# Improving Diabetes Management Programs:

# The Effect of Knowledge and Psychological Status on Glycemic Control

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## Executive Summary

Over 20.8 million people in the United States currently have some form of diabetes. While this is only 7.0% of the United States, due to changes in diet and exercise, diabetes is expected to drastically increase in prevalence over the next few decades. Though diabetes affects people of all ethnicities, people of Hispanic, Native American or African American descent are anywhere between 2 and 5 times more likely to develop diabetes than Caucasians. There are three main theories for why some minority groups suffer disproportionately from diabetes: a genetic predisposition due to increased insulin resistance, the adoption of a western lifestyle and socioeconomic status.

In order to combat rising prevalence of diabetes and provide more adequate health care for patients, diabetes management programs have been implemented across the country. Diabetes management programs provide patients with comprehensive care. Different forms of diabetes management programs function in clinics across the nation, serving many different populations. In all of these places and situations diabetes management programs have improved glycemic control through lowering hemoglobin A1c levels. Not only have these programs improved glycemic control, many of them also save money by lowering the financial cost of diabetes for both clinics and patients.

The Edward R. Roybal Comprehensive Health Center located in East Los Angeles is currently performing a study on their management program. The study analyzes two different aspects of the program: whether the new episodic care model is as efficient as the previous continuous care model, and whether knowledge levels and psychological status effect patient's glycemic control. In this report, the psychological status and knowledge levels were analyzed using both paired t-test and linear regression analysis.

Statistical analysis showed no relationship between psychological status and knowledge on glycemic levels. However, the data was confounded because many of the psychological variables showed little change over time. Currently, little conclusive evidence exists to support or disprove this theory. Though statistical evidence showed no relationship, the study is still progressing to determine whether episodic care is more successful. More research needs to be performed on the relationship between psychological status and glycemic control. With more knowledge, diabetes management programs can be adapted to address psychological barriers.

In order to decrease the number of diabetic patients living with complications, education and outreach programs need to be implemented in order to diagnose patients at an earlier point in the disease progression. Educating children about the risks and symptoms of diabetes will lead to a growing number of children who avoid many of the habits that are cause diabetes. Enacting media outreach campaigns will educate the entire American public about diabetes and increase the number of people who tested for diabetes. Recommended testing by doctors will also allow patients to become aware of their diabetes and receive care at an earlier period.

In order to care for the increased number of diabetics, a general outline for a diabetes management program should be created and disseminated. The general program should address four aspects of diabetes related care: medical advisement, nutrition, education and psychological. This general structure should be used as a template to implement diabetes management programs across the nation. Diabetes management programs have proven effective in many cases, and as the diabetes epidemic continues more management programs will help provide adequate health care to those in need. Increasing the number and efficiency of diabetes management programs will do much to alleviate strain on the United States health care system caused by the diabetes epidemic.

## Introduction

Diabetes mellitus. About 20 years ago, its' prevalence and existence were not a major concern. Diabetes affected mainly the elderly and a much smaller proportion of children. Like a latent virus, which nobody knew existed, diabetes exploded into existence over the last decade with huge increases in prevalence. It now affects not only the elderly and young children it affects middle-aged adults. After ignoring diabetes for so long, the world is now paying attention to this complex disease. It is now obvious that people worldwide have not been properly educated about diabetes and how they can avoid developing it. Along with a lack of education, the world must face the fact that it may be drastically unprepared to provide adequate care for the increasing amount of diabetics.

Having lived with type 1 diabetes mellitus for 12 years, since the age of 9, has given me an idea of the amount of support that is needed to deal with the daily shots, dietary restrictions, risk of hypoglycemia, effects of hyperglycemia and blood glucose testing. In my life, I have been lucky enough to have the kind of support that has enabled me to apply myself day after day to the task of maintaining blood glucose levels. It has made me realize that social support is a necessary part of dealing with diabetes.

As a diabetic, I face the daily worry of developing complications if my blood sugar levels are not properly maintained. A frightening array of complications awaits the unwary diabetic who does not spend enough time focusing on their care. I am not alone in the threat that diabetes poses to my body every day. Almost 200 million diabetics worldwide face the same threat. I believe that it is important to educate more people about diabetes so they are aware of the serious consequences awaiting them if they do not take care of themselves. Through this paper, I want people to take note of the complexity of caring for diabetes and do something to help all diabetics, both new and old, care for themselves properly.

This paper explores the success of diabetes management programs in improving glycemic control in patients as well as lowering the cost of diabetes care. It focuses specifically on the program at the Edward R. Roybal Comprehensive Health Center located in East Los Angeles. The Roybal Comprehensive Health Center serves a low income Hispanic population, one of the groups at highest risk for developing diabetes with the least amount of access to adequate health care. The program has been successful in lowering average glycemic levels in this high risk population, through intensive case management.

The Diabetes Management Center at the Roybal Comprehensive Health Center currently has a grant from the American Diabetes Association to research another type of diabetes management program which may further lower costs for the clinic. The study also researches the effect a patient's knowledge of diabetes and their psychological status, including levels of social support and depression, have on their blood glucose levels. The purpose of the second portion of the study, the part dealing with knowledge and psychological status, is to prove that there is a connection between the two and then begin addressing psychological barriers in diabetes management programs.

This paper also shows how successful management programs that provide comprehensive care can be. There is a whole population of minority and low-income patients who suffer from diabetes yet cannot find or afford decent diabetes care. The implementation of diabetes management programs nation wide may be the answer to provide these patients with quality, low-cost care. It is my hope that the number of diabetes management programs increases so that patients can receive quality care. As the number of diabetics continues to increase, it will become increasingly important to have proper medical programs in place.

Because of what it is addressing this study has personal value to me. I am a firm believer that high levels of social support enabled me to take better care of my diabetes. I believe that people's psychological status should be analyzed and any barriers to care that may come about because of their psychological status should be addressed to improve their care. And just as I have been lucky enough to receive adequate care and support, so should people who cannot afford medical insurance be able to receive adequate health care. All people should have access to the kind of care that will allow them to live complication free lives. It is my belief that diabetes management programs have the ability to provide the large number of diabetics with the care they need to lead normal lives.

Though this report analyzes the numbers and statistics surrounding diabetes, it will not be able to describe what it really means to have and live with diabetes. No words really can. But in between the lines and the written words are the hopes and pain of a young nine year old girl who had to deal with a diagnosis she did not understand. The words of the report reflect her twelve year struggle to be educated about the disease she has to battle every day. In between the lines lay her hope that diabetes can be cured and complications prevented with amazing medical care and the support of family and friends.

## Chapter 1: Overview of Diabetes and Related Issues

Diabetes is a disease that affects the body's ability to produce and absorb insulin, which leads to increased blood glucose levels. In 2000, diabetes affected over 171 million people worldwide.[1] Diabetes has recently been gaining attention because of the dramatic increase in prevalence it has and will experience; by the year 2030, over 366 million people globally are expected to have diabetes.[2] While the prevalence of diabetes has been increasing dramatically, the technology available to treat the disease has also been improving. Scientific advances have increased the effectiveness and availability of oral medications, insulin and blood glucose testing machines, increasing the quality of diabetes care, and prolonging the lives of many people. However, the increased prevalence of diabetes has also lead to an increased amount of people living with diabetes complications, such as heart disease, blindness, kidney disease, and nervous system damage. Even though scientific advances have improved the quality of medications, many diabetics still struggle to control their blood sugar levels.

**Three main forms of diabetes**

According to the Centers for Disease Control 20.8 million people or 7.0% of the population in the United States currently have some form of diabetes.[3] Of this 20.8 million people, only 6.2 million have diagnosed cases, leaving and estimated 14.6 million people in the United States unaware of the fact that they have a chronic and potentially deadly disease.[4] There are three main forms of diabetes, which account for 98% to 99% of all cases of diabetes. The three forms are: type 1, type 2 and gestational. Though all three forms are characterized by a lack of insulin and elevated blood sugar levels, they differ in their time of onset, risk factors and pathology.

Type 1 diabetes, formerly called insulin-dependent diabetes, is characterized by a cessation of insulin production by the pancreas, making manual insulin delivery necessary for survival. Type 1 diabetes is an auto-immune disease which occurs when the body's immune system attacks the beta-cells located in the pancreas. Beta-cells produce the hormone insulin which aids in the breakdown of glucose molecules. In type 1 diabetes, the body eventually stops producing all insulin as the beta cells are all killed by the body's immune system. Because no insulin is present to aid in the breakdown of glucose, a patient's blood sugar levels will remain at abnormally high levels until diagnosed.[5] Because of constant high blood sugars and a relatively short onset period, type 1 diabetes is the easiest of all three forms to diagnose.

Type 1 diabetes accounts for approximately 5 to 10% of diagnosed cases of diabetes.[6] Most type 1 diabetes diagnoses occur in adolescents and young adults, leading to it being commonly referred to as juvenile-onset diabetes. Though most cases of type 1 diabetes occur in people less than 30 years of age, approximately 7.4% of all patients diagnosed between ages 40 and 74 are considered adult-onset type 1 diabetes.[7] There are currently few proven risk factors associated with type 1 diabetes. The only risk factor commonly accepted is that people who have family members with diabetes have a slightly higher chance of developing type 1 diabetes.

Unlike type 1 diabetes, type 2 diabetes does not cause the pancreas to stop producing all insulin. Increased insulin resistance, referred to as impaired glucose tolerance (IGT), characterizes type 2 diabetes. The increase in insulin resistance begins slowly and at first, is undetectable. During this time of initial insulin resistance, beta-cells in the pancreas still produce insulin. In order to make up for insulin resistance, the beta-cells begin a cycle of overproduction, or compensatory hyperinsulinemia. Because of the increase in insulin production normal glucose levels are maintained for a time. In the next stage development, insulin resistance continues to increase and compensatory hyperinsulinemia can no longer produce enough insulin to maintain normal glucose levels.[8] At this point, the blood glucose levels of the patient slowly begin to rise. Because of the gradual increase in blood glucose levels, the symptoms of diabetes begin slowly leading to a slow increase in symptoms, as opposed to type 1 diabetes when the cessation of insulin production is quick, leading to a noticeable change in behaviors. The stages of type 2 diabetes development can occur over many years, so slowly that people often do not notice the development of symptoms until they are severe. At the point of detection it is possible for patients to have had diabetes for years. The slow development of type 2 diabetes and its symptoms are a major reason why an estimated 14.6 million people in the United States are living with undiagnosed cases of diabetes.

Type 2 diabetes is the most prevalent form of diabetes in the world today, accounting for between 90% and 95% of all diagnosed cases of diabetes in the United States.[9] Type 2 diabetes, previously called "adult-onset" diabetes, commonly occurs in people over the age of 30. Though it typically affects people over the age of 30, type 2 diabetes is becoming increasingly prevalent in children. Besides age, other common risk factors include: obesity, a family history of diabetes, lack of exercise and ethnicity. Type 2 diabetes is much more prevalent in Native Americans, Hispanics or Latinos and African Americans than it is in other Caucasians or American-Europeans. The reasons for the difference in prevalence based on ethnicity will be discussed in the following section.

Gestational diabetes is a form of glucose intolerance that occurs during pregnancy, usually in women at an increased risk of developing type 2 diabetes. Gestational diabetes is caused by the hormones released during fetal development. The placenta, which connects the mother to her baby, produces hormones that inhibit insulin absorption. As the pregnancy progresses, the placenta produces more of these hormones, making insulin absorption continually less.[10] If left untreated, gestational diabetes can cause an increased risk of birth trauma and cesarean delivery.[11] After giving birth, most mothers resume normal insulin absorption and can cease treatment. However in 5% to 10% of women what was believed to be gestational diabetes is actually type 2 diabetes.[12]

Gestational diabetes is diagnosed in 3 to 7% of all pregnant women in the United States.[13] Common risk factors for gestational diabetes include ethnicity and weight. Gestational diabetes occurs more often in women of African American, Hispanic or Native American descent and overweight women. These two major risk factors are also risks for developing type 2 diabetes, leading to the conclusion that many women who develop gestational diabetes are also those at high risk of developing type 2 diabetes. In fact, women who have had gestational diabetes have a 20% to 50% chance of developing diabetes in the 10 to 15 years after their pregnancy.[14]

**Treatment Options**

The three main types of diabetes, type 1, type 2 and gestational, differ in prevalence and pathology, however, they are similar in the fact that they all result from a decrease or cessation of insulin production. All forms have similar symptoms, complications and treatment options, however, the difference in the pathology of the three forms of diabetes leads to different intensities of therapy. The degree to which the patient lacks insulin determines the intensity of their treatment regimen, meaning that type 1 diabetics will have more intensive regimens than type 2 or gestational diabetics.

