetes Self Management Patient Interview. Question 28 asked whether or not an individual followed an exercise program. A response of no or yes was given a score of 0 or 1 respectively. Question 30 asked about frequency of exercise ranging from zero (score 0) to daily (score 4). Participants who checked "1-3 times a week" or "4-6

times a week" were given a score of 1 or 2 respectively. Using the American College of Sports Medicine-Center of Disease Control guidelines for activity level and exercise recommendations physical activity level was divided into three categories; low, medium, and high, (Centers for Disease Control and Prevention, 2007)(Table 1).

Table 1: Diabetes Care Profile: Summa Family Practice Center Diabetes Self Management Patient Interview – Exercise Level

Physical Activity Level	Q28[a]: N/Y 0/1	Q30[b]: Frequency 0-3	Possible Total Score
LOW	0	0-1	0-1
MODERATE	1	1	2
HIGH	1	2-3	3-4

[a] Q28 Do you have an activity or exercise program that you follow?
☐0 No (0) ☐1 Yes (1)

Each box indicates includes possible score level of 0 -1.

Example: Any activity beyond what is considered a standard activity of daily living would be considered "yes" and score of 1.

[b] Q30 How often do you exercise?
☐1 daily (3)
☐2 4-6 times a week (2)
☐3 1-3 times a week (1)
☐4 I don't (0)

MNT Knowledge Test Diabetes Meal Planning

The meal planning questionnaire consists of 10 multiple choice questions. The questionnaire was developed from a survey adapted from a Diabetes Knowledge Test used at the Michigan Diabetes Research and Training Center (Fitzgerald, Davis, & Connell, 1996; Fitzgerald, Funnell, & Hess, 1998). Participants were asked to identify the answer that best completes the statement or answer the question pertaining to food choices, carbohydrate timing, and diabetes (Appendix B**:** MNT Diabetes Meal Planning Knowledge Test – Multiple Choice Questionnaire). Participants were categorized into a high knowledge group (7-10 correct answers) or low knowledge group (0-6 correct

answers) based on their Meal Planning Knowledge (MPS) score. A passing grade of ≥ 70% was used to delineate the high knowledge MPS group and ≤ 60% to delineate the low knowledge MPS group.

Medications

Total number of medications taken by each participant was calculated based on information obtained from the Summa Family Practice Center Diabetes Self Management Patient Interview and the patient's initial interview with the registered dietitian. Additional information pertaining to medication history was obtained from the RD's documentation on the initial assessment.

Statistical Analysis

Descriptive analysis including frequency and means was done for variables including gender, hemoglobin A1C (A1C), patient activation measurement (PAM), meal planning knowledge for diabetes, number of medications, and physical activity level. Data supporting the five hypotheses was analyzed using Statistical Package for the Social Sciences (SPSS, 2003). Means were calculated for each category previously listed. The data for three of the five hypotheses was analyzed using a One-way ANOVA to determine differences between two or more independent variables (i.e. patient level of activation and physical activity level, patient level of activation and meal planning knowledge for diabetes and physical activity level and meal planning knowledge for diabetes). A p-value of 0.05 was selected a priori. The Pearsons Product Moment Correlation was used to analyze the two remaining hypotheses for the relationship between number of medications and patient level of activation, and number of

medications, patient level activation and meal planning knowledge for diabetes. An r-value of 0.01 was selected a priori (Table 2).

