THE IMPACT OF ETHNICITY AND DIET COUNSELING ON THE OUTCOMES OF DIABETES EDUCATION

A DISSERTATION

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ABSTRACT

The Impact of Ethnicity and Diet Counseling on The Outcomes of Diabetes Education

Elizabeth Ann Thornton Cabanas December 2001

The purpose of this research was to determine the effect of education intervention on glycemic control and nutritional consumption patterns in individuals of various ethnic backgrounds who completed a diabetes self-management training program. Initial and final hemoglobin A_{1c} and random blood glucose measures were compared in 124 participants enrolled in a diabetes education program. Subjects were of diverse ethnic background, with 33% reporting Black ancestry, 45% reporting Caucasian and 21%, Hispanic. Nutritional intake preceding and following educational intervention was evaluated. Energy intake, percent of energy from fat, and quantities consumed of five food groups from the *Food Guide Pyramid* were determined. Following this diabetes education program, it was observed that glycemic control improved, as evidenced by a significant lowering of hemoglobin A_{1c} for all three ethnic groups studied. Energy intake decreased along with percentage of energy from fat, and vegetable consumption improved significantly. Diabetes education and diet counseling were effective in improving glycemic control and food consumption patterns in this multiethnic population.

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CHAPTER I

INTRODUCTION

Diabetes mellitus is a clinically and genetically heterogeneous group of disorders that have one common feature--abnormally high levels of glucose in the blood due to either insulin deficiency or resistance of the body's cells to the action of insulin. This syndrome has been recognized for centuries with the first written description of nutritional therapy appearing in approximately 1550 B.C. (Powers, 1987). Little was known about the pathogenesis of the disease except that most afflicted with the disorder died of "wasting," or malnutrition and dehydration. Nutritional manipulation has been the primary treatment of diabetes for over 1,000 years. Various diets have been used repeatedly throughout the ages and have fluctuated in the distribution of energy from carbohydrate, fat and protein. With the discovery of insulin in 1921, diet management held a lower priority in the control of hyperglycemia because of the newness and simplicity of pharmaceutical therapy. However, recently the importance of matching medication to carbohydrate intake has been established as a standard of care for individuals with diabetes mellitus.

Over the past several decades, research has led to the discovery of various types of diabetes attributed to a number of causes. Regardless of the type of diabetes, the pathological course is similar. The heterogeneity within the syndrome of diabetes has

important implications for clinical management and research. There are two main types of diabetes mellitus, type 1 and type 2, but the exact causes of both conditions remain unknown after decades of research. Both, however, differ markedly in pathogenesis, natural history, and responses to therapy and preventive measures. Similar complications occurring in both types are blindness, renal failure, stroke, amputation, and premature cardiovascular disease.

The prevalence of type 1 diabetes is increasing steadily while that of type 2 is increasing exponentially in the United States. Changing lifestyles, longer life expectancy, and rapid growth of ethnic populations that have high prevalence rates of type 2 diabetes will double the worldwide prevalence of diabetes within a decade. Although the onset of type 2 is heavily associated with genetics, lifestyle is thought to play a large part in disease onset. Obesity and a sedentary lifestyle have been implicated as major contributing factors in the development of type 2 diabetes in immigrant and urban populations in the United States. Upper body obesity, or truncal localization of adipose tissue, as opposed to generalized or lower-segment (pelvic) obesity, is strongly associated with hyperinsulinemia and type 2 diabetes, especially among such high-risk groups as those with a family history of type 2 in first-degree relatives (American Diabetes Association, 1998).

The prevalence of type 2 diabetes varies substantially among different ethnic groups. Prevalence rates for Blacks, Caucasian females, and Hispanics are consistently

higher than for Caucasian males. It has been suggested that these apparent ethnic and gender differences may reflect population variations in risk factors, such as obesity, physical activity, genetics, and socioeconomic status (Harris, Flegal & Cowie, 1998).

There is unanimous agreement that type 2 diabetes is emerging as a serious clinical condition in this country. Historically, it has not been considered a pediatric disease, therefore, there is limited information about the epidemiology of type 2 in children (Kahn, 2000). However, there has recently been an alarming rise in the incidence of type 2 diabetes in children, with a greater proportion of minority children being affected. The incidence of type 2 diabetes in adolescents increased tenfold between 1982 and 1994. Fewer than 4% of pediatric cases were attributed to type 2 diabetes before the 1990's. However, up to 45% have been reported in recent studies (Kahn, 2000). In some Black populations, the incidence of diabetes is three times that of Caucasian adolescents. Obesity is present in the majority of patients, with body mass index exceeding the 85th percentile, in almost 95% of patients. Sedentary lifestyle is also strongly correlated with type 2 in children, as is a family history of this form of diabetes (Dabelea, Pettitt, Jones, & Arslanian, 1999).

Diabetes mellitus is expected to increase to epidemic proportions in the near future. The cost of health care for individuals with diabetes mellitus is staggering. The average cost of caring for a diabetic patient is approximately four times that of other

patients being cared for in the health care system. The major role of health care professionals today is to implement treatments that will minimize or prevent the complications of diabetes and to develop new methods of preventing or delaying the onset of diabetes and its complications in individuals with genetic predispositions for diabetes mellitus.

Statement of the Problem

Diabetes education has been proven to enhance diabetes outcomes. Diabetes self-management ability and glycemic control are positively affected by encounters with diabetes educators using varied teaching modalities. An obvious lack of research involving ethnic populations, however, has been observed. A few recent research projects have centered upon one particular ethnic subgroup and one specific aspect of diabetes education, e.g., foot care or ophthalmic examinations (Walker et al., 1997). No research has been reported on a comprehensive diabetes self-management training program in a multiethnic population using values for blood glucose and glycosylated hemoglobin A_{1c} (HbA_{1c}) as indices of glycemic control. Numerous areas in the United States are populated by a variety of ethnic groups as opposed to one predominant culture. American society has become diverse, with representation from three or more different backgrounds. Diabetes self-management training in many areas must address the needs of individuals from various backgrounds--often within the same group setting.

This research involves a diabetes education program serving a multiethnic population that is nationally recognized by the American Diabetes Association as meeting national standards for diabetes patient education. Three certified diabetes educators (two RNs and one RD) taught all classes consistently throughout the data period. All three educators had been local residents for over two decades and were, therefore,

knowledgeable about the various ethnic preferences of program participants.

Null Hypotheses

- After completion of the diabetes self-management training program, there will be no change in random blood glucose.
- 2. After completion of the diabetes education program, there will be no change in HbA_{1c}.
- After program completion, there will be no effect of ethnicity on changes in random blood glucose.
- 4. There will be no effect of ethnicity on changes in HbA_{1e} following education.
- 5. There will be no changes in quantities consumed of fruit, vegetables, milk, meat, and bread/grain following education.
- 6. The percentage of subjects eating 30% or less of calories as fat will not change posteducation.
- 7. There will be no change in energy intake of patients with BMI over 28 who were eating in excess of energy needs pre-education.

CHAPTER II

REVIEW OF LITERATURE

Diabetes mellitus is estimated to afflict approximately 17 million people in the United States, but only half of these cases are diagnosed and treated. There are approximately 800,000 new cases of diabetes diagnosed every year. Diabetes is currently the sixth leading cause of death in women and the seventh leading cause of death in men in the U.S. It ranks fourth among some minority groups (e.g., Hispanic and Black) according to the Center for Disease Control National Center for Health Statistics.

Moreover, diabetes is believed to be underreported on death certificates, both as a condition and as a cause of death. Diabetes mortality increased consistently between 1986 and 1996 and this rate has accelerated since 1990 (Murphy, 2000). Approximately 8.2% of people age 20 years or older and 18.4% of all people age 65 and older are estimated to have this condition (American Diabetes Association, 1998).

Chronic complications of diabetes, which usually occur 10 to 15 years after the onset of diabetes, include microvascular ones leading to nephropathy, retinopathy and neuropathy contributing to various visual and neurological problems, macrovascular leading to stroke and myocardial infarction, and peripheral vascular disease leading to amputation. Heart disease is the leading cause of diabetes-related deaths. Male adults with diabetes have heart disease death rates 2 to 4 times higher than adults without

diabetes. Women with diabetes may have even a higher rate of heart disease than men with this condition. Diabetes is the leading cause of new cases of blindness in adults 20 to 74 years old. Diabetic retinopathy causes between 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% of new cases annually and is the fastest growing cause of kidney dialysis and transplantation (over 100,000 cases per year). Additionally, more than half of lower limb amputations were performed each year on people with diabetes. Thus, it is clear that both the quality of life and productivity are compromised for individuals with this debilitating disease.

Classifications

Diabetes mellitus is a condition involving several metabolic abnormalities characterized by hyperglycemia and defects in insulin secretion, insulin action, or both. The pathogenic process of diabetes involves pancreatic beta-cell dysfunction leading to impaired insulin synthesis, release and/or insulin resistance. Diabetes may be diagnosed by the methods listed in Table 1. Of these three methods, the fasting plasma glucose test is preferred. There are four classifications of diabetes mellitus: types 1 and 2, gestational, and secondary conditions associated with endocrine disease or medications-e.g., steroids and thiazides (Lebovitz, 1998). Most individuals with diabetes have either type 1 or type 2, and these types will be discussed in this paper.

Table 1

Diagnostic Criteria for Diabetes Mellitus

Fasting Plasma Glucose	Oral 75 g Glucose Tolerance Test	Casual Plasma Glucose
Normal		
<6.1 mmol/l	<7.8 mmol/l	
<110 mg/dl	<140 mg/dl	
^a IFG		
≥6.1 and <7.0 mmol/l		
≥110 and <126 mg/dl		
^b IGT	≥7.8 and <11.1 mmol/l	
	≥140 and <200 mg/dl	
Diabetes		
≥7.0 mmol/l	≥11.1 mmol/l	≥11.1 mmol/l
≥126 mg/dl	≥200 mg/dl	≥200 mg/dl plus
		symptoms ^c

In the absence of unequivocal hyperglycemia with acute metabolic decompensation, these criteria should be confirmed by repeat testing on a different day.

Note. From "Clinical Practice Recommendations," by American Diabetes Association,

2001, <u>Diabetes Care</u>, 24, (Suppl 1), p. S15.

^aIFG=Impaired fasting glucose. ^bIGT=Impaired glucose tolerance. ^cPolyuria, polydipsia.

Type 1 diabetes develops at any age, but most cases are reported in those under age 30. These individuals are dependent on exogenous insulin to prevent ketoacidosis and to sustain life. Type 1 diabetes results from an autoimmune attack on the beta-cell (Bennett & Todd, 1996; Homo-Delarche & Boitard, 1996; Thai & Eisenbarth, 1993). Pathological changes may occur as long as nine years before the clinical onset of type 1 diabetes. The five stages of development include a genetic propensity for the disease, an environmental trigger, active autoimmunity, progressive beta-cell dysfunction, and, finally, overt diabetes mellitus. The risk for developing type 1 in the general U.S. population is 1 in 300 children. This risk is increased in the offspring of individuals with diabetes to approximately 1 in 20 (American Diabetes Association, 1998).

Environmental triggers have long been suspected in the manifestation of diabetes mellitus. There has been an association between type 1 diabetes and congenital rubella and Coxsackie B4 infection. Bovine serum albumin-specific antibodies are found in some, but not all children with newly diagnosed diabetes. Some have suggested that early exposure to both human and cow's milk may act as an environmental trigger (Scott, Norris, & Kolb, 1996). Some studies show an increased risk of type 1 by 1.5 times in those with a history of early exposure to cow's milk and breast feeding for less than 3 months duration (Gerstein, 1994). Additional factors have been suggested as triggers for type 1 diabetes, including a rise in serum levels of sex steroids (as seen in puberty and

during pregnancy), environmental toxins (such as N-nitroso derivatives and the rodenticide, Vacor), and possibly insulin itself (Leslie & Elliott, 1994).

Active autoimmunity directed against beta-cells results in the appearance of beta-cell autoantigens. The progression to diabetes in relatives of individuals with type 1 is strongly dependent on the presence of biochemical autoantibodies (Verge et al., 1996). Those lacking islet cell antibodies have a 99.9% probability of not developing type 1 diabetes. The pathophysiologic decline of the beta-cell mass is a slow, progressive condition, but overt diabetes may be precipitated by either acute illness or stress that increases the demand for insulin beyond the capacity of the damaged beta-cell.

Another classification of diabetes mellitus is type 2, which is usually, but not exclusively, diagnosed after the age of 30. About 90% of those with diabetes are type 2, with disproportionate representation among the elderly and certain ethnic populations (Hispanic, Black, Native American, and Asian). Insulin resistance (defined as insulin dose requirements over 1.5 Units per kg body weight) is typically present in type 2 individuals. Impaired glucose tolerance (defined as fasting plasma glucose ≥110 but <126 mg/dl) is also present in the initial stages. However, endogenous insulin levels may be normal, increased, or decreased. Approximately 80% of patients are obese at the time of diagnosis. The gradual onset of the disease is slow, often persisting five years or longer before actual diagnosis. Coronary artery disease is widely prevalent in type 2 diabetes.

Heredity plays a major role in the expression of type 2 (Fujimoto, 1996; Moller, Bjorbaek, & Vidal-Puig, 1996). Offspring of individuals with type 2 diabetes have a 15% chance of developing the disease and a 30% risk of developing impaired glucose tolerance (Raffel & Rotter, 1985). A greater than 90% concordance rate exists between monozygotic twins if one has type 2 diabetes, suggesting a strong genetic inheritance pattern. Type 2 is a heterogeneous disease characterized by variable plasma insulin levels with associated hyperglycemia and peripheral insulin resistance (Gerich, 1996).