Diabetes care has made many advances in the past decades. Continual advancement in the understanding of diabetes pathology has enabled the creation of new families of oral medication and insulin types, improving patient's ability to control their diabetes. The creation of small, self-monitoring blood glucose devices allow patients to get accurate blood sugar levels, enabling them to make minor adjustments in their drug regimen to constantly improve blood sugar levels. The wide availability of these glucose-monitoring machines has lead to a significant decrease in price over the last decade, making diabetes management significantly cheaper as well. Several new oral medications and types of insulin have also been released in the past decade. Along with more recent advances in drug therapy and glucose monitoring, diabetes can still be partially controlled with diet and exercise. Through a combination of subcutaneous insulin injections, oral medication, nutrition, exercise, and self-monitoring blood glucose tests, patients can control their diabetes.

Type 1, type 2 and gestational diabetics all use insulin injections to control blood sugar levels. In type 1 diabetics, insulin therapy is always the primary treatment. Because the pancreas no longer secretes any insulin in type 1 diabetics, manual insulin delivery is required multiple times a day in order to imitate the natural secretion process of the pancreas. In type 2 diabetics, the purpose of an insulin regimen is to provide enough insulin to supplement the body's reduction in insulin production and overcome increasing insulin resistance. Though most type 2 diabetics begin controlling their diabetes with oral medications all type 2 diabetics end up taking insulin late in their disease progression.[15]

The types of insulin available in the market today can be broken up into four major groups: rapid-acting, short-acting, intermediate-acting, and long-acting. Typically, a combination of two or more different insulin classes comprise a patient's insulin regimen. Usually a rapid or short-acting insulin is combined with an intermediate or long-acting insulin. Shorter acting insulin is typically taken before meals in order to cover the carbohydrate intake of the patient. Longer acting insulin provides a baseline, which is present at all times in order to break down stored fats and proteins to provide energy for basic bodily functions. The daily insulin regimens of patients can range anywhere from two to eight times a day, depending on intensity and types of insulin used. None of these regimens has been proven better than the others; it is dependent on which best suits the patient.

Oral medications are also used to control blood sugars or to supplement insulin therapies. Five classes of oral medications are currently approved for use in the United States.[16] These five classes of oral medications can be classified again into three major groups: those that increase insulin secretion from pancreatic beta cells, those that increase insulin absorption, and those that moderate carbohydrate absorption. All of these medications are used in type 2 diabetics, however, not for gestational or type 1 diabetics. While women with gestational diabetes can use any of those drug classes, oral therapy is typically not used in this case because of the possible side effects the drugs could have on the unborn child. Type 1 diabetics cannot use the first grouping of drugs, which increase insulin secretion, because their beta cells no longer produce any insulin. Type 1 diabetics do use drugs from the other classes of medication, though it is not common.

Though any of these five drug classes can adequately control blood glucose levels in a type 2 diabetic, they are often combined to create more effective therapy. After therapy with one drug begins to fail, addition of a second drug class has been found more effective than discontinuing or increasing the dosage of the first medication. Though two-drug combination therapy can be used effectively in type 2 diabetics for many years, it is widely acknowledged that eventually this regimen will fail, and while a three-drug combination therapy can be tried the efficacy of this has not yet been proven. Most people whose two-drug combination therapy begins to fail are eventually put on insulin therapy.[17]

While insulin and oral medication therapies are typically the first line of treatment for diabetics, lifestyle changes in diet and exercise are used to supplement medical treatment. While certain lifestyle changes are encouraged for type 1 diabetics, they are mainly recommended for type 2 diabetics because many of the risk factors for type 2 diabetes are caused by lifestyle choices. One of the main risk factors for type 2 diabetes is obesity, caused by an unhealthy diet and lack of exercise. In type 2 diabetic patients permanent lifestyle changes are encouraged in order to combat some of the problems which initially caused the diagnosis including weight, blood pressure and cholesterol.

Nutrition therapy in type 2 diabetics promotes the achievement and maintenance of certain blood glucose, lipids and blood pressure levels. In treatment of type 2 diabetes this is achieved through nutritional goals that encourage weight loss; weight loss of even 10 to 20 pounds has been shown to improve blood glucose, lipid, and blood pressure.[18] To encourage weight loss some physicians create nutritional plans for their patients. The most basic creation of a nutritional program includes the calculation of a patient's usual caloric intake and decreasing it by as little as 250 to 500 kilocalories a day.[19] Many nutritional programs focus on decreasing carbohydrate intake because this change that can bring about the most improvement in blood glucose levels. The most important part of the nutritional therapy, however, is not how strictly the patient follows their recommended caloric intake, but whether he or she makes permanent changes in their eating habits.

Another lifestyle change includes increasing daily exercise. Any increase in the amount of physical activity has been shown to increase insulin sensitivity and glucose tolerance in both type 1 and type 2 patients.[20] While physical activity has been shown as extremely beneficial in stabilizing blood glucose levels, it is difficult to get patients to permanently adapt to physical activity changes. Perhaps due to this lack of adherence, many physicians do not emphasize exercise as much as they should. Thus, the guidelines for how to increase exercise in diabetic patients is much less developed than nutritional therapy. The main goal of exercise therapy is merely to increase the amount of time per day that patients exercise. How physicians should go about increasing patient's exercise is not well defined, but studies have shown that continual motivation, education, slow increases in activity level and peer support are the best ways to encourage unmotivated type 2 diabetics to exercise daily.

**Monitoring Blood Sugar Levels**

The most important part in the management of any form of diabetes is frequent blood glucose monitoring. Glucose monitors available for home use vary in most factors including size, shape, weight, and size of blood sample required. All glucose monitors currently recommended by the American Diabetes Association for use require small amounts of blood from the patient.

The frequency of testing and blood sugar goals are established based on an agreement between the patient and the physician. Recommended testing schedules vary depending on the type of diabetes in question and the complexity of the diabetes management regimen. Patients with type 1 diabetes are encouraged to check their blood sugar anywhere from 4-8 times a day, while some patients with type 2 diabetes test only once a day. For patients who control their diabetes only with nutrition and exercise or oral medications the recommendation is to test blood glucose levels only once a day, alternating the time of day. Type 2 diabetics with stricter regimens, usually involving insulin injections, test their blood sugar level between two and four times a day. Self-blood glucose monitoring is used as a way to check the accuracy of the other treatments being used in patients including both medical treatments and lifestyle changes.

While home blood glucose monitoring provides patients with their blood glucose level at the immediate time of testing, it fails to give the patient an overall idea of their glycemic control. While it is possible for patients to test their blood sugar levels many times a day, it only gives a patient their blood sugar level at one point in time. One of the most important tests performed on diabetics is the hemoglobin A1c test because it gives an overview of blood sugar levels. The hemoglobin A1c test calculates a patient's average blood sugar levels for the past 120 days.[21] The hemoglobin A1c test measures glucose molecules that attach themselves to the hemoglobin molecules which make up red blood cells. The rate of formation for glycosated hemoglobin molecules is directly proportional to blood glucose concentration.[22] Since red blood cells live for an average of 120 days, the A1c test gives an accurate picture of the average blood sugar over that period of time. The hemoglobin A1c test allows the patient to see how well their blood glucose levels are controlled on a broader scope. Patients are encouraged to take this test every three to four months.

**Diabetes Complications**

While diabetes treatments have been improving at a rapid pace over the past few decades, still causes many complications and deaths. In 2002, diabetes was the 6th leading cause of death, contributing to an estimated 224,092 deaths.[23] The death rate for diabetics is about twice that of similar aged people. One of the most shocking aspects of diabetes is its potential to affect many body systems and functions. It currently is linked to problems in the digestive, nervous, and circulatory systems. There are countless diseases and complications caused by diabetes, and many more that scientists are still trying to link to the disease. The most common complications of diabetes are heart disease, blindness, kidney disease, and nervous system damage.

The number one killer of patients with diabetes is cardiovascular related problems. More than 80% of all diabetes related deaths are caused by cardiovascular disease, 75% of which are the result of coronary heart disease.[24] It is unknown which part of diabetes causes increasing cardiovascular problems, however it is known that atherosclerosis, or the hardening of arteries, occurs on a larger scale in diabetics than in non-diabetics and is likely the problem of many diabetes related heart conditions. Diabetics also suffer from decreased blood circulation, which causes many cardiovascular or circulatory problems. Regardless of what part of diabetes causes circulatory problems, diabetics have higher mortality rates due to cardiovascular problems.

Blindness caused by retinopathy, or disease of the retina, is also common in diabetics. Diabetic retinopathy is a circulatory system disease characterized by changes in the blood vessels of the retina. Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness each year and is the number one cause of new cases of blindness each year among adults 20-74.[25] Though blindness is a common result of diabetic retinopathy, if the disease is caught early and treatment is given, blindness can be prevented.[26]

Many studies concerning the prevalence and duration of diabetic retinopathy have shown that glycemic control can decrease the risk of the disease. The Wisconsin Epidemiologic Study of Diabetic Retinopathy discovered that intense diabetes management, consisting of three or more shots a day, reduced the risk of retinopathy by 76%. In patients already diagnosed with retinopathy, intensive diabetes therapy decreases the risk of disease progression by 54%.[27]

Kidney disease is another common complication of diabetes. Diabetes is the leading cause of kidney disease, accounting for 44% of all new cases in the United States in 2002.[28] About 30% of type 1 diabetics, and anywhere from 10% to 40% of type 2 diabetics will eventually develop end stage renal disease.[29] Kidney disease in diabetics takes many years to develop because it is caused by a slow but continual degradation of the kidney's filtering ability. In diabetic nephropathy, the small blood vessels responsible for filtration in the kidneys become damaged. When this occurs, the kidneys are not able to filter properly and wastes build up in the kidneys and extraneous proteins are present in the urine. It is at this stage in the progression of kidney disease that the disease is first detectable. When the kidneys are no longer able to filter correctly, a protein called albumin begins to leak into the urine. In order to detect kidney disease, albumin is regularly tested for in diabetic patients.

Though kidney disease occurs in many diabetics, like all other complications the risk of developing kidney disease can be significantly decreased by control of blood glucose levels. In patients whose therapy succeeded in keeping their blood glucose levels close to normal, non-diabetic levels, the damage to their kidneys was reduced by 35-56%.[30] Frequent visits to a physician can also help to decrease kidney disease development or progression through early detection of albumin in the urine. Early detection decreases the likelihood of the development of kidney failure because treatments and lifestyle changes can begin early enough to prevent more kidney damage.

The most common complication of diabetes is nervous system damage. Between 60% and 70% of all diabetics have mild to severe forms of nervous system damage.[31] Nervous system damage is often expressed in the slow digestion of food, carpal tunnel syndrome, or the most common form, loss of feeling in the outer extremities, such as the hands and feet. Almost 30% of diabetics over 40 years of age have impaired sensation in their feet.[32] The exact pathology of how elevated glucose levels cause nerve damage is still being studied. As with other diabetic complications, nerve damage is progressive, increasing in prevalence based on the length of time a person has diabetes and control of blood glucose levels.

The most common form of nerve damage, peripheral neuropathy, is a progressive condition that usually begins in the lower extremities and slowly progresses inward. In many people, the first signs begin as tingling, pain or numbness in the feet. The pain or tingling is worst at night and can be persistent or intermittent, progressing slowly over a period of weeks or months. There are medical treatments to decrease the pain felt because of neuropathy, however no medical treatments can halt the progression, though proper blood glucose control can slow the disease. In cases where the nerve damage is severe, amputation of extremities may be necessary. In fact, 50% of all non-traumatic extremity amputations occur in patients with diabetes.[33]

All diabetic complications have one thing in common; their effects can be decreased with control of blood glucose levels. Because the risk of developing most of these complications decreases with increased control, hemoglobin A1c tests and blood glucose monitoring become much more important. These tests allow patients to monitor the efficiency of their therapy and allow them to make any necessary therapy changes quickly, decreasing their likelihood for complications. Diabetic complications are often preventable, however the patient must put in the effort to monitor their blood glucose levels, discuss changes in treatment with their doctor, and make the necessary lifestyle changes to ensure proper diabetes care. The ability to avoid many of these serious complications increases the importance of having a good diabetes management team to assist in improving control.