Table 2: Hypotheses & Corresponding Statistical Test

HYPOTHESIS	DATA COLLECTED	MEASUREMENT TESTS
1. There is a difference between low, moderate, and high level of activity/exercise and stage of PAM in patients with type 2 diabetes with A1C > 6.5%.	Appendix C: Summa Family Practice Center Diabetes Self Management Patient Interview – Physical Activity Appendix A: Patient Activation Measure (PAM)	One-way ANOVA
2 There is a difference between Meal Planning for Diabetes Questionnaire and stage of PAM in patients with type 2 diabetes with A1C > 6.5%.	Appendix B: MNT Knowledge Test Diabetes Meal Planning Diabetes Meal Planning Appendix A: PAM	One-way ANOVA
3. There is a relationship between number of medications and stage of PAM in patients with type 2 diabetes with A1C > 6.5%	Appendix D: Summa Family Practice Center Diabetes Self Management Patient Interview - Medication Appendix A: PAM	Pearson's Product Moment Correlation
4. There is a difference between level of activity (low, mod, high) and score on the Meal Planning Questionnaire in patients with type 2 diabetes with A1C > 6.5%.	Appendix C: Summa Family Practice Center Diabetes Self Management Patient Interview – Physical Activity, Appendix B: MNT Knowledge Test Diabetes Meal Planning Diabetes Meal Planning	One-way ANOVA
5. There is a relationship between level of activation, number of medications and score on Meal Planning for Diabetes in patients with type 2 diabetes and A1C > 6.5%	Appendix A: PAM Appendix D: Summa Family Practice Center Diabetes Self Management Patient Interview – Medication Appendix B: MNT Knowledge Test Diabetes Meal Planning Diabetes Meal Planning	Pearson's Product Moment Correlation

CHAPTER IV

RESULTS

Participant Characteristics

A total of 19 participants met the study criteria for A1C > 6.5%. The sample consisted of 11 females and 8 males. Study variables included mean scores for group and gender for hemoglobin A1C (A1C), patient activation measurement (PAM), meal planning knowledge score (MPKS), physical activity level (PA), and number of medications (M) (Table 3).

Table 3: Participant Mean Scores by Group and Gender (N=19)

Study Parameter*	Mean	SD ±
A1C[a]	7.95	
PAM[b]	2.78	± 0.368
MPS (%) [c]	61%	± 2.198
PA[d]	1.47	± 0.373
M[e]	2.65	± 1.065

[a] A1C: glycosalated hemoglobin
[b] PAM: patient activation measurement, possible score 1-4
[c] MPS: Meal Plan Knowledge Score,
[d] PA: Physical Activity Level - involvement in physical activity and frequency per week, range of score 0-4 with 0-1 (low activity level), 2 (moderate activity level) 3-4 (high activity level),
[e] M: Total number of medications taken per day (0-4)

Activity/Exercise Level and Stage of Patient Activation

No significant difference was demonstrated between a participant's level of physical activity and level of patient activation (p = 0.329) (Table 4).

Table 4: Frequency and Mean of Patient Activation Measurement (PAM) and Low, Moderate, and High Physical Activity (PA) Level

Source	n	PAM mean
Low PA Mean ±standard deviation (SD)	11	2.839 ± 0.392
Moderate PA Mean ± SD	2	2.961 ± 0.054
High PA Mean ± SD	6	3.128 ± 0.356

Meal Planning Knowledge for Diabetes and Stage of Patient Activation

Forty eight percent of the participants scored ≤ 60% placing them in the low knowledge group, and 52% scored ≥ 70% placing them in the high knowledge group for meal planning knowledge. No significant difference was demonstrated between high and low knowledge score on meal planning knowledge test and level of patient activation ($p = 0.706$) (Table 5).

Table 5: Frequency and Mean of Patient Activation Measurement (PAM) Low and High Meal Planning Knowledge Scores (MPS)

Source	n	PAM mean
Low MPS Mean ±standard deviation (SD)	11	2.972 ± 0.492
High MPS Mean ± SD	8	2.903 ± 0.098

Number of Medications and Stage of Patient Activation

No significant correlation was demonstrated between the number of medications and level of activation ($r = -0.252$).

Activity/Exercise Level and Meal Planning Knowledge for Diabetes

No significant difference was demonstrated between a participant's level of physical activity and score on the meal planning knowledge test (p = 0.105) (Table 7).

