HEALTH OUTCOMES OF A DIABETES SUPPLY AND DIABETES SELF-MANAGEMENT EDUCATION PROGRAM IN AN AT-RISK POPULATION

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ABSTRACT

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The purpose of this quasi-experimental, pretest-posttest design study was to determine if providing diabetes supplies and diabetes self-management education to uninsured or underinsured diabetics improved health outcomes. Health outcomes included diabetes self-management skills and serum fructosamine. Self-management skills were measured with a Likert scale. Serum fructosamine was measured with a capillary blood sample analyzed in the Duet™ Glucose monitor.

The study used a convenience sample of uninsured or underinsured Type 1 and Type 2 diabetics with serum fructosamine levels greater than 310 μmol/liter. The sample size of twenty was determined by power analysis. Twenty-five participants were enrolled from May 1999 through May 2000, and twenty completed the study.

The setting was a nonprofit community agency in a large southern metropolitan area. Participants met individually with the researcher every two weeks for four sessions. A

fifth session was held one month after session four. At each session a module of the "I'm in Control" diabetes education program (Oklahoma State Department of Health, 1997) was reviewed, and participants were given insulin and diabetic supplies. Data were collected at the first and fifth session.

A dependent t test (one-tailed, $\alpha = .05$) was used to compare the means of the pretest-posttest serum fructosamine levels. Data analysis revealed a statistically significant difference between the pretest-posttest scores ($t = -4.199$, $df = 19$, $p = .000$). Scores decreased an average of 95 μmol/liter. The first hypothesis (At-risk persons with diabetes will have lower mean glucose levels following participation in a diabetes supply and diabetes self-management program.) was supported.

The means of the pretest-posttest self-management skills inventory were analyzed with a dependent t test (one-tailed, $\alpha = .05$). There was a statistically significant difference in the pretest-posttest scores ($t = 6.43$, $df = 19$, $p = .000$). The second hypothesis (At-risk persons with diabetes will have improved diabetes self-management skills following participation in a diabetes supply and diabetes self-management program.) was supported.

Findings suggest that an individualized program for uninsured or underinsured diabetics improves self-management skills and lowers mean glucose levels. Eliminating the financial barrier in this population facilitated "personal readiness" to learn and implement self-management skills.

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CHAPTER I

INTRODUCTION

Diabetes affects over 16 million Americans and is the seventh leading cause of death in the United States (U.S. Department of Health and Human Services [DHHS], 2000). It was estimated that in 1997, the direct and indirect costs for this disease exceeded $98 billion (American Diabetes Association [ADA], 1998). The high mortality rate and exorbitant costs have been directly attributed to the development of short- and long-term complications which can be prevented, or delayed, by maintaining serum glucose at near normal levels (ADA, 2000c; ADA, 2000d; Klein, Klein & Moss, 1996; Ohkubo et al., 1995). Although lowering serum glucose is the goal of diabetes self-management, there are several factors that may interfere with one's ability to reach this goal. Glasgow (1995) calls some of these factors "barriers to self-care."

Barriers to self-care exist in all age groups, and in all populations. They can be patient-related, regimen-related, or provider-related (Burke & Dunbar-Jacob, 1995). One patient-related factor that negatively impacts diabetes self-management is low income. Low-income adults are affected in three ways. First, they are frequently uninsured or underinsured, which means they are less likely to have a regular health care provider to provide the frequent, ongoing monitoring recommended by the ADA (Schoen, Lyons, Rowland, Davis & Puelo, 1997). Second, according to Rathmann (1998), persons with diabetes require twice as many prescriptions as persons without diabetes. Low income and/or being uninsured or underinsured affects one's ability to purchase these needed medications and supplies (Freeman, Aiken, Blendoe, & Corey, 1990). Third, only one third of uninsured diabetics have participated in a diabetes education program (Harris, Cowie, & Eastman, 1994). Lack of education may affect one's understanding of diabetes self-management and elevated serum glucose levels. These three factors probably explain Harris' (1995) finding that uninsured persons with diabetes had higher overall serum glucose levels than insured diabetics.

Elevated serum glucose is the number one risk factor for the development of microvascular and macrovascular diabetic complications. These complications account for the majority of the health care dollars spent on diabetes (Roman & Harris, 1997). The Diabetes Control and Complications Trial (DCCT) clearly demonstrated that microvascular complications can be prevented, or delayed, in Type 1 diabetes with better control of one's blood glucose level (The DCCT Research Group, 1993). Similar findings with Type 2 diabetes have also been reported (United Kingdom Prospective Diabetes Study Group [UKPDS], 1998). Since preventing complications saves health care dollars, communities must be proactive in developing programs that eliminate, or minimize, barriers to proper self-management in all groups. Without question, diabetes management is expensive; however, the economic and human cost of not providing it for all populations is even higher (Gilmer, Manning, O'Conner & Rush, 1997).

Problem of the Study

Diabetes leads to death, disability, and long-term complications if not properly managed. Proper management consists of daily self-management practices by the diabetic, availability of medications and supplies, and routine medical care by a regular health care provider following current standards of practice (ADA, 2000f). The absence of any one of these factors places persons with diabetes at risk for a poor health outcome.

One at-risk group is uninsured or underinsured adult diabetics. This group is particularly vulnerable for several reasons. First, they are twice as likely to be without a regular health care provider as insured diabetics (U.S. Department of Health and Human Services [DHHS], 1995b). Second, they lack the financial resources to purchase needed medications and supplies (Freeman et al., 1990), and third, over two-thirds have never been taught to manage their disease (Harris, et al., 1994). Numerous studies have documented the effectiveness of diabetes self-management education in various populations (Brown, 1990; Padgett, Mumford, Hynes & Carter, 1988), however, none have investigated the effectiveness of a diabetes self-management program in an uninsured or underinsured population. The lack of attention to the unique needs of this group may explain the high percentage who have never been educated about the disease. A program for this population should address three areas. First, it should empower diabetics to self-manage their condition by providing them with the knowledge and skills to do so.

Second, it should provide assistance with expensive medications and supplies so they are able to implement their knowledge and skills. Last, since many have no routine health care provider (Bashur, Homan & Smith, 1994), the program should provide some sort of health status evaluation so referrals can be made before complications occur. It is unclear if addressing these three factors will improve blood glucose control in uninsured or underinsured diabetics. There may be other unidentified factors that prevent this population from achieving good blood glucose control; however, no studies to date have looked at the effectiveness of a combined diabetes supply and diabetes self-management program in a population of uninsured or underinsured persons with diabetes. Therefore, the problem for this study was: Does participation in a diabetes supply and diabetes self-management education program improve health outcomes in an at-risk population?

Rationale for the Study

This study was important for several reasons. First, only 32.6% of uninsured diabetics have participated in a diabetes education program (Harris et al., 1994). This places them at increased risk for short- and long-term complications. Second, the diabetes-related death rate for disadvantaged populations has increased since 1990 (U.S. DHHS, 1995b), suggesting that current methods of diabetes management in this population are ineffective. Third, diabetics age 18-65 without health insurance have higher glucose levels than insured diabetics (Harris, 1995), increasing their risk of costly complications. Fourth, developing programs for at-risk populations will contribute to reaching two of the nation's goals for diabetes, outlined in Healthy People 2010 (U.S. DHHS, 2000), that include decreasing the number of diabetes-related deaths and educating 60% of persons with diabetes by the year 2010. Finally, and most importantly, nursing has an obligation to collaborate with other health care professionals to ensure that accessible, high quality health services are available for persons whose health care needs are unmet (American Nurses' Association Code for Nurses, 1985). A diabetes supply and self-management program for uninsured/underinsured persons with diabetes is one approach to meeting the needs of this population.

Purpose of the Study

The purpose of the study was to determine if providing diabetes supplies and individualized, one-to-one diabetes self-management education to at-risk diabetics improved health outcomes. The health outcomes of interest for this study were decreased continuous mean glucose level and improved self-management skills.

Theoretical Framework

There are two approaches to diabetes management: compliance based and empowerment (Funnell, Anderson & Arnold, 1991). The compliance-based approach is based on the traditional medical model where the patient is expected to follow the recommendations of health care professionals. With this approach, little attention is given to how the treatment plan may impact the patient, or whether the patient has the ability and desire to follow the prescribed plan (Anderson, 1995). Not surprisingly, this approach has fallen out of favor and has been replaced with a more patient-centered approach, patient empowerment.

Empowerment Philosophy

Patient empowerment is based on the philosophical beliefs of Pablo Freire, a Brazilian educator who worked with illiterate, adult peasants in Northern Brazil (Freire, 1970). Freire believed that the ignorance and lethargy of the poor was directly related to economic, social, and political domination which made them victims (Freire, 1970). The poor were powerless, in his opinion, because they assumed the role of an "object," acted upon by the world, rather than assuming the role of a "subject" acting in the world (Freire, 1970; Kieffer, 1984). He proposed that the main task of education was to invite people to believe that they can accomplish a task, and that they have the knowledge and power to do so (Freire, 1973). Education, he believed, should not socialize people to be objects and accept the status quo but rather, encourage individuals to question and participate in their world. According to Freire, the world is not static or a "given reality" that must be accepted. It is a "problem to be worked on and solved" (Freire, 1970, p.13). In Freire's method of education, educators and individuals are viewed as equals in solving problems. These basic tenets of Freire's philosophy have provided the philosophical basis for programs in literacy, peace education, teenage school discipline, adult education, and health education (Wallerstein & Bernstein, 1988). This is also the philosophical basis for an empowerment model of diabetes management.

Rappaport (1987) defines empowerment as the process by which individuals gain mastery over their affairs. Empowerment occurs when individuals have sufficient information to make rational decisions, the control and resources to implement their decisions, and experience to evaluate the effectiveness of their decisions (Funnell et al., 1991). Empowerment is more likely to occur if individuals participate in decisions and activities that are meaningful to them and if the interaction takes place in settings that provide an opportunity for participation (Rappaport, 1987). Although this philosophy is currently popular in the area of health care, there are factors in the health care environment that act as barriers to the empowerment process.

One provider-related barrier to the process of empowerment may be the health care professional. Espousing Freire's philosophy involves a radical change in how health care professionals view their role. A philosophy for health education should reflect the personal and professional values, beliefs, and attitudes of the health care professional. Clearly, Freire's philosophy is incongruent with models that place the health care professional as the expert, imparting selected information to the patient in order to change what the health care professional perceives to be unhealthy behavior that must be changed (Anderson, 1995). In order to base a program on Freire's philosophy, professionals must abandon the behavioral change model, or relinquish the long-held notion that the professional is in the best position to decide what constitutes healthy behavior (Mackintosh, 1995). Once this is done, effective programs can be developed.

In summary, Friere's beliefs provide the philosophical base for a program that empowers patients with a chronic disease, such as diabetes, to self manage their condition. However, based on this philosophy, the health care professional must view the patient as the central figure and the primary decision maker. The goal is not how much one knows about one's condition, but how one uses or applies the information to handle problems encountered in the day-to-day experiences with the disease. Indeed, it fits nicely with several authors' definitions of chronic illness, which can be summarized as a condition that requires patients to assume responsibility for managing their condition (Cluff, 1981; Lubkin, 1998; Mazucca, 1982).

Conceptual Model

Glasgow (1995) developed a conceptual model of diabetes management that includes the variables for the proposed study (see Figure 1). Although he does not use the word "empowerment," the second level of the model clearly depicts the concept of empowerment as conceived by Freire and Rappaport. Glasgow encourages that the model be "evaluated, refined, and adjusted to fit one's own situation" (p.123). Based on his recommendation, the second level of the model has been modified to reflect the role of nursing interactions in empowering persons with diabetes to self-mange their disease (see Figure 2). The Practical Model of Diabetes Management and Education is a systems model that depicts the relationship between factors involved in effective diabetes management. It has three levels or stages. The first level, "background and contextual factors," is described as factors that provide a contextual environment for diabetes management. According to Glasgow, they have been ignored in the diabetes literature but are key factors leading to one's participation in self-management activities. It is readily apparent that these factors also apply to the process of empowerment. The presence of these factors results in a "personal readiness" to become empowered, or to assume

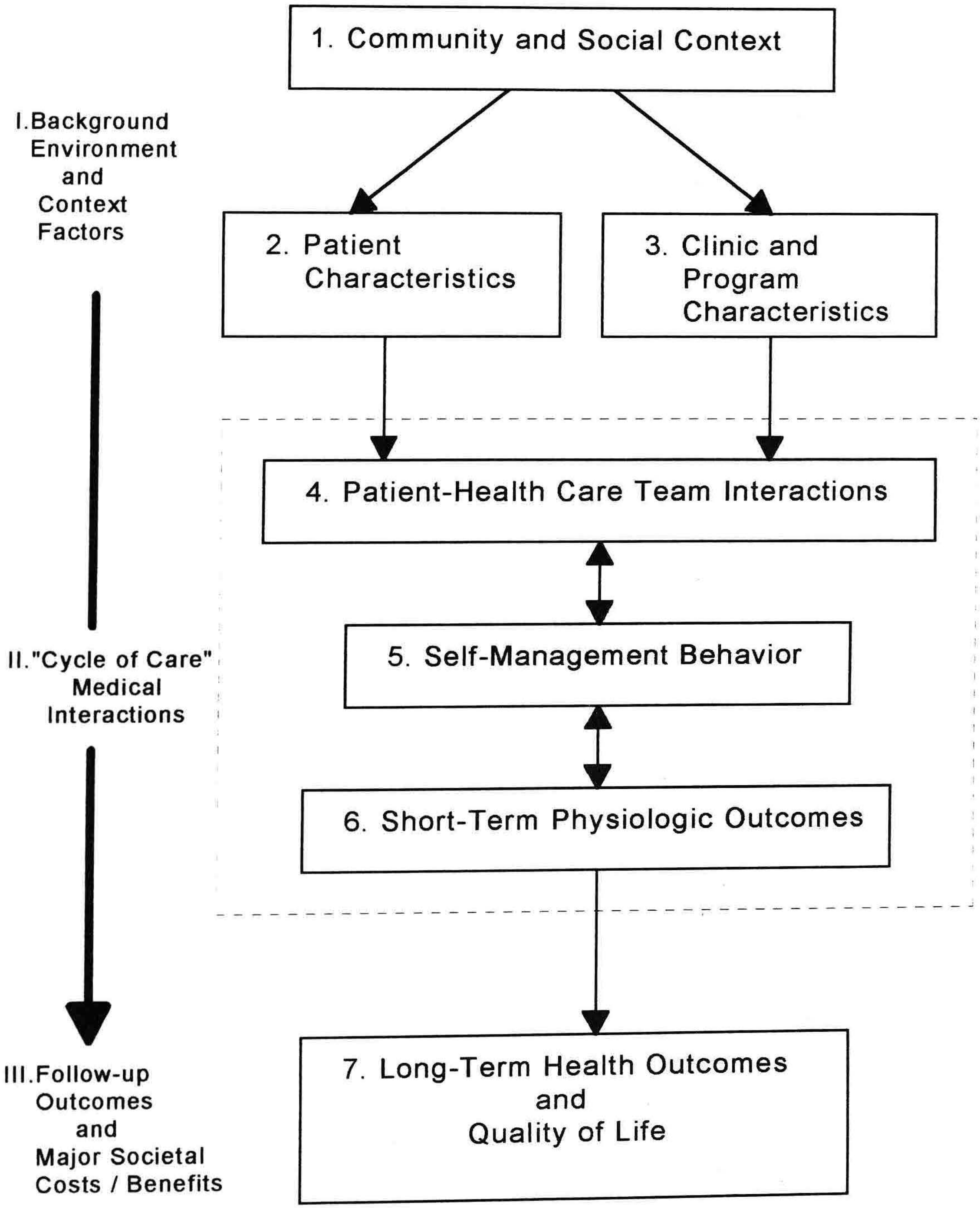

Figure 1. Practical Model of Diabetes Management and Education (Glasgow, 1995)

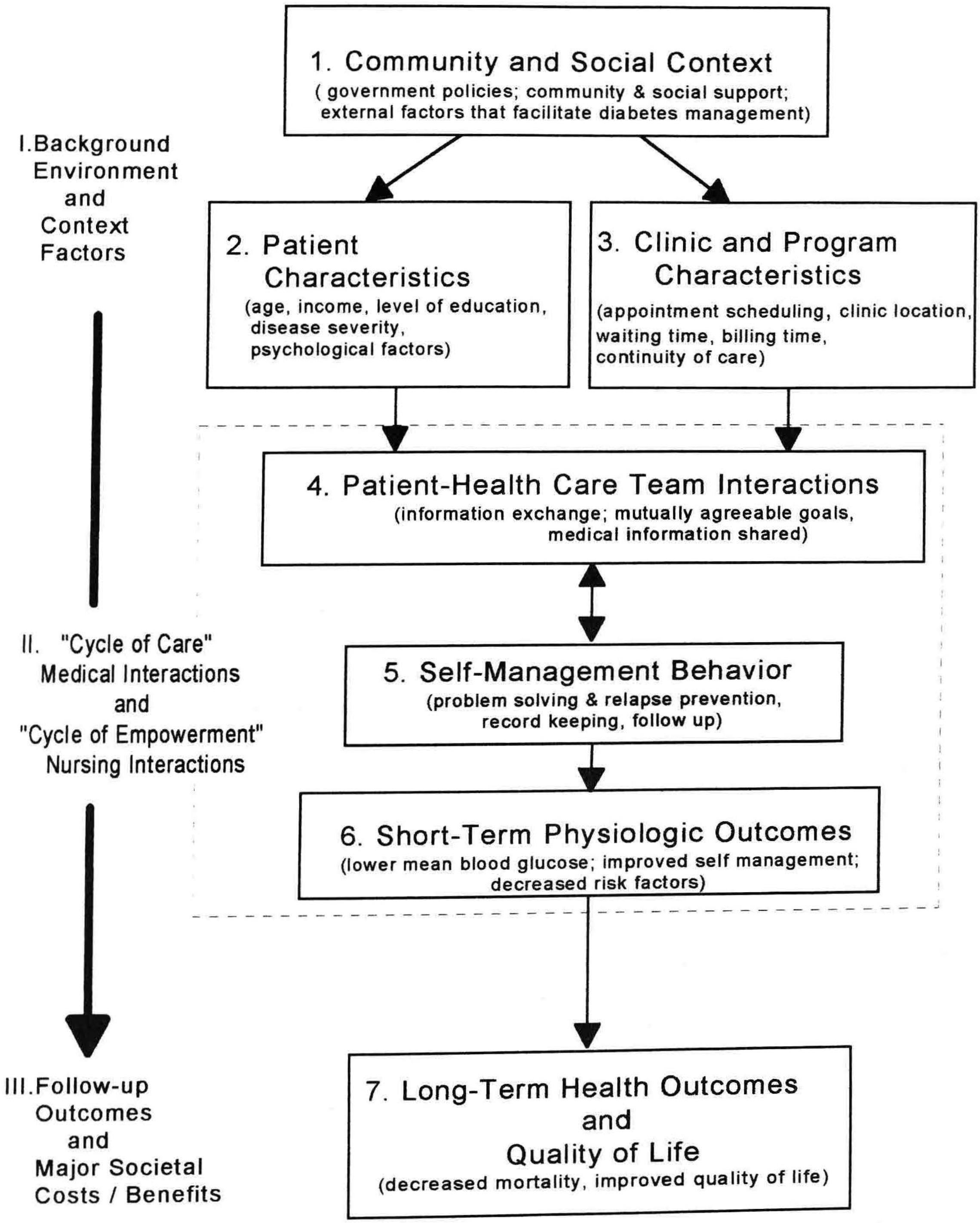

Figure 2. Modified Practical Model of Diabetes Management and Education (Adapted from Glasgow, 1995)

self-management practices. Consequently, the absence of these factors presents a barrier to self-management. Glasgow divides these Level I factors into three groupings: community and social context, patient characteristics, and clinic and program characteristics.

The first group in Level I are community and social context factors which include government policies; work, family, and community support; and the encouragement of behaviors consistent with ADA recommendations for diabetes management. Local, state, and federal government policies impact diabetes self-management practices. For instance, the fact that Medicare does not reimburse for prescriptions is a governmental policy that may negatively impact diabetes management in the elderly. However, the recent Oklahoma Health Care Authority decision to reimburse for diabetes supplies and services for Medicaid recipients should positively impact self-management practices for diabetics enrolled in Oklahoma's Medicaid program (Winslow, 2000).

Community and social support is the second community and social context factor that affects diabetes self-management. Diabetes support groups or walking clubs, free diabetes education, and programs that provide free diabetes supplies to low income diabetics are all examples of community supports that enhance an individual's diabetes self-management. Additionally, several studies have demonstrated that family support also plays a significant role in diabetes self-management (Golin, DiMatteo & Gelberg, 1996; Goodall & Halford, 1991). The third, and last, community and social context factor is encouragement of behaviors consistent with following the diabetes regimen. The recent changes in food labeling facilitate food selection for diet management, making it easier to follow a diabetic diet (Glasgow, 1995). The above described community and social context factors can positively or negatively impact one's ability to self-manage diabetes; however, patient characteristics are equally important.

Patient characteristics are the second group of factors in Level I that affect diabetes self-management. Factors in this group include age, socioeconomic status, level of education, severity of the disease, and psychological factors. Although some of these factors cannot be changed (e.g. age, severity of disease), if one is able to identify them, appropriate interventions can be implemented to minimize their impact. For instance, health care providers can do little to reverse the diabetic retinopathy that may interfere with glucose monitoring and insulin administration. However, teaching patients to use low-vision glucometers and insulin syringe magnifiers can facilitate self-management practices. Socioeconomic group is another patient characteristic that can greatly impact diabetes self-management. Enrolling low-income patients in the indigent prescription programs of drug companies and providing monetary assistance with insulin and supplies are methods of minimizing the financial barrier to diabetes self-management in low-income populations.