Over the past few decades, diabetes care has improved to the point where it is a manageable disease. While a century ago, a diagnosis of diabetes was considered a death sentence, today there are many treatment options for people with diabetes. Continual improvements in home blood glucose monitoring, insulin production, oral medications and scientific knowledge of the disease allow many patients to receive adequate treatment. However, while the treatment options are available, many patients do not have access to proper care in which they can take advantage of advanced treatments.

# Chapter 2: Links Between Latinos and Increasing Prevalence of Type 2 Diabetes

Though diabetes affects 20.8 million people in the United States alone, certain ethnicities are at increased risk for developing the disease. Many minority groups have a higher prevalence of diabetes than Europeans and European Americans. One of the ethnic groups with the highest susceptibility to diabetes are Hispanics, especially Hispanic-American immigrants. Reasons for differences in susceptibility are still unknown, however several theories are being studied. The three main theories of why certain ethnic groups, including Hispanics, African Americans and Native Americans, have a higher incidence of diabetes include: genetic factors due to ethnicity, adoption of a western lifestyle, and socioeconomic factors.

Hispanic Americans have a risk of developing diabetes anywhere from 1.7[34] to 2.5[35] times greater than Caucasians. This risk is higher than all ethnic groups except Native Americans, whose risk is 5 times greater than Caucasians. Though no exact data depicting the number of Hispanic Americans living with diagnosed or undiagnosed forms of type 2 diabetes exists, if the prevalence of type 2 diabetes for Mexican Americans were applied to all Hispanic Americans, about 2.5 million, or 9.5% of the Hispanic American population would be living with diabetes.[36]

**Insulin resistance**

Besides increased prevalence of diabetes in certain ethnic groups, insulin resistance is the prime proof of an ethnic genetic disposition toward type 2 diabetes. As discussed in Chapter 1, high insulin resistance is one of the tell tale signs of developing type 2 diabetes. Higher insulin resistance means that the body must produce more insulin in order to break down the body's intake of carbohydrates, putting the body in a state of hyperinsulinemia. Hyperinsulinemia is detectable through measurements of fasting insulin levels, because people with higher levels of insulin resistance need higher levels of insulin in the blood at all times. The studies described below prove that Hispanic Americans  have higher insulin resistance through the measure of fasting insulin levels.

The first proof of high insulin resistance came from the Insulin Resistance Atherosclerosis Study. This study included 1,100 non-diabetic subjects drawn from three main ethnic groups: Mexican Americans, non-Hispanic whites, and African Americans. Patients in the study received a fasting oral glucose tolerance test the first day and an intravenous glucose tolerance test the second day.(i) Patients' glucose levels were tested two hours after the administration of the glucose tolerance test. Results showed that both Mexican and African Americans had higher fasting and 2 hour post-glucose test insulin levels than non-Hispanic whites. This means that Mexican and African Americans need higher amounts of insulin than non-Hispanic whites in order to break down the same amount of glucose. This translates into both ethnic groups having a higher level of insulin resistance than non-Hispanic whites.[37]

Another study on insulin resistance, performed by *Palaniappan et al.*, compared ethnicity and fasting insulin levels and included a patients' Body Mass Index (BMI) as a possible indicator

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i Glucose tolerance tests are typical tests given to patients to determine if they have or are developing diabetes. Patients are given high doses of glucose and their blood sugar levels are monitored thereafter to determine if of higher insulin resistance. The study by *Palaniappan et al.* consisted of 12,699 participants between the ages of 20 and 80 and who defined themselves as black, white or Mexican American. The fasting insulin levels of all participants were measured. Fasting insulin levels were then analyzed with ethnicity and BMI as the independent variables.

The study concludes that ethnicity may be a contributing cause of higher fasting insulin levels because, in the population sampled, African and Mexican Americans had higher fasting insulin levels than white patients at similar a level of obesity. The ethnic variation in fasting glucose levels found in this study is presumed to be dependent upon both environmental factors and genetic factors that have an effect on obesity and insulin sensitivity levels. The conclusion of this study shows once again that Mexican Americans need higher amounts of insulin in order to deal with their food intake. This translates into them having a lower insulin sensitivity, or a higher insulin resistance level than Caucasians.[38]

**Adoption of a Western Lifestyle**

An environmental factor highly credited with the development of diabetes, especially in immigrant populations, is the adoption of a western lifestyle that occurs when people immigrate to the United States. The adoption of a "westernized" lifestyle consists of changes in diet and exercise, which affect weight. Some ethnicities in the United States show a higher susceptibility to diabetes based on lifestyle, another indicator of a possible ethnic suscpetibility toward diabetes.

A "westernized" lifestyle involves changes in diet and exercise which has a corresponding effect on weight. In the United States, and other westernized nations, diets consist of reduced fiber intake and increased consumption of animal fats and processed carbohydrates. All three of these

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their body has an adequate response to the high glucose levels.

dietary changes have been linked by studies with an increased predisposition to diabetes, mainly through the development of obesity.[39] The adopted dietary changes cause people to increase daily energy intake. However, this increase in energy intake is not matched with an increase in physical activity, causing people to become obese.

Area studies have shown that the process of westernization increases the prevalence of diabetes in many ethnic groups. This was proven by comparing diabetes rates of a certain ethnicity in the United States to the prevalence in that ethnicity's country of origin. For Hispanics, prevalence in the United States was approximately 14%, while the prevalence in the country of origin was about 1%. These comparisons hold true in many other ethncities; Filipinos show a discrepancy of 22% and 8%, Chinese, 14% and 6%, African Americans, 12% and 1%, and Japanese, 20% and 7%.[40] Because of difference in prevalence changes for each ethnic groups, the data supports the existence of an ethnic suscpetibility to diabetes.

Similar results were also found in a study comparing Mexican Americans living in San Antonio to those living in Mexico. The study compared the prevalence of diabetes in low-income "colonias" in Mexico City and similarly low-income San Antonio neighborhoods. The results showed a lower prevalence in Mexico City than in San Antonio.[41]

**Socioeconomic Status**

Another characteristic that may responsible for the higher prevalence of diabetes in Hispanics is socioeconomic status. Many studies have shown an inverse relationship between socioeconomic status and the prevalence of diabetes. This means that people with lower levels of education and income are at an increased risk of developing type 2 diabetes. Socioeconomic status also patterns many proven risk factors for diabetes, such as: obesity, physical inactivity and large waist circumference.[42] It is unkown whether these risk factors cause the link between socioeconomic status and diabetes because the subject area has not been thoroughly examined.

The effect of socioeconomic status on diabetes control is particularly pertinent for Hispanics, because indicators of socioeconomic status generally rank Hispanics lower than most races. For example, according to the U.S. Census Bureau, in 2004 individual Hispanics had a median income of only $14,106.[43] This value is the lowest of all races analyzed; it is $9,742 less than the overall average of $23,848 and almost $2,000 less than African Americans who are the ranked the next lowest. In terms of education, 41.6% of Hispanics aged 25 years and older have not graduated high school, and only 12.1% of the same population who have graduated high school have recevied a Bachelor's degreeor higher.[44] These values are also much lower than the overall average. The average amount of people aged 25 years and older of all races who have not graduate high school is 14.8%, and 27.7% of the same population who have graduated high school have received at least a Bachelor's degree.[45] Hispanics are also the race least likely to have health insurance. According to the U.S. Census Bureau in 2002, only 67.6% of Hispanics reported having health insurance.[46]

These figures show that Hispanics have a socioeconomic status sufficiently lower than the national average. Lower socioeconomic status can be both a possible risk factor for developing diabetes and can also cause problems with health care access, which may lead to lower glycemic control for diabetic patients. Several studies have been performed which identify low socioeconomic status as a risk factor for developing diabetes as well as a cause of barriers to adequate health care access.

The Alameda County Study was a 34 year observational study in which patient socioeconomic status and various health indicators were gathered from 6,928 patients.

Throughout the course of the study, questionnaires were administered to participants five times. In each of the questionnaire waves a participant's diabetes status was determined through several questions asking if a person had diabetes and if they did, what was their date of diagnosis. Participant socioeconomic status was also measured at each wave. The three variables measured to describe socioeconomic status were: education, income and occupation. After the 34 years of the study, some of the original participants were disqualified due to lack of participation. By the end of the study there were 6,147 participants left, and of those 318, or 5.2%, reported developing diabetes.[47]

The study found that, in models unadjusted for extraneous variables, a low or moderate education level, low income and a blue-collar occupation indicated an increased risk of developing diabetes. After adding behavioral variables such as physical activity and smoking, the risk attributed to lower education decreased, however it had little to no effect on income and occupation variables. The study found all socioeconomic variables considered in this study to be significant predictors of diabetes. In models adjusted for age, participants with less than 12 years of education had a 90% increased risk of developing diabetes compared to those who had completed more that 12 years of education. Blue collar workers were at a 42% or 55% higher risk that white collar men and women, respectively. Income had the weakest correlation with development of diabetes, possibly because the average age of diagnosis was 58.6 years of age, a time at which many people have retired, thus they earn a lower income because they are retired, not because of their occupation. Acknowledged by authors is that fact that their data does not include demographic factors such as race, gender or age, which may confound the data.[48]

Not only are Latinos at increased risk for the development of diabetes due to socioeconomic status, low socioeconomic status has also been cited as an indicator for poor glycemic control. A variety of explanations exist for why socioeconomic status is a predictor poor glycemic control. Perhaps one of the most pertinent when dealing with immigrant communities would be access to adequate health care. Lower socioeconomic status often prevents people from receiving regular care. Without sufficient economic support, or health insurance, people are not able to access adequate care and afford the medications necessary to treat their diabetes. While income is not the only barrier to adequate health care, regardless of the type of barrier, patients lacking health care have less glycemic control that patients who have regular health care.

Studies performed in California have revealed that Latinos have more problems with access to healthcare than white citizens. This problem arises mainly from lack of primary care and insurance. In California, Latino adults with diabetes are more likely to have no usual source of care than whites, 12.3% to 3.4%.[49] Latinos with health insurance are more likely to have a source of care and are more likely to follow their treatment regimen. In California, 72.5% of insured Latinos report medication use and 39.4% report daily glucose monitoring, compared to 48.9% and 21.7% of non-insured Latinos.[50] Because patients who have insurance have higher rates of medication usage, patients without insurance have a significant advantage at controlling their diabetes.

Several other barriers which exist for the Latino population which prevent them from receiving adequate healthcare. These barriers include: language, non-citizen status, and low income.[51] Out of all Latinos in California with diabetes, 31.3% primarily speak Spanish and 68.6% have incomes below 200% of the federal poverty level. Latinos whose first language is Spanish have lower rates of insurance coverage and are less likely to have a primary care provider than Latinos who speak both Spanish and English. Latinos who earn below 200% of the federal poverty level are also less likely to have insurance coverage or a usual source of care.

The studies described above give a description of several factors which effect Latinos and Latino immigrants, putting them at a higher risk of developing type 2 diabetes. Their increased risk stems from several factors. Concepts dealing with a genetic predisposition due to ethnicity are supported by studies showing higher fasting insulin levels in Mexican Americans than in non-Hispanic white population. Higher fasting insulin levels also mean that Hispanics have higher insulin resistance, a factor often prevalent in the first stage of the development of type 2 diabetes. Many Hispanics also have problems adjusting to the “western” lifestyle, and suffer from unhealthy eating habits, or obesity which are also risk factors for diabetes. Besides an ethnic or cultural predispositions to diabetes, many Latinos also suffer from problems dealing with socioeconomic status and lack of access to health care. Lower socioeconomic levels are a risk factor for developing diabetes and often predict health care barriers, which have been linked to lower levels of glycemic control.

Together these factors show that Hispanics have a high risk of developing type 2 diabetes and a greater chance of being unable to control their diabetes well. Though some outreach programs address group, not enough programs exist to battle the diabetes epidemic in this highly suscpetible population. The increased prevalence and barriers to health care show the need for better care in areas with high concentrations of Hispanics. Medical professionals need to develop their care to overcome some of the health care access barriers such as language or income. Not enough clinics and programs exist in places with highly concentrated Hispanic populations that are affordable or cater to the culturally based needs of the patient. In order to combat the growing diabetes epidemic in this population who are at high risk of develoing diabetes, low cost and culturally cognizant care alternatives need to be implemented.