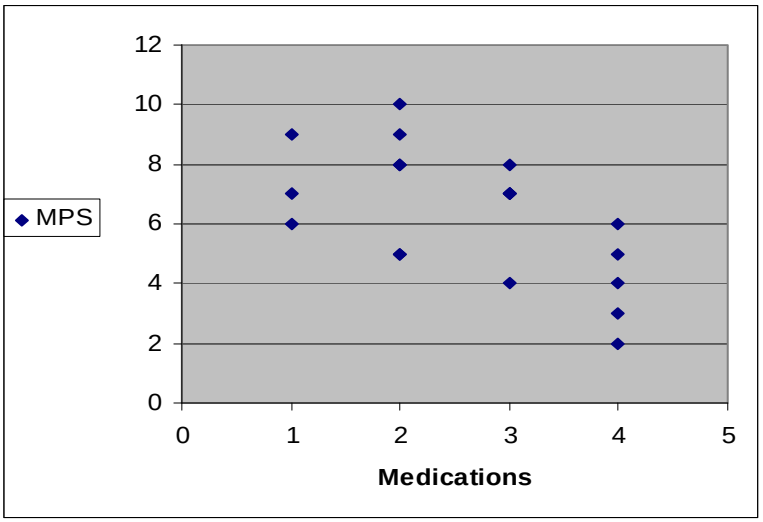
Table 6: Frequency and Mean of Low, Moderate, and High Physical Activity (PA) Level and Low and High Meal Planning Knowledge Score (MPS)

Source	n	MPS mean
Low PA Mean ±standard deviation (SD)	11	5.18 ± 1.779
Moderate PA Mean ± SD	2	8.50 ± 0.707
High PA Mean ± SD	6	6.5 ± 2.588

Patient Activation, Number of Medications and Meal Planning Knowledge for Diabetes

A significant negative correlation was demonstrated between number of medications and meal planning for diabetes knowledge test (r = -0.578). No significant correlation was found between level of PAM and number of medications or between PAM and meal planning knowledge (r = -0.270) (Figure 1).

Figure 1: Scatter plot for number of Medications and Meal Planning Knowledge (MPS) Score



CHAPTER V

DISCUSSION

The purpose of this study was to understand and quantify relationships and differences between a measurement of patient activation, physical activity level, meal planning, and polypharmacy in patients with type 2 diabetes and a hemoglobin A1C (A1C) > 6.5%. The first line of defense in the treatment of type 2 diabetes includes a lifestyle change in nutrition and exercise (Pan et al., 1997). Lifestyle interventions in the form of meal planning and exercise play an important role in a Diabetes Self Management Education (DSME) program. Success in the self-management of type 2 diabetes requires a knowledge base on the disease course, an understanding of the influence of important lifestyle interventions, and a patient who is actively engaged in the management of their health.

Patient Activation Measurement (PAM)

PAM and Physical Activity

PAM is used in research to both quantify and understand patient activation, and also to evaluate interventions (Hibbard et al., 2004). Sixty-three percent of the participants had a PAM level greater than two but less than three, indicating they have the knowledge and understanding regarding the influence of lifestyle in the management of type 2 diabetes. National standards of medical care for diabetes include specific recommendations regarding exercise. In an effort to improve glycemic control, individuals with type 2 diabetes are encouraged to accumulate at least 150 minutes per week of moderate-intensity aerobic physical activity at 50-70% of maximum heart rate and/or at least 90 minutes per week of vigorous aerobic exercise (> 70% of maximum

heart rate. At a minimum, physical activity should be spread out over three days per week with no more than two consecutive days without physical activity. Resistance exercise in the form of three sets of 8 -10 repetitions at a weight that cannot be lifted more than 8 -10 times targeting all major muscle groups three times per week is recommended provided no contraindications exist. These same exercise guidelines can be used for weight management as well as reducing the risk of coronary artery disease for individuals with type 2 diabetes (American Diabetes Association, 2006). The influence of consistent exercise on blood glucose and weight management has been well established. In a study by Church et al., (2004), the benefits of regular physical activity include improved insulin sensitivity and weight control, reduction of cardiovascular risk factors, and a healthier mental outlook. Blood glucose control can improve with regular exercise in individuals with type 2 diabetes, primarily due to decreased insulin resistance and increased insulin sensitivity. In the current investigation, the fact average physical activity level was lower in patients that have the knowledge and understanding to make decisions regarding their health as well as carry out the decisions in the self-management of their disease may provide insight into the need for a prescribed exercise component as part of a comprehensive diabetes self-management program.