Psychological factors, such as one's attitudes and beliefs about the seriousness of the disease, are patient characteristics that also play an important role in one's willingness to participate in self-management practices (Anderson, Fitzgerald & Oh, 1993). Therefore, diabetes management programs should first identify and address attitudes and beliefs that may interfere with the empowerment process. For example, if one believes that "it is just a touch of sugar" because blood sugar levels are not over 150, he/she may not embrace the complex practices required to bring blood sugars to near normal levels, despite the fact that adequate resources are available to do so.

The third, and last, group of background and environmental factors in Level I of Glasgow's model are the clinic and program characteristics. These factors include ease of scheduling appointments, clinic location, ease of access to the clinic, waiting room time, the billing system, and continuity of care. Although these are often ignored when planning self-management programs, they may be the deciding factor in whether or not one is able to participate. For instance, the availability of educational offerings or free diabetes supplies is of little interest to individuals without transportation, if the clinic is not accessible by public transportation.

In summary, background and contextual factors can positively or negatively impact one's ability to self-manage diabetes. These factors include community and social context, patient characteristics, and clinic and program characteristics. They must be addressed before the interaction between the patient and health care provider begins. Collectively they determine whether or not one is ready to move to the next level of diabetes management, the "cycle of care."

Level II is referred to by Glasgow as the "cycle of care" medical interactions. The model was enhanced to reflect the nursing interactions that also occur in this level (see Figure 2). This level of the modified model includes the "cycle of empowerment" because according to Glasgow, patient experiences in this level determine whether, and to what extent, the person with diabetes assumes responsibility for self-management (Glasgow, 1995). This component of the model includes processes which meet Rappaport's (1987) definition of empowerment, which is, a process by which individuals gain mastery over their affairs. Medical and nursing interactions in this level facilitate patient empowerment.

Level II has three components: patient-health care team interactions, self-management behaviors, and short-term physiologic outcomes. Patient-health care interactions involve the active exchange of information between the patient and the health care professional. In this component, the patient commits to working with the health care provider; the patient and health care provider agree on the self-management plan and an achievable blood glucose level; and information in the medical record is shared. According to Glasgow (1995), this session should always begin by first asking the patient what self-management issues they would like to discuss. This provides information about which aspect of diabetes self-management is most difficult for the patient and gives the health care provider insight into the patient's needs. It also is important in determining what interventions may be most effective in empowering the patient. After the patient and health care professional agree to work together, and the patient decides on the treatment goals, attention can then focus on self-management behaviors.

Self-management behaviors, the second component of the "cycle of care" and "cycle of empowerment," include education and training in problem solving; relapse prevention; reviewing personal records; and follow-up. Since the majority of diabetes self-management occurs in the home, the patient is viewed as the expert. For example, when the glucoprotein level is high, this indicates that blood sugars have been elevated for several weeks. Working with the patient to identify contributing factors facilitates what Freire refers to as "a problem to be worked on and solved." The patient then decides what daily practices can be changed to achieve better control. This component also includes training to self-adjust insulin and make decisions based on blood sugar readings. Personal records of blood sugars, dietary behaviors, and exercise logs are also evaluated because according to Glasgow, expecting patients to keep detailed records, which are then ignored, is discouraging and sends the message that it is unimportant.

The goal of diabetes self-management education in Level II is to enable patients to become more knowledgeable about their disease so they can properly manage it on a daily basis (Clement, 1995). According to Funnell et al. (1991), patients have the fundamental right "to have the power to control their own health care behavior" (p.38) and through patient education they can gain the knowledge; skills; and self-awareness of their values, needs, and goals. Patients can then can use this power "to act in their own self-interest."

It is important to remember that although an effective program may be implemented in Level II, it does not mean that patients will embrace it. Wright (1995) points out that many patients prefer the passive, dependent role of the medical model even though this model is incongruent with the daily management and decision making required of diabetes management. The passive resignation of some diabetics can be explained by Freire's theory that some diabetics may perceive themselves as "objects" acted on by the health care professionals. Many diabetics have been encultured to believe that the doctor knows best, making them hesitant to take a more active role in managing their disease for fear it will adversely affect their health. This presents health care professionals with the task of instilling in them the belief that they can take control of their disease. Encouraging active participation in this level improves confidence in making self-management decisions.

According to Wallerstein and Bernstein (1988), an education program based on Freire's philosophy is similar to general health education principles that include identifying the problems of the community, using active learning, and allowing participants to determine their own needs and priorities. There are, however, two main differences. First is the belief that knowledge does not come from the health care professional but from the individual living the experience. The educator serves only as the resource person and "sounding board," but not the problem solver. The second difference is the individualized approach based on the participant's needs rather than following a predetermined curriculum. Curriculums developed and promoted by specialty groups or agencies, such as the American Diabetes Association and the Centers for Disease Control (CDC), should only be used as guidelines, while taking into account the unique needs of each patient.

According to Kieffer (1984), empowerment is both a process and an outcome. The process of developing empowering skills leads to the attainment of participatory competence, which is a set of abiding "commitments and capabilities." Participatory competence, according to Kieffer, is a state of being with three dimensions: a sense of self-competence, a more critical understanding of the surrounding social and political environment, and cultivation of individual and collective resources for action. A diabetic with participatory competence has a sense of competence about their ability to self-manage their condition (e.g. understands what to do on sick days or when hypoglycemia occurs), understands environmental factors (e.g. social policy issues about reimbursement for supplies) that may interfere with this, and has the resources (e.g. diabetes education, supplies) to take responsibility. The process of empowerment leads to the outcome. That is, patients can effectively manage their disease; they are empowered.

The final aspect of self-management behaviors in Level II is the follow-up. Follow-up includes scheduling return clinic visits or keeping in touch by phone if closer interaction is indicated. It has been demonstrated that having a regular health care provider results in better health outcomes (Weissman, Stern, Fielding & Epstein, 1991). Therefore, diabetics without a regular health care provider should be referred to sliding-scale clinics for ongoing monitoring of their diabetes. This stresses the importance of regular monitoring and conveys the message that the health care professional is interested in helping them reach their goals.

The effectiveness of the empowerment process is evaluated in the third component of Level II, short-term physiologic outcomes. Glasgow (1995) suggests that short-term physiologic outcomes include monitoring hemoglobin A1c levels, and providing feedback on risk factors that negatively impact a person with diabetes. Hemoglobin A1c is a laboratory test that provides an index of the mean level of glucose attached to hemoglobin for the past 120 days (Goldstein, 1993). However, if one is meeting with participants in a diabetes self-management education program, who may not return in 120 days, it may be more appropriate to evaluate the glucoprotein, or fructosamine, level which provides a blood glucose average over the past three weeks. The short-term physiologic outcomes provide valuable information. This information either validates that management strategies are effective, or challenges the individual to develop and implement more effective self-management practices.

Feedback on risk factors is the other physiological outcome discussed by Glasgow (1995). This can be accomplished using instruments developed for this purpose. For instance, an easy-to-administer chart developed by the American Heart Association provides immediate feedback on cardiovascular risk factors, since cardiovascular disease is a major cause of death in this population (Glasgow, 1995). Additionally, instruments to evaluate stroke risk or measure the degree of neuropathy can also be utilized. Measuring short-term physiologic outcomes and providing feedback on risk factors moves the patient toward Level III which is what Glasgow refers to as "the bottom line."

The bottom line in diabetes management is the desired long-term health outcomes which are decreased mortality and improved quality of life. The two ultimate reasons for empowering persons with diabetes to manage their disease are to: a) prevent long-term complications, the major factor in high mortality rates for persons with diabetes, and b) improve one's quality of life. However, there is also a monetary benefit that Glasgow does not address. According to the ADA (1998), in 1997 only $7.7 billion of the total $98 billion spent on diabetes went directly for diabetes care and acute glycemic care.

Acute hyperglycemia actually plays a very small role in morbidity, mortality, and the overall total costs (Davidson, 1998). The remaining dollars were spent either directly or indirectly on chronic complications. So clearly, an added benefit to Glasgow's "bottom line" is saving billions of health care dollars.

In summary, the modified Practical Model of Diabetes Management and Education is an appropriate conceptual model for a nursing study of at-risk diabetics. Level I, community and social context, includes those factors identified in the literature that impact one's ability to be empowered, or to assume responsibility, for diabetes self-management. One factor in this level is low income, which prevents the purchase of needed supplies and medications for diabetes self-management. Level II describes the processes involved in diabetes self-management, or empowerment, which ultimately result in short-term physiologic outcomes, such as lower serum glucose levels. These two levels lead to the third level, which is the desired long-term goals of diabetes self-management, decreased mortality, improved quality of life, and saving billions of health care dollars.

In this study empowerment is a participatory educational process that assists patients to develop knowledge, skills, attitudes, and the degree of self-awareness necessary to take responsibility for their diabetes self-management (Feste & Anderson, 1995). The proposed educational program will prepare individuals as equal and autonomous members of the health care team, able to competently provide self-care, and able to judge the costs and benefits of the choices they make (Feste & Anderson, 1995).

Although originally proposed for effecting social and political change by groups, Freire's ideology of empowerment has been utilized in health education with individuals to effect personal change (Anderson, Funnell, Barr, Dedrick & Davis, 1991; Wallerstein & Bernstein, 1988). It is particularly appropriate in today's health care environment, where patients are expected to assume a greater role in managing their health. Its usefulness as a philosophy for a model of diabetes education is evident, and following are several assumptions that follow from this ideology.

Assumptions

The following theoretical assumptions were derived from Freire's ideology and the theoretical model of the study:

1. Persons with diabetes can assume responsibility for their care.
2. Persons with diabetes want normal blood glucose levels.
3. Persons with diabetes are capable of identifying their unique problems and needs.
4. Empowerment improves diabetes self-management.
5. The health care professional and person with diabetes are equals in the educational process.
6. There is a direct relationship between one's ability to implement knowledge and skills of diabetes self-management and mean glucose levels.

Research assumptions are those beliefs and principles about the research process. The following research assumptions guided this study:

1. Fructosamine is an indicator of mean blood glucose levels.

2. The Duet™ Monitor (LXN Corporation) is a reliable and valid instrument.
3. The convenience sample is representative of the population being studied.
4. Participants will honestly respond to items on the skills assessment test.

Hypotheses

The two hypotheses for this study were:

1. At-risk persons with diabetes will have lower mean glucose levels following participation in a diabetes supply and diabetes self-management education program.
2. At-risk persons with diabetes will have improved self-management skills following participation in a diabetes supply and diabetes self-management education program.

Definition of Terms

At-risk Person With Diabetes

An at-risk person with diabetes was theoretically defined as an adult diagnosed with either Type 1 or Type 2 diabetes, who lacked the financial resources to self-manage diabetes on a daily basis. An at-risk person with diabetes was operationally defined as an adult with Type 1 or Type 2 diabetes who met the following criteria: a) had an income level at or below 150% of the 1998 poverty guidelines established by DHHS in 1998 (see Appendix A), b) needed monetary assistance with insulin and diabetic supplies, c) had no health insurance or was underinsured. Underinsured was defined as having health insurance that did not reimburse for insulin and/or diabetic supplies.

Participation

Participation was defined as attending the scheduled sessions with the researcher. Operationally, it was defined as meeting with the researcher for a minimum of four of the five scheduled program sessions.

Diabetes Supply Program

Diabetes supply program was defined as a community program that routinely provides insulin and diabetic supplies to persons with diabetes who lack the financial resources to purchase them. Operationally, it was defined as the provision of insulin, syringes, lancets, and glucose testing strips to persons with diabetes who participated in the study.

Diabetes Self-management Education

Diabetes self-management education was theoretically defined as the empowerment process, depicted in Level II of Glasgow's Practical Model of Diabetes Management and Education, that provided persons with diabetes the knowledge, skills, attitudes, and degree of self-awareness necessary to take responsibility for their diabetes management (Feste & Anderson, 1995). Operationally, diabetes self-management education was defined as five educational sessions with the researcher, based on the "I'm in Control" diabetes education program (Oklahoma State Department of Health, 1997). The four program modules were: "I'm in Control", an overview of diabetes; Diabetes Lifestyle; Diabetes Medicines; and Preventing Complications. A final session clarified information from the four modules. The program included a Skills Assessment measure, used as a pretest-posttest, and a patient information form.

Mean Glucose Level

Mean glucose level is theoretically defined as the glycosylated protein or fructosamine test which is the average of the continuous glucose levels over the past two to three weeks (Cefalu, Parker, & Johnson, 1988). It is operationally defined as the value obtained when a GlucoProtein™ (fructosamine) test is performed on a drop of capillary blood, analyzed in the The Duet™ Monitor (LXN Corporation). The Duet™ Monitor (LXN Corporation) is a portable, hand-held meter used to measure fructosamine.

Self-management Skills

Self-management skills are the nonphysiologic outcomes of the educational empowerment process. They were theoretically defined as the daily practices a person with diabetes performs to decrease, or minimize, short and long-term diabetes complications. Operationally, the outcome of self-management skills was defined as the score obtained on the Skills Assessment measure administered at the first and last session of the "I'm in Control" program.

Delimitations

Delimitations are factors that narrow the scope of the study (Creswell, 1994). The study was delimited by several factors. The participants were delimited to English speaking adults over 18 years of age who sought care at a low-income community clinic in a large metropolitan area. Additionally, the participants had to be uninsured or underinsured and have incomes under 150% of the 1998 federal poverty level.

Limitations

Study limitations are identified weaknesses of the study (Creswell, 1994). Some limitations cannot be prevented, but they may be minimized with careful planning. They affect the validity and reliability of the study which limits the study's generalizability. Eight limitations were identified.

1. The sample of Type 1 and Type 2 diabetics was a convenience sample which limits generalizability. Persons with diabetes who agreed to participate may have been more motivated to follow diet, exercise, and medication regimens than those who did not agree to participate.
2. The Hawthorne effect occurs when patients are more attentive to program requirements because they know they are being monitored. Participants may have been more attentive to diet, exercise, and medication because they knew their blood sugars were being monitored.
3. The GlucoProtein™ (fructosamine) provides a continuous average of serum glucose over the past three weeks. This may have provided a false estimate of glucose control. Extreme fluctuations in serum glucose indicate poor control, however, when averaged they may result in a reading that is in the normal range.
4. Randomization is one method of controlling the extraneous variables. Since there was no randomization of subjects, there may be some extraneous variables that affected the outcome. Although the variable of interest, low-income, was controlled, other influencing factors such as type of diabetes and level of education were not controlled.

5. Data were collected over a 12 month period of time; therefore, history may have threatened the internal validity. Participants who were enrolled in the study during September, when media attention to diabetes increases, may have received an unanticipated advantage.
6. Mortality is the loss of subjects before the study is completed. This posed a threat since the study experienced a 20% mortality rate. Those who did not complete the study may have recognized that their glucose levels were not improving and decided not to continue. Hence, the study's statistically significant results.
7. The skills assessment measure was self-report, therefore, honesty in responses was assumed. It is possible that participants altered their responses on the pretest in order to participate. The posttest responses may have been altered to avoid embarrassment from reporting self-management practices that were perceived as less than ideal by the participant.
8. According to Pedehazur and Schmelkin (1991), regression toward the mean is a limitation that occurs when measures are taken at two different points in time and individuals score "extremely well" or "extremely poorly" on the first measurement (e.g. pretest). On the average, these individuals will score closer to the mean when the second measurement is taken (e.g. posttest). For example, participants with very high pretest fructosamine scores will score closer to the group mean on the posttest fructosamine measure.
9. The last limitation, and perhaps the most serious, was the lack of available reliability

estimates on the "Skills Assessment" instrument used to measure diabetes self-management skills. According to Lynn (1985), "without sufficient and current" reliability estimates for data collection instruments "all study results must be reviewed with caution" (p. 255). Although the reliability estimates for the population studied were acceptable, the researcher was acutely aware of the implications it presents.

Summary

This chapter presented an overview of the study. The purpose of the study was to determine if providing diabetes supplies, and individualized diabetes self-management education, to uninsured, or underinsured, persons with diabetes improved health outcomes. The study was philosophically based on the ideology of Freire. The Practical Model of Diabetes Management and Education, developed by Glasgow (1995), was adapted to reflect the process of empowerment and nursing's role in diabetes self-management education. This model was then used to describe the relationship of the variables, and guide the development of the research project. Hypotheses were derived from the purpose of the study and the study's assumptions, definitions, delimitations and limitations were delineated.

CHAPTER II

REVIEW OF LITERATURE

This study investigated the effectiveness of a diabetes supply and self-management education program in improving the health outcomes of uninsured or underinsured diabetics. This chapter will present a literature review of the following areas: epidemiology and pathophysiology of diabetes, cost of diabetes, the nation's goals for diabetes, diabetes self-management education, and barriers to diabetes self-management education.

Epidemiology and Pathophysiology of Diabetes

Diabetes is a chronic metabolic condition characterized by a deficiency of insulin secretion by the pancreas, insulin resistance in the body, or both. Sixteen million persons, or 6% of the population, are believed to be affected, however, only half have been diagnosed (LaPorte, Matsushima & Chang, 1995). It is one of the most prevalent chronic diseases in the United States (Javitt & Chiang, 1995), affecting all ages and ethnic groups. The greatest number of diabetics, 6.5 million, are 45 years and older, and the disease is more prevalent in Blacks, Hispanics, and Native Americans (Bransome, 1992). Recent studies indicate that 1 in 10 persons age 20 to 44 has diabetes or impaired glucose tolerance; one in four middle-aged persons; and one half of the population over age 65 (Harris, 1996a). According to Helms (1992), the number of diabetics is expected to double by the year 2030 as the "baby boomers" age, placing an additional financial burden on communities. In fact, some authorities believe that because of the high prevalence rate it should be treated as a public health disease. As a public health issue, efforts could then focus on earlier diagnosis through widespread screening, and the prevention of complications through community education programs (Roman & Harris, 1997; Vinicor, 1994).

Types of Diabetes

There are two major classifications of diabetes: Type 1 and Type 2. Prior to 1997, Type 1 was referred to as an insulin dependent diabetes mellitus (IDDM) and Type 2 was referred to as noninsulin dependent diabetes mellitus (NIDDM). It is now recommended that the terms IDDM and NIDDM no longer be used since NIDDM diabetics may also be managed with insulin. Authorities believe that the new Type 1 and Type 2 classifications, based on etiology rather that treatment, will eliminate some of the current confusion regarding treatment (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1998).

Type 1 diabetes is usually the result of an autoimmune process. Insulin production by the pancreas is absent and an absolute insulin deficiency results. This necessitates insulin replacement in combination with diet management and exercise (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1998). It is usually characterized by an abrupt onset before age 30 and the majority of Type 1 diabetics are non-Hispanic white. However, in comparison to the non-Hispanic white population, the incidence is disproportionately higher in Blacks and Mexican-Americans (Cowie & Eberhardt, 1995). While the basis of treatment in Type 1 diabetes is insulin replacement, the etiology and treatment of Type 2 is more complicated.

Type 2 diabetes is more prevalent than Type 1, accounting for 90-98% of all cases (Harris, 1998; Huse, Oster, Killen, Lacey, Colditz, 1989; Roman & Harris, 1997). It has a gradual onset, usually after the age of forty, and involves insulin resistance with relative insulin deficiency (The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1998). Diagnosis of Type 2 diabetes is frequently made during a routine exam or while one is being treated for another condition (Laporte et al., 1995). Unlike Type 1 diabetes, the prevalence increases with age, and obesity is a significant risk factor. Type 2 diabetes is also more prevalent in some ethnic groups. Compared to rates in non-Hispanic whites, Type 2 is 60% more common in Blacks, seven times more common in Native Americans, and two times more common in Hispanics (U.S. DHHS, 1995a). One can anticipate that this disparity between ethnic groups will widen as the number of minorities in the U.S. increases. Since it is usually present for 10 to 12 years before diagnosis, many persons with Type 2 diabetes already have microvascular complications when the diagnosis is made (Roman & Harris, 1997).

Management of Type 2 diabetes is complex. It may require oral hypoglycemic agents combined with exercise, diet modification, and weight loss (if indicated); insulin and oral hypoglycemic agents combined with exercise, diet modifications, and weight loss (if indicated); or merely exercise, diet modification, and weight loss. Regardless of the type of diabetes, the focus of treatment is maintaining a near normal blood sugar level since unmanaged or uncontrolled Type 1 and Type 2 diabetes results in hyperglycemia, the major risk factor for microvascular and macrovascular complications (Klein et al., 1996; Laakso, 1996; Savage, 1996; The DCCT Research Group, 1993). Maintaining blood glucose at near normal levels delays the onset and slows the progression of diabetes-related complications in both Type 1 and Type 2 diabetics by 50-70% (Ohkubo et al., 1995; The DCCT Research Group, 1993; Turner, 1998). Preventing complications in both Type 1 and Type 2 diabetes is essential for improving the quality of life and decreasing costs.

Complications of Diabetes

Persons with diabetes can experience both acute and chronic complications. Acute, or short-term, complications include ketoacidosis, hyperosmolar coma, uncontrolled hyperglycemia, and hypoglycemia. These complications are avoidable and more prevalent in low-income populations, uninsured populations, and certain minorities (Bindman et al., 1995; Pappas, Hadden, Kozak & Fisher, 1997; Sharma, 1995). Weissman et al., (1991) interviewed over 12,000 hospitalized patients from five hospitals in the northeast and found that the poor and uninsured were twelve times more likely than other patients to delay seeking care for medical problems, many of which could have been prevented or minimized with early intervention. Although this study was not limited to persons with diabetes, it clearly demonstrates the effect of socioeconomics on one's health. The ADA estimated that 13.3% of all hospitalizations for diabetes in 1997 were for treating uncomplicated diabetes and acute complications at a cost of $7.7 billion (ADA, 1998). This amounts to 17.4% of the total costs for diabetes.