Although the actual cause of type 2 diabetes is still unknown, it is influenced by the following specific defects: primary beta-cell dysfunction, post-receptor defects, altered glucose transporter function, and specific enzymatic defects that modulate intracellular insulin activity (Moller et al., 1996; DeFronzo, 1992). Limitation of the beta-cell in response to hyperglycemia appears to be another factor in the pathophysiology of type 2 diabetes (Leahy, 1990). Abnormal beta-cell recognition of glucose is associated with a disturbance in insulin synthesis and secretion, further contributing to metabolic compromise. This defect in beta-cell activity in response to hyperglycemia has been referred to as glucose toxicity. Beta-cells become progressively less responsive to elevations in blood glucose after chronic exposure to hyperglycemic conditions.

Another characteristic of type 2 diabetes is the presence of resistance to the biologic activity of insulin noted in both liver and peripheral tissues. This may result in

hyperglycemia followed by hyperinsulinemia and reduction in beta-cell activity. Type 2 diabetes is often associated with a persistent elevated hepatic glucose production, which increases fasting blood glucose levels. In the fasting state, blood glucose is maintained by hepatic glucose production via glycogenolysis and gluconeogenesis. Insulin suppresses these processes in a dose-dependent manner. Those with type 2 diabetes often require larger doses of insulin to maintain euglycemia, indicating a decrease in insulin sensitivity (Taylor, Accili, & Imai, 1994). Thus, regardless of circulating insulin levels, the condition of type 2 diabetes is often associated with a persistent hepatic glucose production that increases fasting glucose levels. The relative roles of insulin resistance and insulin deficiency remain controversial in the mechanism of type 2 diabetes (Taylor et al., 1994).

The differential diagnosis between types 1 and 2 diabetes is generally based on the clinical assessment of the patient upon presentation. Success of oral hypoglycemic or insulin-sensitizing agents, or weight loss/exercise in maintaining euglycemia is indicative of type 2 diabetes, especially in obese patients with a family history of this disease.

Patients with type 1 must use exogenous insulin to prevent diabetic ketoacidosis at the time of disease onset.

Medications

Diabetes is a progressive disease requiring continuous monitoring and change in

therapeutic regimen. If a patient has been unsuccessful in lowering blood glucose through diet and exercise, medications are necessary. Pharmalogical intervention should be viewed as an adjunct to the health care program not as a substitute for appropriate meal planning and exercise. A number of medications are used to control blood glucose and each has a different mechanism of action.

The sulfonylurea medications have been used since 1955 and, although their true mechanism of action is not fully understood, they are known to lower blood glucose predominantly by stimulating insulin secretion from beta-cells (Lebovitz, 1994). Sulfonylureas act by binding to a common receptor on the beta-cell, which is coupled to an ATP-sensitive potassium channel that activates the insulin secretion pathway. Sulfonylureas may also potentiate the action of insulin in liver, muscle and adipose tissue, but the clinical relevance of these actions is controversial. These medications are associated with decreases in hemoglobin A_{1c} of 1.2 to 1.8% and decreases in fasting plasma glucose of about 60 mg/dl.

Metformin is in the class of biguanides and does not stimulate insulin secretion. The mechanism of action is to increase glucose utilization and decrease hepatic glucose production (Vigneri & Goldfine, 1987). It may also potentiate insulin action to increase glucose uptake in muscle and fat. Metformin also causes a decrease in the intestinal absorption of glucose and has an anorexiant effect. Metformin is often used in

combination with a sulfonylurea to further improve glycemic control.

Alpha-glucosidase inhibitors are another class of drugs available in the U.S. for use in diabetes control. Dietary starches are converted to glucose and other monosaccharides by a series of enzymes in the gastrointestinal tract. Alpha-glucosidase inhibitors competitively inhibit these enzymatic steps in the small intestine (Hanefeld, Fisscher, & Schulze, 1991). These drugs delay absorption of glucose after a meal and may cause partial malabsorption of monosaccharides. Postprandial increases in blood glucose are reduced and there is a small reduction in fasting blood glucose (~10-20 mg/dl).

Thiazolidinediones enhance insulin action and increase glucose utilization in peripheral tissues, principally muscle and fat. They may also suppress gluconeogenesis in the liver. The action is probably mediated through stimulation of a class of nuclear receptors--peroxisome proliferator activated receptors (PPAR-gamma)--which increase the expression of genes that encode for the glucose transporter proteins. This class of medications does not induce insulin secretion.

Metiglinides stimulate insulin secretion from functioning beta-cells in the pancreas. Their mechanism of action is similar to the sulfonylureas. The release of insulin is glucose-dependent and, because of this, metiglinides have maximum effect postprandially. Compared to sulfonylureas, the onset of action is more rapid in

metiglinides as is the clearance from circulation. Because of their short duration of action, metiglinides must be taken with meals on a regular schedule.

Insulin therapy must be used in type 1 diabetes; however, an estimated 76% of all insulin-treated patients in the U.S. have type 2 diabetes (Genuth, 1990). The approach to insulin therapy in type 2 is substantially different than in type 1 because of the role of insulin resistance in the disease process and the presence of endogenous insulin secretion. There is an excess hepatic glucose production in some type 2 patients often combined with a defect in glucose utilization by insulin-sensitive tissues and a defect in insulin secretion. Therefore, insulin therapy must be individualized based on the disease state of the patient.

Health Care Costs of Diabetes

Diabetes mellitus is one of the most costly chronic diseases in the U.S. The national health cost for the treatment of diabetes, along with its associated complications, exceeds \$100 billion annually (American Diabetes Association, 1998). Twenty-seven percent of the entire Medicare budget is spent to pay for health care of people with diabetes. The average cost of caring for the individual with diabetes is approximately four times that of other patients in the health care system. Direct medical expenditure for diabetes in 1997 was \$44.1 billion, with 62% attributed to inpatient care, 25% outpatient, and 13% for nursing home care. There were an estimated 2.29 million hospital

admissions (13.87 million hospital days) with an average length of stay of 6.1 days.

Approximately 69.73 million nursing home days were registered in 1997. Most of the disability and costs associated with diabetes are a result of chronic complications. A major goal of the health care system is to implement treatments which prevent or minimize the complications of diabetes and to prevent or delay the development of diabetes and its complications (Lebovitz, 1998). In addition to the costs associated with the healthcare of patients with diabetes, there are detrimental effects on quality of life for patients and family members. Diabetes, therefore, is a disease that mandates the attention of the health care industry.

The chronic complications of diabetes previously mentioned occur in both types 1 and 2. Complications of diabetes were virtually unknown until 10 - 20 years after the discovery of insulin in 1921. During the 1930s and 1940s, descriptions of neuropathy, retinopathy, and renal disease began to appear. However, it was unclear whether the complications were a result of poor blood glucose control or a consequence of the progression of diabetes.

Diabetes Control and Complications Trial

Two large-scale studies have proven that maintaining normal blood glucose levels is directly associated with reduction in risk of developing complications. The Diabetes Control and Complication Trial (DCCT) determined that lowering blood glucose to near

normal range effectively delays and slows the onset of diabetic retinopathy, nephropathy, and neuropathy in subjects with type 1 diabetes mellitus (The DCCT Research Group, 1993). The DCCT was a multicenter, randomized clinical trial carried out at 29 centers throughout the United States. The trial was designed to compare intensive with conventional diabetes therapy with regard to their effects on the development and progression of the early vascular and neurologic complications of type 1 diabetes. The goal of intensive therapy was to achieve blood glucose values as close to the normal range as possible (fasting plasma glucose <110, plasma glucose between 70-120 mg/dl before meals) with three or more daily insulin injections. Conventional therapy consisted of one or two insulin injections per day. A total of 1,441 patients were recruited from 1983 to 1993. In June of 1993, after an average follow-up of 6.5 years (range 3 to 9), or 9,300 patient years, the independent data committee determined that the study results warranted terminating the trial.

Results of this study confirmed that control of blood glucose to near normal range reduced the risk of complications. Intensive insulin therapy reduced the risk of retinopathy by 76%. Intensive therapy was also found to reduce progression of existing retinopathy by 54%, and the risk for photocoagulation therapy for the treatment of proliferative retinopathy was reduced by 56%. The risk of nephropathy was reduced by 43%. The risk of neuropathy was also reduced by 69%. Adverse effects of intensive

insulin therapy were noted. There was a 33% increase in the risk of becoming overweight (20% above ideal body weight) because of increased lipogenesis resulting from insulin therapy. The risk of severe hypoglycemia increased with the decrease in HbA_{1c}.

United Kingdom Prospective Diabetes Study

The United Kingdom Prospective Diabetes Study on 3,867 newly diagnosed type 2 patients found that an 11% reduction in HbA_{1c} reduced the risk of microvascular complications by 25%, although there was no effect on macrovascular disease risk (Turner, Cull, & Holman, 1996). The 10-year study period, however, may not have allowed time to adequately assess the progression of atheroma development. Adverse effects of intensive therapy (decreasing HbA_{1c} to normal range, <7.0%) in type 2 were weight gain (~2.9 kg more than conventional group) and the risk of hypoglycemia.

These studies proved the importance of maintaining normal glycemia in the diabetic population. The glycation of proteins is the main contributing factor in the pathogenesis of diabetic complications. It is essential, therefore, that patients be properly educated in proper diabetes self-management skills. Diabetes is a disease that is controlled primarily by the patient. Health care providers guide patients in the method of care, but the actual day-to-day regimen must be managed by the patient.

Glycation of Proteins

The formation of glycated proteins (i.e., hemoglobin) occurs by the process of

nonenzymatic glycosylation which is the first step of the Hodge pathway of the Maillard or browning reaction between reducing sugars and amines. Nonenzymatic glycosylation of proteins occurs at both terminal amino groups and at epsilon amino groups of intrachain amino acids. It involves the addition of glucose to protein by a slow continuous reaction that is a function of the duration of contact between the reactants and glucose concentrations during the time of contact. The first product formed is an aldimine (or Schiff base), which then undergoes an internal rearrangement of the double bond (an Amadori rearrangement) to form a ketoamine. The kinetics of the latter reaction are essentially irreversible.

Following glycation of amino groups in proteins, lipids, and nucleic acids, a complex cascade of oxidative reactions ensues, leading to further chemical modification, cross-linking, fragmentation and insolubilization of numerous biomolecules. The formation of these advanced glycation end products and their accumulation in tissues is thought to contribute to the chemical modification and cross-linking of tissue proteins, lipids and DNA, and to the pathogenesis of diabetic complications (Sima, 2000). The goal of diabetes therapy is HbA_{1c} of <7% and fasting plasma glucose >70 mg/dl and <110 mg/dl.

Diabetes Education Programs

Diabetes education is considered to be an essential component of the management

of diabetes, and a multidisciplinary team of diabetes healthcare providers offers the best combination of resources for the individual with diabetes (Farkas-Hirsch & Hinschi, 1998). Primarily, improvement in glycemic control and lipid profile, increase in daily activity level, and improvement in healthy meal planning practices are the main outcomes that are considered to be indicators of successful diabetes education. Most agree that diabetes education and patient self-management should be integrally related to, and be a part of, a patient's ongoing care as opposed to considering diabetes education as a single event in the health management process (Glasgow, Vogt, & Boles, 1999). With the plethora of drugs, devices, and treatments used to control diabetes, it is necessary for people with this disease to understand the relationship of these factors to appropriate selfmanagement of blood glucose and to learn how to use medications and devices correctly. Knowledge of diabetes self-management alone, however, does not necessarily translate into behavioral change. Self-management education is both a science and an art in the realms of education and behavioral counseling. The complexity and challenges of behavior change and diabetes self-management are factors to be considered in outcomes evaluation of diabetes education programs. The issues of autonomy, empowerment, and personal choice affect the outcomes of diabetes education, and diabetes education research studies have been done on these topics (Anderson et al., 1995; Williams, Freedman, & Deci, 1998). Cultural sensitivity has recently been addressed and must also

be considered in the educational process (Walker, 1999).

There is a growing trend to evaluate the effectiveness of diabetes education by using outcome measures. These consistently include changes in plasma glucose and glycosylated hemoglobin or HbA_{1e}. Although studies have reported on the impact of education on diabetes outcomes over the past two decades, few have reported outcomes of diabetes education in ethnic populations--i.e., Hispanic, Black, Native American, and Asian. Several meta-analyses of the diabetes education literature have been conducted since 1995. A major research gap was noted in diabetes education conducted in minority groups with a high incidence of type 2 diabetes (American Diabetes Association, 1996). As the managed-care system continues to grow, the benefits of diabetes education must be evaluated to prove its effectiveness. Unfortunately, the value of diabetes education is being challenged, and educational services are being eliminated. Thus, it is imperative to demonstrate that educational programs can improve glycemic control and consequently reduce the complications of diabetes, especially in high-risk populations.

Diabetes Education (1970-1990)

Prior to the 1970s diabetes education programs were primarily provided for hospital-based patients and were individualized for each person. Nurses and dietitians primarily provided education at the patient's bedside, often just before discharge from the hospital. Patient assessment following discharge was often lacking. By the 1980s,

inpatient education programs were on the rise. These programs were designed to provide daily lectures by hospital staff on various aspects of diabetes care. Each week the sessions were repeated, and any inpatient could attend as many sessions as desired. However, with the decreased length of hospital stays, these programs were abandoned since they no longer provided adequate education for the patient (Brown, 1999).

In 1980, a review was published regarding the benefits of traditional didactic diabetes education programs (Watts, 1980). It was noted that these programs were of little value other than improving a patient's knowledge of diabetes. This review focused upon three main variables: 1) knowledge about diabetes and its treatment, 2) self-care and compliance with the treatment regimen, and 3) metabolic control achieved by the patient. It became clear that the behavioral management of diabetes was complicated by a number of factors including individual personality characteristics, basic health beliefs, major fluctuations in stress levels, and health in general. It was suggested that educational programs broaden from the dissemination of information alone to include assessment of patient values regarding chronic illness and health and the application of behavioral methods of self-monitoring and self-regulation.