Patients in the current study did not have a higher physical activity level when paired with meal planning knowledge. Although the difference was not significant in the current study, individuals with a PAM level between two and three scored greater than 70% on the meal planning knowledge test and had a low to moderate physical activity level. It is not clear why this situation presented itself. One possibility for the discrepancy is that exercise may not be a primary medical discussion point for patients and

physicians. As previously stated the standard of medical care for improved glycemic control among type 2 diabetics outlines specific recommendations regarding physical activity in the form of aerobic as well as resistance exercise to improve glycemic control and therefore should be in the forefront of discussion between physician and patient. As Leatherman et al. (2003) pointed out in a recent study, a potential barrier to exercise may include insufficient instruction regarding appropriate exercise due to limited office time for the patient visiting their primary care physician. Competing demands for time are compounded by patient requests during the visit. Fitting both the physician's and patient's agenda into the time allotted for the outpatient visit has important implications physician productivity and patient outcomes (Tai-Seale et al., 2003; Hussain et al., 2006).

It is essential for dietitians assisting patients in the development of effective self-management programs to be well versed in the understanding of patient activation as well as the benefits of exercise beyond simply asking how often a patient with type 2 diabetes exercises. Given the plethora of medically based fitness centers spreading across the country, it would seem important that nutritional professionals counseling patients with type 2 diabetes have a comprehensive understanding on the integration of nutrition and exercise in the lifestyle programs for diabetics. Participants with an activation level greater than three are "able to make decisions in the management of their health even in times of stress" according to the PAM guidelines and therefore may view exercise as an essential component in glycemic control. While a significant difference was not found, participants in this study with a PAM greater than level three tended to be moderately active compared to the physical activity level for all participants. Future patient-centered

research focusing on the concurrent variables of diet, exercise and medication is needed to strengthen the effectiveness of diabetes self-management programs.

In a study of prediabetics by Knowler et al. (2005), consistent exercise as part of a therapeutic lifestyle program was found to be more beneficial than medication or placebo in the prevention of type 2 diabetes. While the group with the low level of activity had a lower mean PAM than the high activity level group, the PAM of participants in this study was not significantly different between those that were low, moderate, or high in terms of physical activity level. This finding may be due to fact that the sample size was too small to determine more specific parameters regarding individual activity levels. Future studies should address specific exercise parameters beyond frequency. The medical-based fitness centers opening up across the country may provide a better venue for patients with type 2 diabetes to increase their knowledge and amount of physical activity. Therapeutic exercise programs that incorporate exercise intensity (i.e. perceived exertion, percent heart rate maximum) and resistance exercise geared for people with type 2 diabetes should be developed and studied, and these medically-based centers may be an ideal location.

PAM and Meal Planning Knowledge

While no significant correlation was found between PAM of participants in this study and test score on Meal Planning Questionnaire for Diabetes, a trend between low level of patient activation and lower meal planning score was noted compared to the participants with a higher level of patient activation. Meal planning is an integral component of diabetes education and optimal glycemic control is enhanced by knowledge in the area of meal planning for patients with type 2 diabetes. Current

standards of practice include various written and educational resources covering carbohydrate, protein and fat metabolism through medical nutrition therapy (MNT), physical activity, blood glucose monitoring and medications (Mahan et al., 2004). Effective diabetic self-management programs assume a level of health literacy on the part of the patient.

Literacy can be described as "an individual's ability to read, write, and speak in English and compute and solve problems at levels of proficiency necessary to function on the job and in society, and to develop one's knowledge and potential" (United States Department of Health and Human Services, 2007). Health literacy encompasses self-efficacy as well as a working knowledge of disease processes. Self-efficacy in the area of health literacy requires basic reading skills and numerical tasks for functioning in the health care environment as well as acting on health care information.

Low literacy is common in the United States. Years of education completed, certain racial and ethnic groups, the elderly, and populations with lower cognitive ability have an especially high prevalence of low literacy. Low literacy may compromise medical care and adequate functioning in the healthcare environment leading to adverse health outcomes. Recent studies have addressed appropriate interventions intended to improve the health among individuals with low literacy. However, prior to initiating self-management interventions, it is imperative to determine a patient's baseline knowledge regarding type 2 diabetes. This study measured baseline meal planning knowledge without measuring literacy. Given the fact recruitment for the study came from the Family Practice Center which serves a mixed population of middle class and economically disadvantaged patients, it would be important to understand literacy level

of the participants prior to testing meal planning knowledge with a written multiple choice exam. Nutrition plays an important role in a Diabetes Self-Management Program, therefore it would be advantageous to understand and study correlations between meal planning knowledge, literacy, and level of patient activation. This may enhance the development of comprehensive culturally sensitive diabetes self-management programs.