Selby, Ray, Zhang and Colby (1997) compared the cost of medical care in 85,209 diabetics with 85,209 age and sex-matched nondiabetics in a managed care population. They reported the total excess costs of acute complications for persons with diabetes to be approximately $9 million, which is 4% of the total excess costs. The main expense was from hospitalizations and emergency room visits, which some studies report are related to lack of diabetes self-management education. An early study by Geller and Butler (1981) found 50% of patients hospitalized with a primary diagnosis of diabetes had some "educational deficit" that led to their admission. It is clear that acute complications are costly, however, they are considerably less costly than the $11,841 billion directly attributed to chronic microvascular and macrovascular complications (ADA, 1998).

Microvascular disease affects small vessels and is manifested in retinopathy, nephropathy, and neuropathy. These complications result in considerable morbidity, mortality, and disability from blindness, end stage renal disease, and loss of limb. Diabetic retinopathy is the leading cause of blindness in the U.S. for people between the ages of 20 to 74 (Harris, 1998). It is estimated that 80% of Type 1 diabetics develop retinopathy within 15 years of diagnosis, and 20% of Type 2 diabetics have retinopathy at diagnosis (Roman & Harris, 1997). A significant factor in the development of retinopathy is increased serum glucose levels which Stolk et al. (1997) demonstrated was linearly related. That is, the severity of retinopathy increased linearly with concurrent increases in blood glucose.

Diabetes is also the leading cause of nephropathy which leads to end-stage renal disease. The ADA estimates that 20-30% of persons with diabetes eventually develop evidence of kidney pathology with treatment costs of over two billion dollars annually (ADA, 2000b; Harris, 1998). However, this number is small compared to diabetics affected with neuropathy.

Estimating the cost of neuropathy is complicated because neuropathy involves both autonomic nerves, which control organs, and peripheral nerves, which control sensation. However, one expense, easily estimated and often reported, is the cost of treating the foot ulcers/lower extremity amputations that result from peripheral neuropathy. According to Eastman et al. (1997), the average cost per person for diabetic foot ulcers is $4400, and the estimated annual cost is $5 billion (Amato, Persson, Lantin, Basso, Martes, 1999). Neuropathy eventually affects 30%-70% of persons with diabetes and is responsible for 50-75% all amputations in the United States (Davidson, 1998; Rathmann, 1998; Roman & Harris, 1997). The development of this complication is also directly related to uncontrolled blood sugar (Klein et al., 1996; The DCCT Research Group, 1996) and can be prevented by educating diabetics about foot care (Malone, Snider & Anderson, 1989). The physical and financial costs of microvascular complications severely impact one's quality of life and contribute to the exorbitant costs attributed to diabetes. These complications are overshadowed only by the effects and costs of macrovascular complications.

Macrovascular disease affects large vessels which results in coronary heart disease, stroke, and peripheral vascular disease. Coronary heart disease and stroke account for 60% of all deaths in persons with diabetes (Roman & Harris, 1997). A study by Krop et al. (1998) found that 33% of Medicare beneficiaries with diabetes had ischemic heart disease. Krop's findings are similar to figures reported by Roman and Harris (1997) that persons with diabetes have a two to three time greater incidence of coronary heart disease, and a two to four time greater risk for stroke than nondiabetic persons. These complications are expensive to treat and ultimately result in disability and/or death. The ADA estimated that the cost of cardiovascular disease in diabetics was $7.6 million in 1997 (ADA, 1998). Research indicates that maintaining normal glucose levels can prevent these complications (Laakso, 1996; Savage, 1996; The DCCT Research Group, 1996).

In summary, studies demonstrate that both microvascular and macrovascular complications cause considerable morbidity and mortality in persons with diabetes. These complications can be prevented or delayed by maintaining normal blood glucose levels. Preventing complications will improve quality of life, decrease morbidity and mortality, and save billions of health care dollars.

Cost of Diabetes

Although confirmed diabetes affects only 3.1% of the population, costs for treatment and management account for 12% of the nation's total health care expenditures (Herman, Dasbach, Songer & Eastman, 1997). According to the ADA, the estimated annual total dollar cost of diabetes is $98 billion (ADA, 1998). Selby et al. (1997) compared the costs of medical care for diabetics in a health maintenance organization (HMO) with age and sex-matched nondiabetics. They found the total health costs of persons with diabetes to be 2.4 times greater than for nondiabetics. The actual estimated cost was approximately $3,500 more per person for persons with diabetes, and nearly 40% of this amount was used to treat long-term complications. Krop et al. (1998) reported similar findings in a population of Medicare beneficiaries with diabetes who, on average, were 1.5 times more costly than nondiabetics. However, according to the ADA (1998), medical expenditures are much higher than the findings of these two studies. In fact, the ADA estimated that in 1997 medical costs were 3.7 times greater for persons with diabetes than for persons without the disease, and per capita expenses for people with diabetes were $10,071 compared to $4,669 for nondiabetics.

Other researchers report that the cost of diabetes increases significantly for every 1% increase in HbA1c over 7%. Gilmer et al., (1997) found a 36% increase in cost when HbA1c levels increased from 6 to 10%. Diabetes is clearly a costly disease to both manage and treat and studies suggest that significant savings would result if complications were prevented.

Direct Costs

Most studies differentiate costs as either direct or indirect. Direct costs are resources used to treat diabetes or the effects of diabetes and may include physician services, prescription drugs, laboratory charges, medical supplies, hospital/nursing home expenses, and nursing care (Javitt & Chiang, 1995; Songer & Ettaro, 1998). The direct costs attributed to diabetes have been estimated at $45.2 billion, and 50% of this cost is attributed to hospitalizations for treating the acute and chronic complications that were previously discussed (Javitt & Chiang, 1995). Direct costs are easy to obtain and readily available, however, estimating indirect costs is more difficult.

Indirect Costs

According to Javitt & Chiang (1995) indirect costs are resources lost as a result of diabetes. Different researchers include different factors when estimating these costs, however, most researchers include factors that result in lost productivity (Javitt & Chiang, 1995; Pracon, 1988). Few would argue that premature death, temporary and permanent disability, and quality of life are important factors to consider when evaluating the indirect cost of diabetes.

Death. In 1996 diabetes was the seventh leading cause of death in the United States, and the sixth leading cause of death in persons over age 45 (Centers for Disease Control (CDC), 1997a). Seventeen percent of all U.S. deaths in persons over 25 years were persons with diabetes (Roman & Harris, 1997). In total, over sixty thousand deaths were directly attributed to diabetes in 1996 (CDC, 1997a). The U.S. Department of Health and Human Services (1995b) estimates that an additional 100,000 deaths annually can be attributed to diabetes, since it is a risk factor for cardiovascular disease, stroke, and end-stage renal disease. According to Roman and Harris (1997), in comparison with nondiabetics, persons with diabetes have a two to four time greater mortality rate and live seven to ten years less than nondiabetics. Additionally, researchers have found that low educational status is associated with higher diabetic mortality rates (Nilsson, Johansson & Sundquist, 1998).

Disability. Another important indirect cost of diabetes is temporary and permanent disability. In 1998 the ADA estimated indirect costs resulting from premature mortality and disability to be $54.1 billion. Javitt and Chiang (1995) used different parameters for reporting indirect costs, but concluded that short term disability (e.g. sick days, physician visits) and permanent disability (e.g. early retirement) cost the nation ten billion dollars annually from lost productivity.

The financial burden of temporary and permanent diabetes-related disability was studied by Argentina researchers, Olivera, Duhalde and Gagliardino (1991). To determine the effect of temporary disability they compared 42 diabetics with 42 nondiabetics that were matched according to age, sex, and job type. Diabetics without complications experienced absenteeism rates similar to their matched nondiabetic cohorts, while diabetics with complications experienced more absences. Therefore, diabetes alone was not predictive of absenteeism, only the presence of complications.

Permanent disability was assessed by examining early retirement and deaths in over 250,000 government employees over a three year period. The average age of early-retired diabetics was 49 for women and 54 for men. The researchers calculated this to represent an average of 11 years of lost work production, at an estimated cost of almost $3 million. In this study, early deaths and permanent disability in diabetics was mainly due to macrovascular complications (stroke, cardiovascular disease). However, retinal damage, a microvascular complication, was also a factor in early retirement. Based on these findings, it seems evident that preventing diabetic complications will prevent early death, decrease temporary and permanent disability, and save millions of dollars. It should also improve the quality of life.

Quality of Life Studies measuring quality of life are plentiful, and findings are difficult to compare. Some researchers believe that quality of life can be measured directly by looking at things such as absenteeism from school and work, or measuring the amount of time spent in self-management practices (Ratner, 1997). However, most researchers that study quality of life use subjective patient measures.

Quality of life has been investigated by researchers from two perspectives, the quality of life one experiences from the effects of the disease, and the quality of life from the burden of maintaining a euglycemic state. The effect of diabetes on quality of life is difficult to evaluate prior to the DCCT because no diabetes-specific quality of life measure was available (Jacobson & The DCCT Research Group, 1994). Prior DCCT studies utilized generic measures such as the Sickness Impact Profile (SIP) or the Medical Outcomes Survey (MOS) which, according to some experts, are too crude and insensitive to measure the small effect sizes for quality of life changes that result from diabetes management interventions and programs (Testa, Simonson & Turner, 1998).

The effects of Type 1 and Type 2 diabetes on patient perception of quality of life was investigated by Jacobson, deGroot and Sampson (1994). Researchers compared the psychometric properties of the Diabetes Quality of Life (DQOL) instrument and a generic quality of life instrument in 240 diabetics. Both were reported to be valid and reliable, however, the DQOL was more sensitive to lifestyle issues and the generic instrument provided more information about functional health status. Quality of life was found to be lower in patients with complications. Similar findings have been reported by Glasgow, Ruggiero, Eakin, Dryfoos and Chobanian (1997) who found quality of life decreased as the number of complications increased. Glasgow et al. (1997) also reported lower quality of life scores in low-income diabetics and diabetics with less education. These studies indicate that diabetic complications decrease the diabetic's quality of life; however, other researchers have investigated the effect of daily diabetes management practices on one's perceived quality of life.

It is believed that patient adherence to diabetes treatment is based on the perceived benefit of complying with treatment recommendations, compared to the overall cost to achieve this benefit (The DCCT Research Group, 1996). Since the demands of intensive treatment may influence patients to modify treatment goals, the DCCT studied the effect of intensive treatment demands on quality of life in 1,441 Type 1 diabetics (The DCCT Research Group, 1996). Quality of life, as measured by a Diabetes Quality of Life (DQOL) instrument, was not affected by intensive treatment. This led researchers to conclude that rigorous diabetic self-management, in a tightly controlled group, did not adversely affect perceived quality of life. In summary, quality of life decreases with the presence of diabetic complications, however, the intense management required to prevent complications has not been found to affect one's perceived quality of life.

The above discussion clearly demonstrates the devastating effects of diabetes. It leads to the loss of productive members of society and drains financial resources. The physical effects of uncontrolled diabetes, combined with the direct and indirect costs, have led government officials to look for programs that are cost effective in both preventing and treating this disease. In fact, diabetes treatment and prevention has been a national health goal for the past 10 years.

The Nation's Goals for Diabetes

Most experts view diabetes as a clinical disease. However, Vinicor (1994) notes that it meets the definition of a public health disorder. It is "common," or has high disease burden, because of the associated complications; there has been a rapid change in disease burden from low to high, or it is more prevalent; and there is fear associated with the diagnosis. In addition, he notes that there is evidence that primary, secondary, and tertiary prevention reduces the burden. Regardless of whether or not diabetes meets the definition of a public health disease as defined by Vinicor, government agencies have addressed it's impact on society.

Because it is a major public health issue, the U. S. DHHS outlined broad objectives to improve the health outcomes of diabetics. These objectives were a component of Healthy People 2000: National Health Promotion and Disease Prevention Objectives, published in

1991. Diabetes related objectives included reducing deaths and complications attributed to diabetes, reducing the risk of Type 2 diabetes by controlling obesity, and increasing the proportion of diabetics who receive formal patient education (U.S. DHHS, 1991). However, despite some progress in meeting the objectives for 2000, the Healthy People 2010 baselines (U.S. DHHS, 2000) indicate there is still much to accomplish by the year 2010.

According to the Healthy People 2000 mid-decade report (U.S. DHHS, 1995b) there was little change in diabetes-related deaths for the total population and death rates for disadvantaged populations actually increased. Although the number of lower extremity amputations among diabetics decreased, there was no decrease in any of the other diabetes-related complications. The fact that there was a decrease in only one diabetes-related complication may be due in part to two factors.

The first factor that may contribute to lack of progress in decreasing diabetic complications is the small percentage of diabetics who report being taught to properly self-manage their condition. According to the recently released objectives for 2010, the percentage of persons with diabetes who received formal diabetes education has increased to 40%, up only 8% from the 1983-1984 baseline. The 2000 goal of 75% fell far short of it's mark. Diabetic education was found to be higher in a study by Harris (1996a) who reported that 59% of IDDM diabetics, and 49% of NIDDM diabetics had received formal diabetes education. However, it should be noted that neither the mid-decade report nor the Harris study defined diabetes education, making the comparison of findings difficult.

Nevertheless, both studies indicate that the nation is still far from the 2010 goal that 60% of the nation's diabetics will receive some type of formal diabetes education. In fact, several researchers have attempted to identify those factors that impact diabetes education. These factors will be discussed later.

The second factor contributing to the lack of progress in decreasing the mortality rate and diabetes-related complications may be that a significant number of diabetics are either uninsured or underinsured. According to Bodenheimer (1992), underinsurance is insurance that requires large out-of-pocket payments. Hahn and Flood (1995) found a significant relationship between having no insurance, which affects 16% of the U.S. population (Monheit, 1994), and being in poor health. According to Harris (1995), 92% of all diabetics have some type of health insurance, and although this number is high compared to the nation as a whole, two factors must be considered. First, coverage varies according to age groups, and second, reimbursable expenses vary from policy to policy, or program to program.

According to age groups, 99% of diabetics over 65 are insured, the majority through Medicare. In the 18 to 65 age group, the age group with the largest number of diabetics, the percentage of insured diabetics drops dramatically. In this group, approximately 14% or 600,000 diabetics are without any form of health insurance (Harris, 1995). Although the majority of persons with diabetes have some form of health coverage, reimbursement for supplies and services varies. For instance, insulin, a nonprescription drug, is reimbursed only while diabetics under Medicare are hospitalized and it may, or may not, be reimbursed under private insurance policies. It was not until mid 1998 that Medicare began reimbursing for blood glucose testing strips for persons with Type 2 diabetes, but there is a monthly cap on the number of strips. Diabetics enrolled in a health maintenance organization (HMO) have a nominal co-payment for medications and syringes; however, home glucose monitoring supplies are reimbursed only if the employer contracted with the HMO to cover them (Geffner, 1992). These reimbursement policies determine the degree to which one may be able to monitor their serum glucose levels, a practice that is essential to the management of diabetes and the prevention of complications.

Studies indicate that families with a diabetic child have out-of-pocket expenses 56% higher than other families (Songer, LaPorte, Lave, Dorman & Becker, 1997). This means that persons with diabetes in lower socioeconomic groups will spend a greater percentage of their income on diabetes supplies than those with higher incomes. Being without adequate health insurance frequently results in practices that are less than optimal and may explain the results of a study reported by Nordberg, Barlow, Chalew and McCarter (1993). According to these researchers, inner-city, indigent diabetics without third-party reimbursement were found to have higher glycosylated hemoglobin levels when compared with diabetics who had partial or full reimbursement.

It is clear that diabetes is a costly disease, personally and financially. However, long-term complications that lead to disability, decreased quality of life, and death can be prevented by maintaining blood sugars in the near normal range (Ohkubo et al., 1995; The DCCT Research Group, 1996). Knowledge about the disease and its management empowers diabetics to manage their condition on a daily basis. However, despite the recognized benefit of diabetes education, most diabetics have never participated in diabetes education classes (Coonrod, Betschart & Harris, 1994). This has led to numerous studies where researchers have attempted to identify the most effective diabetes self-management programs.

Diabetes Self-management Education

Knowledge about diabetes self-management improves the diabetic's ability to provide self-care which results in reduced medication costs, fewer emergency room visits, fewer lower-extremity amputations, decreased hospitalizations, and decreased morbidity and mortality (ADA, 2000f). Ninety-five percent of diabetes management occurs in the home, by the individual, without the expertise of the health care professional (Anderson et al., 1993). Therefore, diabetics must be knowledgeable about the disease, trained to perform necessary skills (i.e. glucose monitoring), able to problem solve, and motivated to assume responsibility for their care.

Several authors have reviewed the abundant studies related to diabetes education and have presented their findings in critical reviews or meta-analyses (Brown, 1988; Brown, 1990; Goodall & Halford, 1991; Kaplan & Davis, 1986; Padgett et al., 1988). The literature on diabetes education is difficult to analyze and compare for several reasons. First, the education sessions are of varying lengths and formats. Second, different outcomes are used to determine a program's effectiveness, and third, researchers utilize different measures of effectiveness. Despite these drawbacks, the researchers are in agreement that overall, diabetic education makes a difference in the outcome measured.

Padgett et al. (1988) reviewed 93 studies and calculated the mean effect size (ES) of eight different interventions including didactic education, enhanced education, diet instruction, exercise instruction, self-monitoring instruction, social learning/behavior modification, counseling, and relaxation training. Diet instruction effect sizes were highest, and didactic and enhanced education were equal. The overall mean ES of all interventions was a moderate +.51. The only intervention that did not yield a statistically significant ES was training in relaxation. Anderson, Hiss, Stepien, Fitzgerald and Funnel (1994) did not calculate ES but reported that patients who received diabetes education scored higher on a knowledge test than those who had not received diabetes education.

Brown (1990) conducted a meta-analysis of 82 studies of diabetes education and reported findings similar to Padgett et al. (1988). Brown looked at the effects of patient education on several outcomes including knowledge and metabolic control. The effects of knowledge were between .49 and 1.05 and self-care behavior was .17 to .57. The effect of education on metabolic control (glycosylated hemoglobin) was .41. She also determined that the older the patient, the lower the ES for patient education. Although Brown reported an overall positive effect of education on metabolic control from the studies she reviewed, Bloomgarden et al. (1987) did not report the same finding. Bloomgarden randomly assigned 345 diabetics to an education group or a control group and measured knowledge and metabolic control with a pretest and posttest. Although knowledge improved in the education group, there was no significant difference between the groups in metabolic control.

Goodall and Halford (1991) reviewed the literature on diabetes education to identify determinants of effective self-management and methods to promote better self-management. They criticized the lack of reliable, standardized, objective measures of self-management which they believe has led to the inappropriate reliance on measures of blood glucose as a measure of self-management. This is an appropriate criticism for a study reported in 1991 since in the 1980's fasting blood sugar was a commonly used measure of glucose control. However, in this author's opinion, the glycosylated hemoglobin test, which is routinely done today, is a measure of glucose control since it provides a three month average of blood glucose. Goodall and Halford (1991) also reported that diabetes education increased knowledge about diabetes management. However, similar to Bloomgarden's findings discussed above, glycemic control did not improve in several studies reviewed by these researchers. This led them to conclude that knowledge alone did not improve blood glucose. However, studies that included skills training, in addition to didactic instruction, did result in improved blood glucose levels.

The above meta-analyses and critical review clearly suggest that diabetes self-management education is effective. Persons with diabetes can be taught to effectively manage their disease; however, the number of persons with diabetes who have participated in diabetes self-management education is small (Harris, 1996a). Therefore, researchers have attempted to identify factors or barriers to diabetes self-management education.

However, before barriers are identified, one must first define diabetes education and identify its components.

Diabetes education is recognized by the ADA as an integral component of the medical care for patients with both Type 1 and Type 2 diabetes (ADA, 2000f). National standards for diabetes education programs ensure that program content and outcomes are comparable. The ADA refers to education programs as self-management education programs and defines them as the "process of providing the person with diabetes the knowledge and skills to perform self-care..."(ADA, 2000f, p S111). According to Clement (1995), the terms self-management education and diabetes education are interchangeable since diabetes education teaches diabetics to manage their diabetes on a daily basis.

There are three components to the ADA self-management program: structure, process, and outcomes. Structure includes the human and material resources required to achieve program goals (i.e. needs assessment of the population, staff, curriculum). The process is the actual utilization of the structure components to achieve program objectives (i.e. implementation of the curriculum by the staff). The structure and process components are fairly consistent among self-management programs discussed in the literature. That is, most programs include a curriculum that someone implements over varying time frames, using different methods. The effectiveness of the structure and process is measured by the last component, outcomes.

Outcomes are the participant and program results. Participant outcomes include knowledge and skills for daily self-management, and improved health outcomes, such as lower glycosylated hemoglobin. According to Brown (1990), knowledge is one of the most commonly evaluated outcomes of patient education programs. However, this has been at the expense of measuring coping skills or self-efficacy which are believed by some authorities to be mediators of behavior change (Glasgow & Osteen, 1992). Program outcomes are just as important as patient outcomes and include achievement of program objectives, reaching the target population, and assisting program participants to meet individual objectives.

Fain (1996) provides a list of program outcomes that is more specific than those discussed by the ADA. Measures of a program's effectiveness, according to Fain, include disease specific physiologic outcomes, such as glycosylated hemoglobin; general health outcomes, such as quality of life and functional status; individual performance outcomes, such as increased knowledge and compliance with diabetic regimen; and patient satisfaction outcomes such as satisfaction with care.