Three meta-analyses were reported in the late 1980s on outcomes of diabetes education intervention (Brown, 1990, 1992; Mullen, Green, & Persinger, 1985; Padgett, Mumford, Hynes, & Carter, 1988). These reviews indicated that self-management

education, regardless of strategy or diabetes-specific intervention (didactic, diet instruction, counseling, self-monitoring instruction) had moderate to large effects on improvement in metabolic control as assessed by the reduction in HbA_{1c}. Diabetes education also resulted in an increase in knowledge outcomes and improved skill performance.

Since this period, more studies have documented the benefits of diabetes self-management education. A meta-analysis of patient compliance literature published between 1977 and 1994 revealed that educational interventions for all diseases studied produced significant effects for all compliance indicators (Roter et al., 1998). Compliance effects were evident for improved health outcomes, and patients with diabetes especially benefited from intervention. Comprehensive interventions combining cognitive, behavioral, and affective components were more effective than single-focus interventions. It was also found that combined educational strategies (e.g., intervention involving one-to-one instruction plus group teaching) achieved higher knowledge gains compared with single interventions and, again, the largest outcomes were found for studies of subjects with diabetes mellitus.

Outcome Measures of Diabetes Education

Numerous intervention trials have reported positive effects of patient selfmanagement training on outcomes of diabetes mellitus. For example, a study of 886 patients receiving diabetes-related medical care in outpatient clinics showed that patients who had not received any kind of outpatient diabetes education showed a more than fourfold increase in the risk of developing a major complication (Nicolucci et al., 1996). Adult participants in the Johns Hopkins Diabetes Center 5-day program (n=82) experienced reduced HbA_{1c} levels, from 11.3% at preprogram to 9.4% at follow-up (Peyrot & Rubin, 1994). Length of hospital stay was shortened in 85 patients treated by a diabetes team in the New York Medical College Medical Center. Patients were also found to achieve better glycemic control earlier than those without intervention (Kopreski, Pretto, & Poretsky, 1997). A randomized trial of 238 patients receiving diabetes education showed significant reduction in HbA_{1c} from 11.9 to 8.4% 3 months following intervention (Campbell, Redman, Moffitt, & Sanson-Fisher, 1996). Another study of 159 patients receiving small-group (5 participants) diabetes education indicated an average decrease in glycosylated hemoglobin from 9.6% to 7.6% twelve months following the classes (Schrock, 1998). An outpatient diabetes education program in Ontario reported a significant reduction in HbA_{1c} from 9.4 to 7.5% in 33 newly diagnosed patients six months following intervention (Tilly, Belton, & McLachlan, 1995).

Diabetes in Minority Populations

There are a multitude of studies that have been published over the past 20 years which have reported beneficial effects of diabetes education on glycemic control and

other outcome measures. Few studies, however, have reported on the impact of ethnicity on diabetes education outcomes (American Diabetes Association, 1996).

Diabetes is becoming the most prevalent health problem in the U.S., with annual costs (primarily due to the chronic complications of diabetes) estimated at \$100 billion (American Diabetes Association, 1998). The frequency and burden of diabetes and its complications are greater in those very communities least able to effectively manage these health care problems - minority and elderly populations (Vinicor, 1994; Haffner, Hazuda, Mitchell, Patterson, & Stern, 1991).

Diabetes complications are a significant cause of morbidity and mortality in the U.S., especially among ethnic subgroups. The rate of diabetes is rising in this country even though the incidence and mortality from heart disease and stroke are declining (Harris et al., 1998), and this is especially true for some minority groups. According to the third National Health and Nutrition Examination Survey from 1988-1994, the prevalence of diagnosed diabetes was estimated to be 5.1% for the overall U.S. adult population over the age of 19 years. Approximately 2.7% were estimated to be undiagnosed (fasting plasma glucose >126 mg/dl) and 6.9% had impaired fasting plasma glucose (110 to <126 mg/dl). Similar rates existed for women and men, but the rates for Blacks and Hispanics were 1.6 and 1.9 times higher than non-Hispanic Caucasians (Harris et al., 1998).

Diabetes is of obvious public health importance for all ethnic groups in the United States (Eberhardt, Lackand, Wheeler, German, & Teutsch, 1994). Over the past 30 years, the prevalence of diabetes in the Black population has more than tripled (Tull & Roseman, 1995). In 1998 diabetes was the fifth most frequently listed underlying cause of death for Black males and the fourth most frequently listed underlying cause in Black females. The death rate per 100,000 population (based on diabetes as the underlying cause of death) was 23.7 for Black males and 36.5 for Black females (Murphy, 2000). These data should be viewed with caution because of the documented substantial underreporting of diabetes on death certificates (Bild & Stevenson, 1992). Data on the frequency of diabetes complications are limited; however, evidence indicates that the Black population experiences higher morbidity and excessive frequency of diabetic complications when compared with the U.S. Caucasian population (Harris, 1990; Tull & Roseman, 1995).

The prevalence of type 2 diabetes has been observed to be two to three times higher among Hispanics as compared to non-Hispanic Caucasians. The Hispanic Health and Nutrition Examination Survey conducted in 1982-84 was the first survey to provide data on the prevalence of diabetes in Hispanic subgroups (Stern & Mitchell, 1995). All-cause mortality in Hispanic adults with diabetes was at that time not excessive relative to non-Hispanic Caucasians (Stern et al., 1990), although the prevalence of complications-

especially peripheral vascular disease and microvascular complications-were somewhat higher.

Hyperglycemia in Minority Populations

Although the prevalence of diabetes is higher in these ethnic populations, there has been a lack of research on diabetes and intervention plans for these two subgroups. In 1994, a study of 248 Black patients indicated a lesser degree of glycemic control among Blacks with type 2 diabetes when compared to other ethnic groups (Weatherspoon, Kumanyika, Ludlow, & Schatz, 1994). A study reported in 1997 observed that after adjusting for gender, marital status, socioeconomic status, and medical treatment protocol, Blacks had significantly higher HbA_{1c} than Caucasians (Wisdom et al., 1997).

A study involving 4,875 subjects (65% Hispanic) focused on the effects of hyperglycemia on mortality from cardiovascular disease. It was found that participants with type 2 diabetes were older (52.9 ± 0.6 years), more frequently Hispanic, and had higher body mass index (BMI), elevated lipid profile, blood pressure, and fasting insulin levels. For both genders, those with type 2 diabetes had higher cardiovascular disease and all-cause mortality. More Hispanics than non-Hispanic Caucasians had higher fasting plasma glucose levels (Wei, Gaskill, Haffner, & Stern, 1998). The need for culturally sensitive patient education programs is evident and must be addressed by diabetes educators.

Diabetes Education in Minority Populations

There have been some recent studies focusing on education programs in specific ethnic groups, but these have involved either one specific area of disease control (e.g., foot care or weight control) or a specific educational tool as an intervention designed for one particular ethnic group. No studies have reported diabetes outcomes following comprehensive education programs in multiethnic populations. Diabetes education program recipients in certain areas of the U.S. represent three or more distinct ethnic subgroups. Therefore, the diabetes educator must be prepared to interact with small, heterogeneous groups meeting in a shared classroom in such a manner that each individual can relate to the educational interventions regardless of ethnicity. In brief, the educator must be sensitive to the learning needs of each individual within the group.

Ethnicity or culture is an adult learner characteristic that affects the learner as well as the intervention for learning. There are two categories of adult education-formal and informal. Formal education involves high school and university classes, or professional continuing education, but informal education may encompass skill training and human resource development or health education. Unlike other adult education, people with diabetes do not choose to participate in these programs unless they have a diagnosis of diabetes. The measure of this type of educational achievement is not just acquired information, but also a change in long-established lifestyle behaviors (Knowles, 1990).

Cultural background has a tremendous influence upon lifelong learned behaviors and must be thoroughly understood and incorporated into the educational process.

A number of research groups have developed interventions for Hispanics (Brown & Harris, 1995; Corkery, et al., 1997; Weller, Baer, & Pocater, 1999) and for Blacks (Anderson et al., 1991; Walker et al., 1997). A study in New York City using a low-income, Black population (N = 24), found a preference for multicultural materials in a foot care program among participants under age 60. Those over 60 reported that using Afro-centric materials made them feel singled out and different (Ledda, Walker, & Basch, 1997). The authors also elucidated that there are diverse cultural groups among Black people in America (e.g., Africans, Caribbean Blacks, Haitians, Black Hispanics, and African-Americans), each with its own lifestyle behaviors and eating patterns. Other studies have stressed the importance of culturally-sensitive educational programs in Black populations (Keyserling et al., 2000).

Hispanic populations have also been studied. Reasons for failure of diabetes education programs in Hispanic populations have been reported (Oomen, Owen, & Suggs, 1999). These included language barriers between provider and patient (which limits effectiveness of communication), inadequate health care insurance, and lack of cultural sensitivity. Regarding Hispanic women in particular, the importance of the family structure must be considered in the educational process (Bernal, Wolley, Schenzul,

& Dickinson, 2000; Bautista-Martinez et al., 1999). Among Hispanic women, adherence to a treatment regimen may be viewed as self-indulgent by many. Preparing food in ways contrary to her family's taste may appear selfish. Thus, theories and models of health beliefs that encourage self-oriented methods of diabetes management, diet compliance, and glycemic monitoring may not be well received in some Hispanic patients.

A successful diabetes education program among Hispanics in south Texas stressed the importance of culturally-sensitive, bilingual instructors and health care providers (Brown & Harris, 1999). Because of the diverse backgrounds of Hispanic subgroups in the U.S., culturally sensitive educational interventions must consider the individual's country of origin.

Cultural diversity is of obvious importance in diabetes education interventions because of the disease's lifelong course and constant focus on culturally embedded behaviors. Awareness of the cultural traditions and norms of minority populations is imperative in the design and implementation of diabetes education programs (Murphy, Satterfield, Anderson, & Lyons, 1993). An important aspect of culturally specific interventions is the question of their role in a multicultural setting in major U.S. cities.

CHAPTER III

METHOD

Part 1

The first part of this study was a retrospective chart review of data collected on patients who participated in a single-center diabetes education program to evaluate program efficacy and the impact of ethnicity on the ability of the recipient to practice self-management of blood glucose.

Subjects

Subjects (n=983) for this study were adult patients (over the age of 18) from throughout the state of Texas who entered the diabetes education program during a 1-year data collection period. Ethnicity was diverse, with patients identifying themselves as Black (B), 33%; Hispanic (H), 21%; or Caucasian (C), 45%. See Table 2. Economic status, as determined by a financial counselor, revealed that 58% had incomes less than 175% of the federal poverty index. The data indicated that, in this patient population, 8.5% had type 1 diabetes, 91.5% had type 2 diabetes, 58% were female, the average age was 51.6 ± 0.8 years, and 41% were within two years of diagnosis. See Tables 3-5. A preliminary assessment of the data indicated there was improvement in self-care skills as a result of education and further research was needed to confirm the positive effects of diabetes education on glycemic control.

Table 2 Original Population Entering Diabetes Education Program (Types~1~&~2),~N=983

	Hispanic	Black	Caucasian
<u>N</u>	207	333	443
%	21	33	45

Table 3 $\begin{tabular}{ll} Total Population Characteristics, $N=983$ \end{tabular}$

Age (yr)	51.6 ± 0.8
^a BMI	33.3 ± 0.7
Random blood glucose (mg/dl)	191.4 ± 7.6
^b HbA _{1c} (%)	8.5 ± 0.3
Female:	
<u>N</u>	570
%	58
Male:	
<u>N</u>	413
%	42
Type 1:	
<u>N</u>	84
%	8.5
Type 2:	
<u>N</u>	899
%	91.5

 $\underline{Note}.$ Data expressed as mean \pm SD.

 $[^]aBMI$ =Body mass index . $^bHbA_{1c}$ =Hemoglobin A_{1c} .

Table 4

Population Characteristics by Ethnicity, N=983

	Hispanic	Black	Caucasian
Age	50.0 ± 0.8	51.6 ± 0.8	53.2 ± 0.7
^a BMI	32.3 ± 1.1	33.4 ± 0.5	34.2 ± 0.4
Random blood gluce (mg/dl)	ose 186.0 ± 9	207.2 ± 10	181.1 ± 4
^b HbA _{1c} (%)	$8.3~\pm~0.2$	8.5 ± 0.4	8.7 ± 0.3
Female	122	190	258
Male	88	139	186
Type 1	4	13	66
Type 2	206	316	378

 $[^]aBMI$ =Body Mass Index . $^bHbA_{1c}$ =Hemoglobin A_{1c} .

Table 5 $\label{eq:total formula} \textit{Total Group Initial HbA}_{1c}, \textit{Random Glucose, and BMI, N=983}$

Random blood glucose (mg/dl)	191.4 ± 7.6
^a HbA _{1c} (%)	8.5 ± 0.3
^b BMI	33.3 ± 0.7

 $\underline{Note}.$ Data expressed as mean \pm SD.

 $[^]aHbA_{1c}$ =Hemoglobin $A_{1c.}$ bBMI =Body mass index.

Patient Consent

Because human subjects were used, the researcher sought approval from the University of Texas Institutional Review Board and Texas Woman's University Human Subjects Review Committee (see Appendix A). Patient consent to be entered into this study was received by oral patient request announcement made prior to the class (see Appendix B). Patients were assured of identity confidentiality and were informed that data gathered would be used to determine efficacy of the education program.

Experimental Design

Part 1 was undertaken at a university-based out-patient diabetes center. The study subpopulation (N=124) consisted of patients with HbA_{1 c}>8% who completed the 14-hour diabetes education program. Data were collected over a period of one year at the initial assessment and after completion of the diabetes education program (approximately five months after initial assessment). The distribution of subjects within the three ethnic groups of the subpopulation was similar to that of the original population (N=983). See Table 6. Population characteristics in the study sample completing the 14-hour program (N=124) are listed in Tables 7 and 8.