Physical Activity and Meal Planning Knowledge

As previously stated, the first line of defense in the treatment of type 2 diabetes includes a lifestyle change in nutrition and exercise (Pan et al., 1997). In fact, optimal glycemic control is enhanced by consistent exercise and an appropriate eating plan specific to the individuals needs. While no significant difference was found between a participant's level of activity and nutrition knowledge, the current study found that participants with a low level of physical activity had a lower average score on the meal planning test compared to the high physical activity group. A previous study with larger sample size supports the trend in the current study (Howteerakul, Suwannapong, & Rittichu, 2007). In a recent cross-sectional study measuring adherence to a treatment regimen among 243 type 2 diabetic patients, Howteerakul et al. (2007) determined diet and exercise were the two most important significant variables associated with glycemic control. The current study demonstrates a trend among people with type 2 diabetes linking nutrition and exercise as part of a therapeutic lifestyle program for glycemic control.

Wolf, Siadyaty, and Yaeger (2006), measured health care costs for a lifestyle intervention (diet and exercise) program in a high-risk obese population with type 2 diabetes. Compared to usual medical care (i.e. written information), a registered dietitian-

led lifestyle case-management intervention did not increase health care costs and suggested modest cost savings among obese patients with type 2 diabetes. Savings were in the form of medical costs and fewer in-patient admissions. Certainly larger studies are needed to determine if these findings can be applied to a broader population, however, this study emphasized the role of a registered dietitian in therapeutic lifestyle programs of nutrition as well as exercise. It is important for a dietitian to have the depth and breadth of knowledge regarding the effects of nutrition and exercise in glycemic management for diabetics. The foundation for such programs starts with a thorough understanding of the patient's knowledge and understanding of the role of diet and physical activity.

Polypharmacy, Meal Planning Knowledge, and Patient Activation

The average number of medications taken by patients with type 2 diabetes is four. In the current study, the average number of medications was 2.65 per participant. The type 2 diabetic patient can be a challenged with adverse drug reactions (ADR), especially when multiple medications are prescribed. The relationship between a patient's level of activation and their prescribed number of medications per day is not known. This study found no significant correlation between the number of prescribed medications and level of patient activation. However, a significant negative correlation was found between number of medications and score on meal planning questionnaire for diabetes. Participants who scored low on a meal planning questionnaire took more medications per day compared to participants who scored higher on a meal planning questionnaire. This finding may provide insight on the how adults with type 2 diabetes view the role of nutrition in a diabetes self-management program. In addition it brings to the surface the

question, “Are adults who take more medications per day not as concerned with nutrition knowledge or do they simply not know about the effect of nutrition on glycemic control?”

A recent study by Hill, Yeh, and Cary, (2007) found improved self-reported diabetes problem solving, medication adherence and lower A1C levels among type 2 diabetics who scored higher on the Diabetes Problem-Solving Scale. The scale may help identify associations between diabetes-related problem solving (i.e. meal planning) and self-management in order to improve glycemic control. Utilizing a problem-solving method to test meal planning knowledge and educate patients with type 2 diabetes may prove beneficial in programs that address health outcomes and quality of life.

The relationship between medication adherence and lifestyle interventions is complex. Individual personality traits, side-effects and compliance of medication, as well as the perception of the role of medication are just a few of the many factors to consider (Mordenti, D’Angiolini, & Murgia, 2000). Oral hypoglycemic medications and insulin regulate blood glucose levels in patients with type 2 diabetes. Studies have shown that patients taking insulin may not be as conscientious about the effect of carbohydrates on blood glucose levels (Mordenti et al., 2000). Opposition and ambiguity along with less self-confidence were described by Mordenti et al. (2000) in a study on the attitudes toward insulin prescription in type 2 diabetic patients non-compliant with diet therapy**.**

Strengths

Strength of this research was the use of a valid and reliable instrument (PAM) to measure differences and relationships between variables essential to management of

glycemic control in type 2 diabetes. The current study may begin to open the dialogue in the medical community on the complexity between patient activation, physical activity, polypharmacy, and knowledge of nutrition for individuals with type 2 diabetes prior to medical nutrition therapy.