# Chapter 3: Diabetes Management Programs

Though diabetes currently affects only 7% of the US population, in 2002, complications due to diabetes accounted for over 11% of national health care expenditures. Including both direct and indirect costs of diabetes, due to work loss or disability, the total cost of diabetes in 2002 was $40 billion.[52] The United States is all ready experiencing huge losses due to the diabetes epidemic, and the expected increases in diabetes prevalence over the next few decades will only lead to an even greater amount of money being spent on diabetes. Combining the increasing prevalence of diabetes, the high amount of uninsured citizens, and the high cost of diabetes presents a huge problem for the future. The current health care system is not built to handle this incredible increase in patients and costs. In fact, the current health care system does not deal with the current amount of diabetics very well. To provide better care for patients, avert soaring costs, and prevent excess strain on the health care system, successful treatment programs need to be enacted.

In order to provide better medical care and education to the increasing number of diabetic patients, diabetes management programs have become increasingly popular. These programs provide comprehensive care for patients, in the hope that their glycemic control will improve. Many diabetes management programs are located in community clinics that serve low income and minority patients, the population in greatest need of medical care. While not all diabetes management programs serve minority populations, most are based on the need to improve glycemic control while reducing health care costs for both patients and health providers. The following chapter describes studies of different diabetes management programs and their outcomes.

It is important to realize that the term diabetes management program can address any number of different programs. There is by no means one specific way to implement a program. Diabetes management programs vary in scope as well as content.[53] However, the basic definition of a disease management program is any multifaceted program which is devoted to the care of a population with a chronic disease.[54] Thus, for the purposes of this report, a diabetes management program will be any program which addresses more than one aspect of diabetes care.

**Low-Income and Culturally Specific Diabetes Management Programs**

The California Medi-Cal Type 2 Diabetes Study aimed to determine whether intensive diabetes case management using population specific case management strategies could improve glycemic control. Their study population was type 2 diabetic patients in Southern California, receiving Medi-Cal that attended a clinic frequented mainly by minorities. Study participants were chosen from three clinics in three different counties. All participants started with baseline hemoglobin A1c levels over 7.5%. Patients were randomly assigned to either the control group or the intervention group.[55] Patients in the intervention group were monitored by registered nurses, dietitians and endocrinologists. Each patient's potential barriers to care were identified based on demographic and socioeconomic characteristics and treatments were individualized to address as many of the barriers as possible.

Results showed that the intervention group had significant improvement in hemoglobin A1c levels compared with the control group. At the start of the study the intervention group had an average hemoglobin A1c level of 9.54%, while the control group had a baseline hemoglobin A1c level of 9.66%. At the end of the study and follow-up period the intervention group's average hemoglobin A1c level had dropped to 7.66%, a drop of 1.88%, while the control group's hemoglobin A1c level had dropped to 8.53%, a decrease of only 1.13%.[56] The decreases in both groups were statistically analyzed to determine the significance of each value. When comparing the hemoglobin A1c levels for the intervention and control groups, the p-value (which measure statistical significance) was less than .01 over every time interval. Since a p-value less than or equal to .05 is considered statistically significant, the statistical analysis shows that the larger decrease in the intervention group's hemoglobin A1c levels to be significant.  Thus, the management program had significant success over and above the control group's success, showing that this diabetes management program was successful.  When applying the statistical results to the study population, it was concluded that, "diabetes case management is feasible and can substantially improve glycemic control in a racial/ethnic minority and/or low-income Medi-Cal population."[57]

Though the primary outcome of the study was glycemic control as measured through hemoglobin A1c levels, secondary outcome variables of weight, blood pressure and lipid status were also analyzed.  Each of these secondary variables showed a response to case management; however none of them showed a response as dramatic as hemoglobin A1c levels.  The intervention group showed significant improvements in blood pressure, LDL cholesterol, HDL cholesterol and total cholesterol.  All of these improvements were shown to be statistically significant.  The other secondary variables which were studied showed improvements as well, in both the control group and the intervention group.  However, none of these improvements were statistically significant.

While the California Medi-Cal Type 2 Diabetes study analyzed a low-income, mostly minority population, it is also important to show that there are culturally specific diabetes management programs which can have a similar impact.  Project Dulce is a culturally sensitive, nurse case management and peer education project which serves a predominantly low-income Latino population in San Diego County.  Over 72% of patients enrolled in the population were of Latino descent, 68% had an annual income of <$10,000 and 52% had an education level of eighth grade or lower.[58]  In order to overcome the education and language barriers, a medical assistant fluent in Spanish translated the information for the patient.  Patients were also visited by a dietician in their appointments; all dietitians were bilingual to overcome the language barrier.

The unique aspect of Project Dulce was its use of peer educators to help overcome some of the misrepresented cultural beliefs about diabetes. Peer educators of a similar ethnicity with many patients in the study were recruited from the project population in order to lead educational sessions. Peer educators would undergo 4 months of training and mentoring programs where they were provided with a detailed teaching curriculum for their classes. Peer educators would then teach classes in their fellow patients' native language and throughout the class would cover "diabetes and it complications; the role of diet, exercise, and medication; and the importance of self monitoring [blood glucose levels]."[59] Though peer education classes were optional, approximately 50% of patients participated in the classes, and average attendance were for 4 class sessions, showing that attendance at peer outreach programs was fairly high.

Project Dulce, like other diabetes management programs, caused improvement in hemoglobin A1c, blood pressure, and LDL cholesterol levels. Over the course of the study, the average hemoglobin A1c level decreased from 8.5% to 7.3%. The average blood pressure decreased from 131.9/76.7 mm Hg to 124.8/69.2 mm Hg, while LDL cholesterol levels dropped from 112.6 to 94.4. Each of these changes was found to be statistically significant.

When compared to the improvements in the population of the California Medi-Cal Type 2 Diabetes Study, the hemoglobin A1c results of Project Dulce seem to be smaller. However, when comparing the two studies it is important to note the length of the study. Many of the patients in the Medi-Cal study were followed for three years, while the Project Dulce study was only for one year. It should also be noted that the average hemoglobin A1c of patients in Project Dulce both started and ended at lower values. Starting at a lower hemoglobin A1c level makes improvements harder because the patient's control of their diabetes must be much better to make the same amount of improvement. While it is nearly impossible to compare these two studies on an even basis, the comparison does show that a culturally specific program such as Project Dulce is at least as efficient, if not more, than other management programs at improving glycemic control.

**Management Program with Risk Stratification**

Another study, which targeted managed care organizations, implemented a diabetes management program which included patient education as well as risk stratification and psychosocial evaluation. After patients agreed to participate in the study, they were classified into high-, moderate- or low-risk groups. Patients were classified based on seven different categories: glycemic control, cardiovascular disease, nephropathy, retinopathy, hyper/hypoglycemia, amputation and psychological disorders.[60] Their classification into one of these risk groups affected the care they would receive from physicians.

While patients were stratified based on the intensity of care they would need, they were also were required to attend three two-hour educational classes as a way to decrease their risk factors. These classes catered to patients based on risk stratification, as they were recommended to attend classes which would most help their diabetes care. For example, patients received an initial psychosocial evaluation based on their answers to the Problem Areas In Diabetes (PAID) survey. Patients who scored abnormally on the PAID survey would be identified to physicians and educational courses by the clinical psychologist were performed for these patients.

After 12 months of the study, enough data was available from 193 patients to assess the outcomes based on hemoglobin A1c, blood pressure and lipid levels. The data showed significant improvement in hemoglobin A1c values for patients in each of the three risk categories. The number of patients in the low risk category (A1c levels <7%) increased from 47 to 71 patients, the number of patients in the moderate-risk category (A1c levels between 7 and 8%) increased from 70 to 74, while the number of patients in the high-risk (A1c levels >8%) category decreased from 76 to 28 patients. There was also a reduction in blood pressure levels. At 12 months, the percentage of patients with blood pressure levels below 140/90 mmHg increase from 38.9% to 66.8%. Finally, lipid levels showed improvement in those most at risk for developing coronary heart disease, decreasing from 25.4% of patients being at risk to 20.2%.[61]

This program was unique based on risk stratification as well as its education of both patients and providers. The risk stratification served as an indicator to physicians as to which patients would need more intensive care and treatment regimens. It tentatively shows classification based on psychological status to be beneficial. Patients also received a minimum of 6 hours of diabetes education, increasing their diabetes knowledge to a level where they could understand more of what the physician was presenting to them. The program helped physicians serve patients by developing suggested interventions and care plans. Patients were given a copy of the suggested interventions allowing them to be more involved in planning their treatments. This enabled both the physician and the patient to have a more comprehensive discussion about treatment options as they both had educational materials to help them. This study addressed diabetes care in a way that few diabetes management programs had, showing that risk stratification was an efficient way to determine patient care. It also proved that diabetes can be well controlled in the primary care setting and referral to a specialty diabetes clinic is not always necessary.

**Lowering the Financial Cost of Diabetes**

Though diabetes management programs improve glycemic control as well as other health factors, such as cholesterol levels and blood pressure, diabetes management programs can also save money. Because of the large number of complications and hospital visits that diabetes can cause, the cost to patients, health insurance companies, and taxpayers can be great; making it important to find a way to minimize the cost of diabetes. For example, in 2002, 11% of total US health care expenditures, or $9.2 billion, was spent on diabetes even though only an approximated 7% of US citizens have diabetes.[62] Reducing health care costs becomes even more important when the health care costs being reduced are those of the uninsured or Medicare or Medicaid patient. Reducing the health care costs of that population would reduce the cost to tax payers, and free up more government dollars to be used for more patients. The following studies analyzed the efficiency of diabetes management programs at improving a patient's control of his or her diabetes as well as its effect on health care costs to the patient and their insurance company.

A study performed in the mid-1990's was one of the first studies to address the short term financial effect of a diabetes management program for a managed care organization. The study analyzed data from seven different managed care organizations by using a comprehensive management program called Diabetes NetCare, which tracks the entire diabetic population of a managed care organization. The Diabetes NetCare program consisted of a team that worked with both physicians and patients to cause behavioral changes and maintain desirable behaviors in the future. The team also provided patient support through sending reminders to patients about physicians' visits, diagnostic tests, and preventative screenings, and encouraged patients to participate in educational classes. Case coordinators were also assigned to patients who had higher hemoglobin A1c levels or had recently been hospitalized. The case coordinator worked with both the patient and the physician to change risk factors such as high blood pressure, cholesterol, and hemoglobin A1c levels.

The study found improvements in hemoglobin A1c values as well as economic costs. Among patients who had at least two hemoglobin A1c tests, their average level fell from 8.9% to 8.5%. In order to determine the economic impacts, medical costs were divided into five categories:

the inpatient, outpatient, physician, pharmacy and other. Total costs decreased by $44, or 10.9%, per patient per month.[63] The decrease in cost was inpatient hospitalizations, which fell by $47 per patient per month. Both physician and "other" costs stayed fairly stable, while prescription costs actually rose by $10 per patients. However, the large decrease in inpatient costs, as well as an $8 decrease in outpatient costs, offset the rise in prescription costs. When applying the individual savings to a population of 1,000 diabetic patients, researchers found a gross savings of $600,000 in the first year.[64] The study showed that the use of a diabetes management program such as Diabetes NetCare can lead to substantial financial savings for insurance companies as well as improved glycemic control in diabetic patients.

The Geisinger Health Plan (GHP), a health maintenance organization in Pennsylvania, performed two studies on the effectiveness of their diabetes management program. The first study found the effectiveness of the program at improving glycemic control, while the second, retrospective study analyzed the economic results of the program. In 1997, GHP began recruiting patients to their diabetes management program, which entailed primary care nurse educators and case managers. The nurses provided patient education and case management for all clinics in the GHP primary care system. All patients who participated in the program were educated about the use of an at home glucose monitoring system, the importance of diet, exercise and hemoglobin A1c testing, and medication management. Patients were encouraged to visit nurse educators quarterly, at the same time they received a hemoglobin A1c test.

The first study performed on this information was based on hemoglobin levels over the period of participation in the program. Results showed GHP's diabetes management program to be successful. At the beginning of the program, the average hemoglobin level was 8.76%. A one year follow up showed that the program had succeeded in lowering the average hemoglobin A1c level to

7.41%.[65] On average, patients who participated in the management program achieved a decrease in hemoglobin A1c levels of 1.35%. The fact that the data proved the management program was successful, lead to a retrospective study to determine if there were any reduced costs through the implementation of the program.