The diabetes education program was structured according to the guidelines set by the American Diabetes Association and was recognized as meeting national standards for diabetes education. Content areas are described in Table 9. All patients received

Table 6

Study Sample Completing 3-class Program (Type 2 Only), N=124

	Hispanic	Black	Caucasian
\underline{N}	26	42	56
%	21	33	45

Table 7

Total Population Characteristics (Type 2 Only), N=124

Age (y	r)	52.9 ± 11.6
ВМІ		33.5 ± 6.3
Randor	n glucose (mg/dl)	190.6 ± 17.7
HbA _{1e}	(%)	10.0 ± 0.7
Female		70
	<u>N</u>	72
	%	58
Male:	<u>N</u>	52
	%	42

 $^{{}^}aBMI$ =Body mass index. ${}^bHbA_{1c}$ =Hemoglobin A_{1c}

Table 8

Population Characteristics by Ethnicity (Type 2 Only), N=124

	Hispanic	Black	Caucasian
Age	51.0 ± 12	54.9 ± 13	53.0 ± 10
^a BMI	30.4 ± 2.9	33.7 ± 8.1	33.5 ± 7.9
Random glucose (mg/dl)	157.9 ± 25.2	223.2 ± 14.3	190.9 ± 14
^b HbA _{1c} (%)	9.6 ± 0.8	10.8 ± 0.6	9.6 ± 0.6
Female	16	24	32
Male	11	17	24

 $\underline{Note.}$ Data expressed as mean \pm SD.

 $[^]aBMI$ =Body mass index. $^bHbA_{1c}$ =Hemoglobin A_{1c} .

Table 9

National Standards for Diabetes Self-management Education Program

Content Areas

- a. Diabetes overview
- b. Stress and psychosocial adjustment
- c. Family involvement and social support
- d. Nutrition
- e. Exercise and activity
- f. Medications
- g. Monitoring and use of results
- h. Relationships among nutrition, exercise, medication, and blood glucose levels
- i. Prevention, detection, and treatment of acute complications
- j. Prevention, detection, and treatment of chronic complications
- k. Foot, skin, and dental care
- Behavior change strategies, goal setting, risk factor reduction, and problem solving options for improving glucose control
- m. Benefits, risks, and management options for improving glucose control
- n. Preconception and gestational diabetes

Note. From "National Standards for Diabetes Self-management Programs," by American Diabetes Association Task Force, 1998, <u>Diabetes Care</u>, 21, (Suppl 1), p. S95.

education in small groups of 3 to 5 participants. The program consisted of three classes (Basic Skills Class, Meal Planning Class, and Graduation Class) providing 14 hours of education. The first 3-hour class (Basic Skills) was taught by the Certified Nurse Educator. Patients were weighed in full dress prior to class, and weight and height were recorded. HbA_{1c} levels were measured at the University Diabetes Center (see Appendix C). Topics covered in this first class included pathophysiology, acute and chronic complications, stress management and family involvement, medications, exercise, foot, skin, and dental care, and blood glucose monitoring. Random plasma glucose was measured during this class using an Accu-Chek meter (see Appendix D).

The second class involved meal planning and individual nutritional recommendations. This class was entitled "Meal Planning" and lasted 2 ½ hours. It was offered following the Basic Skills class on either the same day or at a later date depending on patient preference but within a 10-day period. Meal Planning was taught by the Principal Investigator, who is a Registered Dietitian and a Certified Diabetes Educator. Nutritional instruction followed the American Diabetes Association Exchange List concept with portion selection based on an energy level appropriate for each patient. Participants were instructed to consume meals at regular times daily. If a meal must be taken off schedule, it should be no earlier or no later than 1 hour from the usual meal time. Food models and measuring utensils were used to depict portion sizes and appropriate meals

were planned and demonstrated during the class using food models. Each patient received a meal plan. Kcalorie levels were determined by multiplying ideal body weight (lbs) by 10 kcalories per lb. Frequency of meals was based upon the participant's preference. If a person preferred to have between meal feedings, foods from the meal plan must be saved for consumption at a later time. A detailed lecture was given on food preparation and ways to reduce sodium, fat, and cholesterol in the diet. A thorough discussion of the Exchange Lists and individual meal plans followed (see Appendix E). The dietitian recommended increasing complex carbohydrate by choosing whole grain bread/starch exchanges and consuming 3 fruit exchanges and at least 3 vegetable exchanges daily. Dessert items were discussed and the dietitian recommended appropriate exchanges based on the American Diabetes and Dietetic Association exchanges for Other Carbohydrates, e.g., ½ cup sugar-free pudding = 1 carbohydrate exchange, and so forth. The impact of fat on blood glucose level and insulin sensitivity was discussed and a diet containing no more than 30% of energy as fat was emphasized. Participants were taught that while only 10% of fat was metabolized to glucose (and therefore had an insignificant metabolic effect on blood glucose level), the kcaloric contribution of fat was significant. The dietitian explained that protein from the meat exchange list did not contribute significantly to blood glucose since only 45 to 55% of protein was metabolized to glucose. However, meat should be consumed at the level of 4 to 6 ounces daily to control kcalories, fat and

cholesterol. Participants were instructed that a 3-ounce portion of meat was about the size of a deck of cards. They were not instructed to weigh meat portions. Class discussion was strongly encouraged and participants were asked to compare diet recommendations to what was usually consumed and discuss how changes could be made. Following the meal planning session, a Certified Nurse Educator facilitated a brief review of the Basic Skills class. Blood glucose monitoring was observed and questions were answered.

The third and final class, the Graduation Class, was 3 months after Class 2, and was taught by a multidisciplinary team. The class lasted approximately four hours and was divided into five 45-minute sessions. 1) A social worker addressed psychological adjustment, stress, and behavioral issues pertaining to diabetes mellitus. 2) A physical therapist addressed activity and exercise prescriptions based on the individual's needs and physical state. 3) Activities of daily living were discussed by an occupational therapist trained to assist those with chronic illness. 4) The nurse educator assisted patients in goal setting and problem solving and, once again, observed patient technique in blood glucose monitoring and recorded random blood glucose level. 5) The dietitian discussed foods for occasional use (e.g., desserts) and combination foods (e.g., casseroles and soups), fast foods, and food selection when dining in various restaurants. Questions regarding nutritional intake were answered.

At the end of the Graduation Class, patients were instructed to contact the diabetes educators by phone at any time as concerns arose. A final HbA_{1e} was measured and patients were weighed again in full dress. Final HbA_{1e}, random blood glucose, and weight were recorded. Educators contacted graduates by mail three months following the Graduation Class to assess patient progress on goals set in the final class. This data is not included in this research.

Data Analysis

Data for hypotheses 1 and 2 were analyzed using paired <u>t</u> tests. Data for hypotheses 3 and 4 were analyzed by using 3 x 2-way repeated measures analysis of variance (ANOVA). SPSS software, release 10.1 (Chicago, IL, 2000), was used for data analysis.

Values for HbA_{1e}, random blood glucose and body mass index (BMI) recorded at the Basic Skills class and the Graduation class were compared. Pre- and post-intervention results for each individual were compared using two-tailed, paired \underline{t} tests to determine whether the individual experienced a significant change in glycemic control and weight. The \underline{t} tests were calculated at the \underline{p} < .05 significance level. Data for each ethnic group were compared using repeated measures ANOVA to determine the effect of ethnicity on the results. If a difference existed, the Tukey HSD (Honestly Significant Difference) post hoc test was used to determine which ethnic group(s) were affected. Significance level

was set at p < .05.

Part 2

A second part (Part 2, N=42) was prospective in nature and was designed to determine if favorable changes in diet, assessed by 24-hour recall, would occur following diabetes education. This could help to explain improvements in glycemic control and reinforce the positive role of the registered dietitian who teaches nutritional management in this program. Assessment parameters for dietary compliance were 1) consuming a diet in keeping with the *Food Pyramid* (as listed below), 2) reduction in fat to 30% or less of total energy, and 3) reduction of energy intake if intake at baseline was in excess of needs. If BMI exceeded 28, total calories should be decreased.

Per *Food Pyramid*-e.g., a daily intake of at least:

16 oz milk (2 servings)

1 - 1.5 cups fruit (2-3 servings)

1.5 cups vegetables (3 servings)

4 - 6 oz meat (2-3 servings)

At least 6 servings bread/grain

Improvement in consumption patterns in 2 of these 5 categories was considered a successful nutritional education program.

Dietary 24-hour recalls were taken from patients attending the diet class (Class 2)

and the graduation class (Class 3) over the 4-month data collection period. It was estimated that a patient population of 96 type 2 patients would complete the diabetes education program during this period. According to the current completion rate of 44%, this gave a total of 42 records to be analyzed. Population characteristics are listed in Tables 10-12. This population was different from the 124 study participants in Part 1 of this study.

Data Analysis

The two 24-hour dietary recalls for each individual taken at the Meal Planning class and the Graduation class were analyzed for percent of total energy from fat and total energy content using *Food Processor*. The researcher calculated amounts consumed of the following food groups from the *Food Guide Pyramid*: servings of bread/grain (1 serving = 1 oz bread or ½ cup pasta, rice, cereal), ounces of meat, poultry, fish, cups of vegetables (1 serving = 1/2 cup cooked or 1 cup raw), cups of fruit (1 serving = 1/2 cup fruit), and ounces of milk. Differences in consumption patterns were analyzed using two-tailed, paired ½ tests (SPSS Release 10.1). A chi square test for paired data was used to determine if the percent of subjects consuming 30% of energy from fat changed following education. Food consumption differences among ethnic groups were determined using repeated measures ANOVA and the Tukey HSD post hoc test if a difference existed. Significance level was set at p < .05.

Table 10

Part 2, Population by Ethnicity (Type 2 Only), N=42

	His	spanic	Black	Caucasian
-	N	8	15	19
	%	21	33	45

Table 11

Part 2, Population Characteristics (Type 2 Only), N=42

 61.63 ± 7.8 Age (yr) ${}^{a}BMI$ 36.1 ± 5.7 ${}^{b}\text{HbA}_{1c}(\%)$ 10.0 ± 2.9 Random glucose (mg/dl) 168.4 ± 72.2 Female: 26 $\overline{\mathbf{N}}$ % 58 Male: $\overline{\mathbf{N}}$ 16

Note. Data expressed as mean \pm SD.

%

^aBMI=Body mass index. ^bHbA_{1c}=Hemoglobin A_{1c}.

42

Table 12

Part 2, Population Characteristics by Ethnicity (Type 2 Only), N=42

		^a <u>H (n=9)</u>	^b B (n=15)	^c C (n=18)
Age		63.2 ± 5.2	59.3 ± 8.3	61.4 ± 9.4
^d BMI		34.1 ± 4.3	37.3 ± 6.4	36.8 ± 6.4
°HbA _{1c} ((%)	9.9 ± 2.0	10.4 ± 2.8	9.9 ± 3.5
Random	glucose	203.9 ± 70.0	166.5 ± 53.9	154.9 ± 83.4
(mg/dl)				
Female:	<u>N</u>	5	9	12
	%	58		
Male:	<u>N</u>	3	6	7
	%	42		

Note. Data given as mean \pm SD.

^aH=Hispanic. ^bB=Black. ^cC=Caucasian. ^dBMI=Body mass index.

 $^{^{}e}HbA_{1c}$ =Hemoglobin $A_{1c..}$

RESULTS

Part 1

Results of initial and final HbA_{1e} , random blood glucose (RBG) and BMI were analyzed from 124 participants completing all three diabetes education classes. HbA_{1e} , RBG and BMI were measured at the first class and again at the final class, which was approximately three months later. Two-tailed, paired \underline{t} tests were used to determine if a change occurred between initial and final measures. See Table 13. Repeated measures ANOVA was used to determine if a difference occurred among the three ethnic groups. Significance was set at the level of p < .05. See Table 14.

Mean initial HbA_{1c} levels (given as mean \pm SD) were above normal (5.3 to 6.0%) in all three ethnic groups: Hispanic (H) 9.6 \pm 0.8, Black (B) 10.8 \pm 0.6, Caucasian (C) 9.6 \pm 0.6. Final HbA_{1c} levels were significantly lower than initial values in all three groups: (H) 7.9 \pm 0.8, (B) 8.9 \pm 0.5, (C) 7.7 \pm 0.6. There were no differences in final mean values for HbA_{1c} among ethnic groups.

Mean initial RBG levels (given as mean \pm SD) were all above normal for acceptable postprandial plasma glucose level (70-120 mg/dl) and there were no significant differences among ethnic groups: (H) 157.9 \pm 25.2, (B) 223.2 \pm 14.3, (C) 190.9 \pm 14. The final mean values for random blood glucose levels decreased in all three ethnic groups, but the difference was not significant in H. The final RBG levels (mg/dl)

Table 13 $Total\ Group\ Comparison\ of\ Initial\ and\ Final\ HbA_{1c},\ Random\ Glucose\ and\ BMI,\ N=124$

	<u>Initial</u>	<u>Final</u>
$^{a}HbA_{1c}(\%)$	10.0 ± 0.7	8.2 ± 0.6*
bRBG (mg/dl)	190.6 ± 17.7	155.2 ± 14.9*
ido (mg/ui)	170.0 ± 17.7	100.2 1 110
^a BMI	32.5 ± 6.3	31.2 ± 3.6
Weight (lbs)	224.3	216.3

 $[^]a$ HbA $_{1c}$ =Hemoglobin A $_{1c}$. b RBG=Random glucose. c BMI=Body mass index.

^{*}Two-tailed, paired \underline{t} test, significant difference (initial vs. final) at $\underline{p} < .05$.