Limitations

The primary limitation of this research was the small sample size. The small sample size made it difficult to test for significance between subgroups. For example, physical activity level was divided into three categories (low, medium, and high), and only two participants fell within the range for moderate activity level. This uneven distribution of participants made it difficult to test for statistical significance. Therefore a larger sample size could result in outcomes with greater statistical significance. In addition, the 10 multiple choice questions used to assess meal planning knowledge for diabetics may not depict an accurate perception of a patients understanding of the role of nutrition in the management of type 2 diabetes.

Future Studies

Future studies should include a larger sample size and address specific details concerning the role of exercise in diabetes. The exercise component in future studies could be strengthened by addressing specific exercise details (i.e. intensity, aerobic vs. weight training). In that participants for the current study were recruited from a mixed population of middle class and economically disadvantaged patients, future studies should consider including the cultural and socioeconomic background of the participants in the design of the study.

Conclusion

Statistical analysis from this study found no significant difference or relationship between the level of participant activation and level of physical activity, meal planning knowledge score, and number of medications. While the number of medications taken per day was not significantly related to patient activation level, a significant negative correlation between number of medications and meal planning for diabetes knowledge test was found. This suggests two concepts that require deeper investigation. First, individuals with type 2 diabetes who are not knowledgeable about meal planning for glycemic control, may end up taking more medications to achieve optimal blood glucose levels, and second, some individuals with type 2 diabetes may not be as concerned about nutrition thereby relying on medication to achieve optimal blood glucose levels.

Application to Practice

Type 2 Diabetes is a chronic illness associated with multiple medical complications particularly when blood glucose level is poorly controlled over many years duration. Successful self-management of type 2 diabetes requires active participation on the part of the patient that includes therapeutic lifestyle interventions in the form of meal planning and exercise. Patients with type 2 diabetes who actively participate in their healthcare decision making process will have better health outcomes (Wagner, 2001). Achieving the desired level of patient activation (i.e. 3-4) requires both a broad range of knowledge pertaining to factors that influence glycemic control, as well as the skill set to implement the information - particularly in times of stress (Hibbard et al., 2004). Nutrition professionals are an important member of the Diabetes Self-Management

Education (DSME) program. Therefore, it is imperative for nutrition professionals to have a comprehensive understanding of patient activation when providing DSME (i.e. nutrition and exercise) to patients with type 2 diabetes. It is also important for the nutrition professional to have a comprehensive understanding of the influence and patients perception of polypharmacy when providing DSME.

APPENDICES

APPENDIX A: PATIENT ACTIVATION MEASURE

Appendix A: Patient Activation Measure

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. *Your answers should be what is true for you and not just what you think the doctor wants you to say*.
If the statement does not apply to you, circle N/A.

When all is said and done, I am the person who is responsible for managing my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
Taking an active role in my own health care is the most important factor in determining my health and ability to function	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know what each of my prescribed medications does	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident I can tell a doctor concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can follow through on medical treatments I need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I understand the nature and causes of my health condition(s)	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know the different medical treatment options available for my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I have been able to maintain the lifestyle changes for my health condition that I have made	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I know how to prevent further problems with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident I can figure out solutions when new situations or problems arise with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
I am confident that I can maintain lifestyle changes, like diet and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

APPENDIX B: MNT DIABETES MEAL PLANNING KNOWLEDGE TEST

Appendix B: MNT Diabetes Meal Planning Knowledge Test

Multiple Choice

Identify the letter of the choice that best completes the statement or answers the question.