At the time of the retrospective study, 3,118 (45.8%) of patients who qualified as diabetics had been seen at least once by a GHP nurse. Over the two years of the retrospective study, patients enrolled in the diabetes management program had a significantly lower paid claim average per month than those not enrolled in the program. Patients involved in the study had $394.62 in total paid claims per month, while other diabetic patients had an average of $502.48 per month, a difference of $107.86.[66] The differences in costs were caused by several factors. First, program patients had lower hospital costs, with an average of .12 admissions and .56 inpatient days per patient per year, compared to an average of .16 admissions and .98 inpatient days per patient per year for non-program patients. Secondly, the mean number of emergency room visits for program patients was lower, with .49 for program patients and .56 for non-program patients.[67] These statistics, when controlled for age, sex, enrollment duration, type of pharmacy benefits, and type of insurance, were all statistically significant, except for emergency room visits.

While program patients did have lower hospital costs due to lower admissions, inpatient visits, and emergency room visits, they did have a higher level of primary care physician visits. Program patients had an average of 8.4 visits per patient per year, while non-program patients had an average of 7.8. While program patients had a higher average of primary care office visits than non-program patients, the monetary difference between those two figures is minuscule in comparison to hospital visits. Even though program patients had higher levels of primary care visits, they had fewer hospital visits, which made the diabetes management program more cost effective.

This study shows that in terms of economic cost it is cheaper for insurance companies to encourage involvement in diabetes management program. Patients involved in diabetes management programs will have lower hemoglobin A1c levels, putting them at a lower risk for other diabetes complications, which can decrease the amount of hospital visits. While $107.86 per patient per month does not seem like a significant amount of savings, when that monthly savings is applied only to the 3,118 patients who were continuously enrolled in the program, GHP would be saving $4,035,689.70 per year. In the opinion of GHP, the over $4 million dollars a year of savings is worth the approximately $1.81 million dollars they would have to invest to continue and expand the diabetes management program.[68]

**Conclusion**

This chapter has shown that there are a many different kinds of diabetes management program, and all of them have been successful in their target populations. However, there is a growing need for these management programs to serve low income minority communities. These communities are suffering the most, both from the increase in diabetes prevalence, as well as a lack of services. Studies performed on programs serving low-income or minority populations, Project Dulce and the California Medi-Cal Type 2 Diabetes study, were proven just as efficient as all other programs, showing that improvement is possible in these populations. The diabetes management program describe in the next chapter, which is the location of the study analyzed in this report, serves a low income, Latino population in need of the services a diabetes management program can provide.

# Chapter 4: Overview of Roybal Community Health Center and Study

Diabetes management programs can overcome many barriers to care and improve hemoglobin A1c levels in low-income and minority populations. Diabetes management programs can also lead to decreased medical costs through fewer hospitalizations. However, many programs require intensive management on the part of the health professional. Due to numerous visits on behalf of the patient, health professionals are able to monitor fewer patients, increasing the cost per patient from the clinic's perspective. Because of this, clinics with intensive diabetes management programs serve fewer patients, and in the case where the clinic's patients are low income and lack health insurance, the high cost of serving patients is detrimental to the financial situation of the clinic. From the point of view of a community clinic serving mostly uninsured patients, the ideal diabetes management program would achieve the same success as more intensive diabetes management programs, yet require less doctor's visits.  Finding a diabetes management program that requires fewer visits to a diabetes clinic, which will reduce cost, is the primary purpose of the grant received by Dr. Anne Peters from the American Diabetes Association.

Dr. Anne Peters received a grant from the American Diabetes Association to perform a study at the Edward R. Roybal Comprehensive Health Center.  Located in East Los Angeles, the Edward R. Roybal Comprehensive Health Center (CHC) serves a predominantly low income Latino population.  In order to reduce costs to the clinic, enable them to serve more patients and improving the quality of care, the Roybal CHC study aims to increase the efficiency of their current diabetes management program through changes in the frequency and type of care the program offers.

The community of East Los Angeles is over 80% Hispanic and over 20% of residents live below the poverty level.[69]  The population served by the clinic consists of a higher concentration of Hispanics than the surrounding area.  The majority of clinic patients are immigrants, either from Mexico or other Central and Southern American countries, who do not have any form of health insurance, including Medical or Medicaid.  Because of the large Hispanic population of the area, many of whom are low-income and lack health insurance, East Los Angeles has suffered a dramatic increase in diabetes-related morbidity over the past 10 years.[70]

**"One Stop" Care**

The Edward R. Roybal Comprehensive Health Center was built in 1979, to serve the population of East Los Angeles.  Since 1996, Roybal has been part of the Los Angeles County and University of Southern California Medical Center hospital system.  The Los Angeles County and

USC hospital system serve over 1.5 million people in eastern Los Angeles County, over 40% of who have no health insurance.[71] Roybal CHC is one of three comprehensive health centers in the LA County and USC hospital system which serve as outpatient centers. In order to better serve the Hispanic population of the area, in 2000, Roybal CHC opened a Diabetes Management Center.

Upon its inception, the Diabetes Management Center aimed to create a culturally sensitive individual case management system. The case management system used nurse case managers to care for individual patients under the supervision of a diabetologist. Patients are referred to the system by their primary care physician when they have a hemoglobin A1c over 8%. At each appointment, the patient receives “One Stop” care, which provides patients with all of the medical care and testing they need in one visit. This minimizes the number clinic visits, a benefit in a population of patients who often have trouble getting time off of work or finding transportation.

At their appointments, all of a patient’s necessary laboratory results (serum glucose, creatinine, hemoglobin A1c, lipid panel and urine albumin levels) are available in the clinic’s computer system within 20 minutes of the patient’s arrival. After the lab results are processed, the patient undergoes a physical examination and is prescribed any necessary medications. After this, the patient’s diabetes knowledge is assessed along with any psychological stressors that may be affecting the patient’s diabetes. The patient meets with their case manager at the end of the appointment, and the two work together to create a plan for effective diabetes care. The patient is given basic explanations of their medication regimen, and their nutritional and physical activity levels are discussed. The patient returns for appointments every three months until they are released from the program.

In order to determine the success of this diabetes management program a pilot study was performed. The pilot study ran for six months and consisted of 151 patients. The study was successful in lowering hemoglobin A1c levels as well as LDL cholesterol and blood pressure levels over the 6 months of the program.  The average hemoglobin A1c level fell from 10.3% to 8.2%, an average drop of 2.1%.  LDL cholesterol levels fell from 118 mg/dl to 94 mg/dl.  In addition to these improvements, the program also increased the use of drugs to lower cardiovascular risk. [72]

Though the pilot study showed that the Roybal CHC's diabetes management program effectively lowered hemoglobin A1c levels, several problems existed within the program.  When the "One Stop" care program was first implemented, patients were enrolled in the program when their hemoglobin A1c levels were over 8%.  Patients would continue in the program until their hemoglobin levels fell to less than 8%.  However, as soon as the patient's levels would increase above 8% again, they would be re-enrolled in the program.  As patients learned the system, many would keep their hemoglobin A1c levels slightly above 8% so that they could remain in the program.[73]  Thus, the clinic was suffering from a continual turnover of the same patients, when the point of the education and one on one interaction in the program was to give patients a better understanding of their diabetes and allow them to become more self-sufficient.

The other problem with the program was a lack of resources.  In this continual care system, where patients are seen every three months until they reach target hemoglobin levels, nurses could only monitor 150 patients.  Because there are few nurses in the clinic, only 1,000 patients were being treated by the clinic at any one time, while approximately 5,000 patients needed to receive care at the clinic and a waiting list of 100-150 patients existed at all times.  In order to serve the remainder of patients who had no other place to receive care, a more cost and time efficient diabetes management program needed to be implemented.

**Testing the episodic care model**

In order to discover a more effective management program, Dr. Anne Peters, applied for a grant from the American Diabetes Association. The new type of management proposed by Dr. Peters in her grant is an episodic care model. In an episodic care model, patients have an initial visit at the clinic followed by two more visits every three months. In other words, the patient follows a continuous care model for six months. After six months, the patient is released and returns only for annual visits. These annual visits are supplemented with follow up by the diabetes clinic with the primary care provider. Follow up with the primary care provider consists of each patient's nurse advising the primary care provider on how to improve on-going diabetes care. It should be noted that primary care provider follow up is easier in this setting because each patient's primary care providers is located within the Roybal CHC. All providers in the health center are connected through the network, so a patient's lab results are visible to all clinics in the health center.

The study proposed by Dr. Peters observes two sets of patients for two years; one group is enrolled in a continuous model of care, while the other group receives episodic care. Throughout the course of the study, 200 Hispanic patients with type 2 diabetes and hemoglobin levels above 8% will be enrolled in the study. Patients will be randomly assigned to the continuous care or episodic care model. The randomization of the patients is stratified based on gender, body mass index and duration of diabetes in order to minimize the baseline differences between the two groups.

Patients on both continuous and episodic care tracks receive the same care for their first six months in the study; both sets of patients have an initial appointment as well as appointments at three and six months. After that the two tracks begin different regimens. Patients on the continuous track continue to have appointments every three months until completion of the study at 24 months. After six months, patients on the episodic track come to the Diabetes Management Center only at 12 and 24 months for their annual follow up visit.

The study proposes to determine two things. Primarily it is structured to determine whether the episodic care model is as efficient in terms of diabetes care, yet more cost effective, than the continuous care model. The secondary outcome being monitored is a patient's knowledge, understanding of and adherence to their diabetes self-management program as well as their levels of stress and depression and the effect those variables have on their diabetes control. It is hypothesized that the episodic care model, supplemented by primary care follow-up, will create improved levels in diabetes outcomes which can be sustained for long periods of time at a lower cost than the continuous case management program. Secondly, it is hypothesized that patients with higher levels of knowledge, understanding of, and adherence to their diabetes self-management program, as well as lower levels of diabetes related stress and depression will have greater improvements in their glycemic control as the study progresses.

The primary measures of the outcomes being tested are: hemoglobin A1c levels, LDL cholesterol levels, cost effectiveness and changes in behavioral and knowledge surveys. All outcomes, except cost effectiveness, are collected from patients every three months. Hemoglobin and LDL cholesterol levels are both measured at the patient's appointments. Cost effectiveness is an ongoing calculation of the costs of diabetes, measured in the price and amount of medications taken, hospitalizations, diabetes-related surgeries, and complication related appointments. All information needed to complete the cost effectiveness calculations is accessible through the LA County and USC medical network. The final measures of outcome, the surveys, are administered during the patient's appointment. If behavioral surveys are not completed when patients are in the health center, they are completed by phone calls. There are four different knowledge and behavioral surveys study participants complete at each appointment

The first test, which measures a patient's knowledge of diabetes, is the Diabetes Knowledge Test, developed by the Michigan Diabetes Research and Training Center. This test has been developed and extensively validated. It functions as a reliable knowledge test for diabetes educators and researchers throughout the country.[74] The test is 23 questions and covers a variety of subjects relevant to diabetes, from foot care, to dietary issues, to insulin doses.

The second test, the Summary of Diabetes Self-Care Activities (SDSCA) survey, measures a patient's level of diabetes self-management. This survey measures the number of times per week a patient has performed certain activities which are either helpful or detrimental to their diabetes care. Though this survey will be performed only over a two year period, the SDSCA has been found to have a high correlation with longer measures of a similar nature.[75] For the purpose of this study, the SDSCA will be used to determine frequency of blood glucose self-monitoring, dietary behaviors, adherence to medications, and foot care.

The Diabetes Empowerment Scale, the third survey, measures self-efficacy, or a person's attitude toward his or her ability to succeed in their diabetes treatment. Self-efficacy has been shown to improve glycemic control.[76] This 28 question survey asks patients to rate on a scale of one to five, one being "strongly disagree" and five being "strongly agree, how they are dealing with three different psychological aspects of their diabetes. These three aspects are: how they are managing the psychological aspects of their diabetes, their dissatisfaction or readiness to change, and how they are setting and achieving their diabetes goals.

The final survey, called the Problem Areas in Diabetes (PAID) scale, measures psychological distress. The PAID survey measures how well a patient emotionally adjusts to having diabetes. It asks patients to rate on a scale of 0 to 5, 0 being "not a problem" and 5 being “serious problem,” how serious of a problem they rank certain their feelings about their diabetes. These questions range from how satisfied a patient is with their medical care and physician, how they feel about following their diabetes care regimen, how worried they are about their diabetes, and how the patient believes their friends and family feel about their having diabetes. This survey was authored by the Joslin Diabetes Center and has been used in several studies which found it to be sensitive to change in the study population throughout the duration of the study.

**Conclusion**

While previous studies have shown diabetes management programs effective at lowering both cost and hemoglobin A1c levels, this study aims to find a diabetes management program that is more cost effective than their current program. It also aims to find a diabetes management program that will be able to serve more patients, which is increasingly important for clinics serving low-income patients. The study will also show whether there are links between psychological status and glycemic control. If proven true changes in diabetes management programs would be made to address this issue.