Table 14

Initial and Final HbA1c, Random Glucose and BMI by Ethnicity, N=124

<u>aHbA_{1c} (%)</u>	<u>Initial</u>	<u>Final</u>
bH	9.6 ± 0.8	7.9 ± 0.8*
cB.	10.8 ± 0.6	8.9 ± 0.5*
$^{\rm d}{ m C}$	9.6 ± 0.6	$7.7 \pm 0.6*$
Random Glucose (mg/dl)		
Н	157.9 ± 25.2	$155.4 \pm 21.1^{\text{ f}}$
В	223.2 ± 14.3	$151.3 \pm 12.1*$
С	190.9 ± 14.0	158.9 ± 11.7*
<u>eBMI</u>		
Н	30.4 ± 2.9	29.8 ± 4.1
В	33.7 ± 8.1	32.4 ± 4.4
С	33.5 ± 7.9	31.4 ± 2.2

^aHbA_{1c}=Hemoglobin A_{1c}. ^bH=Hispanic. ^cB=Black. ^dC=Caucasian. ^eBMI=Body mass index.

^fTukey HSD post hoc test, H significant difference compared to B and C at p < .05.

^{*3} x 2 repeated measures ANOVA, significant difference (initial vs. final) at $\underline{p} < .05$.

were as follows: (H) 155.4 ± 21.1 , (B) 151.3 ± 12.1 , (C) 158.9 ± 11.7 . Hispanics did not show a significant decrease in RBG and this differed from B and C.

Initial mean BMI was high in each ethnic group, H=30.4 \pm 2.9; B=33.7 \pm 8.1; C= 33.5 \pm 7.9. The final mean values for BMI (H=29.8 \pm 4.1; B=32.4 \pm 4.4; C=31.4 \pm 2.2) were not significantly different from initial values.

Part 2

Twenty-four hour diet recalls were analyzed from 42 program participants completing all three diabetes education classes. Population characteristics for this study sample (N=42) are listed in Tables 15 and 16. Characteristics by ethnic group are listed in Table 17.

Diet diaries were analyzed for total fat as percentage of energy consumed and total energy intake. Two-tailed, paired \underline{t} tests were used to compare initial and final values for total energy intake and percent of energy as fat. Fat as percent of energy (given as mean \pm SD) decreased from $38.9\% \pm 10.7\%$ to $30.9\% \pm 7.3\%$. A chi square test was used to determine if the percent of subjects consuming 30% or less of total energy as fat decreased following education. There was no significant decrease in this percentage.

All 42 participants had a BMI>28, indicating the need for a decrease in total energy consumed. An average energy intake of 2017.6 \pm 1002.3 kcalories was reported initially. Final energy intake as reported averaged 1433.2 \pm 413.9. The difference

Table 15

Comparison of Initial and Final Food Consumption, N=42

Result	<u>Initial</u>	<u>Final</u>
% subjects with $\leq 30\%$ energy fat from fat (n)	21.4 (9)	45.2 (19)*
% energy from fat	38.3 ± 9.0	31.3 ± 7.1**
Energy intake (kcal/day)	2017.6 ± 1002.3	1433.2 ± 413.9**
^a Bread/grain (servings/day)	6.3 ± 4.6	4.9 ± 2.3
Fruit (cups/day)	1.6 ± 3.5	2.2 ± 0.9
Vegetables (cups/day)	2.3 ± 1.3	3.1 ± 1.5**
Milk (ounces/day)	5.2 ± 5.1	5.7 ± 4.6
Meat (ounces/day)	6.6 ± 3.8	6.2 ± 1.8

Note. Values expressed as mean \pm SD.

^aBread/grain servings as per portions listed on Food Guide Pyramid (U.S.D.A., 1993).

^{*}Chi square for paired data, no significant decrease in percent consuming \leq 30% total energy as fat, $\underline{p} < .05$.

^{**}Two-tailed, paired \underline{t} test, significant difference (initial vs. final) at $\underline{p} < .05$.

Table 16

Part 2, Group Means for Initial and Final HbA1c, Random Glucose and BMI, N=42

	<u>Initial</u>	Final
^a HbA _{1c} (%)	10.0 ± 2.9	8.8 ± 1.5*
Random glucose (mg/dl)	168.4 ± 72.2	139.3 ± 34.7*
^b BMI	36.1 ± 5.7	35.2 ± 6.5*

 $[^]aHbA_{1c}$ =Hemoglobin A_{1c} . bBMI =Body mass index.

^{*}Two-tailed, paired \underline{t} test, significant decrease (initial vs. final) at $\underline{p} < .05$.

Table 17

Part 2, Comparison of Initial and Final HbA_{1c}, Random Glucose and BMI

Among Ethnic Groups

^a HbA _{1c} (%)	<u>Initial</u>	<u>Final</u>
$_{ m p}$ H	9.9 ± 2.0	8.9 ± 1.3*
°В	10.4 ± 2.8	8.7 ± 1.4*
^{d}C	9.9 ± 3.5	8.8 ± 1.8*
Random glucose (mg/dl)		
^β H	203.9 ± 70.0	148.0 ± 27.4*
°В	166.5 ± 53.9	133.6 ± 40.6
^d C	154.9 ± 83.4	136.3 ± 36.2
<u>BMI</u>		
^{b}H	34.1 ± 4.3	33.7 ± 5.1
°В	37.3 ± 6.4	35.9 ± 7.3*
^d C	36.8 ± 6.4	35.9 ± 7.1

^aHbA_{1c}=Hemoglobin A_{1c.} ^bH=Hispanic. ^cB=Black. ^dC=Caucasian. ^cBMI=Body mass index. ^fTukey HSD post hoc test.

^{*3} x 2 repeated measures ANOVA, significant difference (initial vs. final) at \underline{p} < .05.

between initial and final values for reported energy intake was significant at the level of p < .05. The large standard deviation indicates variation in food consumption as reported.

Diet diaries were analyzed before and after intervention for quantities consumed of five food groups of the *Food Guide Pyramid* - servings of bread/grain (i.e., 1 serving = 1/2 cup cereal, rice, pasta or 1 oz bread), cups of fruit (1 serving = 1/2 cup), cups of vegetables (i.e., 1 serving = 1/2 cup cooked vegetables, 1 cup raw vegetables), ounces of milk, and ounces of lean meat. Two-tailed, paired tests were used to determine if there was a change in food consumption patterns. Table 15 illustrates changes observed in food consumption patterns following nutrition education. It was observed that vegetable consumption increased significantly, and total energy and percent of energy as fat decreased significantly. Initial and final quantities of fruit, milk, meat, and bread/grain did not differ significantly.

Initial and final HbA_{1c}, random glucose and BMI were assessed in this sample (N=42). Two-tailed, paired <u>t</u> tests were used to determine if there was a change in initial and final values following education. Group data are listed in Table 16. There was a significant decrease in HbA_{1c}, RBG, and BMI. Repeated measures ANOVA was used to determine if there was a difference between initial and final values for HbA_{1c}, RBG and BMI among the ethnic groups. Results are given in Table 17. There was no significant difference in HbA_{1c} among ethnic groups. Hispanics showed a decrease in random

blood glucose from initial to final value (N=42). When comparing across ethnic groups, Hispanics decreased more than Blacks and Caucasians and this is the opposite of what was found in study Part 1. There was a significant decrease in BMI when initial and final values were compared, but Blacks decreased more than Hispanics and Caucasians.

The effect of ethnicity on initial and final food consumption patterns was determined using 3 x 2 repeated measures ANOVA. Initial and final values for percent of energy from fat decreased significantly, but there were no differences among groups.

Initial and final values for total energy decreased significantly, but Caucasians showed greater decrease than Blacks and Hispanics. Vegetable consumption increased significantly, and Caucasians increased more than Blacks or Hispanics. See Table 18.

The change in percent of subjects eating 30% or less of energy as fat initially and following education was determined using the chi square statistic for paired data. This percentage increased significantly from 21.1% to 45.2%.

Table 18

Part 2, Comparison of Initial and Final Values Among Ethnic Groups, N=42

% Energy as fat	<u>Initial</u>	<u>Final</u>
^a H	38.6 ± 5.9	32.8 ± 6.3*
^b B	37.9 ± 12.2	32.3 ± 8.6*
°C	38.5 ± 8.9	28.9 ± 6.4*
Total Energy (kcalories)		
^a H	2257.3 ± 976.3	1649.3 ± 631.7^{d}
bВ	1832.3 ± 921.5	1382.9 ± 258.3^{d}
°C	1963.2 ± 1119.2	1267.4 ± 361.9*
Vegetables (cups)		
$^{\mathrm{a}}\mathrm{H}$	2.3 ± 0.8	2.9 ± 0.9^{d}
${}^{\mathrm{b}}\mathbf{B}$	1.6 ± 1.1	2.5 ± 1.9^{d}
$^{\circ}\mathrm{C}$	2.9 ± 2.1	3.9 ± 1.6*

^aH=Hispanic.^bB=Black.^cC=Caucasian^dTukey HSD post hoc test, H and B differed from C.

^{*3} x 2 repeated measures ANOVA, significant difference (initial vs. final), p < .05.

CHAPTER V

DISCUSSION

This study confirms other findings that diabetes self-management training has positive effects on glycemic control. Numerous studies have reported positive results following diabetes education over the past 20 years (Brown, 1990; Brown, 1992; Brown, 1995; Campbell et al., 1996). Although recent research has addressed the needs of specific ethnic populations (Anderson et al., 1991; Bautista et al., 1999; Walker et al., 1994; Weatherspoon et al., 1994), few studies have reported on outcomes of diabetes education programs in multiethnic populations. American society has changed considerably over the past two decades in many areas of the country, with larger cities often inhabited by two or more ethnic groups. This impacts health care in that providers must be knowledgeable about cultural values and health care beliefs that may affect health care delivery. The diabetes education program in this research was presented by a Spanish-speaking dietitian, and one Black and one Caucasian nurse educator. All three educators were familiar with ethnic variations of this patient population. It is interesting to note that this population was well integrated socially, and all three ethnic groups had similar dietary habits. Therefore, discussions of exchange lists included choices such as, barbecue (a traditionally Black American food), Mexican food, Chinese food, fast foods and other American type cuisine. There were few ethnic differences in foods reported on 24-hour diet recalls. Class discussion was encouraged and group participation was well accepted by the majority of patients attending group education sessions. A cohesiveness among participants developed as a result of group interaction during classes.

Successful diabetes education classes (5 participants per class) were described by Schrock in 1998. Of 39 persons enrolled in classes, the average drop in HbA_{1c} was from 9.6 to 7.6% (a 2.3% decrease). According to patient reports, 89.6% of class participants indicated they were maintaining a blood glucose level of 70 to 150 mg/dl. A 1.9% decrease in HbA_{1c} following education was reported by Tilly et al., in 1995 (N=33), and by Peyrot & Rubin in 1994 (N=82). The research in this paper reported an overall 1.8 % decrease in HbA_{1c} following this education program (N=124).

This study included a multiethnic population receiving diabetes education in small groups (3-5 participants per class). Outcomes measured were indicators of improved glycemic control and changes in food consumption patterns. Indices of glycemic control were assessed initially and following completion of the program. Food consumption pattern changes were determined based on pre- and post-education 24-hour diet recalls submitted by participants.

Part 1

Part 1 compared initial and final HbA_{1c} and random blood glucose levels in three ethnic groups participating in a diabetes education program. Subjects attended small

group classes, 3-5 participants, of varied ethnicity.

Null Hypothesis 1

The first hypothesis stated that following diabetes education there would be no change in RBG. RBG levels decreased in all three ethnic groups, but the decrease was significant (p < .05) in the Black and Caucasian participants only. Null hypothesis 1 was rejected. Initial random glucose levels were lowest in Hispanics in this study. In 1996, Wei et al. reported higher fasting glucose levels in a Hispanic vs. a Caucasian diabetic population in San Antonio, TX. The Hispanic population in the San Antonio area may be newer immigrants and may have less exposure to health care and, therefore, be less knowledgeable about diabetes and its diagnosis. The Hispanic participants in this research study were generally third or fourth generation Americans, were educated in the state public school system, and had insurance for health care coverage. This generally indicates a more informed population.

Null Hypothesis 2

The second null hypothesis of this study stated that following completion of the diabetes education program, there would be no change in HbA_{1c.} Numerous studies have reported positive effects on lowering of blood glucose levels following diabetes education programs (Brown, 1990, 1992; Mullen et al., 1985: Roter et al., 1998; Peyrot and Rubin, 1994; Kopreski et al., 1997; Schrock, 1999). Table 13 lists the initial and final measures

of HbA_{1c} in patients completing all three diabetes education classes (N=124). HbA_{1c} decreased significantly (p < .05) and the null hypothesis was rejected.

Null Hypothesis 3

The third hypothesis stated that there would be no effect of ethnicity on changes in random glucose following diabetes education. Final random glucose levels were analyzed by 3 x 2-way repeated measures ANOVA to determine if a difference existed among ethnic groups. The Tukey post hoc test was used to determine which ethnic group varied. There was no difference in decrease in random glucose levels among Blacks or Caucasians (p < .05). Random glucose level in Hispanics was not significantly lower compared to Blacks and Caucasians following education. Null hypothesis 3 was rejected. Null Hypothesis 4

The fourth null hypothesis stated that there would be no effect of ethnicity on changes in HbA_{1c} following education. The 3 x 2-way repeated measures ANOVA determined that final HbA_{1c} levels were significantly lower than initial values and there was no difference among ethnic groups (p < .05). The null hypothesis failed to be rejected.

Part 2

The second part of this study compared initial and final 24-hour recalls reported by 42 subjects completing this diabetes education program. Food consumption patterns

were assessed prior to the Meal Planning class of this diabetes education program and after program completion. Participants were asked to record diet recalls for the 24-hour period preceding the Meal Planning class and the Graduation class. Both 24-hour recalls were analyzed using *Food Processor*. Total energy intake and percent of energy from fat were determined. Quantities consumed of foods from the *Food Pyramid* were determined from the diet recalls. Table 18 summarizes the findings of this experiment.