Glasgow and Osteen (1992) reviewed the literature on outcomes of diabetes education programs and came to the conclusion that researchers have been focused too narrowly on two outcomes: knowledge, which they categorize as a process or mediating variable; and glycosylated hemoglobin, which they categorize as a short-term health outcome. They discuss six categories, and believe evaluators should focus on outcomes from each of the six categories. The six categories are: a) environmental and social, such as social support, health insurance, time, cost and location of classes, and community resources to support diabetes self-care; b) process and mediating, such as problem solving and coping skills, knowledge, social support, attitudes, and self-efficacy; c) short-term health outcomes, such as glycosylated hemoglobin, the most frequently measured physiologic outcome (Brown, 1990), blood glucose variability, hypoglycemic episodes, and quality of life; d) diabetes management, such as exercise, eating behavior, medication adherence, glucose testing, and foot care; e) patient characteristics, such as participant demographics, attrition and participation rates, comorbidity, and representativeness of the final sample; and f) long-term health outcomes, such as stroke, mortality, retinopathy, and cost effectiveness. According to Glasgow (1995) long-term health outcomes are "the bottom line" of any educational endeavor. Most health professionals would agree that each of the above six categories of outcomes is important to measure. However, the time and effort involved in measuring each of these outcomes is beyond the human and financial resources for most health care professionals implementing diabetes self-management education programs.

Interestingly, Glasgow and Olsteen (1992) do not include hospitalizations as an outcome measure. As previously discussed, diabetic hospitalizations contribute considerably to the direct and indirect costs. Schwartz, Zaremba and Ra (1985) studied 813 participants in a diabetes self-management program over three years and found that program participants had a 32% decrease in hospital admissions. Sinnock (1986) reported an even more dramatic 73% decrease in hospital admissions among those who had participated in some form of diabetes education program.

The current ADA standards recommend that comprehensive training in self-management include education about the following: frequent monitoring of blood glucose, meal planning, regular exercise, insulin or oral glucose lowering medications, and prevention of complications. Education should be reassessed annually, and continued education should be provided and encouraged.

Although the ADA defines specifics about program content, the method of imparting the knowledge is left to the educator, who must keep in mind the unique needs of each population. Therefore, diabetes education program planners are interested in the most effective method of providing diabetes education for different populations. Clearly, as the above discussion demonstrates, diabetes education is effective in improving health outcomes, regardless of the outcome measured. The challenge to program developers is to identify those factors that act as barriers to diabetes education. Barriers to participation have been the focus of several studies and will be discussed in the following section.

Barriers to Diabetes Self-management Education

Empowering persons with diabetes to assume responsibility for their overall health is multidimensional. However, educators must be able to recognize barriers that affect participation in classes on diabetes self-management, as well as barriers that may interfere with implementing newly acquired knowledge and self-management skills. Once barriers are identified, educators can develop interventions to eliminate or minimize them.

Diabetes self-management classes are successful, beneficial, and reduce health care costs (Brown, 1990; Glasgow & Osteen, 1992; Kaplan & Davis, 1986; Ongoing education, 1999). Sinnock (1986) analyzed 15 studies that demonstrated cost savings associated with diabetes and found that diabetics who had attended diabetes education sessions had a 73% decrease in hospitalizations. However, despite the fact that most private insurance policies, HMO's, Medicare, and some state Medicaid programs cover diabetes education, only 35% of all diabetics report having attended a class on diabetes management. When evaluated according to type, 41% of Type 1 diabetics, 51% of insulin-treated Type 2 diabetics, and 76% of noninsulin-treated Type 2 diabetics have never attended a diabetes education class (Coonrod et al., 1994). Furthermore, it is not uncommon to have attrition rates of 40% or greater (Irvine & Mitchell, 1992; Kaplan & Davis, 1986). Poor attendance and high attrition rates have prompted researchers to identify those factors that enhance or deter participation in diabetes education.

Glasgow's model of diabetes management and education identifies factors that result in one's personal readiness to participate in diabetes self-management education. According to Glasgow (1995) they have been ignored in the literature, however, if not addressed they "decrease the probability of self-management behaviors" (p. 118). These factors are referred to by Glasgow and other researchers as barriers (U.S. DHHS, 2000). In Level 1 of Glasgow's model he identifies three groups of factors that determine one's "readiness" or "lack of readiness" to participate in diabetes self-management. These factors are community and social context, patient characteristics, and clinic and program characteristics. Following is a discussion of barriers to diabetes self-management in relation to Level I of Glasgow's model.

Community and Social Context

Community and social context factors play a major role in diabetes management. In fact, they may be the only barrier to proper self-management. Barriers in this category include government policies, community support (either local or state) for diabetes programs, and family support. Eliminating or minimizing these barriers is an important step in facilitating diabetes self-management.

Governments frequently dictate the guidelines for eligibility and/or the reimbursement practices of different healthcare programs. For instance, guidelines are established for Medicaid eligibility, and current legislation dictates that employers must provide health insurance to full-time employees. It is well known that there is a direct relationship between the medical insurance premium paid and the amount of services that are reimbursable. That is, the more one pays in a monthly premium, the less one spends out-of-pocket for supplies and services. Individuals with policies that only cover catastrophic events are frequently referred to as underinsured. The underinsured are likely to have major events covered; however, treatments, supplies, and medications to prevent these events are not reimbursed. According to a study by Monheit (1994) persons most at risk to be uninsured live at or near the poverty level or are "low income." He defines low income as earnings between 125% to 200% of the federal poverty level. In fact, Bennefield (1998) reports that one half of poor, full-time workers are uninsured. However, while employment decreases the risk of being uninsured, the uninsured are mainly workers and their families.

Programs such as Medicare and Medicaid provide some degree of insurance for vulnerable populations (Winslow, 2000). However, they also have guidelines and restrictions that may impact the degree to which individuals in these programs are able to implement self-management practices. For instance, insulin, a nonprescription drug, is reimbursed only while diabetics under Medicare are hospitalized, and it may, or may not, be reimbursed under private insurance policies. A study of Medicaid recipients suggests that some of these policy restrictions may actually be detrimental. Schoen et al. (1997) reported that Medicaid beneficiaries were more likely than uninsured, or privately insured, to have health problems. This may be explained by the additional finding that only half of the uninsured were "poor" (i.e. incomes up to 100% of the federal poverty level) in comparison to 71% of the Medicaid participants.

Reimbursement restrictions may also impact the health of Medicare recipients. In 1998 Medicare began reimbursing for glucose testing strips for persons with Type 2 diabetes, but placed a monthly cap on the number of strips. This limits the number of glucose tests one may be able to perform in a month. Insured persons with diabetes also face restrictions on reimbursement. Diabetics enrolled in a health maintenance organization (HMO) have a nominal co-payment for medications and syringes; however, home glucose monitoring supplies are reimbursed only if the employer contracted with the HMO to cover them (Geffner, 1992).

The above discussed reimbursement policies determine the degree to which one may be able to monitor one's serum glucose levels, a practice that is essential to the prevention of complications (ADA, 2000e). Peyrot and Rubin (1994) studied 82 adults at six and twelve months after an outpatient diabetes education program. They found that increased monitoring of blood glucose significantly improved mean blood glucose levels.

Although more frequent monitoring improves blood glucose control, other researchers have identified that cost impacts glucose testing. Jones, Remley and Engberg, (1996) surveyed 74 diabetics about glucose testing practices and found cost to be one of the most common barriers. However, one cannot achieve normal glucose levels without routine glucose monitoring, a skill performed by only 40% of Type 1 diabetics and 26% of Type 2 diabetics (Harris, Cowie & Howie, 1993). Therefore, insurance reimbursement policies present a major barrier to self-management practices.

Cost of supplies and self-management classes is closely related to inadequate insurance coverage. Diabetic supplies and medications are expensive. According to Rathmann (1998), the annual per capita pharmaceutical expenses for persons with diabetes are $1,056, compared to $201 for nondiabetics. Although most of the 208 subjects in a study by Ary, Toobert, Wilson and Glasgow (1986) reported taking their diabetic medication, 10% of those who did not take their medication as directed identified inadequate financial resources as the reason. Cost is a greater barrier to low-income diabetics since they must spend a greater percentage of their income on prescriptions and supplies (e.g. insulin syringes, glucose testing strips). The ADA (2000e) recommends that persons with Type 1 diabetes test their blood glucose three to four times a day, and Type 2 diabetics test frequently enough to achieve treatment goals. However, the cost of blood glucose testing strips has been identified in several studies as a barrier to performing this self-management practice (Goldstein & Little, 1997; Jones et al., 1996; Tu & Morrison, 1996).

An early study by Harris et al. (1993) found that the majority of persons with diabetes did not routinely test their blood glucose. However, the likelihood of routine testing increased if patients were college educated, made frequent physician visits, and had participated in a diabetes management class. Contrary to other findings, health insurance and income did not affect one's practice of routine blood glucose testing.

Cost of classes, which is closely related to inadequate health insurance coverage, is one factor that affects participation in diabetes education classes. Sixty-seven percent of the 640,000 diabetics without health insurance have not participated in diabetes education classes (Harris, 1995). According to Nordberg et al. (1993), lack of health insurance is related to low income and less than a high school education. Therefore, a plausible explanation for uninsured diabetics to not participate in diabetes self-management education is the out-of-pocket cost for the classes and/or self-management supplies.

According to Tobin (1993), the average charge for diabetes education is $42.57/hour for individual sessions and $1 to $900 per program for group sessions. Seventy-two percent of third party payers reimburse, all or a portion of the cost, for both individual and group education sessions if they are provided outpatient. However, as an out of pocket expense, this may be an unaffordable luxury for individuals with limited financial resources. The working poor often do not qualify for public assistance and rely on community agencies to meet some of their health care needs. Programs specific to at-risk diabetics could be funded either through state or private monies through established providers or offered free if subsidized with grant funding.

Nordberg et al. (1993) studied 158 indigent diabetics with an average household income of $5,000-14,000/year over thirteen months. Those with no third party reimbursement had a worsening of HbA1c from the beginning to the end of the study. They concluded that innovative programs for this population may prevent the development of complications.

In summary, although most diabetics are covered by health insurance, reimbursement of supplies (insulin, syringes, glucometers) and services (patient education) is policy dependent. Since prevention of complications is cost effective, local, state and federal governments must develop programs that ensure all persons with diabetes have the necessary supplies and equipment to adequately self-manage their disease. Developing effective community programs eliminates another barrier identified by Glasgow, lack of community support.

Cooperative community efforts to improve diabetes care have demonstrated remarkable improvements in overall health status. In Michigan, local heath care providers (hospitals, health departments, and home health agencies) implemented a comprehensive program to improve the quality of diabetes care and education. The program participants experienced a 45% decrease in hospitalizations, 31% decrease in lower extremity amputations, and 27% lower death rate than non-participants. As a result, the program was implemented state-wide (Centers for Disease Control and Prevention Division of

Diabetes Translation, 1996). Mazzuca, Farris, Mendenhall and Stoupa (1997) also reported positive results with a community nursing intervention for diabetics. Self-care behaviors improved significantly in the 22 participants who participated in the experimental home visit program.

Community support can also be demonstrated by attention to the cultural differences in different communities that may act as barriers to implementation of self-management practices. That is, communities that recognize the unique needs of their members and address them, eliminate some of the barriers to improved health. For instance, Hispanics view work as taking precedence over clinic visits and self-management classes (Engel, Shamoon, Basch, Zonszein & Wylie-Rosett, 1995). Allowing flexibility in scheduling may increase participation in this population. Health programs that are sensitive to cultural differences and provide materials that take into account language, literacy skills, and ethnic food preferences, are more likely to increase participation of minority populations than those programs that ignore these differences (Mayeaux et al., 1996). For instance, a culturally specific video was preferred over a traditional video by a group of black women attending a diabetes education focus group (Maillett, Melkus & Spollett, 1996). The women felt they could relate better to the main character because she was of the same ethnic group.

The last community and social context factor listed by Glasgow (1995) is family support which, according to Fisher et al. (1998), has received little attention. Since a diagnosis of diabetes involves changes in one's lifestyle, it seems only logical that researchers would be interested in the family's role in diabetes self-management.

Treatments that are long term and require continuous intervention are reinforced with social support or support by significant others (Burke & Dunbar-Jacob, 1995; Garay-Sevilla et al., 1995). Social support increased appointment keeping in low-income chronically ill Blacks (Uzoma & Feldman, 1989), and was a modest predictor of adherence to self-care behaviors in another study by Tillotson and Smith (1996). Wikblad, Leskell and Wibell (1996) found that patients living with a partner had a lower mean A1c than those living alone. Ford, Tilley and McDonald (1998) reviewed six studies that examined the effects of social support on black adults with diabetes. They concluded that social support positively impacted self-management practices but was not necessarily accompanied by increased glucose control.

The above studies support the role of social support in facilitating diabetes self-management practices and although it is an important component of diabetic compliance and improved health outcomes (Kaplan & Hartwell, 1987), attendance at diabetes education classes does not appear to be related to social support. Coonrod et al. (1994) found that Type 1 diabetics who lived alone were 80% more likely to have had diabetes education than diabetics who lived with a spouse, other relatives, or nonrelatives.

In summary, government policies and community and social support influence one's participation in diabetes self-management practices. However, patient characteristics also play an important role.

Patient Characteristics

Patient characteristics include demographic factors, such as age, race, level of income and years of schooling; medical history; severity of the disease; patient knowledge of the disease; and the patient's beliefs and expectations (Glasgow, 1995). Irvine and Mitchell (1992) compared attenders with nonattenders in a community diabetes education program and reported that nonattenders had fewer financial resources and more obstacles to self-care than attenders. Discriminant analysis revealed a significant difference between the attenders and nonattenders. Nonattenders were younger, in poorer health, less educated, had lower incomes, had diabetes twice as long, and reported more barriers to self-care.

Contrary to Irvine and Mitchell's findings, Glasgow, Toobert and Hampson (1991) found that older respondents were least likely to participate in self-management classes, and education level was not a predictor of participation. Findings from other studies indicate that diabetics least likely to have participated in a diabetes education were Type 2, less educated, uninsured, and had yearly incomes under $10,000 (Coonrod et al., 1994; Harris et al., 1994). Overall, most sociodemographic variables are not predicators of participation in diabetes education programs. However, based on the studies reviewed, diabetics with lower incomes and less education were less likely to participate than diabetics in higher socioeconomic groups with more education.

The relationship between psychosocial variables and patient survival in 343 Type 2 diabetics was investigated by Davis, Hess and Hiss (1988). Three categories of predictor variables were studied: demographic and clinical (e.g. age, duration of diabetes, glycosylated hemoglobin, number of hospital admissions), psychosocial (e.g. social impact, barriers to adherence), and categorical (e.g. gender, smoker, use of insulin). Data on the predictor variables was collected, and four years later information on the same predictor variables was collected along with data on the patient's current condition. If the patient was deceased, information was collected from the death certificate and medical records. Surprisingly, the researchers found HbA1c was not predictive of mortality, causing the researchers to question the role of HbA1c as a reliable outcome measure for intervention studies. However, the social impact subscale, which measured the effects of diabetes on activity and social interactions, was related to mortality. They suggest that including interventions that lessen the social impact of diabetes, may decrease mortality. One limitation of the study was the possibility that the sickest patients or the patients with more complications may have been the ones who reported the greatest social impact when data was first collected. Based on these findings, they concluded that self-management programs that include information about eating out, traveling, and how to continue with usual activities may be more valuable than interventions to tightly control blood sugar.

An important component of diabetes self-management is knowledge about the disease, therefore, personal beliefs and attitudes about diabetes may interfere with, or deter self-management practices or participation in self-management classes. No studies were located that investigated the effect of attitudes, or patient expectations, on participation in diabetes education. However, numerous studies have investigated the effect of attitudes on compliance with diabetes self-management.

Anderson et al., (1993) categorized 1202 diabetics as "low adherence" or "high adherence" based on their responses to a questionnaire about self-care practices. The two groups were then administered the "Diabetes Attitude Scale" to assess attitudes about diabetes and its treatment. Although both groups recognized that diabetes had a negative impact on their lives, diabetics with higher levels of adherence had a more positive attitude toward diabetes. The "high adherence" group had attitudes that recognized the relationship between glucose levels and development of complications, had a better overall understanding of diabetes, and they were in better health. This study suggests that a better understanding of diabetes may lead to a more positive outlook and better self-care practices. Other studies, however, report somewhat different results.

Boyer et al., (1996) compared patient and physician perceptions of diabetes-specific health beliefs and the patient's adherence to self-care practices. Using Likert scales, the patients' and physicians' perceptions were evaluated in four dimensions: severity of the disease, cost or inconvenience of self-care, expected immediate benefits of adherence, and expected long-term benefits. The degree of discordance was calculated, and then compared to the subject's level of adherence and the glycosylated hemoglobin level. In this study, adherence did not correlate with glycemic control. Patients believed their condition was less severe, and that adherence was less costly and more beneficial than their physicians believed. This study suggests that a better understanding of diabetes may be counterproductive to self-management practices.

Lack of knowledge about the availability of diabetes self-management education programs is an obvious barrier to participation. Clark (1998) discusses efforts by the "National Diabetes Education Program" to increase awareness of education activities that include media barrage and resources appropriate for the target audience. Health care providers that encourage participation and provide information about cost and times increase the likelihood that diabetics will attend. However, using traditional methods of advertising may not reach certain populations (Mayeau et al., 1996).

Clinic and Program Characteristics

The last group of factors that affect one's level of readiness to participate in diabetes education and diabetes self-management practices are the clinic and program characteristics. Clinic and program characteristics are factors related to the health care provider and include things such as cost, which was previously discussed; program title; distance; accessibility or availability; and provider and consumer relations.

Title. One factor, not addressed in the literature, that may act as a barrier to participation is the title of the program. Health care professionals frequently use the word "education" or "classes" when advertising or soliciting class participants. Because individuals in lower socioeconomic groups are often not well educated, these words may arouse negative feelings such as fear of failure, anxiety that their poor reading and writing skills may be tested by a better educated health care professional, and embarrassment about their lack of formal education (Mayeaux et al., 1996). Although there is no research to support this, these negative associations may prevent them from participating in classes and educational offerings on diabetes self-management. Additionally, many have learned to survive without much formal education, leading them to believe that this situation is no different from any others they have encountered over the years. This may be reinforced by the absence of any long-term complications, giving them a false impression that their method of management is adequate.

Distance. Distance and/or transportation to the clinic is another factor that affects participation in diabetes education. Coonrod et al. (1994) reported that diabetics living in a metropolitan area were 43% more likely to have had a diabetes education class than those who lived outside the metropolitan area. Glasgow et al. (1991) experienced difficulty recruiting participants for an education program for diabetics over 60. They investigated the differences between the attenders and nonattenders and found 13% of the nonattenders cited traveling distance as a factor for nonparticipation. Hahn (1996) reported that attendance at diabetes education classes for a low-income, at-risk population increased when the classes were moved to community centers in low-income neighborhoods and participants were offered free transportation. These findings are not surprising since many low-income individuals have unreliable transportation or rely on others to take them places. In fact, Hitchcock, Larme and Meyer (1998) reported that 16% of patients enrolled in a diabetes education class who did not complete the program cited transportation as the main reason. Offering incentives such as taxi fare or bus tokens to at-risk individuals may increase attendance at diabetes education classes in low-income populations. However, even if transportation is available, the classes must also be available and accessible.

Availability/accessibility. The availability and accessibility of classes also impacts participation in diabetes education. Although most clinics, hospitals, and HMO's provide free classes for their patients, persons without insurance are not likely to have a regular health care provider (Hahn & Flood, 1995). Therefore, access to free classes is limited for the uninsured.

Class attendance may be improved by scheduling classes in a building that is easy to access, since the majority of diabetics are elderly. The accessibility barrier may also be minimized by scheduling classes during the day so individuals can attend class after a clinic or lab appointment, and by offering classes that participants are able to schedule individually if group sessions are inconvenient. Some populations may also view free babysitting during class times as an incentive to participate (Hahn, 1996).

Time. According to Melynk (1988), time is a barrier for the poor who use clinics, but not for those with private physicians. There is no evidence to support or refute this in relation to diabetes education classes. However, time was the most frequently cited obstacle to attendance at diabetes education classes in a study of diabetics over 60 years of age (Glasgow et al., 1991). When considering time in respect to the time of day that classes are offered, it may be a barrier that is population dependent. A study by Hitchcock et al., (1998) found that 19% of participants who did not complete the diabetes education program cited inability to leave work as the major obstacle. Diabetics who work during the day may prefer a single all day seminar on the weekend or classes in the evening. However, older, retired individuals may prefer weekly daytime sessions.

Provider/consumer relations. Provider/consumer relations' barriers are described by Melynk (1988) as barriers that the provider presents, such as lack of interest or expertise. Lack of provider empathy was cited as a barrier to diabetes health care in a small sample of black women participating in a focus group (Maillet et al., 1996). A health care provider's lack of interest may be related to his/her lack of expertise in the management of diabetes.

Lack of expertise in the area of diabetes management, and lack of expertise in presenting information may also affect class participation. Poorly educated populations may become discouraged if oral and written information is difficult to understand, or the educator does not present information in a format that easily understood. According to Siminerio and Frith (1993), 87% of the written and oral instruction to diabetics is provided at the ninth grade level or above, yet 20% of the adult population reads at the fifth grade level or below (Fain, 1991). Because people with diabetes have lower literacy skills than the population as a whole (Siminerio & Frith, 1993), educators must carefully evaluate materials to be sure they are appropriate for the population. By individualizing content and materials to each population and providing more hands on learning, provider/consumer relations can be strengthened. It is highly plausible that the high attrition rates are because information and materials are above the participant's level of comprehension.

In summary, diabetes is a costly disease that leads to long- and short-term complications if not properly managed. Despite the recognized benefit of diabetes self-management education, the majority of persons with diabetes have not participated in diabetes self-management classes. Numerous factors have been identified as barriers to participation in diabetes education classes. Implementing programs that ignore or fail to identify barriers that are likely to impact the population of interest, may be one factor affecting poor participation. Glasgow's model of diabetes depicts numerous factors that can act as barriers to the uninsured or underinsured. Attention to these barriers in the program planning stages should improve attendance and decrease attrition rates.