____ 1. Which should NOT be used to treat low blood sugar?
   a. 3 hard candies
   b. 1/2 cup orange juice
   c. 1 cup diet soda
   d. 1 cup skim milk

____ 2. If you drink 100% fruit juice, what might happen to your blood sugar?
   a. lowers it
   b. raises it
   c. has no effect
   d. depends on what kind

____ 3. Corn belongs in what diabetes meal planning food group?
   a. vegetables
   b. carbohydrates
   c. fruits
   d. starches
   e. b and d

____ 4. Which is the most important change for someone with diabetes to make in their meal plan?
   a. eat more high-iron foods
   b. eat regular meals
   c. avoid sugar and sugar-containing foods
   d. eat an hs snack

____ 5. Which pairs of foods are about the same in carbohydrate?
   a. 1 cup cooked vegetables and 3 ounces smoked turkey
   b. 1 cup cooked rice and 1 slice of bread
   c. 1/2 cup green peas and 1 cup milk
   d. piece of fruit pie and 1 cup pasta
   e. c and d

____ 6. If you are having a low blood sugar reaction (hypoglycemia) you should
   a. Eat a protein food, such as eggs or cottage cheese.
   b. Eat a balanced meal

c. Drink some juice or regular soda, 1 tablespoon sugar or honey or crackers and recheck sugar in a little while.
d. Call 911

____ 7. Jenny has type 2 diabetes and uses insulin. She has the stomach flu, and hasn't eaten anything all day. She should
a. not take her insulin until she can keep some food down
b. check her blood sugar at least 4 times a day
c. try to eat soups, juices, ice cream, and regular soft drinks
d. take her insulin as usual
e. b, c, and d

____ 8. In the meal plan for diabetes, cake should be
a. substituted for fat exchanges
b. substituted for fruit and/or starch exchanges
c. avoided
d. sugar-free

____ 9. Which of the following foods contains sugar?
a. plain, unsweetened yogurt
b. medium apple
c. 1/2 cup unsweetened orange juice
d. all of the above
e. none of the above

____ 10. Lowfat cheese is in the
a. meat group
b. milk group
c. carbohydrate group
d. Saturated fat group

Diabetes Meal Planning

Answer Section MULTIPLE CHOICE

1	C	6	C
2	B	7	E
3	E	8	B
4	B	9	D
5	E	10	A

Total correct answers	Score
10	100%
9	90%
8	80%
7	70%
6	60%
5	50%
4	40%
3	30%
2	20%
1	10%

APPENDIX C: SUMMA FAMILY PRACTICE CENTER DIABETES SELF MANAGEMENT PATIENT INTERVIEW - MEDICATIONS

Appendix C: Summa Family Practice Center Diabetes Self Management Patient Interview - Medications

Oral Hypoglycemic Medications

Q12: Are you currently taking any of the following diabetes pills? (circle one answer on each line)

	No	**Yes**
1. Glucotrol (glipizide)	0	1
2. Micronase, Glynase, or Diabeta (glyburide)	0	1
3. Amaryl (glimepiride)	0	1
4. Tolinase (tolazamide)	0	1
5. Diabinese (chlorpropamide)	0	1
6. Glucophage (metformin)	0	1
7. Precose (acarbose)	0	1
8. Rezulin (troglitazone)	0	1
9. Prandin (repaglinide)	0	1
4. Other (please specify below): _____	0	1

APPENDIX D: DATA COLLECTION SHEET

Appendix D: Data Collection Sheet

SUMMA Medical Record Data Collection Form

Study ID# __ __ __ Facility: FP / IM MR# __ __ __ __ __ __ __ __ MD: _____

FMCRN# __ __ __ __ __ __

Last FMC Visit Date: _____

DOB ___/___/_____ Age __ __ Gender: M / F

INSURANCE

Circle one and note type of commercial.

Medicare Medicaid Commercial _____ Not Listed

SOCIAL

Employed: Y / N / Retired Smoke: Y / N

Dr OK exercise: Y / N

HEIGHT/WEIGHT

Weight __ __ __ lb (__ __ __ kg)

DIABETES

Type: Type 1 / Type 2 / unknown

Insulin: Y / N Oral Agent: Y / N Rx: Y / N Rx _____

Evidence of foot checks during last office visit? Y /N

HISTORY

HTN: Y / N CAD: Y / N CHF: Y / N Depression: Y / N

HLP : Y / N Nephropathy: Y / N Retinopathy Y / N

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