Null Hypothesis 5

The fifth hypothesis of this study stated there would be no change in quantities consumed of fruit, vegetables, milk, meat and bread/grain following education. Quantities of food reportedly consumed in the initial and final 24-hour recalls were compared. It was determined that consumption of vegetables increased significantly (p < .05). The null hypothesis was, therefore, rejected.

Initial and final quantities of fruit, milk and meat were not significantly different. Meat consumption was adequate (mean of 6.6 oz per day) in all 42 individuals on the first 24-hour recall, but not milk. Milk consumption was extremely low (average of 5.2 oz per person per day) and remained low on the second 24-hour recall (average of 5.7 oz per person). Lactose intolerance was not stated as a problem by any of the 42 subjects reporting 24-hour recalls. Bread/grain consumption was considered appropriate if servings per day were reported. Average consumption was 6.3 ± 4.6 servings in the first

recall and 4.9 ± 2.3 in the final recall.

In this study food consumption patterns changed following nutrition education in that reported intakes of fat and energy decreased and vegetable intake increased. There was an upward trend in fruit consumption, but the increase was not significant. The period of time between 24-hour recall reporting was approximately three months. The effect of nutrition education on changing lifelong consumption behaviors may require a longer period of time than that measured by this study.

Null Hypothesis 6

The sixth hypothesis stated that the percentage of subjects eating 30% or less of energy as fat would not change post-education. Nine participants (21.1%) reported an initial intake of 30% or less kcalories from fat compared to 19 participants (45.2%) at final assessment. A chi square test for paired data was used to determine if there was a change in the percent of subjects consuming \leq 30% energy as fat. There was an increase in the percentage of subjects eating 30% or less of energy as fat and this was significant at the level of p \leq .05. The null hypothesis was rejected.

Null Hypothesis 7

The seventh hypothesis stated there would be no change in energy intake in patients with BMI>28 who were eating in excess of kcaloric needs pre-education. An average of 2017.6 \pm 1002.3 kcalories was reportedly consumed at the time of the first 24-

hour recall compared to 1433.2 ± 413.9 kcalories reported at the final 24-hour recall. See Table 15. This difference was significant at the level of $\underline{p} < .05$. The null hypothesis was rejected. All patients reporting had a BMI>28 and would benefit from a reduction in kcalories. Obesity is highly correlated with the incidence of type 2 diabetes and numerous studies report an elevation in BMI in type 2 patients (Stern & Mitchell, 1995; Wei et al., 1998; Tull & Roseman, 1995). This study also revealed a high percentage of subjects who had a BMI>28 indicating a high degree of obesity in this multiethnic population. The large standard deviation indicates the need to increase the sample size in this experiment.

Diabetes Education Attrition Rate

Glycemic control, as measured by pre- and post-education HbA_{1c} and RBG, indicated that this self-management training program was effective in the population studied (n=124). The sample size of 124 subjects completing the diabetes education program represents only 12% of the original population of 983, who attended 1 or 2 classes only. However, the data collection process includes all initial patient visits for a 12-month period. The third class was offered only once a month and a maximum of twelve participants were allowed per class because of limited space in the classroom. For this reason only 144 participants could be expected to complete all three classes of the diabetes education program during the 12-month data collection period. The first two

classes were offered on a daily basis and for this reason, there appears to be a large decrease between the number of participants entering the program (attending only 1 or 2 classes) and the number completing all 3 classes (983, initial vs. 124, final).

The nature of this patient population also affects the program completion rate.

Because of the high percentage of indigent patients (58%) attending this program,

transportation to the Diabetes Center and the ability to pay for diabetic education classes

were often restrictive. Patients often rescheduled appointments during this data collection

period stating that they could not meet other financial and medical obligations, so opted

to postpone diabetes education in order to meet these other obligations.

A confounding factor in determining causes for improvement in glycemic control in diabetes is the use of medications. Changes in medication doses can improve blood glucose levels and this could influence HbA_{1c}. In this study only those with type 2 diabetes were studied to reduce the effect of insulin on blood glucose levels. Individuals included in Experiment 2 involving the analysis of initial and final 24-hour recalls were on oral medications only at the time of reporting. Although medications were not included in the formal data collected for this study, it should be noted that eleven participants reported an increase in dose of oral medication, and three patients were placed on insulin prior to the final class. Also, a number of commonly used medications are known to compromise glycemic control (i.e., thiazides, beta-blockers, diazoxide)

therefore, polypharmacy in diabetes patients must be considered.

Another confounding variable having the potential to affect blood glucose levels is the activity level of the individual. Increasing daily activity is recommended by the multidisciplinary health care team in the treatment of type 2 diabetes. Therefore, the level of physical activity could affect glycemic control. Exercise was not assessed in this study, although none of the participants reported any sizable increase in activity.

Psychosocial status of the patient may also affect glycemic control because stress hormones are known to counter the effect of insulin in the body. Chronic illness is considered a source of added stress to the patient especially in those with poor coping skills. Assessment of participant stress factors was not included in this study.

There is a paucity of research in multiethnic populations receiving diabetes self-management training. Because of changes in demographics in American society, educational programs will be accessed by individuals from various ethnic backgrounds. Numerous studies report on programs offered in areas where one ethnic group is heavily predominant (Brown & Harris, 1995; Corkery et al., 1997; Weller et al., 1999; Anderson et al., 1991; Walker et al., 1997). More studies are needed concerning multiethnic populations receiving diabetes education in groups. The trend in health care is to provide effective services to more individuals without increasing costs. The only apparent solution is to provide group education and distance learning opportunities.

The diabetes self-management program that is the subject of this research considered the ethnicity of the patient population. Although classes consisted of 5 participants from various ethnic groups, individual preferences of each patient were considered in the classroom discussion. Patients were encouraged to verbalize their feelings about diabetes concepts and all were invited to share cultural influences with the group. Food habits were generally a topic of interest to the group, and as is true of most adult learning, knowledge sharing was well received by the majority of participants.

Because of the integrated nature of this population, no apparent differences in dietary habits were reported by participants. All subjects were English-speaking and were covered by private health insurance or Medicare so it is assumed that even though participants were of varied ethnicity, they shared similar educational and social backgrounds.

Many cities in the United States are multiethnic and there is considerable diversity of origin within specific ethnic populations. Keyserling et al. (2000) stressed the importance of culturally sensitive programs in Black populations. Ledda et al. (1997) revealed that there are well-defined cultural differences in Blacks from Africa, the Caribbean, Haiti and the United States. Therefore, not all individuals in the same ethnic group may be assumed to have the same health beliefs nor would they respond to an educational program directed for inner city black cultures in the United States. Hispanics

from Mexico, Puerto Rico, Cuba, various countries in South America and the southern

United States have widely varying food preferences and health care practices. The present
study suggests that in a multiethnic population, diabetes education in small groups of
ethnically diverse participants is effective. In this study, all participants spoke English so
a language barrier was not present as described by Oomen et al. (1999) in certain

Hispanic populations.

Diabetes self-management training is unequivocally an essential component of health care for diabetes patients. Diabetes educators must be prepared to meet the educational challenges of their patient population. In multiethnic areas of the country the educator must also be sensitive to cultural differences and special needs of minority populations. Diabetes educators are skilled in patient educational and empowerment practices, but must also be cultural translators in areas of the country where several ethnic groups reside in the same community. The ability of the educator to address the needs of patients from varied cultural backgrounds enhances the success of an educational program. Murphy et al. (1993) stated that awareness of cultural traditions and norms of the population served is necessary when planning a diabetes education program. The three certified diabetes educators who taught the education program in this study were lifelong residents of the region in which they worked, and had a thorough understanding of the traditions and norms of this population. The registered dietitian was bilingual in

Spanish and was versed in food patterns of a wide variety of cultures. Of the two nurse educators, one was black and one was Caucasian, both from the surrounding area. All three were between the ages of 45 and 55 years. It is suggested that the diversity of backgrounds of these three educators provided an essential multiethnic blend that was well received by this culturally diverse population.

In this study, participants of this diabetes self-management training program succeeded in lowering HbA_{1c}. It was noted that Hispanics did not show a decrease in RBG in Part 1 (N=27) as was seen in Part 2 possibly because of the small number studied in Part 2 (N=9). Also, initial values were lower in Hispanics than for the other two groups in Part 1. Food consumption patterns improved as indicated by the decrease in energy from fat and total energy intake reported on diet recalls. It is important to note that while a large energy decrease was reported, BMI did not decrease as would be expected. The reason for this may involve inaccurate dietary reporting practices of patients. Weight in lbs was measured and is given in Appendices F and G. In Part 1, a gain of 4.3 lbs was observed. However, initial and final weights were available for only 47 of 124 participants. In Part 2, an overall loss of 8.54 lbs was noted (N=42). Significant improvement in HbA_{1c} was noted with a non-significant modest reduction in BMI. Lifestyle changes pertaining to dietary discretion and modest increase in activity can affect glycemic control and may over a longer period of time reveal more impressive

weight management results. Vegetable consumption increased significantly and there was a trend toward increased fruit intake. It is suggested that diabetes education programs offered to multiethnic populations in small group settings can be effective in facilitating glycemic control in individuals with diabetes mellitus.

References

- American Diabetes Association. (1996). Diabetes Vital Statistics. Alexandria, VA.
- American Diabetes Association. (1998). Diabetes Vital Statistics. Alexandria, VA.
- American Diabetes Association Task Force. (1998). National Standards for Diabetes Self-Management Education. *Diabetes Care*, 21, S95-S98.
- American Diabetes Association. (2001). Clinical practice recommendations. *Diabetes Care*, 24, S5-S20.
- Anderson, R.M., Herman, W.H., Davis, J.M., Friedman, R.P., Funnell, M., & Neighbors, H.W. (1991). Barriers to improving care for black persons. *Diabetes Care*, 14, 605-609.
- Anderson, R., Funnell, M., Butler, P., Arnold, M., Fitzgerald, J., & Forte, C. (1995).

 Patient empowerment: results of a randomized controlled trial. *Diabetes Care*, 18, 943-949.
- Bautista-Martinez, B.S., Aguilar-Salinas, C.A., Lerman, I., Velasco, L., Castellanos, R., Zenteno, E., Guillen, L.E., Murcio, R., Wong, B., Gomez-Perez, F. J. & Rull-Rodrigo, J.A. (1999). Diabetes knowledge and its determinants in a Mexican-American population. *The Diabetes Educator*, 25, 374-381.
- Bennett, S.T., & Todd., J.A. (1996). Human type 1 diabetes and the insulin gene:principles of mapping polygenes. *Annual Review of Genetics*, 30, 343-370.

- Bernal, H., Wolley, S., Schensul, J.J., & Dickinson, J.K. (2000). Self-efficacy among Hispanic adults with diabetes. *The Diabetes Educator*, 26, 673-680.
- Bild, D.E., & Stevenson, J.M. (1992). Frequency of recording of diabetes on U.S. death certificates: analysis of the 1986 National Mortality Followback Survey. *Journal of Clinical Epidemiology*, 45, 275-281.
- Brown, S.A. (1990). Studies of educational interventions and outcomes in diabetic adults: a meta-analysis revisited. *Patient Education & Counseling*, 16, 189-215.
- Brown, S.A. (1992). Meta-analysis of diabetes patient education research: variations in intervention effects across studies. *Research in Nursing & Health*, 15, 409-419.
- Brown, S.A. (1999). Interventions to promote diabetes self-management: state of the science. *The Diabetes Educator*, 25, 52-58.
- Brown, S.A., & Harris, C.L. (1995). A community-based culturally sensitive education and support-group intervention for Mexican Americans with NIDDM: A pilot study of efficacy. *The Diabetes Educator*, *21*, 203-210.
- Brown, S.A., & Harris, C.L. (1999). Culturally competent diabetes education for Mexican Americans: the Starr County study. *The Diabetes Educator*, 25, 226-236.
- Campbell, E.M., Redman, S., Moffitt, P.S., & Sanson-Fisher, R.W. (1996). The relative effectiveness of educational and behavioral instruction programs for patients with NIDDM: a randomized trial. *The Diabetes Educator*, 22, 379-386.

- Corkery, E., Palmer, C., Foley, M.E., Schecter, C.B. Frisher, L., & Roman, S.H. (1997).

 Effect of a bicultural community health worker on completion of diabetes education in a Hispanic population. *Diabetes Care*, 20, 254-257.
- Cowie, C.C., Port, F.K., Rust, K.F., & Harris, M.I. (1994). Differences in survival between black and white patients with diabetic end-stage renal disease. *Diabetes Care*, 17, 681-687.
- Dabelea, D., Pettitt, D.J., Jones, K.L., & Arslanian, S.A. (1999). Type 2 diabetes mellitus in minority children and adolescents. An emerging problem. *Endocrinology and Metabolism Clinics of North America*, 28, 709-729.
- DeFronzo, R.A. Bonadonna, R.C., & Ferrannini, E. (1992). Pathogenesis of NIDDM: a balanced overview. *Diabetes Care*, 15, 317-368.
- The Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-treated diabetes mellitus. New England Journal of Medicine, 329, 977-986.
- Farkas-Hirsch, R., & Hinschi, I.B. (1998). Role of diabetes education in patient management. In H.E. Lebovitz (Ed.), *Therapy for Diabetes Mellitus and Related Disorders* (pp. 104-108). Alexandria, VA: American Diabetes Association.