Summary

Diabetes is the most prevalent chronic condition in the United States (Javitt & Chiang, 1995), and accounts for 12% of the nation's total health care expenditures (Herman et al., 1997). It crosses all ages and ethnic groups and leads to considerable morbidity and mortality. Authorities agree that both microvascular and macrovascular complications can be prevented or delayed by maintaining normal serum glucose levels (Laasko, 1996; Ohkubo et al., 1995; The DCCT Research Group, 1996), a critical component of diabetes self-management. Despite this unchallenged evidence, the majority of diabetics have not been educated to self-manage their disease (Coonrod et al., 1994), and less than 40% of Type 1 and Type 2 diabetics routinely monitor their serum glucose (Harris et al., 1993).

Diabetes education is an integral component of diabetes management (ADA, 2000a) and most researchers agree that it improves health outcomes of persons with diabetes (Brown, 1988; Brown, 1990; Goodall & Hall, 1991; Padgett et al., 1988). Knowledge generally improves with self-management education (Anderson et al., 1994; Brown, 1990; Padgett et al., 1988); however, this may or may not translate into better metabolic control. Although a meta-analysis by Brown (1990) found education improved metabolic control, other researchers did not find this to be the case (Bloomgarden et al., 1987; Goodall & Hall, 1991). This discrepancy in findings has led to considerable disagreement as to which health outcome is indicative of good self-management practices.

Overall, researchers agree that diabetes education is beneficial, therefore, researchers have attempted to identify those factors that act as barriers to participation. Glasgow (1995) developed a model of diabetes management and education and Level I of the model depicts factors that result in "personal readiness" to participate in diabetes self-management education. These factors have been identified in the literature as barriers and include: low income (Goldstein & Little, 1997; Monheit, 1994; Rathmann, 1998; Songer et al., 1997; Tu & Morrison, 1996), lack of health insurance (Nordberg et al., 1993), government policies (Schoen et al., 1997), community support and family support (Garay-Sevilla et al., 1995; Kaplan & Hartwell, 1987), patient characteristics (Coonrod et al., 1994; Davis et al., 1988; Irvine & Mitchell, 1992), and clinic characteristics (Coonrod et al., 1994; Glasgow et al., 1991). Identifying and addressing barriers for the population of interest should enhance participation in diabetes self-management education.

Diabetes is a costly disease, and it is costly to manage (Rathmann, 1998; Songer et al., 1997), therefore, low income is a barrier in some populations. Low-income adults with diabetes who are uninsured or underinsured are at greater risk for poor health outcomes (Bodenheimer, 1992). They have higher glycosylated hemoglobin levels than insured diabetics (Nordberg et al., 1993), they do not routinely monitor their blood glucose (Tu & Morrison, 1996), and 67% have not participated in a diabetes self-management class (Harris, 1995). Developing programs that facilitate diabetes self-management in this population will accomplish two things. First, it will minimize the financial barrier to improved health, and second, it will move the nation closer to reaching two of the Healthy People 2010 goals for diabetes. These goals are: a) 60% of persons with diabetes will have participated in a diabetes self-management program, and b) a decrease in the diabetic mortality rate.

CHAPTER III

PROCEDURE FOR COLLECTION AND TREATMENT OF DATA

This chapter contains a discussion of the research methods used in the study. A description of the design, setting, population and sample, protection of human subjects, instruments, data collection plan, and data treatment is presented and discussed.

The study was a quasi-experimental, one-group, pretest-posttest design (see Figure 3) that utilized a convenience sample of persons with diabetes. According to Spector (1981), this type of design is commonly used when one is attempting to draw conclusions about the effectiveness of a particular program when control or comparison groups are unavailable. With this design subjects serve as their own controls, and measurements of the dependent variable are taken before and after the treatment or intervention.

Figure 3. One group pretest-posttest design.

Initial meeting	**2wk**	**4wk**	**6wk**	**10wk**
0_1X_1	X_2	X_3	X_4	X_50_2

In this study, the participants' serum fructosamine levels and diabetes self-management skills were the two dependent variables. Serum fructosamine was used to measure blood glucose control. Serum fructosamine and self-management skills were measured before the treatment and at the conclusion of the treatment. Although more frequent measures of serum fructosamine would have been ideal, cost restrictions made this impossible. The treatment, or independent variable, was the diabetes supply and self-management education program that occurred over a ten to twelve week time frame.

Although the design is simple, one must keep in mind that it does have several limitations that are discussed by Spector (1981). First, one cannot be sure that events or factors other than the treatment did not affect the outcome. This was minimized by following participants over a relatively short time frame of ten to twelve weeks. However, this short time frame made it impossible to draw conclusions about the long-term effects of the intervention. A second limitation is the Hawthorne effect. Since there was no comparison group it is difficult to separate the effects of the treatment from the effects of knowing that one is in a study. For instance, participants may have been particularly attentive to diabetes self-management because they were aware they were being monitored. Lastly, the pretest may have cued the participants to what the researcher was expecting to find, and this may have affected their responses on the posttest. Despite the limitations, it would have been difficult to obtain a comparison group, therefore, this was an appropriate design for evaluating the effects of the intervention.

Setting

The setting was a nonprofit, community agency in a large southern metropolitan area. The agency is centrally located on a city bus route and is handicap accessible. The two main sources of funding for the agency are United Way and private donations. The agency has numerous offices and conference rooms. A small office in the clinic was utilized for the education sessions and fructosamine measurements.

The agency provides a variety of social and health services to individuals in need, providing they meet the income guidelines. One component of the agency is the health clinic, staffed mainly by volunteer nurses and physicians. The clinic offers several services including free adult and pediatric clinics, assistance with medications for chronic diseases, free eye exams by a volunteer optometrist, free group diabetes education, and a program that provides yearly assistance with diabetic supplies (e.g. syringes, glucose testing strips). Two other programs, free mammograms, and monetary assistance with AIDS medications, have strict eligibility criteria and are funded with government grants. The majority of those seeking assistance at the clinic are either uninsured or underinsured.

Participants in the diabetes supply program are referred by word of mouth, home health nurses, and local hospitals and clinics. When initially undertaken several years ago, the diabetic supply program was able to provide emergency assistance with insulin and supplies, to indigent diabetics, four times a year. Lack of funding, combined with increased demand, forced the agency to gradually decrease assistance to once a year. At the present time, the agency assists approximately 30 to 35 persons with diabetes each month. Insulin and supplies are distributed during the daytime and prior to distribution participants must have a physician prescription and patient information form on file. Once a month the agency also offers a one hour group diabetes information class. The group classes are in the evening and each insulin-dependent diabetic receives a free bottle of insulin at the conclusion of the program. The group sessions are not well attended despite the incentive to attend. This may be attributed to the unavailability of public transportation in the evening.

Population and Sample

The target population of this study was low-income adult persons with diabetes who were eligible for assistance from the above described agency. Eligibility guidelines for agency assistance include being a resident of the county, and earning no more than 150% of the federal poverty guidelines (see Appendix A).

The age, race, and gender of individuals seeking assistance through the diabetes program at the agency from January 1, 2000 through April 30, 2000 was analyzed to determine characteristics of the population. The agency does not collect data on living arrangement, education level, diabetes type, or years since diagnosis. The mean and median age of the agency diabetic population (N = 121) was 48 and the mode was 51. Additionally, 82 (64%) were female and 47 (36%) were male. Gender was also similar to the study participants with 72 (60%) white, 43 (36%) Black/African-American, and 6 (4%) American Indian or Hispanic. The majority also used insulin (Hansen, Smith, Morris, 2000). A convenience sample of 25 diabetics from the described population participated in the study. However, only 20 completed the study.

Convenience sampling is a form of nonprobability sampling. According to Kerlinger (1986), this is the weakest form of sampling, but it is also the most frequently used. This method of sampling was selected after weighing the cost and time involved in obtaining a probability sample. However, the researcher kept in mind that it limited the generalizability of the study's findings. Although every effort was made to seek participants from outside the agency who met the agency and researcher's inclusion criteria, the majority of the participants enrolled after seeking assistance at the agency.

Assuming the research hypothesis is true, it is important to know what sample size is sufficient to provide a reasonable chance of it being proven correct (Kraemer & Thiemann, 1987). Therefore, a power analysis was used to determine the optimal sample size. Power analysis is important in the planning stages of a study because any study presents the risk of a Type 1 or Type 2 error. An a priori power analysis ensures that resources are used efficiently, while at the same time ensuring that the sample is sufficient to obtain meaningful data (Burns, 2000).

Based on a .05 alpha level of significance, medium effect size, and a power of .70, the Kraemer and Thiemann (1987) master table suggests a sample size of twenty-two. This is comparable to the twenty subjects suggested by Cohen's tables (1977). Calculating the number of subjects was also done in consultation with a statistician, (V. Dennenberg, personal communication, October 28, 1999) and will be discussed in the following paragraphs.

The first component of a power analysis is the alpha level of significance which controls the probability of committing a Type 1 error. The smaller the alpha, the harder it is to find statistical significance (Burns, 2000). Type 1 errors occur when the researcher rejects the null hypothesis when the null is actually true; that is, the researcher concludes that there is a difference when there is not. The alpha level of significance in this study was set at .05 (one-tailed). This meant the researcher would have a 5% chance of finding a significant difference in the predicted direction when there was no difference. Although the number is arbitrary, a .05 level of significance is commonly used (Polit, 1996), especially when the risk of error is not life threatening. The decision to use a one-tailed level of significance was based on the literature review that clearly demonstrated similar programs, in other populations, were effective.

The next component of a power analysis is effect size (ES) which according to Cohen (1977), is the degree to which a phenomenon is present or the "degree to which the null hypothesis is false" (p. 10) and is some nonzero value between zero and one. According to Kraemer and Thiemann (1988) an effect size of zero means the researcher's theory is false, where as an ES of 1.0 is an "open and shut case." Cohen (1977) standardized effect sizes in standard deviation units as small (.2), medium (.5), and large (.8). The effect size, determined by the researcher, was based on review of the literature and knowledge of the phenomenon.

A medium effect size, according to Cohen, is one large enough to be visible to the naked eye and the smaller the ES, the larger the sample size needed to find differences. Brown (1988) conducted a meta-analysis of the effects of diabetic patient education on knowledge, self-care behaviors and metabolic control. Based on 47 studies, she concluded that diabetic patient education had a moderate effect on both self-care behaviors and metabolic control. The overall, unweighted mean ES across all studies was estimated at .91. However, after adjusting the ES for differences in sample size and effect size variances, the ES was reduced to a more conservative .33. The estimated effect size for studies using glycosylated hemoglobin as an indicator of metabolic control ($\underline{N}$ = 13) was .84. The overall mean ES for one-group, pretest-posttest design studies was .53 ($\underline{N}$ = 20). In 1990, Brown repeated the meta-analysis with 82 studies and found similar results. Brown used insulin injection skill and urine testing to estimate ES for skills, two skills not measured in the present study. Therefore, the ES calculated by Padgett et al. (1988) was evaluated. Padgett et al., (1988) analyzed 22 studies employing "enhanced education" and estimated an ES of .52. They defined "enhanced education" as including self-monitoring training with "behavioral emphasis" and "using a combination of techniques" (p. 1010). Based on the above effect size estimates, the researcher estimated a medium ES of .70 for this study.

The last component of an a priori power analysis to determine the number of subjects is power. Power is the probability of finding a significant difference or relationship, if one exists. In other words, it is the probability of correctly rejecting the null hypothesis. In contrast, the probability of making a Type 2 error, in which the researcher accepts a false null hypothesis, is 1-power. According to Kraemer and Thiemann (1987) power should be in the .70-.90 range which gives the researcher a 70-90% probability that the finding is not due to chance. This provides the rationale for setting power at .70.

Based on the above discussion of power analysis, it was determined that a minimum of twenty participants was needed. Over sampling to ensure that the final sample was at least twenty, resulted in a convenience sample of 25 persons with diabetes. Twenty participants were Type 2 diabetics and five participants were Type 1 diabetics.

Four Type 2 participants and one Type 1 participant did not complete the study which resulted in a final sample of twenty. This resulted in a 20% attrition rate which is considerably less than the 40% rate reported by researchers (Funnell & Haas, 1995). Two participants did not return after the first session, two did not return for the final session, and one participant was hospitalized for a foot infection after the third session.

Participants were required to give written consent, be over 18 years of age, not pregnant, earn no more than 1.5 times the 1998 federal poverty guidelines, and have fructosamine levels greater than 310 μmol/liter. Additionally, they had to be uninsured or have insurance that did not reimburse for insulin or diabetic supplies. Participants who did not read and understand English were also excluded because the researcher did not speak a foreign language.

It should be noted that 15 diabetics who volunteered to participate in the study did not have fructosamine levels greater than 310 μmol/liter when tested at the initial session. It was decided by the researcher to provide this group education and supplies, however they were not included in the data analysis. Seven of the 15 completed the program and one individual in this group notified the researcher after completing the program that he had been taken off insulin and placed on oral medication. Four of the eight participants with normal fructosamine levels did not return after the first session and four attended all but the final session.

Letters outlining the inclusion criteria of the study were sent to diabetes educators at the local hospitals, the internal medicine department of the two local medical schools, and indigent clinics in the metropolitan area. Information sheets outlining some of the inclusion criteria (e.g. insurance status, income guidelines) and the researcher's phone number were also available at the desk where diabetes supplies are distributed. Additionally, flyers were posted in the agency's clinic waiting room. Although participants were not solicited from the city/county jail, three recently released males indicated that they had received information about the study from the nurse at the jail. Two of the three referrals from this source completed the study.

Protection of Human Subjects

Permission to conduct the study was obtained from the researcher's Dissertation Committee in December of 1998 (see Appendix B). The Graduate School and Human Subjects Review Committee at Texas Woman's University (TWU) approved the study in early 1999 (see Appendices C, D). Protection of human subjects was addressed with the agency consent form, explanation of the study, and subject consent.

The agency consent form was completed and signed in triplicate by the director in November of 1998 (see Appendix E). One copy of the consent form was filed with the TWU Human Subjects Review Committee, one copy was kept by the researcher, and one copy was kept by the agency director. The researcher was required to follow agency protocol before distributing insulin. Although insulin is over-the-counter, participants were required to present a physician prescription for insulin at or before the second session.

A verbal explanation of the study was presented to persons expressing an interest in participating and who met the income eligibility requirements for participants. This explanation included an overview of the study including the benefits of free diabetes supplies and increased knowledge, an explanation of the sessions with the researcher, and an explanation of the blood glucose record that participant's were expected to keep. The ten to twelve week time frame and serum fructosamine test was also explained. Risks were clearly stated and included pain from the fingerstick and possible emotional distress from the increased knowledge of the disease and its complications. It was emphasized that participation was voluntary and that withdrawal from the study would not affect their eligibility for any of the other agency services.

Procedures by the researcher to maintain confidentiality were also explained and included: only the researcher would have access to the participant files, file information would not be shared with other individuals without written permission from the participant, study results would be reported anonymously, and computer files and hard copies of the data would be destroyed after three years.

Each participant who voluntarily agreed to participate was asked to read and sign the "Subject Consent to Participate in Research" form (see Appendix F). This form was also signed and dated by the researcher. It was then photocopied and the photocopy was given to the participant. The original form was kept by the researcher and subsequently filed with the TWU Office of Research and Grants Administration at the conclusion of the study. This consent form clearly outlined the purpose of the study, that participation was voluntary, and the time commitment involved in participating. It also included an explanation of the data collection forms and individual sessions with the researcher, delineated possible benefits and risks, and provided the researcher's phone number and pager number in the event that the participant needed to reach the researcher between sessions. The form also included the phone number for the TWU Office of Research and Grants Administration in the event of questions or concerns about the research project.

At the conclusion of the study, paper files were moved to the researcher's home office and will be shredded three years after the study's completion. Data stored in the researcher's computer will be kept in a protected file and deleted after three years.

Instruments

There were six instruments used in the study. Four were used to collect demographic data or information about type of insulin . A Likert scale was used to measure diabetes self-management skills; and a small, portable, hand-held instrument (the Duet™ Monitor) was used to measure fructosamine levels.

Demographic Data Collection Forms

The first demographic tool was a revised form of the data collection tool used in an agency survey in 1998. Unclear items were rewritten or deleted, and several additional items were added (see Appendix G). The revised form included items related to previous diabetes education, current blood sugar level, level of education, exercise, and race. It did not include information that was already available on the other two forms utilized by the agency for the supply program.

As per agency protocol, two clinic forms were included for data collection. They were: the "Diabetes Supply Program Patient Information" form and "Physician Prescription" form (see Appendices H, I). The "Diabetes Supply Program Patient Information" form was utilized to verify income and type of insurance. The "Physician Prescription" form was used to verify the type of insulin used by the program participant. It also gives approval or disapproval to switch between insulin brands, since certain brands of insulin may not always be available. It was required to be completed and signed by a physician. Although insulin does not require a prescription and can be purchased over the counter, the physician verification form is agency policy and had to be on file before the second visit.

Two additional instruments were also utilized as they were a required component of the "I'm in Control" diabetes education program (Oklahoma State Department of Health, 1997) which was purchased from the health department for a nominal fee of fifty dollars. They were the "Patient Information Form" and "The Skills Assessment" (see Appendices J, K). The "Patient Information Form" included a short demographic survey, a section to document a brief health assessment, and a section to record the attendance date for each of the four modules. The dates of attendance and pretest-posttest scores of the Skills Assessment were included in the final report to the health department at the conclusion of the program. Permission was obtained from the health department to use initials, instead of names, on the final report to protect the confidentiality of the participants (T. Neese, personal communication, November 4, 1998).

Skills Assessment Instrument

The "Skills Assessment" instrument was used to measure diabetes self-management skills (Oklahoma State Department of Health, 1997). Developers of the "I'm in Control" program request that program users have participants complete this instrument as a pretest and posttest. It includes 11 items and two optional items that are scored from 1 (not at all) to 5 (completely). The optional items were not utilized in the study. The score for each item is added together for a total score ranging from 11 (answering 1 to all items) to 55 (answering 5 to all items). The total score can then be divided by the total number of items to obtain an average pretest score. No validity or reliability scores were available from the health department for the skills assessment instrument which presented a challenge to the researcher.

Although Pedhazur and Schmelkin (1991) state that content validity is not a type of validity, other authorities disagree (Carmines & Zeller, 1990; Nunnally & Bernstein, 1994). Nunnally and Bernstein (1994) believe that establishing content validity is primarily determined by the researcher based on "appeal of propriety of content and the way it is presented" (p. 103). The instrument was reviewed by the researcher and a diabetes educator prior to the study and determined to have content validity because each question addressed an important component of diabetes self-management.

Fructosamine Measure

Fructosamine is a serum glycated protein which is a protein with glucose attached. It can be objectively measured with the GlucoProtein Test ™ using a small, hand-held meter called The Duet™ Monitor (LXN Corp). This meter uses a sample of capillary blood from a fingerstick and was approved for clinical use in December of 1997 by the U.S. Food and Drug Administration (FDA). It has been given "waived" test status under the Clinical Laboratory and Improvement Act (CLIA) which means that it can be used in clinics, by health care professionals with no formal laboratory training. Because of it's recent FDA approval, The Duet™ Monitor (LXN Corp) has not been used in any reported studies to measure fructosamine levels, however, prototypes of the monitor have been used for several years. Earlier studies have supported fructosamine as a valid measure of glucose control (Baker, Johnson & Scott, 1984; Baker, Metcalf, Johnson, Newman & Reitz, 1985; Baker, O'Conner, Metcalf, Lawson & Johnson, 1983; Johnson, Metcalf & Baker, 1982), and the ADA recently recognized fructosamine as an appropriate measure of glycemic status over the preceding two to three weeks (ADA, 2000e).

The Duet™ Monitor (LXN Corp) performs a GlucoProtein™ Test to measure the amount of glucose attached to albumin, a protein with a half-life of approximately two to three weeks. According to the developers of the instrument, LXN Corporation (1998), when glucose attaches to blood proteins (albumin), it forms fructosamine. The glycated proteins can reduce dyes, under alkaline conditions, to form a colored substance called formazan. The rate of formation of formazan (purple color on the test strip) is directly proportional to the concentration of fructosamine in the blood sample. The monitor measures the amount of purple color on the strip and converts it to a fructosamine concentration number that is displayed on the monitor in four minutes. Because it measures the amount of color on a strip, it is sometimes referred to as a colorimeter assay meter (Johnson et al., 1982).

An information packet provided by the instrument developers included reports of three clinical studies conducted during the development of the meter (LXN, 1998). In the first study, researchers asked three hundred and one patients to perform two fingersticks. One sample of capillary blood was tested in the meter by the patient, and one was tested in the meter by a trained laboratory technician. These results were then compared to a clinical laboratory test that used a venipuncture sample of blood (Roche ROTAG™) fructosamine). There was a high correlation between the participant and laboratory technician (r =.867). Correlations were slightly lower when the venipuncture sample was compared to the capillary sample (r = .771 for the professional and the clinical laboratory test; r = .75 for the participant and the clinical laboratory test).

The second study by Redmon, Bell-Farrow, Wang, McBride and Cefalu (1997) reported similar results when a prototype of the meter was evaluated in a crossectional study that included both diabetic and control subjects (n = 51). Redmon et al. reported significant correlations between the fructosamine results obtained on the meter and laboratory fructosamine results (r = .80, p<.001). This study also found a significant correlation between fructosamime and A1c results (r =.81, p<.001).

The high correlations in the Redmon et al. study (1997) were not found by Norwegian researchers who conducted a similar study. Furseth, Bruusgaard, Rutle and Vaaler (1994) investigated the correlation between blood glucose, fructosamine, and A1c in 87 Type 2 diabetics and reported the following correlations: blood glucose/fructosamine correlations, $\underline{r} = .45$, HbA1c/blood glucose, $\underline{r} = .64$, and HbA1c/fructosamine, $\underline{r} = .39$. Because the blood samples were analyzed in two different clinical laboratories, and the type of analyzer is not mentioned, one must view these findings with caution. Other earlier studies support the colorimetric method as a valid and reliable method for evaluating fructosamine (Cefalu, Ettinger, Bell-Farrow & Rushing, 1993; Johnson et al., 1982).