# Chapter 5: Statistical Analysis

At the beginning of 2006, approximately 150 patients were participating in Dr. Anne Peters' study at the Edward E. Roybal Community Health Center. However, because patients enroll in the study continually, all patients are at different stages of the study. As not all patients have been participating in the study for the near two years it has been running, few patients had data higher than their 6 month visit where their care regimen would change from continuous to episodic. Thus, there is not yet sufficient data to compare costs and the effectiveness of the episodic care model. Because of this, the data analyzed in the following chapter compares the behavioral survey results to hemoglobin A1c levels to determine if behavioral factors influence glycemic control.

The purpose of the analysis is to prove whether the hemoglobin A1c level fluctuates because of changes on the psychological and knowledge surveys. In this analysis, the hemoglobin A1c level is considered the dependent variable and the scores on the four behavior and knowledge surveys are the independent variables. This classification assumes that hemoglobin A1c levels are influenced by psychological and knowledge status, and that hemoglobin levels, in turn, have no effect on a psychological status. If the two have a strong relationship, it means that psychological status and knowledge levels could be used to determine the degree of a patient's glycemic control.

At the time of data collection in January 2006, 66 patients had six months of available data. Out of the 66 patients, 20 were male and 46 were female, translating to 30.30% and 69.70% of the sample population, respectively. The average age of the population was 54.68±10.66 years, ranging from 26 to 72 years of age. Fifty-seven, 86.36%, of the patients spoke Spanish as their first

language. All but three of the patients analyzed in this report are first generation immigrants.

**Table 1. Demographic variables**

| Demographic | Statistic |
|---|---|
| Age | 54.68±10.66 |
| Gender (% female) | 69.70 |
| Hispanic/Latino (%) | 100 |
| Spanish as first language (%) | 86.46 |
| Immigrant from Mexico (%) | 86.36 |
| Formal education (years) | 6.26±4.14 |

Fifty-eight, or 87.88%, of the study population are immigrants from Mexico, four patients are from El Salvador, three are Mexican-American citizens, and one patient is from Puerto Rico. Patients had an average of 6.26±4.14 years of formal education, ranging from 0 to 16 years.

**Statistical Methods**

In order to analyze the data using different statistical tests, the raw data was classified and calculated in several different ways. The hemoglobin A1c value from 0, 3 and 6 months for each patient was gathered, rounded to one decimal place, and entered into a database. The results of the four surveys at each time period were scored according to the provided criteria and entered into a database for comparison with the lab results. The change in survey scores and hemoglobin A1c levels were also calculated over three different time periods: from 0 to 3 months, 3 to 6 months and 0 to 6 months.

The data was analyzed using two different statistical analyses, both chosen upon the instruction of Dr. Peters. The analyses were performed using the statistical computer program InStat. This program was chosen based on the recommendation of Dr. Peters because she uses this program to perform all of her statistical analyses. InStat was used in this report in an effort to maintain comparable results and a consistent form of analysis in case Dr. Peters deemed further data analysis necessary before publication.

The first test performed was a paired t-test. The paired t-test proves whether the difference in the average of a single variable at two different points in time diverges significantly from zero. The purpose of this test was to determine whether the change in each variable was significant, in other words, whether the change in the variable was greater than would be expected due to normal variance. The t-test will show whether the change in each variable is large enough that change could be caused by something other than chance. This test was performed on each variable independently over time. For this study if a variable has significant change it means there was likely a specific cause for the deviation. If the variable is not statistically significant that means any variance experienced is due to only to normal deviation, the change is not large enough to have a specific cause.

In t-test analysis, the important statistical value is the p-value. The p-value is the probability of obtaining values that significantly deviate from the expected value. A smaller p-value indicates a more significant relationship. In statistical analysis, a p-value less than or equal to .05 proves a significant change in the variable.

The second statistical analysis, linear regression, compared changes in survey scores and changes in hemoglobin A1c levels. A linear regression analysis compares the two variables and determines whether the data has a discernable linear relationship. In this case there are four different independent variables being analyzed against one dependent variable. The four independent variables in this study are the scores on the knowledge and behavioral surveys. The dependent variable is the patient's hemoglobin A1c level. This means that the patient's psychological status causes changes in the patient's hemoglobin A1c level. If the two variables have a strong relationship then the change in the survey scores correlates to a proportional change in the hemoglobin A1c level for most of the patients' results.

In linear regression analysis, the most important variable used to determine the strength of the linear relationship is the r, or correlation, value. The r-value can be any number between -1 and 1. The farther from 0 a correlation value is, the stronger the relationship. For the purposes of this analysis, an r-value with an absolute value greater than or equal to .8 and less than 1.0 ($.8 \leq |x| < 1$) will be considered a strong linear relationship. An r-value with an absolute value greater than or equal to .5 and less than .8 ($.5 \leq |x| < .8$) will be considered a moderate linear relationship, and any other r-value ($0 \leq |x| < .5$) will be considered a weak linear relationship.

**Hemoglobin A1c Level**

The average hemoglobin A1c levels throughout the study period were 8.90±2.12%, 7.72±1.58% and 7.78±1.81%, at the 0, 3 and 6 months, respectively. The greatest decrease in hemoglobin levels occurred between the baseline and three-month visit, while the hemoglobin levels at the 6 month appointment increased by .06%. Most patients had a large initial drop in hemoglobin levels from 0 to 3 months, yet the decrease did not continue at the same rate. In many patients, their hemoglobin levels actually rebounded a slightly at the 6 month appointment, as seen in the increase of the 6 month average hemoglobin A1c. However, the average hemoglobin level still decreased by 1.12% over the six month time period.

When analyzed using a paired t-test, two time periods were found to be statistically significant.  Both the analysis of data from 0 and 3 months and from 0 and 6 months had p-values <.0001, meaning they were extremely significant.  This means that the changes in hemoglobin A1c levels over these time period were due to something other than normal fluctuation.  These results are unsurprising because the effect of the management program produced these significant

| | **0 months** | **3 months** | **6 months** |
|---|---|---|---|
| **HbA1c** | 8.90±2.12% | 7.72±1.58% | 7.78±1.81% |
| **DKT** | 51.91±16.56 | 57.11±19.86 | 54.20±24.15 |
| **SDSCA** | 3.94±1.29 | 5.11±1.10 | 4.52±1.34 |
| **DES** | 2.14±1.094 | 2.05±.9166 | 2.23±.9904 |
| **PAID** | 37.01±21.29 | 36.90±24.36 | 34.92±27.06 |

**Table 2. Average values**

decreases.  The p-value for the data from 3 and 6 months was .2281, which is not statistically significant.  This data is not significant because of the rebound effect of hemoglobin levels described previously.  It may also be insignificant because of missing data.  That this decrease in hemoglobin levels was not significant leads to the belief that the efficiency of the diabetes management program decreases between 3 and 6 months.  This also means that there was no other influence on the value, meaning that over this time period any change in psychological status did not cause a change in hemoglobin A1c levels.

**Diabetes Knowledge Test**

The average score on the Diabetes Knowledge Test (DKT) varied over the six month period.  The average score at the baseline period was 51.91±16.56, 57.11±19.86 at 3 months and 54.20±24.15 at 6 months.  According to these scores, patients' diabetes knowledge increase at the 3 month visit and decreased at their 6 month visit.  The data from the 6 month visit, however, may not be accurate because of missing data. Only 37 patients' scores at 6 months were available for analysis. In the 6 month data almost half of the patients being analyzed did not have data, making the average result questionable.

Possibly due to the lack of data for the 6 month analysis, when the DKT scores were analyzed using a paired t-test, none of the time periods were shown to be statistically significant. The analysis of data from 0 and 3 months had a p-value of .0554, which is almost statistically significant. However, the other two analyses had very high p-values; from 3 to 6 months the p-value was .7507 and from 0 and 6 months was .8335. In the comparison of hemoglobin A1c levels and DKT scores, the results will not be definite, as there is so many missing 6 month survey scores and because the p-values showed none of the changes to be statistically significant. Because there was not a large change in the scores, except in the 0 to 3 month data, it will be difficult to prove that a large change in hemoglobin A1c level was caused by a small change in knowledge.

Linear regression did not show a strong relationship between a patient's score on the Diabetes Knowledge Test and their hemoglobin A1c levels. The results from the comparison of the changes over three different time frames are, in fact, surprising as the direction of correlation changes. The correlation value between the changes in the two values from 0 to 3 months is .257 and from 3 to 6 months is .1571. Though neither are strong correlations, because the r-value is positive it means that as one variable increases, or decreases, so does the other. Those results mean that as a person scored higher on their diabetes knowledge test (as their diabetes knowledge increased) their hemoglobin A1c level would increase as well, or as they scored lower on their knowledge test, their hemoglobin level decreased. These results disagree with the original hypothesis that an increase in knowledge would lead to a decrease in hemoglobin A1c levels.

While the changes in variables from 0 to 3 and 3 to 6 months showed a positive relationship, the analysis from 0 to 6 months both showed a negative, albeit weak, relationship. Data from 0 to 6 months shows a negative relationship of -.1364. Though this relationship is weak, the negative direction of the relationship supports the original hypothesis that an increase in knowledge will correlate with a decrease in hemoglobin A1c levels. However, because the correlation is so weak and none of the p-values showed the change in the variables to be statistically significant the hypothesis is not supported by linear regression analysis.

In order to ensure that a non-linear relationship did not exist between the variables, they were re-analyzed using non-linear regression analysis. This time the variables were analyzed to determine whether there was any non-linear relationship between them, such as parametric, quadratic or exponential. None of the analysis showed that the data deviated significantly from linearity. In fact the p-value for the change from 0 to 6 months was .9540, showing that any deviation from linearity is very insignificant.

**Summary of Diabetes Self-Care Activities**

The Summary of Diabetes Self-Care Activities (SDSCA) questionnaire addressed five different areas of self-care: diet, exercise, blood glucose monitoring, foot care and smoking. Because there were so few smokers in the study, that area was not included in the scoring of the survey. The scores represent the number of days in a week a patient performed the recommended actions with regard to the five different areas. The average number of days at the baseline was $3.94 \pm 1.29$, at 3 months was $5.11 \pm 1.10$ and at six months decreased to $4.52 \pm 1.34$. This data matches the results of the DKT survey where the score increased at three months and decreased at six months. The sudden increase and decrease at three and six months could possibly be explained by an initial enthusiasm after enrollment in the program which tapers off over time. It is important to note that the level at six months is still higher than the initial level.

The paired t-test analysis showed all of the changes in data to be significant or nearly significant. The p-value for the scores from 0 and 3 months was <.0001, and from 3 to 6 months was .0072, both of which are considered significant. The p-value from 0 to 6 months was .0643, a nearly significant value. These p-values show that the deviation in the mean significantly varied from zero, meaning that changes in self-care activities over time were significant and were likely influenced by the diabetes management program.

Analysis through linear regression did not show a strong correlation between self-care activities and hemoglobin A1c levels. In fact the direction of correlation changed in the analysis. The correlation of the changes in SDSCA score and hemoglobin A1c levels from 0 to 3 months was -.1400 and was -.1978 from 0 to 6 months. However, the correlation for the changes in the two variables from 3 to 6 months was .3557. The change in the direction of the correlation occurred because of the variance in scores. While the changes in hemoglobin A1c levels were continually decreasing, the changes in the SDSCA score were positive over the intervals from 0 to 3 months and 0 to 6 months and decreasing from 3 and 6 months. The analyses from 0 to 3 months and 0 to 6 months both support the hypothesis that increasing levels of self-care will lead to a decrease in hemoglobin A1c levels. In comparison to the other surveys analyzed in this report, the correlation

| | **0 & 3 months** | **3 & 6 months** | **0 & 6 months** |
|---|---|---|---|
| **HbA1c** | <.001 | .2281 | <.001 |
| **DKT** | .0554 | .7507 | .8335 |
| **SDSCA** | <.0001 | .0072 | .0643 |

| | | | |
|---|---|---|---|
| **DES** | .3043 | .0629 | .1700 |
| **PAID** | .9506 | .7600 | .9388 |

**Table 3. P-values from t-test analysis.**

| | **Δ 0-3 months** | **Δ 3-6 months** | **Δ 0-6 months** |
|---|---|---|---|
| **DKT** | .257 | -.0859 | -.1364 |
| **SDSCA** | -.1400 | .3557 | -.1978 |
| **DES** | .2433 | -.0100 | .2322 |
| **PAID** | -.3303 | -.0492 | -.1305 |

**Table 4. Correlations between survey scores and hemoglobin A1c levels**

values are fairly strong, even though on an individual basis none of the values would be considered anything above a weak linear relationship**.**

The data was then analyzed using non-linear regression. The data did not appear to have any type of non-linear relationship. The p-value for the comparison of changes in 0 to 6 months was .7839, showing that any deviation from a linear relationship is extremely insignificant.