- Fujimoto, W.Y. (1996). Overview of non-insulin-dependent diabetes mellitus in different population groups. *Diabetic Medicine*, 13, S7-S10.
- Gerich, J.E. (1996). Pathogenesis and treatment of type 2 diabetes mellitus. *Hormone & Metabolic Research*, 28, 404-412.
- Gerstein, H. (1994). Cow milk exposure and type 1 diabetes mellitus. *Diabetes Care*, *17*, 13-19.
- Genuth, S. (1990). Insulin use in NIDDM. Diabetes Care, 13, 1240-64.
- Glasgow, R., Vogt T., & Boles S. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal of Public Health*, 89, 1322-1327.
- Haffner, S.M., Hazuda, H.P., Mitchell, B.D., Patterson, J.K., & Stern, M.P. (1991).

 Increased incidence of type II diabetes mellitus in Mexican Americans. *Diabetes Care*, 14, 102-108.
- Hanefeld, M., Fisscher, S., & Schulze, J. (1991). Therapeutic potentials of acarbose as first-line drug in NIDDM insufficiently treated with diet alone. *Diabetes Care*, 14, 732-737.
- Harris, M.I. (1990). Noninsulin-dependent diabetes mellitus in black and white Americans.

 Diabetes Metabolism Reviews, 6, 71-90.

- Harris, M.I., Couric, C.C., & Howie, L.J. (1993). Self-monitoring of blood glucose by adults with diabetes in the U.S. population. *Diabetes Care*, 16, 1116-1123.
- Harris, M.I., Flegal, K.M., Cowie, C.C., Eberhardt, M.S., Goldstein, D.E., Little, R.R.,
 Wiedmeyer, H.M., & Byrd-Hold, D.D. (1998). Prevalence of diabetes, impaired
 fasting glucose, and impaired glucose tolerance in U.S. adults: the Third National
 Health and Nutrition Examination Survey, 1988-94. *Diabetes Care*, 21, 518-524.
- Homo-Delarche, F., & Boitard, C. (1996). Autoimmune diabetes: the role of the islets of Langerhans. *Immunology Today*, 17, 456-460.
- Kahn, R. (2000). Type 2 diabetes in children and adolescents. *Diabetes Care, 23,* 381-389.
- Keyserling, T.C., Ammerman, A.S., Samuel-Hodge, C.D., Ingram, A.F., Skelly, A.H., Elasy, T.A., Johnston, L.F., Cole, A.S., & Henriquez-Rollan, C.F. (2000). A diabetes management program for African American women with type 2 diabetes. *The Diabetes Educator*, 26, 796-805.
- Knowles, M. (1990). The Adult Learner: A Neglected Species. Houston, TX: Gulf.
- Kopreski, J., Pretto, A., & Poretsky, L. (1997). Effects of an intervention by a diabetes team in hospitalized patients with diabetes. *Diabetes Care*, 20, 1553-1555.
- Leahy, J.L. (1990). Natural history of beta-cell dysfunction in NIDDM. *Diabetes Care*, 13, 992-1010.

- Lebovitz, H.E. (1998). Diagnosis and classification of diabetes mellitus. In: H.E. Lebovitz (Ed.), *Therapy for Diabetes Mellitus and Related Disorders*, (pp. 5-7).

 Alexandria, VA: American Diabetes Association.
- Lebovitz, H.E. (1994). Oral antidiabetic agents. In C.R. Kahn (Ed)., Weir W.C. Joslin's Diabetes Mellitus. pp. 510-523. Philadelphia, PA: Lea & Zebinger.
- Lebovitz, H.E. (1998). Therapy for diabetes mellitus and related disorders.

 Alexandria, VA: American Diabetes Association.
- Ledda, M.A., Walker, E.A., & Basch, C.E. (1997). Development and formative evaluation of a foot self-care program for African Americans with diabetes. *The Diabetes Educator*, 23, 48-51.
- Leslie, R.D., & Elliott, R.B. (1994). Early environmental events as a cause of IDDM. Evidence and implications. *Diabetes*, 43, 843-850.
- Moller, D.E., Bjorbaek, C., & Vidal-Puig, A. (1996). Candidate genes for insulin resistance. *Diabetes Care*, 19, 396-400.
- Mullen, P.D., Green, L.W., & Persinger, G.S. (1985). Clinical trials of patient education for chronic conditions: a comparative meta-analysis of intervention types.

 *Preventive Medicine, 14, 753-781.
- Murphy, F.G., Satterfield, D., Anderson, R.M., & Lyons, A.E. (1993). Diabetes educators as cultural translators. *The Diabetes Educator*, 19, 113-118.

- Murphy, S.L. (2000). *National Vital Statistics Reports*, (Report No. 48-11). Atlanta, GA:
 U.S. Department of Health and Human Services. Centers for Disease Control and
 Prevention.
- Nicolucci, A., Cavaliere, D. Scorpiglione, N., Carinci, F., Capani, F., Tognoni, G., & Benedetti, M.M. (1996). A comprehensive assessment of the avoidability of long-term complications of diabetes. *Diabetes Care*, 19, 927-933.
- Oomen, J.S., Owen, L.J., & Suggs, S.L. (1999). Culture counts: Why current treatment models fail Hispanic women with type 2 diabetes. *The Diabetes Educator*, 25, 220-225.
- Padgett, D., Mumford, E., Hynes, M., & Carter, R. (1988). Meta-analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus.

 **Journal of Clinical Epidemiology, 41, 1007-1030.
- Peyrot, M., & Rubin, R.R. (1994). Modeling the effect of diabetes education on glycemic control. *The Diabetes Educator*, 20, 143-148.
- Powers, M.A. (1987). *Handbook of Diabetes Nutritional Management* (1st ed., pp. 47-53). Rockville, MD: Aspen.
- Raffel, L.J., & Rotter, J.I. (1985). The genetics of diabetes. Clinical Diabetes, 3, 49-54.

- Roter, D.L., Hall, J.A., Merisca, R., Nordstrom, B., Cretin, D., & Svarstad, B. (1998).

 Effectiveness of interventions to improve patient compliance: a meta-analysis.

 Medical Care, 36, 1138-1161.
- Schrock, L.E. (1998). Review of cost efficiency of delivering a diabetes education program in a southwest rural healthcare facility. *The Diabetes Educator*, 24, 485-492.
- Scott, F.W., Norris, J.M., & Kolb, H. (1996). Milk and type 1 diabetes. *Diabetes Care*, 19, 379-383.
- Sima, A.F. (Ed.). (2000). Chronic Complications in Diabetes. Detroit, MI: Harwood.
 Stern, M.P., Patterson, J.K., Mitchell, B.D., Haffner, S.M., & Hazuda, H.P.
 (1990). Overweight and mortality in Mexican Americans. International Journal of Obesity, 14, 623-629.
- Stern, M.P., & Mitchell, B.D. (1995). Diabetes in Hispanic Americans. In National Diabetes Data Group (Eds.), *Diabetes in America* (pp. 631-658). Bethesda, MD: National Institutes of Health.
- Taylor, S.T., Accili, D., & Imai, Y. (1994). Insulin resistance or insulin deficiency? Which is the primary cause of NIDDM? *Diabetes*, 43, 735-740.
- Thai, A.C., & Eisenbarth, G.S. (1993). Natural history of IDDM. *Diabetes Reviews, 1*, 1-14.

- Tilly, K.F., Belton, A.B., & McLachlan, J.F.C. (1995). Continuous monitoring of health status outcomes: experience with a diabetes education program. *The Diabetes Educator*, 21, 413-419.
- Tull, E.S., & Roseman, J.M. (1995). Diabetes in African-Americans. In National DiabetesData Group (Eds.), *Diabetes in America* (pp. 613-629). Bethesda, MD: National Institutes of Health.
- Turner, R., Cull, C., & Holman, R. (1996). United Kingdom Prospective Diabetes Study:

 A 9-year update of a randomized, controlled trial on the effect of non-insulindependent diabetes mellitus. *Annals of Internal Medicine*, 124, 136-145.
- UK Prospective Diabetes Study (UKPDS) Group. (1998). Effect of intensive blood-glucose control with metformin on complications in patients with type 2 diabetes.

 Lancet, 352, 854-865.
- Verge, C., Gianani, R., Kawasaki, E., Yu, L., Pietroapolo, M., Jackson, R., Chase, H., Eisenbarth, G. (1996). Prediction of type 1 diabetes in first-degree relatives using a combination of insulin, GAD, and ICA 512 bdc/IA-2 autoantibodies. *Diabetes*, 45, 926-933.
- Vigneri, R., & Goldfine, I.D. (1987). Role of metformin in treatment of diabetes mellitus.

 Diabetes Care, 10, 118-122.
- Vinicor, F. (1994). Is diabetes a public-health disorder? Diabetes Care, 17, 22-27.

- Walker, E.A., Basch, C.E., Howard, C.J., Kromholz, W.N., Zybert, P.A., & Shamoon, H. (1997). Incentives and barriers to retinopathy screening in African Americans with diabetes. *Journal of Diabetes Complications*, 11, 298-306.
- Walker, E. (1999). Characteristics of the adult learner. The Diabetes Educator, 25, 16-24.
- Watts, F.N. (1980). Behavioural aspects of the management of diabetes mellitus: education, self-care and metabolic control. *Behaviour Research and Therapy, 18*, 171-180.
- Weatherspoon, L.J., Kumanyika, S.K., Ludlow, R., & Schatz, D. (1994). Glycemic control in a sample of black and white clinic patients with NIDDM. *Diabetes Care*, 17, 1148-1153.
- Wei, M., Gaskill, S.P., Haffner, S.M., & Stern, M.P. (1998). Effects of diabetes and level of glycemia on all-cause and cardiovascular mortality. *Diabetes Care*, 21, 1167-1172.
- Wei, M., Mitchell, B. D., Haffner, S. M. & Stern, M. P. (1996). Effects of cigarette smoking, diabetes, high cholesterol and hypertension on mortality in Mexican-American. *American Journal of Epidemiology*, 144, 1058-1065.
- Weller, S.C., Baer, R.D., & Pocater, C.M. (1999). Latino beliefs about diabetes. *Diabetes Care*, 22, 722-728.

- Williams, G., Freedman, Z., & Deci, E. (1998). Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care*, 21, 1644-1651.
- Wisdom, K., Fryzek, J.P., Havstad, S.L., Anderson, B.M., Dneiling, M.C., & Tilley, B.C.
 (1997). Comparison of lab test frequency and test results between African
 Americans and Caucasians with diabetes: opportunity for improvement. *Diabetes*Care, 20, 971-977.

APPENDICES

APPENDIX A

IRB Approval Form

The University of Texas Medical Branch at Galveston

School of Medicine Graduate School of Biomedical Sciences School of Allied Health Sciences School of Nursing Marine Biomedical Institute Institute for the Medical Humanities UTMB Hospitals and Clinics

Institutional Review Board

September 21, 2000

MEMORANDUM

TO:

Fannie Smith, MD, PhD/E. Ann Cabanas, MPH, RD, CDE

Endocrimplogy 188

FROM:

Wayne R. Patierson, PhD

Director of Institutional Research Review

Institutional Review Board - 0137

SUBJECT: Expedited Review, Human Subjects

Project Director: <u>Fannie Smith, MD, PhD/E. Ann Cabanas, MPH, RD, CDE</u>

IRB #00-384

Project Title: The Impact of Ethnicity on the Outcomes of Diabetes Education

Under the Institutional Review Board's policies and procedures for reviewing protocols by an expedited review process, your project referenced above was approved on <u>September 21</u>, <u>2000</u>. I am, therefore, pleased to inform you that you may proceed with this project immediately.

This project will require annual review by the IRB and will be due in August, 2001.

Project Directors of approved projects are responsible for reporting to the Institutional Review Board any unanticipated adverse reactions observed during the conduct of the project as well as any severe or serious side effects whether anticipated or unanticipated.

Should your project require modification which alters the risk to the subject or the method of obtaining informed consent (if applicable), the project must be reevaluated by the Institutional Review Board before the modification is initiated.

If applicable to the study, completed subject consents should be maintained in the designated place for at least three years after the termination of the project. In order to be in compliance with the requirements of the FDA regulations, 21 CFR 56.27a, a copy of the completed consent document must be provided to the subject.

COMMENTS: This project is limited to a retrospective chart review study and the use of an anonymous questionnaire and the return of the completed questionnaire implies consent.

WRP/as

XC:

Lucy Limones, Manager

Health Information Management - 0782

The University of Texas Medical Branch at Galveston

School of Medicine Graduate School of Biomedical Sciences School of Allied Health Sciences School of Nursing Marine Biomedical Institute Institute for the Medical Humanities UTMB Hospitals and Clinics

Institutional Review Board

September 21, 2000

MEMORANDUM

TO:

(Fannie Smith, MD, PhD/E. Ann Cabanas, MPH, RD, CDE

Endacrinology 1188

FROM:

Washe R. Patterson, PhD

Director of Institutional Research Review

Institutional Review Board - 0137

SUBJECT: Expedited Review, Human Subjects

Project Director: <u>Fannie Smith, MD, PhD/E. Ann Cabanas, MPH, RD, CDE</u>

IRB #00-391

Project Title: The Impact of Diet Instruction on the Outcomes of Diabetes Education

Under the Institutional Review Board's policies and procedures for reviewing protocols by an expedited review process, your project referenced above was approved on <u>September 21</u>, <u>2000</u>. I am, therefore, pleased to inform you that you may proceed with this project immediately.

This project will require annual review by the IRB and will be due in August, 2001.

Project Directors of approved projects are responsible for reporting to the Institutional Review Board any unanticipated adverse reactions observed during the conduct of the project as well as any severe or serious side effects whether anticipated or unanticipated.

Should your project require modification which alters the risk to the subject or the method of obtaining informed consent (if applicable), the project must be reevaluated by the Institutional Review Board before the modification is initiated.

If applicable to the study, completed subject consents should be maintained in the designated place for at least three years after the termination of the project. In order to be in compliance with the requirements of the FDA regulations, 21 CFR 56.27a, a copy of the completed consent document must be provided to the subject.

COMMENTS: This project is approved for obtaining oral assent. All data will be coded to protect confidentiality.