The third study, provided by developers of the meter, was also by Redmon et al. (1997). In this study, the researchers used a prototype of the Duet™ meter to test it's accuracy in monitoring short-term changes in blood glucose. Fructosamine was evaluated weekly in twenty, Type 2 diabetics for a period of six weeks. Patients were given mono or combination blood sugar lowering agents, and by the end of week six fasting glucose levels had dropped significantly. The researchers reported that fasting glucose was significantly correlated with the fingerstick fructosamine (weekly correlation =.75, $\underline{p} < .001$). The above three studies support the assertion that fingerstick fructosamine testing, on meters comparable to the Duet™, is a reliable and valid measure of glucose control over the past two to three weeks. Additionally, the ADA recently included fructosamine testing as an acceptable measure of glycemic status over the past two weeks (ADA, 2000e).

Data Collection

Pilot Study

Limited funding necessitated a modified pilot test in March of 1999. The modified pilot included the administration of the paper and pencil tests to five volunteer friends and associates of the researcher and testing the Duet™ Monitor on a small number of family members. Those who pilot tested the forms found the Skills Assessment confusing and expressed concern that participants may find it difficult to complete. Based on this information it was decided to read the skills test questions to the participants and circle the correct answer for them. The researcher introduced the skills assessment with a statement that there was no right or wrong answer and that they were to respond based on how they felt they were performing on each item at this point in time. It was also decided to combine the pretest data collection with the first education session since completion of the forms and fructosamine testing took less than fifteen minutes.

The cost of each fructosamine test was approximately eight dollars, which amounted to a considerable portion of the research budget. Because of the researcher's experience collecting blood samples using a capillary tube and testing blood samples with similar instruments, the researcher only piloted the instrument on four family members (two diabetics and two non diabetics). This was done to evaluate ease of use, ease of obtaining samples, and verify length of time for results to appear on the monitor. No difficulties were encountered with the preliminary instrument testing and results were within the expected norms for each individual tested. Official data collection then began in May of 1999 and continued through May of 2000.

The Study Intervention

Interested participants were provided with an explanation of the study either by phone or in person by the researcher. Subjects wanting to participate were then scheduled for the initial one-on-one session with the researcher. At this session, questions were answered and the consent form was explained and signed. The participants then completed the demographic forms; the skills assessment pretest was administered; a fructosamine blood sample was obtained from the left index finger; the logbook for recording daily blood glucose readings, exercise, and medication was explained; and Module I of the "I'm in Control" program was reviewed. At the completion of this session, the diabetic supplies were distributed, and the second meeting was scheduled.

The fructosamine capillary blood sample, analyzed in the first and last session, was obtained by pricking the middle finger of the left hand with a lancet and drawing approximately 25 microliters of blood into a measured sampling straw (LXN Corporation, 1998). Using the sampling straw ensured that the appropriate amount of blood was placed onto the GlucoProtein ™ Test strip. This minimized inaccurate results and eliminated the necessity to retest because of an insufficient amount of blood. The blood was then placed onto the test strip which had been placed in the meter before beginning. All protocols for using the Duet™ meter, outlined in the User's Guide, were followed. Although the manufacturer recommended that the meter be recalibrated at least daily with the calibrating test strip, the machine was recalibrated before each patient. The researcher also followed OSHA guidelines for preventing the transmission of blood borne pathogens.

The second, third, and fourth one-on-one sessions were scheduled approximately two weeks apart over the next six weeks. Occasionally, scheduling conflicts (e.g. researcher out of town, participant out of town, holidays) resulted in appointments that were greater than two weeks apart. However, all participants completed the study in a ten to twelve week time frame.

Each session included a review and discussion of the blood sugars recorded in the logbook, identification and discussion of patient problems and needs, and a review of the information in the module for that session. Each session took approximately 45 minutes to one hour and at the conclusion of each session, the easy to read program materials were placed in a colored binder with the participant's name. Participants were allowed to take the binder home and were asked to bring it to the next session. Since many of the clinic patients did not have a phone, reminder postcards were mailed one week prior to each scheduled meeting.

At the second session participants were given the guidelines for eligibility at the county pharmacy and information to apply for assistance with insulin through a major drug company's indigent drug program. Although not part of the "I'm in Control" program, it was deemed morally and ethically imperative that the participants be made aware of available resources for insulin at the conclusion of the research study. At the third session, as recommended in the "I'm in Control" program, participant's were given a form to complete for a free medic alert bracelet or necklace. The researcher included a self-addressed, stamped envelope for mailing the form.

The fifth and final session was scheduled approximately one month after session four. This session included a review of any content patients had questions about, administration of the skills assessment posttest, and performing a posttest fructosamine test. Results of the skills test and fructosamine test were explained, and then recorded in the patient's colored binder. Participants were also given a final allotment of diabetic supplies.

Self-management issues that were presented and reviewed in the four modules were from the "I'm in Control" diabetes education program (Oklahoma Department of Health, 1997). According to T. Neese, spokesperson for the Oklahoma State Department of Health, this program was developed for presentation of diabetes information in short time frames to low-literacy populations, and the sequence could be adapted to meet patient needs (personal communication, October 28, 1998). This program's philosophy is based on the "empowerment approach to diabetes self-management" (Oklahoma State Department of Health, 1997, Introduction) and is comprised of four modules.

Module I included basic information about diabetes, monitoring one's diabetes control, and setting goals. Module II included basic information on meal planning, activity, and managing stress. Module III reviewed medications. Module IV addressed complications and lifestyle changes that may prevent complications. Following is a time chart and overview of the sessions for this study.

Session 1:	Sign consent, complete demographic forms, administer skills assessment test, provide overview of study, perform fructosamine test on blood, review module I, distribute supplies.
Session 2	Discuss and review logbook, review module II, distribute supplies.
Session 3	Discuss and review logbook, review module III, distribute supplies.
Session 4	Discuss and review logbook, review module IV, distribute supplies.
Session 5	Discuss and review logbook, review material from all four modules, administer posttest skills assessment test, perform fructosamine test on blood sample, explain results and of pretest and posttest scores, distribute supplies.

Treatment of Data

This section discusses the reliability testing conducted on the Skills Assessment measure and descriptive data analysis used to describe the sample. The t test for dependent groups was used to test the two directional hypotheses which predicted a difference in the mean pretest and posttest fructosamine level and Skills Assessment test.

Reliability Testing

Coefficient alphas were computed for the skills assessment instrument. This is a measure of the internal consistency of the instrument and is based on the average correlation of items within a test (Nunnally & Bernstein, 1994). Items that correlate highly indicate measurement of a common attribute or concept. According to Nunnally and Bernstein (1994) one hopes for an alpha of .70, which is considered an acceptable estimate of reliability. Alpha coefficients of .80 or .90 provide estimates of internal consistency, however, alpha coefficients may be lower on new instruments. Tests with very low alphas may be comprised of items that have little in common or the result of an instrument that is too short.

Demographic Data

The sample is described by gender, age, ethnicity, living arrangement, income, and education level. It is further described as to the type of diabetes, years since diagnosis, and participation in previous diabetes education sessions. A description of the sample in both narrative and table format provides frequencies, percents, and measures of central tendency for demographic variables, as appropriate. Summary tables are often used to succinctly present information on the background characteristics of the sample (Polit, 1996). Summary tables provide the reader with concise information about the sample in an easy to read format.

Data Analysis of Hypothesis One

Hypothesis # 1: At-risk persons with diabetes will have lower mean glucose levels following participation in a diabetes supply and diabetes self-management education program. A t test for dependent groups is used to compare the means of two related groups or sets of scores (Polit, 1996). This statistical test was used to compare the means of the pretest and posttest fructosamine levels obtained at the first and last session.

According to Spector (1991) the dependent t test is the appropriate statistical test for a one-group, pretest-posttest design.

Data Analysis of Hypothesis Two

Hypothesis #2: At-risk persons with diabetes will have improved self-management skills following participation in a diabetes supply and diabetes self-management education program. As described above, a t test for dependent groups was used to compare the mean scores of the pretest and posttest skills assessment that was administered during the first and last session.

In summary, this was a quasi-experimental, one-group, pretest-posttest design study conducted at a nonprofit, community agency in a large southern metropolitan area. The target population was low-income adult diabetics. A convenience sample of 25 participants were enrolled in the study, and 20 completed the study.

Data were collected with four demographic forms, one Skills Assessment measure, and one instrument to measure serum fructosamine which were tested in a modified pilot study. The five individual one-on-one education sessions were conducted over a 10 to 12 week time frame. Diabetes self-management skills and serum fructosamine was measured at the first and last session. One-on-one diabetes education sessions were scheduled every two weeks for four sessions and a fifth session was held one month after the fourth session. Reliability estimates on the untested Skills Assessment measure were calculated and a dependent t test was used to test the two hypotheses.

CHAPTER IV

ANALYSIS OF DATA

The purpose of this study was to demonstrate the effectiveness of a diabetes supply and diabetes self-management education program in a group of uninsured or underinsured diabetics. Twenty Type 1 and Type 2 diabetics completed the three month study that included individual diabetes education sessions and the provision of insulin and diabetic supplies. Overall, the participants demonstrated a significant increase in diabetes self-management skills and a significant decrease in their average blood glucose levels. The chapter begins with a description of the participants and follows with the study findings. Instrument reliability is also discussed.

Description of the Sample

Twenty-five subjects with fructosamine levels greater than 310 μmol/liter were enrolled in the study over an 12-month period of time. Three males and two females did not complete the study, resulting in an 80% completion rate. The reasons for nocompletion of the study were unique to each of the five individuals. After the third session one male participant was referred for medical treatment of a serious foot infection which resulted in a two week hospitalization. Two males, one referred by the homeless shelter and one referred from the county jail, did not return following the initial session. The researcher was unable to contact either one but was told that the male from the homeless shelter had "moved on to Texas." One female participant did not return for the final session. Follow-up attempts by the investigator found that her phone had been disconnected. The last participant who did not complete the study came to all but the final session. When contacted to reschedule, she reported that she had seen her physician two weeks ago and was taken off insulin. Although she was encouraged to come for a final session, she did not do so. This participant had gradually decreased her insulin dose during the study and was following a 2000 calorie diet and exercise program.

Descriptive statistics were used to describe the population. This information is summarized in Table 1. Fourteen of the participants (70%) were female and six (30%) were male. Participants ranged in age from 25 to 79 years. The mean age was 49 and the median was 51 years. Fourteen participants (70%) were Caucasian and six (30%) were Black/African-American. Only three of the participants indicated they were married; however, an additional four reported a significant other with whom they resided. The remaining 12 either lived alone ($\underline{n}$ =8), with friends ($\underline{n}$ = 3), or with family members ($\underline{n}$ = 2). Of the eight that lived alone, two were widows.

Consistent with some of the health programs at the data collection site, study participants were required to meet income guidelines. Inclusion criteria for this study required that the total household income of participants did not exceed 1.5 times the 1998 federal poverty guidelines (see Appendix A). This resulted in a homogenous group in respects to income. The mean monthly income was $426/month with a median of

$440/month. As depicted in Table 1, six (30%) of the participants reported no income and indicated that they were being supported by family members or friends, nine (45%) reported monthly incomes between $0 and $600, and five reported monthly incomes greater than $600.

Five of the participants (25%) reported they had not completed high school, six completed high school, and the majority (n = 8) indicated that they had received some formal education beyond high school. One participant did not answer this question.

In the next step, the demographic information related to disease was analyzed. As summarized in Table 2, 4 of the 20 participants (20%) who completed the study were Type 1 diabetics (three males and one female) and 16 (80%) were Type 2 diabetics (three males and thirteen females). These percentages differ slightly from the normal distribution of persons with diabetes. According to the ADA, only 10% of all cases of diabetes are Type 1 and 90% are Type 2 (ADA, 2000a). The number of years the participants had been diabetic ranged from 6 months to 45 years with a mean of 11.3 years and a standard deviation of 10.2 years.

Descriptive information was also obtained on previous participation in a diabetes education program. Thirty-five percent (n = 7) reported that they had received diabetes education in the past year and 20% (n = 4) indicated that it had been over a year, but less than 5 years, since they had participated in a diabetes education program. Only one participant indicated that it had been longer than five years. Nearly half (45%) of the participants reported that they had never had diabetes education (n = 8).

The percentage of study participants reporting never receiving diabetes education was compared to other findings. This study's finding of 45% is considerably less than the 60% reported by the U.S. DHHS (2000) and the 66% reported by Harris et al. (1994). This finding may be attributed to two factors. First, the Healthy People 2000 initiative was to increase the number of persons with diabetes who had been educated from 32% to 75% by the year 2000 (U.S. DHHS, 1995b). As a result of this initiative, the local health department has increased its efforts to educate the public, and the nation may be moving closer to its goal. Second, some of the study participants heard about the study at the monthly, informal group session that focuses on broad diabetes-related topics such as food preparation and new products. Although the focus of these classes is more information than diabetes management, some of the participants considered this diabetes education. In fact, several listed the group sessions at the clinic when asked where they had attended diabetes education classes. Diabetics who attend the monthly group sessions are given a bottle of insulin at the end of each monthly program so a large number of diabetics seeking assistance at the clinic are given information about the monthly sessions. Table 2 summarizes the diabetes-related demographic data and includes type of diabetes, years since diagnosis, and previous diabetes education.

As with any study it is important to determine if study participants are representative of the population. Therefore, the age, race, and gender of individuals seeking assistance through the diabetes program at the agency from January 1, 2000 through April 30, 2000 was analyzed. The agency does not collect data on living arrangement, education level, diabetes type, or years since diagnosis.

The mean and median age of the agency's insulin-dependent diabetic population was 48 and the mode was 51 (N = 121). Additionally, 82 (64%) were female and 47 (36%) were male. Ethnicity was also similar to the study participants with 72 (60%) white, 43 (36%) Black/African-American, and 6 (4%) American Indian or Hispanic.

In summary, the study participants were representative of the agency's insulin-dependent diabetic population. The majority were white, female, Type 2 diabetics, and between 41 and 60 years old. They also had some post-high school education and nearly half had no previous diabetes instruction.

Table 1

Descriptives of gender, age, ethnic group, living arrangement, income, education level

Variable	Frequency	Valid %	Central Tendency	Range
Gender				
Male	6	30.0	Mode:	
Female	14	70.0	Female	
Total	20	100.0		
Age				
20 - 40 years	5	25.0	Mean:	
41 - 60 years	12	60.0	49 years	25-79
61years or over	3	15.0	Median:	years
			51 years	
Total	20	100.0		
Ethnicity				
Black/African American	6	30.0	Mode: Caucasian	
Caucasian	14	70.0		
Total	20	100.0		
Living Arrangement				
Live alone	8	40.0		
Married	3	15.0	Mode:	
Not married/			Live alone	
Live-in partner	4	20.0		
Live with friend	3	15.0		
Live with family member	2	10.0		
Total	20	100.0		
Income				
No income	6	30.0	Mean:	0 to
Income 0 > and < $600/mos	9	45.0	$426/mos	$1087/
Income >$600/mos	5	25.0	Median:	month
Total			$440	

Table 1 (continued)

Variable	**Frequency**	**Valid %**	**Central Tendency**	**Range**
Education level				
Did not complete high school	5	25.0		
Completed high school	6	30.0	Mode: Education post high school	
Education post high school	8	40.0		
Missing	1	5.0		
Total	20	100.0		

Table 2
Descriptives of type of diabetes, years since diagnosis, and previous diabetes education

Variable	Frequency	Valid %	Central Tendency	Range
Type of diabetes				
Type 1	4	20.0	Mode:	
Type 2	16	80.0	Type 2	
Total	20	100.0		
Years since diagnosis				
0 through 5 years	6	30.0		
6 through 10 years	5	25.0	Mean:	.5-45
11 through 15 years	4	20.0	11.3 years	years
16 through 20 years	3	15.0	Median:	
over 21 years	2	10.0	10 years	
Total	20	100.0		
Previous diabetes education				
Never	8	40.0		
Under 1 year ago	7	35.0	Mode:	
<1 year but >5	4	20.0	Never	
<5 years	1	5.0		
Total	20	100.0		

Instrument Reliability

The instruments used for data collection included forms for recording demographic information, a skills assessment measure, and the Duet Glucose Control Monitoring System ® (LXN Corporation). Data obtained from these instruments were analyzed with a computer program, Statistical Package for Social Sciences, Version 7.5 (SPSS, 1996).

The "I'm in Control Skills Assessment" is an assessment tool that is a required component of the "I'm in Control" education program. This tool is a short, 11-item Likert scale that measures diabetes self-management skills. It has a fifth grade reading level as indicated by a Flesch-Kincaid grade level score of 5.2. Included on the Skills Assessment are items related to one's understanding of blood glucose readings, blood glucose testing, insulin administration, diet, exercise, foot care, and physician follow-up. Participants were to rate the items between 1 (not at all) to 5 (completely). Possible range of scores was from 11 (responding "1" to all items) to 55 (responding "5" to all items). The sample scale mean on the pretest was 28.85 with a standard deviation of 8.14 based on 11 items. The posttest scale mean was 36.4 with a standard deviation of 5.24 based on 10 items. Posttest item 8, related to yearly eye exams, was not included in the posttest analysis because it had no variance in the posttest.

The "I'm in Control" education program was obtained from the local health department. It was determined to be the most appropriate program for the target population because of it's readability and content, however, no reliability studies had previously been reported on the "I'm in Control Skills Assessment" tool. This tool was the required pretest-posttest that accompanied the program. Diabetic educators who use the program are required to report pretest and posttest scores to the state health department when education sessions are completed. Since previous reliability scores were not available, reliability scores were computed for this study and reported with the pretest-posttest scores.

Cronbach's alphas were computed on both the pretest and posttest "I'm in Control Skills Assessment" (N = 20). Cronbach's alpha is an "index that summarizes the correlation between all items in a scale and the scale total" (Polit, 1994 , p. 249). In this study it provided information about how well the items in the scale measured a single attribute, which in this instance is one's ability to self-manage diabetes. The computed pretest alpha for this population was .72, an acceptable score according to Polit (1996) who states it should be at least .70. Nunnally and Bernstein (1994) feel that a modest reliability of .70 is acceptable in early stages of predictive or construct validation research and point out that strenuous and unnecessary efforts may be needed to obtain reliabilities of .90 and above. It should be noted, however, that an estimation of internal consistency for this tool may not be appropriate, since the majority of correlations between items were low (.30 or less).

Correlations among the pretest items were examined in a correlation matrix (see Table 3). A correlation matrix is used to see if there are a number of high correlations between items. High correlations indicate common variance which suggests that scale items may be measuring the same thing. According to Nunnally and Bernstein (1994), items correlated greater than .70 suggest there is enough common variance to examine using factor analysis. Factor analysis was not done to extract factors since pretest question 3 and 6 were the only scale items that were highly correlated (.68). Low correlations between items suggest that the tool lacks internal consistency; therefore underlying factors would not be expected (Nunnally & Bernstein, 1994). That is, each question in a short scale may be an individual factor.

Table 3

Correlation matrix of 11 Skills Assessment pretest items

Items	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
1	1.00										
2	-.052	1.00									
3	.413	.131	1.00								
4	-.296	.226	.105	1.00							
5	-.218	.114	.281	.055	1.00						
6	.349	.296	**.677**	.372	.316	1.00					
7	-.049	-.219	.081	.220	.400	.329	1.00				
8	.072	.014	.378	.233	.269	.381	.396	1.00			
9	-.051	.227	.399	.151	.141	.371	.219	.574	1.00		
10	-.158	.421	.191	.276	.132	.106	-.153	.405	.589	1.00	
11	.441	-.217	.160	-.036	-.100	.369	.149	.291	.113	.056	1.00

The posttest Cronbach's coefficient alpha (.51) on the "I'm in Control Skills Assessment" was low .51 (N = 20). The posttest scale mean was 36.4 with a standard deviation of 5.24 based on 10 items. Posttest item 8 was not included in the analysis due to circumstances that made getting an eye examination between the pretest and posttest possible for everyone; thus, on the posttest everyone increased to a rating of 5 on this item. At the first session, all study participants were made aware of the free dilated eye exams available at the agency by a volunteer optometrist. Therefore, those who had not had their eyes examined in the past year took advantage of this service, resulting in no variance (e.g. all participants scored this item a "5").

When each item measures a different factor, overall test reliability will be low and there will be little common variance between items. As with the pretest, this can be supported by examining the posttest items in a correlation matrix. Again, internal consistency demonstrated mainly low correlations between items (see Table 4). Only posttest items 5 and 11 were highly correlated (.85) so factor analysis was not done. Low correlations between items are expected when tools, such as The Skills Assessment are utilized. The Skills Assessment indexes an individual's self-reported skill to perform self-management behaviors; thus the meaning of the total score may simply be viewed as the person's skill set. It represents a measure of one's ability to manage diabetes before and after a class on diabetes self-management.

Table 4

Correlation matrix of 10 Skills Assessment posttest items

Items	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**9**	**10**	**11**
1	1.00									
2	.134	1.00								
3	.389	-.041	1.00							
4	-.099	.455	-.028	1.00						
5	.223	.211	.085	.000	1.00					
6	.309	.194	.407	.076	.255	1.00				
7	-.255	.298	-.063	.239	-.111	.078	1.00			
8	not included									
9	-.364	-.129	-.085	.000	-.024	.194	-.013	1.00		
10	-.067	.262	.424	.276	-.181	.502	.227	-.038	1.00	
11	.258	.176	.232	.075	**.847**	.096	-.087	-.171	-.148	1.00

Findings

Paired samples t tests were used to test the two research hypotheses. Paired sample t tests, also referred to as dependent t tests, are used to compare the means for one group at two different points in time. In this study, diabetes management skills and mean blood glucose levels were tested before the intervention and again after the intervention. The first hypothesis was: At-risk persons with diabetes will have lower mean glucose levels following participation in a diabetes supply and diabetes self-management education program. A fructosamine test was used to measure mean glucose levels. The mean pretest fructosamine was 390.3 (SD = 78.5, SEM 17.6) which equates to a three week average blood glucose level of about 235mg/dl or an HbA1c of approximately 10% (Dinsmoor, 1998). The mean posttest fructosamine was 294.95 (SD = 69.2, SEM = 15.5). This mean equates to a three week blood glucose level of approximately 155 mg/dl or a HbA1c of approximately 7% (Dinsmoor, 1998).