**Diabetes Empowerment Scale**

Like the previous two tests, the average scores on the Diabetes Empowerment Scale (DES) varied over the six month period. The average DES score started off as 2.14±1.094 at 0 months, decreased to 2.05±.9166 at 3 months, and increased to 2.23±.9904 at 6 months. On the Diabetes Empowerment Scale, a higher score on the survey indicates a higher feeling of empowerment. Thus, patients had a decrease in empowerment over the first three months, followed by an increase in the next 3 months. These fluctuations do not match those of the other averages. The averages of the DKT and SDSCA surveys as well as the hemoglobin A1c levels experience a drop off or decrease from 3 to 6 months, while the empowerment scale experiences its greatest increase over that time. While there was an overall increase in empowerment, the deviation in the averages was only .18 over the whole six months. The level of deviation is so small that the level of empowerment essentially stays the same.

Because of the low amount of deviation in the average values, t-test analysis did not show the values to have any statistical significance. The comparison of DES scores from 0 to 3 months had a p-value of .3043, from 3 to 6 months, .0629, and from 0 to 6 months, .1700. The paired t-test analyzes whether the mean differences of the two variables differ significantly from 0, and since the differences in the averages are so small the mean differences are not much greater than 0. The greatest deviation is from three to six months, which has the most significant p-value.

Linear regression comparison between the changes in DES survey scores and hemoglobin A1c levels differ in direction between the three analyses. Linear regression analysis of the changes from 0 to 3 and 3 to 6 months show a negative correlation of -.2433 and -.0100. These results support the hypothesis. A higher score on the Diabetes Empowerment Scale translates into a higher feeling of empowerment. The negative correlation between the two values shows that as a patient feels more empowered about their diabetes (as their score on the Diabetes Empowerment Scale increases) their hemoglobin A1c level decreases.

The variables from 0 to 6 months have a positive correlation of .2322. In this analysis, the correlation is still weak; however the overall correlation changes the direction of the relationship. This correlation does not support the hypothesis. This means as that over six months as a patient's empowerment level decreased, their hemoglobin A1c level continued to decrease. However, the correlation between the two values is too weak to draw any conclusions from this data set. The hypothesis cannot be proven or disproven from the results of linear regression analysis.

These two variables were also analyzed to determine whether they deviated from a linear relationship. The data set did not deviate significantly from linearity. The p-value for the analysis of the 0 to 6 month data was .5814, which is not significant.

**Problem Areas In Diabetes**

The average score on the Problem Areas In Diabetes (PAID) survey slowly decreased over the six months of analysis. The average value at 0 months was 37.01±21.29, 36.90±24.36 at 3 months, and 34.92±27.06 at 6 months. The overall decrease in the six months was 2.09, with the largest decrease of 1.98 occurring between 3 and 6 months. This slow decrease means that patients were having fewer problems with their diabetes as the study progressed.

No changes over the time period were shown to be statistically significant when analyzed using a t-test. The analysis from 0 and 3 months had a p-value of .9506, from 3 and 6 months, .7600, and from 0 and 6 months, .9388. Considering that the possible range of scores was from 0 to 100 and the deviation in the average survey score was only 2.09, the results are not surprising. Because the overall difference in averages was small considering the possible range the difference in the averages would not be large enough to achieve statistical significance. Because the changes in survey scores were so small, there was basically no change in a patient's emotional status according to this survey. Because there was little to no change, it will be nearly impossible to prove a connection between the PAID score and the hemoglobin A1c level.

Linear regression analysis showed a weak correlation between the changes in the survey score and hemoglobin A1c levels. The correlation between the values from 0 to 3 months was -.3303. None of the other r values were even as high as that; the correlation from 3 to 6 months was -.049229 and -.1305 from 0 to 6 months. Because the of low correlation values, no linear relationship between the change in hemoglobin levels and PAID survey score was proven to exist.

In order to ensure that a non-linear relationship did not exist between the two variables, they were tested again through regression to determine whether a significant departure from linearity present was present in the data. Analysis of the changes from 0 to 6 months showed no significant departure from a linear relationship, with a p-value of .6210. Thus, the two variables had no significant relationship of any sort. Because the PAID survey was used to determine how a patient was adapting emotionally to having diabetes, the results through statistical show that no relationship exists between emotional status and hemoglobin A1c levels, or glycemic control.

**Discussion**

The proposed hypothesis, that knowledge and psychological status affect glycemic control, was not supported in any of the statistical analysis. None of the linear regression analyses showed a strong or significant relationship between changes in survey scores and changes in hemoglobin levels. In fact, the highest correlation value was only .3557, a value that can only be considered weak at best. While none of the statistical analyses were strong enough to prove the hypothesis, they do not disprove the hypothesis. This data merely shows the relationship to be weak; it does not deny the existence of such a relationship. Though this data is inconclusive, other studies may prove the relationship between the variables.

Though there have not yet been any concrete results from similar studies, the results from this analysis do disagree with the general consensus of the effects of psychosocial barriers on hemoglobin A1c levels. In a review of all types of studies on psychosocial barriers, Glasgow *et al.* found that "…at least some psychosocial barriers may have direct as well as indirect effects on metabolic outcomes."[77] The barriers which they found to be the most strongly and consistently associated with low levels of diabetes self-care and glycemic control were low levels of support from family and other friendship networks.[78] Glasgow also stated that there are several other areas in which there looked to be promising relationships, including depression.

In this analysis, the psychosocial barriers were determined through the Diabetes Empowerment Scale and the Problem Areas in Diabetes survey. The results from the analysis of both of these surveys were inconclusive. Neither the DES nor PAID survey scores showed substantial changes over the six-month period. The change in average scores over the entire six-month period for both surveys was so small that it was difficult to determine either the strength or direction of the relationship accurately. Neither survey had strong enough correlations to provide any significant conclusion one way or the other.

The knowledge of a patient concerning their diabetes has also been shown to have an impact on glycemic control. The more a patient knows about their diabetes, the better they will know how to treat themselves when having a hyper- or hypoglycemic episode. Support of this hypothesis can be seen in studies analyzing the effectiveness of an educational program on hemoglobin A1c levels (ii) or in the success of diabetes management programs with an education component.

Though the strongest relationship displayed in the statistical analysis was the relationship between self care activities and hemoglobin A1c levels, the relationship was not nearly as strong as expected. It is generally agreed that increasing levels of self care have a positive effect on glycemic levels. While the results of this analysis did not disagree with prior studies, neither did they strongly support the general consensus.

The effects of all types of self care have been highly correlated with improved hemoglobin A1c levels. The self care activity with the greatest effect on hemoglobin levels is blood glucose monitoring. Patients with a higher frequency of blood glucose monitoring have significantly lower hemoglobin A1c levels. For example, one study showed that 70% of patients who frequently monitored blood glucose had hemoglobin A1c levels below 8%. Of patients who irregularly or never performed blood glucose tests, only 18 and 22%, respectively, had hemoglobin levels below 8%.[79] With incredibly strong correlations being shown in all other studies on self care activities, the results from this analysis should have strongly supported the same general hypothesis.

Addressing psychological barriers has the potential to increase the efficiency of diabetes management programs everywhere. However, no proof currently exists showing the benefits of addressing psychological concerns. While some studies show a correlation between psychological status and glycemic control, this analysis shows no significant correlation between the two variables. Because the analyses so far have been inconclusive, further research should be performed analyzing the relationship between psychological barriers.

**Problems with Statistical Analysis**

Several problems exist within the study that affected the statistical analysis and may have caused questionable results. First, the relatively small sample size harmed the statistical analysis results. Statistical analysis was only performed on the data from 66 patients. Because the of the small sample size, the data from each patient held more weight in the statistical analysis, giving extreme values more weight than they would have in a larger study. If there were several patients in the data set whose results vastly differed from the rest of the population's they would be able to alter the results significantly. This increases the likelihood that the data analyzed was not representative of the population as a whole.

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ii See Keers *et al.*, 2005.

The problem of a small sample size is exacerbated by the second problem; that there was often missing data for patients. While the majority of the hemoglobin A1c scores were present, in some cases, patients did not have any survey scores for a specific test and most patients were missing at least one survey score at one time period. Again, in a larger sample this would not be a problem, however in a smaller study population a patient missing several values cannot be analyzed, further diminishing the sample size. For example, if a patient is missing their 6 month score for a survey, their information cannot be used in the analysis of data from 3 to 6 months or from 0 to 6 months. However, their information will be used in the analysis from 0 to 3 months. Thus, the number of patients being analyzed at each time period will vary, which exacerbates the problem described in the previous paragraph. This problem can also be seen in this study in the analysis of the Diabetes Knowledge Test at 6 months. Due to missing data only 37, or 56.1%, of the patients had available data, causing the analysis to be unrepresentative of the whole study population and producing questionable results.

**Improving the Study**

Several aspects of the study could be changed to improve results and provide useful information for improving diabetes management programs. The major problems with the study concern its use of surveys. The survey scores were the only way the knowledge and psychological status of the patient were determined, basing the psychological status of the patient solely on their answers. The usage of surveys presented a problem and the best ways to improve the study would involve changes in its structure.

Several general problems occur in all studies that use surveys. First of all, patients interpret survey answers in different ways. Patients may interpret the degree of their psychological problems differently than another person. For example, on the PAID survey where patients rated how much of a problem certain issues were related to their diabetes, one patient's interpretation of a problem could be completely different from another's. What one patient ranks as being a minor problem, a "1", may be rated by another patient as a "somewhat serious problem", a "3", even though the problem may be relatively in both scope and intensity. This creates a study in which the study results are hard to compare, because there is no guarantee that patients with comparable survey scores actually have comparable levels of depression or stress.

Another major problem with the majority of survey studies is response bias, which occurs when the method of testing produces values that tend to differ from the actual value. Often when taking a survey, patients censor their answers in order to appear normal. Patients do not want to be identified as a having an additional problem and thus, may not answer the survey truthfully. In this study, a patient's psychological status is determined no other way, so the study is completely dependent on the truthfulness of the patient. While this by no means is a recommendation to eliminate the surveys from the Roybal study, the accuracy of the patient's psychological status according to survey analysis could be confirmed if a medical professional analyzed patients to determine if the results are consistent.

The problem of response bias can be somewhat avoided in studies through the use of standardized surveys. In standardized surveys, many of the problems with interpretation and accuracy have been eliminated. Of the questionnaires used in this study, the Diabetes Knowledge Test and Problem Areas In Diabetes questionnaire have both undergone extensive testing to determine their efficacy. However, neither the Summary of Diabetes Self-Care Activities nor the Diabetes Empowerment Scale has undergone the same amount of testing. Because these two surveys have not been tested extensively, their accuracy is questionable.

This problem finding surveys that have been sufficiently tested highlights a larger problem with studies using surveys to ascertain barriers; few standard questionnaires exist to be used in these types of situations. Just as glycemic control is always ascertained through hemoglobin A1c test results, the extent of psychosocial barriers should be established through standard tests. The development of standard questionnaires in these areas would eliminate some of the problems of accuracy and bias. Standard questionnaires will have been tested and adapted to overcome response bias and would produce values closer to the true value, eliminating some of the problems with variability.

Another way to improve the study would be to study the psychological effects separately from any other research to provide a better overall picture of either variable. Currently, in the study, the psychological variables hypothesis comes second to the idea that an episodic care model with primary care follow-up could be a more cost efficient management program. The primary focus of the study is not on the results of the psychological analyses. Because the two hypotheses being researched are unrelated it is difficult to focus properly on either one. Analyzing the psychological effects separately would allow a more thorough analysis of the data as the study progressed.

The final recommendation concerning the study would involve a complete change in the structure of the study. Currently, the study is merely observational. In order to determine the effect that a patients' psychological state has on their diabetes, the study should be turned into an intervention study. In an intervention study, a patient's psychological and social barriers to diabetes care would be addressed. Instead of showing whether there was a problem, an intervention study would show effective ways to overcome psychological problems. The study could analyze the effect of the intervention study on the patients' psychological status as well as their hemoglobin A1c levels. Measuring the effect of a purely psychological intervention strategy would show whether some barriers will be resistant to change or whether they may not produce improved outcomes.[80] In an observational study, any number of variables, many of which are not being measured, could cause the fluctuations in hemoglobin levels.