WRP/as

APPENDIX B

Oral Consent Form

Oral Consent Request

Before we begin the diet class for diabetes education, please recall all food and beverages consumed over the past 24 hours including portion size and method of food preparation. It is helpful for one to know present food intake habits in order to plan for dietary changes necessary to control diabetes mellitus.

At the next class, you will again be asked to recall your food intake for the previous 24 hours. The diet diary will be compared and changes will be observed.

Changes will be stored in a database and compared to lab values for hemoglobin A_{1c} , random blood glucose and weight before and after diabetes education. Your records will not be listed in your name so will remain anonymous.

If you do not wish for your record to be used in this database, you need not turn in your diet recall today. You may keep it for your own information.

APPENDIX C

HbA_{1c} Measurement Technique

Hemoglobin A_{1c} Bio-Rad Variant II

Source of Method

Therapy for diabetes requires the long-term maintenance of a blood glucose as close as possible to a normal level. An accurate index of the mean blood glucose concentration may be established by the measurement of hemoglobin A_{1c} (HbA_{1c}) which reflects metabolic control during the preceding two to three months. The Variant II Hemoglobin A_{1c} Testing Program is based on chromatographic separation of HbA_{1c} on a cation exchange cartridge.

Principle

Whole blood is used in the first step in which hemoglobin is lyzed from the cell and blood is fractionated.

Utilizing the principles of ion exchange high performance liquid chromatography (HPLC), the samples are automatically mixed and diluted on the Variant II Sampling Station and injected to the analytical cartridge.

In the Variant II Chromatographic Station dual pumps deliver a programmed buffer gradient of increasing ionic strength to the cartridge, where the hemoglobins are separated based on their ionic interactions with the cartridge material.

The separated hemoglobins then pass through the flow cell of the filter photometer, where changes in the absorbance at 415 nm are measured. An additional filter at 690 nm corrects the background absorbance.

The data collected form each analysis. Two-level calibration is used for adjustment of the calculated HbA_{1c} values. A sample report and a chromatogram are generated by the clinical data management software for each sample. The A_{1c} peak is shaded. This area is calculated using an exponentially modified gaussian algorithm that excludes the labile A_{1c} and carbamylated peak area.

Bio-Rad, Inc. 4000 Alfred Nobel Drive Hercules, CA 94547

APPENDIX D

Self Blood Glucose Monitoring Technique

Glucose Accu-Chek Advantage

Test Principle

The Advantage test strip contains the enzyme glucose dehydrogenase which converts the glucose in a whole blood sample to gluconolactone. This liberates an electron that reacts with a mediator. The oxidized form of the mediator hexacyanoferrate (III) accepts the electron, forming the reduced form of the mediator, hexacyanoferrate (II). The Advantage test strip employs the electrochemical principle of biamperometry.

The monitor applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the monitor.

The Advantage monitors glucose using capillary, venous, or arterial whole blood. The reading will register \pm 15% of a standard venous plasma laboratory analysis.

Roche Diagnostic Corporation 9115 Hague Road Indianapolis, Indiana 46256

APPENDIX E

Meal Planning with Exchange Lists

MEAL PLANNING WITH EXCHANGE LISTS

Follow your meal plan carefully and eat meals at about the same time of day everyday.

It is important to eat low fat, low cholesterol foods. Prepare foods with as little fat as possible. Use lean meat trimmed of fat, pan sprays instead of oil or shortening, and fat free or light salad dressings, mayonnaise, and margarine.

Include whole grain breads and cereals in diet to increase the amount of fiber consumed.

Cut down on salt, especially if you have high blood pressure. Most Americans eat too much salt so it would be best for most of us to reduce our salt intake.

Alcohol provides empty calories and a high intake of alcoholic beverages may cause several health problems.

There are only 6 groups of foods that we eat.

- Starch/bread
- 4. Meat
- 2. Fruit
- 5. Fat
- 3. Milk
- 6. Vegetables

The first 3 groups contain carbohydrate which becomes blood sugar. These 3 food groups should be consumed in the same amounts at specific meal times to control diabetes. Overeating and meal skipping can increase cholesterol and triglycerides also.

Saccharin (Sweet 'n Low, Sugar Twin, Sweet-10, and Sprinkle Sweet), acesulfame K (Sweet One), aspartame (NutraSweet, Equal) and Splenda (sucralose) are artificial sweeteners which do not add calories to the diet. Avoid table sugar.

STARCH/BREAD LIST

Each portion listed contains approximately 15 grams of carbohydrate, 3 grams of protein, and 80 calories.

Cereals/Grains/Pasta/Vegetables

Serving size is $\frac{1}{2}$ cup unless otherwise stated.

Bran cereals, flaked	½ cup	Corn	½ cup
Cooked cereals	½ cup	Dried beans	½ cup
Grapenuts	¹ ₄ cup	Peas, Green	½ cup
Pasta, spaghetti	½ cup	Potato	3 oz
Rice, cooked	1/3 cup	Squash, winter	1 cup
Wheat germ	3 Tablespoons	Yam	½ cup

BREAD

Serving size is 1 ounce unless otherwise stated.

Bagel	<u>1</u>	English Muffin	1/2
Bread sticks	2	Pita	$\frac{1}{2}$
Bread, sliced	1	Tortilla	1

Bun, hot dog or hamburger $\frac{1}{2}$

CRACKERS/SNACKS

Animal crackers	8	Graham crackers, 2 ½"	3
Melba toast	4	Oyster crackers	24
Popcorn, popped	3 cups	Pretzels	$\frac{3}{4}$ ounce
Saltines	6	Rice Cakes, 4"	2

Starch foods prepared with additional fat. Count as 1 starch and 1 fat.

Biscuit	2 ½"
Chow mein noodles	½ cup
Cornbread (2" cube):	2 oz
Dressing	1/3 cup
French Fries	16 - 25
Muffin, plain	1 ½ oz
Pancake (4")	2
Taco shells	2
Waffle $(4 \pm ")$	1

Whole wheat crackers, fat added, such as Triscuit: 4-6 pieces (1 oz)

FRUIT LIST

NOTEN FOLITT

Each portion contains about 15 grams of carbohydrate, and 60 calories. Serving size is $\frac{1}{2}$ cup unsweetened unless otherwise stated.

Apple	1 Official	DRILLOIT	<u> </u>	
Applesauce	½ cup	Raisins	2 Tablespoons	
Apricots	4	Prunes	3 Medium	
Banana	1 Small (4 oz)			
Cantaloupe	1/3			
- ·· ·	1	ראו ודד דו	LITCE C 1 C	

Fruit, canned	½ cup	FRUIT JUICES ½ Cup
Grapefruit	½ Large	Apple Juice
Grapes	17	Grapefruit Juice

OI apos		Or aport a
Honeydew	1/8	Orange
Kiwi	1	Pineapple

1 Small

Mango	$\frac{1}{2}$
Orange	1 Small

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Papaya	1 Cup	FRUIT JUICES 1/3 Cup

Peach	1 Medium	Cranberry Juice
Pear	½ Large	Grape Juice
Pineapple	½ Cup	Prune Juice

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Plums	2	Fruit Juice Blends, 100% Juice

Strawberries	1 ½ cup
Tangerines	2

Watermelon 1 ½ cup

MILK LIST

Each portion contains approximately 12 grams of carbohydrate, 8 grams of protein, and 0, 5, or 8 grams of fat, and 90, 120, 150 Calories. Serving size is 1 cup unless otherwise stated.

Skim, $\frac{1}{2}$ %, or 1% (90 Calories) 2% milk (120 Calories) Whole milk (150 Calories) Lowfat buttermilk 1 cup Dry nonfat milk 1/3 cup Yogurt, plain, nonfat

Yogurt, made with NutraSweet, fruit flavor (Lite) 1 cup

₹ cup

FATLIST

Each portion listed contains approximately 5 grams of fat and 45 calories.

<u>Unsaturate</u>	<u>:d</u>		<u>Saturated</u>	
Avocado	1/8	В	utter	1 teaspoon
Margarine	1 teaspoon	Во	acon	1 slice
Margarine, diet	1 Tablespoon	Cl	hitterlings	$\frac{1}{2}$ ounce
Mayonnaise	1 teaspoon	Co	oconut	2 Tablespoons
Mayo, light	1 Tablespoon	Co	offee creamers	4 teaspoons
		Cı	ream sour	2 Tablespoons
		Cı	ream cheese	1 Tablespoon
		S	alt Pork	$\frac{1}{4}$ ounce
		Nuts/Seed	ds	
Cashews	6	0	Dil	1 teaspoon

Peanuts 10

Pecans

Pumpkin seeds 3 teaspoons

2 Whole

Salad dressings, all varieties 1 Tablespoon
Salad dressings, reduced-fat 2 Tablespoons
Salad dressings, Free 3 Tablespoons

MEATLIST

Olives

8 Large

Each portion listed contains approximately 7 grams of protein, 3 grams of fat, and 55 calories per ounce.

Beef, lean: Round, sirloin, flank, tenderloin, lean ground beef
Pork: Fresh ham, boiled ham, tenderloin, Canadian Bacon

Veal: Chops, roasts

Poultry: Without skin

Fish: All fresh and frozen

Crab, lobster, scallops, shrimp, clams: 1-1/2 oz.

Oysters: 6 medium

Tuna (canned in water) 1-1/2 oz Herring (Uncreamed or smoked) Sardines (canned) 2 medium

Meat List Continued:

Wild game: Venison, rabbit, squirrel, pheasant, duck, goose (no skin)

Cheese: Cottage Cheese $\frac{1}{4}$ cup

Grated Parmesan 2 Tablespoons

Diet Cheeses

Other: 95% fat-free luncheon meat

egg whites 3

Bake, broil, roast, grill, or boil these foods rather than fry. Use a panspray instead of oil or shortening to reduce fat. Trim meats of all visible fat before cooking.

The following meats are high in fat and calories and should be avoided. A one ounce portion contains 8 grams of fat and 100 calories.

Spare ribs, ground pork, sausage, fried fish, regular cheese, luncheon meats, frankfurters, and peanut butter (1 $\frac{1}{2}$ Tablespoons).

VEGETABLES

Each serving contains 5 grams of carbohydrate, 2 grams of protein, and 25 calories

Artichoke Eggplant Sauerkraut
Asparagus Greens Spinach

Beans, Green, wax, Italian Jalapenos Summer squash

Bean sprouts Kohlrabi Tomato

Beets Leeks Tomato/vegetable juice

Broccoli Mushrooms Turnips

Brussels sprouts Okra

Cabbage, cooked Onions Water chesnuts

Cactus Pea pods Zucchini

Carrots Peppers
Cauliflower Rutabaga
Cucumber Salad Greens

FREE FOODS

A free food is any food or drink that contains less than 20 calories per serving. You may eat two or three servings per day of those items that have a specific serving size. Be sure to spread them out through the day.

DRINKS:

Bouillon

Carbonated drinks, sugar-free

Club soda

Cocoa powder, unsweetened (1 Tablespoon)

Coffee-Tea

Drink mixes, sugar-free

Nonstick pan spray:

Salad greens

Lettuce

Spinach

Vegetables, raw, 1 cup (cabbage, celery, cucumber, green onion, peppers, mushrooms, radishes, zucchini)

Condiments:

Catsup (1 Tablespoon)

Horseradish

Mustard

Pickles, dill, unsweetened 1-1/2 large

Salad Dressing, fat-free (1 Tablespoon)

Seasonings (Basil, garlic, pepper, rosemary, thyme, etc.)

Taco sauce (1 Tablespoon)

Vinegar, lemon juice

Sweet Substitutes

Gelatin, sugar-free

Gum, sugar-free

Jam/Jelly, sugar-free (2 teaspoons)

Pancake Syrup, sugar-free (1-2 Tablespoons)

Whip Topping (2 Tablespoons)

APPENDIX F

Weight in Lbs

Part 1

APPENDIX F

Initial Weight	Final Weight
247	
370	
169	
175	
116	
168	
199	
144	
193	
232	
97	
245	
239	
347	337
188	
308	344
171	
214	
157	169
138	
280	
208	
334	
190	182
198	
296	
242	
420	

220	225.8
160	
194	186
251	
165	
169	
232	
182	186.2
229	236
183	182
162	162
150	174
241	260
108	135.6
220	196
176	192
148	152
205	
165	157
245	
368	
166	161
171	184
109	104
164	
155	
241	
187.8	
229	
191	

151	
215	
243	
169	
250	
184	
170	
184	194
185	
213	218
149	153
186	
185	184
215	214
166	
225	230
300	
218	226
144	154.8
175	
179	
238	
200	201
264	287
191	182
154	160
	293
109	
212	216
201	212

300	
186	183
210	
214	215
196	208
307	304
143	152
295	
304	307
403	397
170	
	139
165	169
219	225.8
240	234
	319
230	233
187	186
177	
194	195
114	
238	
158	
140	
242	
160	
198.8	
230	
187	
348	

305

140.6

162

160.4

195.6

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X = +4.3

APPENDIX G

Weight in Lbs

Part 2

APPENDIX G

<u>Initial</u>	<u>Final</u>	<u>Change</u>
244	248	-4
248	241	+7
187	181	-6
198	169	-29
255	246	- 9
180	176	-4
254	244	-10
250	253	+3
179	177	-2
230	225	-5
183	178	-5
198	199	+1
203	196	-7
178	140	-38
201	198	-3
334	326	-8
186	178	-6
196	190	-6
233	224	-9
242	242	-0
211	189	-22
232	226	-6
185	178	-7
190	179	-11
278	265	-13
229	218	-11
208	213	+5

199	189	-10
298	287	-11
203	171	-32
305	302	-3
256	248	-8
191	189	-3
248	256	+7
208	206	-2
186	183	-5
222	218	-4
234	236	+2
213	202	-11
289	256	-33
<u>193</u>	<u>181</u>	<u>-12</u>

X = -8.54