A paired samples t test (one-tailed, $\alpha = .05$) was used to test the first hypothesis. Analysis of the data revealed a significant difference between the pretest and posttest fructosamine scores ($t = -4.199$, $df = 19$, $p = .000$). The mean difference between the pretest-posttest was -95.3 (SD = 101.5, SEM 22.7). The results are summarized in Table 5.

Table 5

Paired samples t test for fructosamine and Skills Assessment

Variable	Pretest (N = 20)		Posttest (N = 20)			
	Mean	**SD (SEM)**	**Mean**	**SD (SEM)**	**t**	**p***
Fructosamine	390.3	78.5 (17.6)	294.95	69.2 (15.5)	-4.12	.000*
Skills Assessment	28.8	8.3 (1.95)	41.6	5.4 (1.21)	6.43	.000*

*$p < .05$ (one-tailed)

Overall, the participants with fructosamine scores over 310 μmol/liter (inclusion criteria) lowered their scores by approximately 95 points after three months. It is interesting to note that although the results were significant at the .000 level ($\underline{p}$ = .05, one-tailed), two participant's fructosamime scores increased, and both increases were in participants with Type 1 diabetes.

One male participant's fructosamine increased by 47 μmol/liter. At the final session he reported that he was taking antibiotics for a "sinus infection." This participant also had a history of psychiatric illness and was treated with lithium "a few years ago." However, at the time of enrollment in the study he denied being on any medications except insulin.

The other participant who experienced a fructosamine increase was female, and her level increased 122 μmol/liter. This dramatic increase resulted despite recommendations at each session to increase her insulin dose. This 25 year old, single mother was involved in a custody battle with her ex-husband, was attempting to start a new catering business from her home, and was enrolled in twelve hours of classes at the local community college. Clearly stress could have played a significant role in her dramatically increased fructosamine level since it is well documented that stress can affect blood glucose control regardless of self-management practices (Frenzel, McCaul, Glasgow & Shafer, 1988; Goodall & Halford, 1991; Halford, Cuddihy & Mortimer, 1990). Goetsch, Abel and Pope (1994) had eight Type 2 diabetics monitor their stress, mood, coping responses, and glucose for eight days. Blood glucose was significantly higher on "high-stress" days as opposed to "low-stress" days.

The second hypothesis tested was: At-risk persons with diabetes will have improved self-management skills following participation in a diabetes supply and diabetes self-management education program. Self-management skills were measured with the previously discussed Skills Assessment tool. The mean pretest Skills Assessment score was 28.8 (SD = 8.3, SEM = 1.9) out of a possible 55, or an overall average of 2.61 on the 11 items. Their overall diabetes self-management skills before the intervention were between 2 (somewhat) and 3 (OK).

The mean posttest Skills Assessment score was 41.6 (SD =5.4, SEM = 1.2) out of a possible 55 or an overall average of 3.78 on the eleven items. Their overall diabetes self-management skills after the intervention were between 3 (OK) and 4 (fairly well). Their scores increased on each item an average of 1.17 points. The means and standard deviations for each item are presented in Table 6.

Table 6

Skills Assessment pretest-posttest item means, standard deviations

Variable	Pretest Mean	Pretest SD (SEM)	Posttest Mean	Posttest SD (SEM)
1. Understand goals for blood sugar	2.20	1.32 (.30)	3.35	1.31 (.30)
2. Testing blood glucose	2.80	1.67 (.37)	4.30	0.57 (.13)
3. Understand glycosylated Hbg	1.75	1.45 (.32)	2.45	1.54 (.34)
4. Take insulin/pills as instructed	4.30	.86 (.20)	4.50	0.60 (.14)
5. Adjust medication, diet, and exercise	2.50	1.10 (.25)	3.60	1.05 (.23)
6. Follow meal plan	2.10	1.21 (.27)	3.60	1.14 (.26)
7. Exercise	2.45	1.47 (.33)	3.15	1.27 (.28)
8. Yearly eye exam	2.70	1.78 (.40)	5.00	0.00 (.00)
9. Regular foot care	2.30	1.68 (.37)	3.80	1.28 (.29)
10. See doctor every 3 to 6 months	3.30	1.80 (.40)	3.85	1.72 (.39)
11. Coping with diabetes and managing stress	2.45	1.19 (.27)	3.80	1.15 (.26)

Key: 1 = Not at all, 2 = Somewhat, 3 = OK, 4 = Fairly well, 5 = Completely

A paired samples t test (one-tailed, $\alpha = .05$) was used to test the second hypothesis. Analysis of the data revealed a significant difference between the pretest and posttest Skills Assessment scores ($t = 6.43$, $df = 19$, $p = .000$). The mean pretest-posttest difference was 12.8 (SD = 8.9, SEM = 2.0). The t-test results are summarized in Table 6.

A paired samples t test (one-tailed, $p = .05$) on each of the Skills Assessment items revealed significant differences in pretest and posttest scores for eight of the eleven items (see Table 7). Items 3, 4, and 10 demonstrated no significant difference in the pretest-posttest scores. These items were further examined to explain the lack of significant pretest-posttest changes.

Item 3 asked respondents about the glycosylated hemoglobin test. There was very little difference in the pretest-posttest scores. The mean pretest response for this item was 1.75 (SD = 1.45), indicating that the participant's understanding was between 1 (not at all) and 2 (somewhat). The mean posttest response was 2.45 (SD = 1.5) indicating their understanding was between 2 (somewhat) and 3 (OK). Although they scored better on this item, their understanding did not significantly improve. The terminology is not in lay language which may explain the insignificant increase in their understanding of this concept, even though it was reviewed in the first session. Additionally, since this was defined and discussed in the first session (after the pretest) and not discussed again, the participants may not have remembered what the medical term "glycosylated hemoglobin" meant after three months. A study by Levetan et al. (2000) found that most diabetics are unable to recall the name "glycosylated hemoglobin," "hemoglobin A1c," or "glycated hemoglobin." The researchers gave 110 participants a card with one of the above names printed in large letters while being told that this was the name for a "blood test giving you the best indication of glucose control over the past three months." Twenty-four hours later they were asked to recall the name of the test described the previous day. Although more were able to recall "hemoglobin A1c," this was not a statistically significant finding.

The next item with no significant change in the pretest-posttest response was Item 4 which asked participants to rate how they took their prescribed insulin and pills. The pretest mean for this item was 4.3 and the posttest mean was 4.5 indicating that they rated their insulin taking practices between 4 (fairly well) and 5 (completely). When looking at this response in comparison to the other responses, the participants clearly understood the importance of taking their prescribed dose of insulin from the beginning of the study. In fact, several had not seen a physician in several years but were still taking the same insulin dose despite blood sugar readings consistently above 200 mg/dl. Although the participants' responses on the pretest indicated they had little knowledge of other self-management practices, they did understand to take their insulin. This corresponds to findings reported by Ary et al. (1986) who asked 208 persons with diabetes about diabetes management practices. Eighty-seven percent reported taking their insulin as prescribed.

The third item that did not reveal any significant change was Item 10. This item asked participants about seeing a physician every three to six months for a check-up. Surprisingly, the pretest mean was 3.3, with a standard deviation of 1.8. As a whole, the participants rated their practice of regular check-ups between 3 (OK) and 4 (fairly well). The responses did not change much in the posttest where the item mean was 3.85 with a standard deviation of 1.73, an increase of only .5 from the pretest-posttest. In retrospect, as required by the agency, participants were asked to have a physician-signed form before the second session verifying insulin usage and amount. Participants who did not have a physician were given information about the free clinic, staffed by the local medical school residents, to have the form completed. As per protocol, patients seen in the indigent clinic with chronic conditions are then encouraged to have follow-up appointments at the medical school's sliding scale clinic.

Table 7

Paired samples t test: Skills Assessment pretest-posttest items

Variable	Paired Differences Mean	SD (SEM)	t	p*
1. Understand goals for blood sugar	1.15	2.25 (.50)	2.28	.012*
2. Testing blood glucose	1.50	1.57 (.35)	4.27	.000*
3. Understand glycosylated Hbg	.70	2.34 (.52)	1.34	.100
4. Take insulin/pills as instructed	.20	.89 (.20)	1.00	.170
5. Adjust medication, diet, and exercise	1.10	1.45 (.32)	3.40	.002*
6. Follow meal plan	1.50	1.36 (.30)	4.94	.000*
7. Exercise	.70	1.63 (.36)	1.93	.030*
8. Yearly eye exam	2.30	1.78 (.40)	5.78	.000*
9. Regular foot care	1.50	1.99 (.44)	3.38	.002*
10. See doctor every 3 to 6 months	.55	2.28 (.51)	1.08	.148
11. Coping with diabetes and managing stress	1.35	1.46 (.35)	4.13	.000*

*p < .05 (one-tailed)

As previously discussed, the Skills Assessment instrument provides an index of the participants' self-reported diabetes self-management skills. Therefore, analyzing the participant responses on each pretest-posttest item provided additional information about overall performance on individual items, as well as each participant's overall performance. As depicted in Table 8, 17 of the 20 participants had improved scores from the pretest to the posttest. Gains ranged from + 6 to + 25 with average gain of 13.6 points. Three participants, one Type 1 diabetic and two Type 2 diabetics, had lower posttest scores, however, they were essentially unchanged from the pretest (pretest = 41, posttest = 40; pretest = 30, posttest = 29; pretest = 36, posttest = 40). The greatest decrease from the pretest was experienced by a Type 1 diabetic who also experienced a higher posttest serum fructosamine. Participant 3, 9 and 16 each had decreases in 3 individual items, however, there was no consistency in the individual items that decreased. Although they experienced decreases in three items, participants 9 and 16 both scored eight points higher on the posttest. Participant 3 experienced a decrease of one point on the posttest.

Individual items were evaluated for consistencies in decline from the pretest to the posttest. Only one item appeared to be problematic. Five participants (25%) had lower scores on the posttest for Item 1. This item asked participants about their understanding of goals for blood glucose control. An attempt to explain this finding is purely speculation, however, there is one possible explanation. The first pretest was administered before a relationship with the researcher had been established. It is possible that the participants did not want to admit they did not know such a key principle of diabetes management, and consequently gave themselves inflated scores. They have been more honest on the posttest after they had established a relationship with the researcher. Although Item 1 was troublesome for some participants, nearly half of the participants (n = 9) scored the same or higher on all 11 items.

Table 8

Skills Assessment individual scores: Item scores and total gain or loss

Person	Pretest Items 1	2	3	4	5	6	7	8	9	10	11	Posttest Items 1	2	3	4	5	6	7	8	9	10	11	Gain/ Loss
1	2	4	1	4	3	2	1	1	2	1	1	5	4	4	4	2	4	3	5	4	5	2	(+20)
2	1	1	1	4	1	1	2	2	1	1	1	4	4	3	4	2	3	3	5	3	5	2	(+22)
3	1	5	5	4	4	3	2	5	5	5	2	4	5	1	5	4	4	3	5	1	4	4	(-1)
4	2	2	1	5	1	2	1	1	4	4	2	2	4	1	5	2	4	5	5	4	5	3	(+16)
5	2	1	1	4	1	1	1	1	1	1	4	5	4	4	4	4	4	1	5	2	5	5	(+25)
6	4	4	2	4	2	2	4	4	4	5	4	2	4	3	5	4	4	3	5	5	5	5	(+6)
7	1	1	1	5	3	1	3	5	3	4	3	2	3	1	5	3	1	2	5	3	1	3	(-1)
8	2	5	1	5	2	4	4	4	5	4	4	4	5	1	5	5	4	4	5	4	4	5	(+6)
9	3	5	1	5	2	2	1	5	1	4	2	2	4	2	4	4	3	1	5	5	5	4	(+8)
10	2	3	2	4	4	1	1	2	1	5	2	2	4	4	4	4	4	3	5	4	5	4	(+16)
11	1	4	1	5	3	2	2	1	2	5	1	4	5	4	5	4	4	3	5	4	5	4	(+20)
12	2	3	1	3	2	1	4	1	1	1	1	2	4	1	3	4	2	5	5	3	1	4	(+14)
13	1	1	1	5	4	2	5	1	1	1	2	4	4	1	4	4	4	4	5	4	4	4	(+18)
14	5	1	1	2	2	1	1	1	1	1	3	4	5	1	5	4	1	3	5	4	1	5	(+19)
15	5	1	5	5	3	5	5	5	1	1	4	1	5	1	5	1	3	4	5	5	5	1	(-4)
16	1	5	1	5	4	3	3	2	1	3	2	5	4	1	4	4	5	1	5	5	1	3	(+8)
17	2	1	2	3	4	3	3	5	4	5	4	4	4	4	4	4	4	2	5	5	1	5	(+6)
18	1	1	1	5	2	1	4	5	5	5	1	4	4	5	5	4	5	5	5	5	5	4	(+20)
19	4	4	5	5	2	4	1	2	5	5	2	2	5	2	5	5	5	4	5	5	5	4	(+8)
20	2	4	1	4	1	1	1	1	1	5	2	5	5	5	5	4	4	4	5	1	5	5	(+25)

Additional Findings

There was an additional unexpected finding. Although the researcher did not request the information, three program participants reported that they had been taken off insulin by their respective physicians. Two of the participants taken off insulin had fructosamine levels greater than 310μmol/liter at the initial session. One completed the study, and one came to all but the final session. Although the inclusion criteria required fructosamine levels greater than 310μmol/liter, it was predetermined that no diabetic who wanted to participate would be refused the education sessions and supplies, however, they were informed that they would not be included in the final data analysis. Fifteen diabetics with serum fructosamine scores less than 310μmol/liter enrolled in the program and seven completed the program. One of these seven program participants reported being taken off insulin two months after the final session.

One must always consider the overall cost of implementing any health education program. The program costs should then be weighed against the perceived benefits. The comparison of costs against perceived program benefits is beyond the scope of a three month study. However, research clearly indicates that lower mean glucose levels are directly related to lower medical costs in adults with diabetes (Gilmer et al., 1997). It is unknown if the program resulted in any long-term, cost-saving benefit since participants were only followed for ten to twelve weeks.

An itemized inventory of the supplies utilized in the study, including their retail costs (the most costly method of purchasing), is presented in Table 9. As indicated in the table, the cost for supplies averaged approximately $107/month per participant. The most expensive supply was the cost of testing strips, which is also one of the most important diabetes self-management tools. One cannot perform the frequent glucose testing needed for glucose pattern recognition without glucose testing strips. It is recommended that persons with Type 1 diabetes test blood glucose three to four times a day, and that persons with Type 2 diabetes test often enough to reach treatment goals (ADA, 2000a). However, the cost of testing strips makes this an unlikely practice for most uninsured or underinsured diabetics. Therefore, although not ideal, after blood glucose patterns were established, testing was decreased to two times a day and the time of testing was alternated. For example, one day participants tested at breakfast and dinner and the following day they tested at lunch and bedtime. They were also instructed how to recognize glucose pattern changes and to resume more frequent monitoring if patterns changed.

Additional costs not depicted on Table 9, but which must also be considered, are the cost of the education materials and the educator's time. Although the program fee was nominal, photocopying all program materials was an additional total cost of approximately $200. Participant's were not charged for the educator's time, but one should keep in mind that in 1993 Tobin estimated the cost at $42.57/hour for individual sessions.

Table 9

Itemized costs for three month diabetes supply program (N=20)

Supply	Cost of item*	Average # per person	Total number distributed	Total $ cost
Syringes	$20 for 100	132/person	2,367	540.00
Insulin	$21/10cc vial	5.3 vials (10cc)/person	106	2,226.00
Lancets	$6/ box of 100	137	2750	168.00
Testing strips	$39 box of 50	4 boxes (50 count)	81 boxes	3,153.00
Fructosamine test strips for pre/posttest	$116 box of 16	2 strips/person	3 boxes	348.00
				$ 6,435.00 or $107/ month/ person

* costs listed are retail estimates rounded to the nearest dollar

Summary of Findings

The results of this study support the two hypotheses. Findings indicate that uninsured or underinsured adult persons with diabetes can significantly improve their diabetes self-management skills and reduce their blood glucose levels when provided with the knowledge and tools to do so. In this study fructosamine scores dropped an average of 95 points over three months. Stated another way, three week average blood glucose levels decreased from an average 235mg/dl, or a HbA1c of approximately 10%, to approximately 155 mg/dl, or a HbA1c of approximately 7%. Two participants who met the inclusion criteria, and one who did not meet the inclusion criteria, reported being taken off insulin after completing the program.

A paired samples t test of the mean pretest-posttest scores on the self-management skills was also statistically significant. Participants' mean scores improved by approximately 12.8 points. A paired samples t test of individual items on the skills assessment found significant differences in pretest-posttest scores for 8 of the 11 items. Reliability estimates for the untested skills assessment instrument were acceptable, however, further testing on this instrument is indicated. The pretest Cronbach's alpha was .72 and the posttest Cronbach's alpha was .52.

CHAPTER V

SUMMARY OF THE STUDY

This study investigated the effects of a diabetes supply and diabetes self-management education program in uninsured or underinsured persons with diabetes. Additionally, since no previous reliability estimates were available for the skills test, a required component of the program utilized, reliability estimates were calculated and reported to the health department at the conclusion of the study. The cost of implementing such a program was also estimated.

Glasgow's Practical Model of Diabetes Management and Education (Glasgow, 1995) was modified and used as the conceptual framework for the study. A convenience sample of 25, Type 1 and Type 2 uninsured or underinsured diabetics with serum fructosamine levels greater than 310μ mol/liter agreed to participate. Participants were followed for 10 to 12 weeks, and 20 completed the study. Sixteen of those that completed the study were Type 2 diabetics and four were Type 1. Diabetes self-management skills and serum fructosamine levels were measured at the beginning and end of the study.

The findings suggest that a program that eliminates financial barriers to participation in an uninsured or underinsured population improves health outcomes. The health outcomes measured were diabetes self-management skills and mean blood glucose. However, although there was a statistically significant difference in the group mean for both measures, the effectiveness of this program for individuals with Type 1 diabetes is unclear. Seventeen of the twenty participants scored higher on the diabetes self-management skills posttest and 3 of the 20 participants' posttest scores were essentially unchanged. However, while all of the participants with Type 2 (N = 16) diabetes experienced lower mean serum glucose levels after 10 to 12 weeks, only two of the four participants with Type 1 diabetes had lower mean serum glucose levels on the posttest.

Summary

The purpose of this quasi-experimental, pretest-posttest design study was to determine the effectiveness of a diabetes supply and diabetes self-management education program in improving the health outcomes of at-risk diabetics. At-risk was defined as being uninsured or underinsured. There were two hypotheses: 1) At-risk persons with diabetes will have lower mean glucose levels following participation in a diabetes supply and diabetes self-management education program. 2) At-risk persons with diabetes will have improved diabetes self-management skills following participation in a diabetes supply and diabetes self-management education program.

The study rationale was based on several factors. First, only a small number of uninsured persons with diabetes have participated in a diabetes education program (Harris et al., 1994). Second, according the U.S. DHHS (1995b), the death rate for disadvantaged populations has increased since 1990, suggesting that specific interventions are needed for this population. Third, uninsured persons with diabetes age 18-65 years, have higher glucose levels than insured diabetics (Harris, 1995), increasing their risk of long- and short-term complications. Fourth, implementing effective programs for at-risk populations will contribute to reaching two of the nation's goals for diabetes, outlined in Healthy People 2010. That is, a decrease in the diabetes-related death rate, and an increase in the number of persons with diabetes who have been educated about the disease (U. S. DHHS, 2000). Finally, nursing has an obligation to collaborate with other health care professionals to ensure that accessible, high quality health services are available for all persons whose health care needs are unmet (American Nurses' Association, 1985). Establishing a program for an at-risk diabetic population is one method of meeting this obligation.

The study was based on the philosophy of empowerment which extends from the ideology and beliefs of Freire (1970). Freire proposed that the main task of education was to incite people to believe that they can accomplish a task and that they have the knowledge and power to do so (Freire, 1973). The study variables were depicted in a conceptual model, the Practical Model of Diabetes Management and Education (Glasgow, 1995). This model is comprised of three levels including personal readiness (Level I); cycle of care, which includes the process diabetes self-management (Level II); and long-term health outcomes, such as decreased mortality and improved quality of life (Level III). Although Glasgow does not use the term "empowerment," the second level of the model includes components essential to the process of empowerment as conceived by Freire. This level was modified to include "cycle of empowerment." "Nursing interactions" was also added to the second level with Glasgow's "medical interactions" to reflect the role of nursing in the empowerment of patients.

Limitations

There were several limitations to the study. The first limitation was the convenience sample which limits generalizability. There was no control group and subjects were not randomly assigned. Administering a pretest-posttest allowed participants to act as their own controls, however the lack of randomization affects both the external validity and generalizability of the study. Without randomization one proceeds with caution when drawing the conclusion that no factor besides the treatment affected the outcome. One must also keep in mind that with a convenience sample those who agree to participate may be more motivated to learn and implement diabetes self-management practices than those who choose not to participate.

The program was taught by the researcher which ensured consistency in presenting material. However, this may also have inadvertently biased the study. Some aspect of the researcher's personality may have enhanced self-management behaviors. Replication of the study by other researchers would increase the generalizability of the findings.