As seen in this study, often times in observational studies a patient's psychological status does not deviate highly. In this study, it meant that small changes in survey scores were being analyzed against large changes in hemoglobin levels. Because psychological barriers were not being addressed, the values were not changing greatly, while the hemoglobin A1c levels were changing greatly because of the diabetes management program. It was difficult to determine whether the small changes in psychological status were affecting hemoglobin A1c levels, because, as proven by the paired t-test, in many cases the changes in psychological status were not significant enough to effect another variable. An intervention study would provide a stronger correlation between the two variables and save the next step of determining how to overcome the problem.

# Chapter 6: Recommendations

Unfortunately, the analysis of data from the Edward R. Roybal Comprehensive Health Center study did not show benefits in addressing a patient's psychological status in a diabetes management program. While it is questionable whether addressing psychological barriers will be the best way to improve comprehensive diabetes care, several issues still exist around diabetes that need to be addressed in order to provide adequate care to the increasing number of diabetics in the world. The two main issues are first, identifying people who have developed diabetes and secondly, implementing a sufficient amount of diabetes management programs to deal with the large number of new diabetics.

**Increasing the Detection of Diabetes**

The enormous financial cost of diabetes occurs mainly because of the large amount of serious medical complications diabetics develop after having diabetes for years, as described in the first chapter. These complications are caused by nothing other than poor glycemic control. However, the risk of complications decreases by 40% with every corresponding 1% drop in hemoglobin A1c level.[81] In an effort to decrease the number of complications, patients need to control their blood glucose levels from the earliest possible moment. Currently, the Centers for Disease Control estimate that 20.8 million Americans have some form of diabetes; however, 14.6 million people of these diabetics have not been diagnosed.[82] This means that almost 70% of diabetics are unaware they have diabetes and are not managing their blood glucose levels. In order to provide diabetics with proper care and allow them to control their blood glucose levels, the rate and punctuality of diagnosis must increase. Diagnosis rates can be improved by doing two things: increasing education and outreach programs, and increasing testing for diabetes.

First, Americans need to be educated about diabetes and the symptoms of diabetes. While many Americans are aware of the fact that diabetes exists, few know the symptoms of diabetes. If patients were aware of the symptoms of diabetes, many would be more likely to request diabetes testing from their doctor. In order to overcome this lack of knowledge outreach programs should be organized and implemented. These outreach programs should address multiple population groups in several different ways.

Diabetes education should begin early, with children. Though diagnosis of type 2 diabetes is uncommon, the lifestyles that put children at risk for developing diabetes later in life begin when they are young. Diabetes education should be implemented into school health classes starting in elementary. Just as the majority of students in public schools today receive sexual education several times throughout their education, they should also receive diabetes education. In the curriculum of each diabetes education class, the teacher should emphasize what the symptoms of diabetes are, what factors and activities put people at increased risk of development, as well as how children can change their activities to reduce their risk. Reaching children at a young age will keep them aware of the possibility of developing diabetes throughout their lives. If children know the symptoms are, they may also be more likely to report these problems to their parents or their doctor.

While education through schools will increase the awareness of children, adult Americans, who have the highest risk of developing type 2 diabetes, also need to be educated about diabetes. The way to reach this population is through outreach programs in all forms of media: print, radio, and television. Because the medium used by the greatest number of Americans is television, the majority of adults could be reached through commercial campaigns. The problem with television or radio commercials is that they cannot provide viewers with a large amount of information.

While a commercial campaign would educate people about their risk for diabetes and possibly encourage them to be tested for diabetes, the medium through which people will learn the most about diabetes is through print. While another advertisement campaign would be useful in magazines, advocates and organizations should begin courting journalists to produce more articles about diabetes in general. Full length, feature stories would provide people with more information than would be possible in a 30 second commercial or a small advertisement.

Concerned interest groups, diabetes activists, and large national organizations such as the American Diabetes Association and Centers for Disease Control should begin media programs and advocating for education programs in schools. The National Institutes of Health and the Centers for Disease Control all ready have a federally funded program in place called the National Diabetes Education Program (NDEP) which could be used to fund many of these projects. NDEP is a federally funded project that has over 200 partners on the federal, state, and local level working to reduce diabetic mortality and morbidity rates. Expanding the goal and membership program of this organization would allow it to take on a much larger role in educating people about diabetes.

The second way of increasing diagnosis rates is through periodic testing by health professionals. Currently, tests for diabetes are given only when patients exhibit and describe to their doctor symptoms of diabetes. In order to increase the number of diabetes tests administered, doctors should recommend that patients receive periodic testing. Doctors all ready recommend that people receive certain periodic tests, for example it is recommended that women receive yearly mammograms after they turn 21 years of age. If doctors began recommending testing for diabetes with the same intensity that they recommend other tests, diabetes could be caught at early stages of development. While it would be best for people to receive testing annually, even testing every few years would be increase the chance of early detection. While it is important for doctors to ensure that patients with high risk factors receive tests, they should also encourage periodic testing in patients with low risk factors.

Even though these recommendations would reach most Americans, admittedly, not all Americans may be convinced to receive diabetes testing. While this population may always be resistant to receiving testing, the recommendations provided above would reach a large proportion of Americans. Any of these recommendations would increase the number of people diagnosed with diabetes and decrease the 14.2 million people currently living in the United States with undiagnosed diabetes. Increasing diagnosis rates will allow more patients to control their diabetes from an earlier time than in the current health care system. Once patients knew that they had diabetes they would be able to seek proper treatment. Earlier diagnoses would also decrease some of the financial strain on the health care system because improved glycemic control would lead to a decrease in the prevalence and severity of diabetes complications over the next few decades.

**Implementing Diabetes Management Programs Nationally**

With higher rates of diagnoses and an increase in prevalence, sufficient amounts diabetes management programs need to be created across the country to deal with the influx of diabetics. This could be done through encouraging clinics to transition to a diabetes management program. The development of guidelines for a general diabetes management program would ease the transition for many diabetes clinics. The structure should be general so that it can be adapted to fit into any clinical situation.

The general diabetes management program should have at least three different aspects to their care regimen: medical advisement, nutrition, psychological and education. The medical advisement portion of the program involves the performance necessary lab tests and changes in a patient's medication dosages. In this portion of the visit, the medical professional administering care, either the doctor of nurse, should take special care to ensure the patient understands their medication regimen. In an effort to improve patient compliance with their treatment regimen, the medical professional should also take the time to discuss possible changes or adaptations to the patient's medical routine that would make it easier for the patient to achieve their care goals. In many cases, problems with patient compliance occur because patients do not understand why they are performing certain tasks, or are unable to make drastic lifestyle changes necessary for compliance with their medical routine. If the medical professional slowly adapts the medical regimen to the patient's need, their compliance rate should improve leading to an improved outlook for the patient.

During an appointment, professionals should also be present to address a patient's nutritional and psychological needs. While nutrition can be partially addressed in educational classes, a nutritionist should still visit with patients at each appointment. Nutritionists should discuss eating habits with the patient in order to determine his or her dietary habits. Once a general diet profile has been created, the nutritionist should discuss what the patient could do to improve their eating habits.

In addition to meeting with a nutritionist, patients who have sufficient need should also meet with a social worker, or someone similar, who can help them overcome their emotional problems with diabetes. All patients should meet with the social worker for their first few visits. After that period, the social worker should determine whether follow up visits are necessary. The social worker should work with patients to overcome the psychological barriers that may be preventing them from achieving adequate levels of self-care. A patient's psychological status should be addressed even though results are inconclusive as to whether intervention is beneficial.

The final part of the diabetes management program should be education. While educational classes should not be a requirement, they should be highly encouraged and available for patients to participate in. Educational classes should cover a variety of topics that increase a patient's understanding of their diabetes and encourage them to better care for themselves. Topics of classes should include topics such as nutrition, exercise and the importance of blood glucose monitoring. These three subjects are merely suggestions, it is up to the discretion of each individual clinic as to which subjects would benefit their patients the most. Many of these issues would also be covered in the patient's appointments; however, reinforcing the point may improve patient's compliance.

In addition to these aspects of care, diabetes management programs should be cognizant of the ethnicity of the population they are serving. It would be difficult to provide guidelines for how to cater programs to specific ethnicities, thus it should be left up to individual clinics how to best serve their patients. Clinics should adapt the way they serve patients in order to address some of the specific concerns or misconceptions that certain ethnicities are more prone to have. For example, certain cultures may have preconceived notions about the effectiveness of insulin or dietary changes. The clinic should be aware of these factors and take special care to address these issues in appointments and educational classes. In addition, clinics should overcome any language barriers by having educational materials available in the languages of the majority of their patients. There should also be staff members that speak these languages in order to help the patient understand conversations.

The Centers for Disease Control and the National Institutes of Health should compile and disseminate this general structure. The National Institutes of Health and Centers for Disease Control can use the National Diabetes Education Program to disseminate this information. The program all ready has resources available for health care professionals to use to improve their practice. Adding the general structure for a diabetes management program to this list of resources would enable medical professionals to see the monetary and glycemic benefits of such a program. It would encourage them to implement such a program in their clinic.

The implementation of diabetes management programs nation wide will require a strong commitment from the government and associated health organizations. The federal government will have to increase funding for organizations such as the National Institutes of Health and the Centers for Disease Control to allow them to promote the implementation of diabetes management programs. In the beginning, it may be beneficial to have incentives for clinics to implement these programs. This could be done through the awarding of small grants to clinics for the first few years of their transition to such a program. While the federal government or organizations such as the Centers for Disease Control or the National Institutes of Health can give these grants, it would be beneficial to include organizations like the American Diabetes Association. The American Diabetes Association funded the study that took place at the Edward R. Roybal Clinic and may have grant money available to support the implementation of further diabetes management programs.

**Conclusion**

Diabetes management programs have proven successful in many situations and could be the answer to addressing the diabetes epidemic. However, before serving patients, they must first be diagnosed. Many of the minority groups who are at the highest risk for developing diabetes are the least likely to receive testing. By implementing outreach and education programs as well as systematic testing more patients will be diagnosed with diabetes at earlier stages in development. This would allow patients to attain care at earlier points in the progression of diabetes, which decreases the likelihood of developing complications.

With a larger amount of patients looking for care options, diabetes management programs with their success at improving hemoglobin A1c levels as well as other secondary health outcomes such as cholesterol levels or blood pressure in many different settings, will be the best option for patients to receive quality care. Diabetes management programs will also save money for patients and insurance companies by reducing hospitalizations. On a national level, diabetes management programs would save the government millions of dollars in health care expenditures.

Diabetes management programs are also culturally adaptable and can address the concerns of certain ethnic and cultural communities. The adaptability of management programs will become increasingly important as the prevalence of diabetes in minority groups continues to increase. Because certain minority groups such as Latinos, Native Americans and African Americans, have a higher susceptibility to diabetes, they will be more in need of diabetes management programs that groups who do not have high rates of diabetes, such as Europeans and European Americans. The development and implementation of diabetes management programs which address the cultural concerns and prejudices of certain groups will be useful as the number of people with diabetes continues to increase.

Though the hypothesis of this report, that psychological status and knowledge affect glycemic control, was not supported by the data, the area of research may provide beneficial evidence to enhance diabetes management programs. Psychosocial barriers to care should be the next aspect of diabetes care researched because of its potential to improve the quality and comprehensiveness of patient care. If a consensus is reached and a general intervention plan established, the efficiency of diabetes management programs could be further improved. The more efficient and comprehensive medical professionals can make diabetes management programs, the greater its chances become to have a significant and lasting effect.

The federal government and national health organizations should be responsible for creating and encouraging the implementation of diabetes management programs. The success of diabetes management programs have been proven in many studies and should be replicated in as many clinics as possible. Efficient diabetes management programs have the potential to help control the effects of the current diabetes epidemic. With the prevalence of diabetes increasing at an exponential rate, and the expected rate of increase continuing to increase in the future, it is important to begin the foundation of medical services which can address this increase. Diabetes management programs are an effective way to both lower costs to all parties involved and improve glycemic levels. With the expected increase in diabetes, preventing complications through the lowering of hemoglobin A1c levels will be beneficial to the national medical system as well as the patient. It will not only save money, it will enable diabetics to have a quality of life equal to people without diabetes.

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# Appendix:

## Knowledge And Psychological Surveys