The Hawthorne effect may also have been a factor in this study. The participants knew they were being monitored, therefore, they may have been more attentive to self-management practices. Different researchers have reported different findings about the long-term effects of diabetes education. For example, Goodall and Hall (1991) reported that glycemic control diminished after a period of time. In contrast, Rubin, Peyrot and Saudek found patients were able to maintain lower mean blood glucose at six and twelve months after participating in a diabetes education program. Measuring self-management practices and serum fructosamine at six months and twelve months would provide information about this program's effectiveness over a longer time frame.

Another limitation was the serum fructosamine test. Although this test is recognized by the ADA as a measure of mean blood glucose control, one must keep in mind that it provides a serum glucose average of the past three weeks. Extreme fluctuations in blood glucose indicate poor control, however when averaged they may result in a fructosamine reading that is in the normal range.

The attrition rate for this study was 20%, so mortality was also a limitation and threat to validity. Those who did not complete the study may not have been following the treatment recommendations, which resulted in no change in blood glucose levels. Additionally, some participants who did not complete the program may have been following the treatment recommendations, but recognized that blood glucose levels were not improving and subsequently dropped out. If those who did not complete the study had done so, and their fructosamine levels were elevated on the posttest, the study results would have been dramatically different.

The last limitation to the study was the lack of reported reliability estimates for the required Skills Assessment test. The researcher reviewed several diabetes self-management education programs in the planning stages of the study. The newly developed "I'm in Control" program, available for a nominal fee from the local health department, was determined to be the best program for this population because of its readability and content. Health care providers who used the program were required to administer the included pretest-posttest and report the scores to the health department. According to Nunnally and Bernstein (1994) coefficient alpha (α) should be computed and reported for any test that will be widely used, however no previous reliability estimates were available. Despite this limitation, the researcher made the decision to utilize it as a pretest-posttest measure and report reliability findings to the health department for the benefit of further researchers wanting to use the program. Goodall & Halford (1991) reviewed the research on diabetes self-management and concluded that a major difficulty in studying diabetes self-management is reliable measurement since standardized, objective measurements are uncommon.

Instrument Reliability

The reliability estimate for the "I'm in Control" pretest was $\alpha = .72$ and the posttest estimate was .51. Nunnally and Bernstein discuss standards of reliability and propose that in the early stages of instrument testing, modest reliability estimates are acceptable (e.g. .70), and increasing reliabilities beyond .80 wastes both time and money. Estimates that are very low (less than .30) suggest that an instrument is too short or that items have very little in common (Nunnally & Bernstein, 1994). Although not ideal, the instrument reliability for this population was acceptable.

It should be noted that an estimate of internal consistency for this instrument may not be appropriate, since the majority of correlations between items were low (.30 or less).

Low correlations suggest that each question in a short scale may be in individual factor and when each item measures an individual factor, overall test reliability will be low. However, the results of the Skills Assessment pretest-posttest should be reviewed with caution since the instrument reliability had not been previously established.

Data Collection

Data collection occurred over 12 months. Agency and participant consent was obtained with signed consent forms. All participants completed the program in 10 to 12 weeks. This is a fairly short time frame and long-term glycemic control cannot be assumed. Several studies have found that the benefits of diabetes education decrease after a period of time (Estey, Tan & Mann, 1990; Goodall & Halford, 1991; Lockington, Farrant, Meadows, Dowlatshahi & Wise, 1988). Although this program suggests that extending an education program over three months provides reinforcement that results in better self-management skills and lower mean glucose, one cannot assume that the effect lasts longer than this time frame, or that long-term benefits occur. Studies that incorporate additional post-testing are needed to establish any benefits beyond three months.

Twenty-five uninsured or underinsured adults with diabetes initially enrolled in the study, and twenty completed the study. Two of the five who did not complete the program attended only the introductory session and two attended all but the final session. One participant did not return after the third session for health reasons.

Outcomes

The first hypothesis (At-risk diabetics will have lower mean glucose levels following participation in a diabetes supply and diabetes self-management education program.) was tested with a dependent t test (one-tailed, $\alpha = .05$). There was a statistically significant difference in the mean pretest-posttest fructosamine levels (t = -4.199, df = 19, p =.000). The mean pretest-posttest difference in fructosamine scores was -95.3 (SD = 101.5, SEM 22.7). Although the results were significant at the .000 level, two of the four participant's with Type 1 diabetes experienced an increase in fructosamine levels. However, on the brighter side, one participant who completed the study and one participant who attended all but the final session reported that they had subsequently been taken off insulin and placed on oral medication.

The second hypothesis (At-risk diabetics will have improved diabetes self-management skills following participation in a diabetes supply and diabetes self-management program.) was also tested with a dependent t test (one-tailed, $\alpha = .05$). There was a statistically significant difference in the mean pretest-posttest skills assessment scores (t = 6.43, df = 19, p =.000). The mean pretest-posttest difference was 12.8 (SD = 8.9, SEM =2.0) and a paired samples t test (one-tailed, $\alpha = .05$) on each of the eleven skills assessment items revealed significant differences in eight items. Those items that did not demonstrate a significant difference in the pretest-posttest score were items related to understanding of the term "glycosylated hemoglobin," insulin-taking practices, and the practice of seeing a physician every three to six months.

There were two additional outcomes from the study. First, a reliability estimate for the 11-item "I'm in Control" Skills Assessment (N = 20) was estimated. The state health department required that health professionals who use the program administer the pretest-posttest and report the scores to the health department. Despite this requirement, there were no previous reliability estimates available for researchers to determine whether the instrument was reliable. Cronbach's alphas were computed for the pretest and posttest and reported to the health department for future reference. The computed pretest Cronbach's alpha for this population was .72, an acceptable score according to Polit (1994), and the posttest Cronbach's alpha was (.51). Item correlations on the pretest and posttest correlation matrix were low which suggests that each item on the instrument was an individual factor. The Skills Assessment indexes an individual's self-reported skill to perform self-management behaviors; thus, the meaning of the total score may simply be viewed as the person's skill set. It represents a measure of one's ability to manage diabetes before and after a class on diabetes self-management.

The second additional finding was an estimate of the cost for health care professionals interested in implementing a similar program with similar populations. It was estimated that supplies (insulin, testing strips, syringes) would average about $100/month. Program materials (patient booklet in three ring folder) would be an additional one-time cost of approximately $4.00. The cost of the educator was not included, but one must also take this into consideration when investigating the feasibility of such a program.

Diabetes care is expensive and establishing the program's cost-effectiveness was beyond the scope of the study since cost savings from improved glucose control are realized many years later. However, research has established that elevated blood glucose is the number one risk factor for the development of complications, and as mean blood glucose increases, costs increase (Gilmer et al., 1997). Diabetes self-management education plays a key role in reducing health care costs related to diabetes (Clement, 1995).

Discussion of Findings

Researchers must not only report findings from the study, but must also analyze the findings with an attempt to extrapolate their meaning. Inherent in this analysis is identifying the strengths and weaknesses of the study. Findings are discussed in relation to the model, population, and study outcomes.

Findings Applied to Glasgow's Model

A good theory and/or conceptual framework should explain the study's findings. According to Glasgow's model of diabetes management and education there are background environment and contextual factors that result in a personal readiness to participate in diabetes education. These factors are the first level of the model and include community and social support, patient characteristics, and clinic and program characteristics. The factors in this first level determine the extent to which one will take responsibility for his/her diabetes. Factors in this level can also act as barriers to diabetes management and self-management education. One barrier identified in the literature is the lack of financial resources to adequately perform self-management practices (Harris, 1995; Ary et al., 1986), and studies have demonstrated that uninsured diabetics have higher glucose levels than insured diabetics (Harris, 1995). Eliminating this barrier facilitates moving to the second level where individuals interact with the health care team, learn self-management skills, become empowered to implement self-management behaviors, and realize short-term physiologic health outcomes.

In this study, a perceived barrier to participation in the uninsured or underinsured was low socioeconomic status, or lack of financial resources. Providing the self-management education free of charge and including the supplies necessary for effective diabetes self-management facilitated progression to the second level. On the second level participants became empowered, self-management skills improved, and mean glucose levels dropped. Factors on the third level, long-term health outcomes and quality of life, were not measured in this study.

Mortality and Sample Size

The mortality or dropout rate for this study was 20% ($\underline{N}$ = 5), lower than the 40% or greater attrition rate cited by some researchers (Funnell & Haas, 1995; Irvine & Mitchell, 1992), but within the 0 to 45% reported by Glasgow et al. (1996). In this study, the incentive of free supplies and insulin probably contributed to the lower attrition rate. One participant was contacted when she did not come for the final appointment. She did not wish to reschedule the appointment since she was without a car and stated "...besides, I went to the doctor two weeks ago and my blood sugar is doing so well he took me off insulin and put me on pills." One can speculate that the incentive (insulin, syringes) to participate was gone.

Because of the small number who did not complete the study, it is difficult to draw conclusions about them. According to researchers this information is important to collect (Glasgow et al., 1996; Irvine & Mitchell, 1992), but only half of the researchers address this (Kaplan & Davis, 1984). Irvine and Mitchell (1992) found that dropouts were less educated, younger, in poorer health, and had more barriers than those who complete a diabetes education program. However, the dropouts in this study had all completed high school, ranged in age from 29 to 61, and only one reported dropping out because of health (e.g. foot infection requiring hospitalization). It should be kept in mind that although the number of dropouts was small, this could have affected the outcome if they did so because their blood glucose levels were not improving.

Many would argue that the sample size was also a limitation. However, according to Knapp (1996), statistically significant results from a small sample are more impressive that a statistically significant result from a large sample that can "buy" effects. Although the sample was small, the number of participants was determined a priori by power analysis. The .70 ES was established from diabetes education effect sizes reported in the literature (Brown, 1990; Padgett et al., 1988). A post hoc power analysis is conducted when no statistical significant difference is found to determine if there was a sufficient number of participants to find a significant result (if there is one). This was not done since both hypotheses were supported.

Demographics

The sample was predominantly white (N = 14), middle-aged, and female (N = 14). They had a mean income of $426/month and the mean age was 49 years. The group was homogenous with respects to income because inclusion criteria for participants required that income be no greater that 1.5 times the federal poverty level (see Appendix A). Although the sample was representative of the population from which it was drawn, there were some differences when compared to the diabetic population as a whole.

Four of the twenty participants (20%) were Type 1 diabetics and sixteen (80%) were Type 2. According to Roman & Harris (1997) only 10% of the diabetic population are Type 1, therefore, Type 1 diabetics were over represented in the sample. Gender and race were similar to those reported by Cowie and Eberhardt (1995) however, the study sample's median age was 51, much less than the diabetic population median age of 63 years.

According to Cowie and Eberhardt (1995), the majority of the diabetic population is married (64%). This is a dramatic difference from the small percent of the sample in this study that were married (15%). Although it was anticipated that the majority would have less than a high school education, 40% of the participants (N = 8) reported that they had some formal education beyond high school. This is consistent with the 50% reported by Cowie and Eberhardt (1995). The number of years the participants had been diabetic ranged from 6 months to 45 years with a mean age of 11.3 years.

In summary, the participant's gender, race and education were similar to the adult diabetic population as a whole. However, differences were noted in marital status, age, and type of diabetes. It is possible that a larger sample may have provided a group more representative of the adult diabetic population. Despite the above differences, they were representative of the population from which they were drawn, which was discussed in Chapter II.

Diabetes Self-management Skills Test

Reliability estimates of the Skills Assessment instrument had not been previously reported so one cannot draw conclusions about the instrument in comparison with other populations. The pretest Cronbach's was .72, an acceptable number in the early stages of instrument testing (Nunnally & Bernstein, 1994). The posttest Cronbach's was low at .51. Although further testing of the instrument is indicated, these early findings suggest that he skills test may be a reliable measure of one's ability to manage diabetes before a class on diabetes self-management. However, it may not be a reliable measure of one's ability after participating in a diabetes self-management class. Additionally, pretest and posttest item correlations were low, suggesting that each item was an individual factor. Further instrument testing with different populations is indicated before conclusions can drawn from this preliminary reliability testing.

The mean difference in the pretest-posttest scores of the skills test was statistically significant. In fact, 17 of the 20 participants had improved scores. Three participants' posttest scores decreased from their pretest scores however, the posttest-posttest scores were essentially unchanged (pretest = 41, posttest = 40; pretest = 30, posttest = 29; pretest = 36, posttest = 40). Although the greatest decrease was only four points, this decrease was in a Type 1 participant who also experienced an increase in the mean serum fructosamine.

This statistically significant finding is consistent with other studies that report diabetes self-management classes are successful in improving one's understanding of diabetes self-management (Bloomgarden et al., 1987; Brown, 1990; Clement, 1995; Glasgow & Osteen, 1992; Goodall & Halford, 1991; Padgett et al., 1988). It is important to note that none of the above studies looked at the success of a diabetes self-management education program in an uninsured or underinsured population.

Critics of the study will argue that providing the tools for self-management provided an incentive for participation which affected the results. Indeed this may be an accurate assertion. However, a program that does not address a recognized barrier for the population of interest is doomed for failure. It is unlikely that the participants in this study would have been able to perform frequent blood glucose testing, an integral component of diabetes self-management, without the glucose testing strips. It is also possible that they would be hesitant to increase their insulin for fear of running out. The study suggests that including diabetes supplies with self-management education was not a wasted expense, but an important component of a diabetes education program for uninsured or underinsured diabetics. Seventeen of the twenty participants improved their self-management skills scores, and eighteen decreased their mean serum glucose levels.

There was no statistical difference in pretest-posttest scores for 3 of the 11 Skills Assessment items. The first item with no statistical difference was the item related to their understanding of the glycosylated hemoglobin test (HbA1c), however, these findings are consistent with other researchers' findings. The mean pretest score was 1.75, indicating their understanding was between "not at all" and "somewhat." The mean posttest score was 2.45, indicating understanding had improved slightly to between "somewhat" and "OK." According to the CDC (1997b) only 32.5% of insulin dependent diabetics in North Carolina had ever heard of HbA1c. Additionally, Levatan et al. (2000) reported that diabetics have difficulty recalling terminology, such as glycosylated hemoglobin or HbA1c, 24 hours after an explanation by researchers. Health care professionals must to a better job in facilitating the understanding of this important measure of diabetes management. Educators should focus on the use of lay terms when explaining and assessing this concept.

The second item with no statistical difference in the pretest-posttest was related to insulin taking practices. The mean pretest score was 4.3 and the mean posttest score was 4.5, indicating they rated their insulin taking between "fairly well" and "completely." This was a surprising finding since Tu & Morrison (1996) found lack of money was a barrier to medication taking in indigent diabetics, and Polonsky et al. (1994) found insulin omission to be a common practice in women between 13 and 60 years of age. However, the findings are consistent with the findings of Ary et al. (1986) who reported that diabetics take their insulin as prescribed In respects to this study, it should be noted that although the participants self-reported not omitting insulin, many had been taking the same dose of insulin despite consistently elevated blood glucose levels.

The last item with no significant difference in the mean pretest-posttest score was related to seeing a physician every three to six months. The mean pretest score was 3.3, indicating they rated this item between "OK" and "fairly well." The posttest mean increased only .5 from the pretest. Although the literature is overwhelming that uninsured or underinsured persons frequently have no regular health care provider (Freeman et al., 1990; Hahn, 1994; Schoen et al., 1997), the participants in this study reported that they had seen a physician for their diabetes in the past three months.

There are two possible explanations for this unexpected result. First, flyers about the study were sent to the two local medical school sliding scale clinics and some participants were referred from there. Second, the researcher may have biased this response because of the required "Physician Prescription Form." Participants are given this form to be completed when they come for assistance at the diabetes supply clinic. They are required to have it completed by their physician before insulin is distributed. If they do not have a physician, they are given information about the free clinics on the premises, staffed by the medical school residents. After being seen at the free clinic, the medical residents make the appropriate arrangements for follow-up care at the medical school's sliding scale clinic. Many of the participants volunteered for the study when coming for assistance with diabetes supplies. Hence, many of the participants had recently seen a physician when getting the "Physician Prescription Form" completed.

Physiologic Outcome

There was one physiologic measure, the mean serum glucose, measured with a pretest-posttest serum fructosamine level. The serum fructosamine provided a three week average blood glucose, and participants decreased their mean serum fructosamine scores by an average of 95 μmol/liter. The difference in the mean pretest-posttest fructosamine scores was statistically significant but no studies to date have used this new measure of mean serum glucose. Therefore, comparing the results of this study with previous studies' findings is done with caution.

Most studies reviewed used the glycosylated hemoglobin, which is an indicator of one's average glucose for the past three months. Despite the differences in these two tests, this study's finding was consistent with other researchers' findings that mean serum glucose improved with self-management education (Berger & Muhlhauser, 1999; Brown, 1990; Goodall & Halford, 1991; "Ongoing Education," 1998; Padgett et al., 1988). However, the finding that mean serum glucose improved refutes other researchers' findings that self-management education does not improve mean serum glucose (Estey et al., 1990; Mazzuca et al., 1997).

Brown (1990) concluded that the effects of patient education on Type 1 and Type 2 diabetics was difficult to analyze because most studies combined the effects of the interventions on Type 1 and Type 2 diabetics. Therefore, it is important to differentiate the effects of the program for each subgroup. Although the results were statistically significant, and all the Type 2 participants had some decrease in mean serum glucose, two of the four Type 1 participants had higher fructosamine scores at the end of three months. Additionally, one of the two Type 1 participants with increased mean glucose also scored lower on the skills posttest (pretest = 40, posttest =36). However, one must exercise caution in the interpretation of the results.

Since only half of the Type 1 participants demonstrated improved mean blood glucose, additional studies with greater numbers of Type 1 diabetics are necessary to establish the benefits of this program for this subgroup. There are several possible explanations for the less than favorable results in the Type 1 participants. First, the number of Type 1 participants was not large enough to evaluate the program. It is possible that a study with larger numbers of Type 1 would have an outcome similar to that demonstrated with Type 2 diabetics. Second, the three to four times a day glucose testing may have been insufficient for persons with Type 1 diabetes to recognize blood glucose trends, resulting in ineffective self-management. Third, it is possible that a longer time frame was needed before improvement in Type 1 diabetics was demonstrated. A longer program with additional measures would be beneficial to establish if, and when, improvements in this subgroup are demonstrated. Clearly, without additional research the benefits of this program for persons with Type 1 diabetes cannot be established.

Conclusions and Implications

There are several conclusions that can be drawn from the study's findings. First, a diabetes supply and diabetes self-management education program for at-risk diabetics improves outcomes for persons with Type 2 diabetes, at least for a three month time frame. Additional studies will be needed before the long-term effects of this program are known. Second, although the results were statistically significant for the sample, further research is needed before the benefits of the program for Type 1 diabetics can be determined. Third, although the sample was representative of the population from which it was drawn, it was not entirely representative of the diabetic population as a whole. Therefore, the study results cannot be generalized unless studies with larger samples demonstrate the same effect. Finally, the term "glycosylated hemoglobin" is difficult for the lay person to understand. Educators must focus on identifying more effective methods to improve the understanding of this important concept.

The results of this study have implications for diabetes education program developers who work with uninsured or underinsured diabetics and for health policy makers. This study suggests that diabetes educators, who address and eliminate financial barriers to participation, facilitate the learning and implementation of diabetes self-management practices. Removing the barrier to participation resulted in "personal readiness" to become empowered.

Programs for the uninsured or underinsured must include both self-management education and diabetes supplies. One without the other is a prescription for failure, a waste of health care resources, and borders on unethical practice. For instance, providing assistance with diabetes supplies and insulin without self-management education may be facilitating the continuation of poor behaviors (e.g. insulin doses too small to achieve glucose control, inappropriate monitoring of blood glucose). On the other hand, providing self-management education to diabetics unable to afford diabetes supplies and insulin is unlikely to result in better glucose control since good glucose control is dependent on the administration of insulin based on blood glucose testing performed several times a day.

Nursing has an obligation to ensure that accessible, high quality, health services are available for persons whose health needs are unmet (American Nurses' Association Code for Nurses, 1985). Securing grant monies to implement programs that improve the health outcomes of at-risk diabetics is essential until other sources of funding or programs are available. However, nursing must also provide policy makers with research supporting successful programs.

The study also has implications for policy makers. Healthy societies are productive societies. Prior research has demonstrated that lower mean blood glucose significantly delays or prevents long- and short-term complications. Vinicor (1994) makes a strong argument for treating diabetes as a public health disease, switching the focus from treatment to prevention. Clearly, preventing diabetes would be cost effective, however, it is not likely that this will occur in the immediate future since it would require universal access to preventive services (Vinicor, 1994). Therefore, the current issue for health policy makers to decide is if monies are to be spent on preventing costly complications or in treating them.

The cost of implementing such a program is minimal when compared to the short- and long-term benefits. Health policy makers frequently overlook the obvious when making reimbursement decisions. It is ludicrous to reimburse for insulin when the tools for determining the safe amount of insulin (e.g. glucose testing strips) are not reimbursable. This study demonstrated that uninsured or underinsured diabetics can achieve better glucose control when resources are made available to them.

Medicare does not cover insulin or syringes but does cover diabetes education, lancets, monitors, and one hundred test strips a month for diabetics using insulin. However, to be covered one must have Medicare Part B or be enrolled in a Medicare managed care program. On the other hand, Medicaid varies from state to state and only provides assistance to the very poor (Roberts, 2000). The recent decision in Oklahoma to reimburse for education, glucometers, and testing strips is encouraging, however, one must remember the uninsured or underinsured are mainly working adults that do not qualify for Medicare or Medicaid (Monheit, 1994).

In summary, eliminating the financial barrier in uninsured or underinsured diabetics facilitates the learning and implementation of diabetes self-management skills. By "leveling the playing field," this at-risk population can achieve lower mean serum glucose. Unless long term assistance with diabetes supplies, specifically glucose testing strips and insulin, is made available, it is unlikely that uninsured or underinsured diabetics will be able to maintain effective self-management strategies. Therefore, efforts to reach this population are essential. These efforts can be at the local, state, or federal level.

Recommendations for Further Study

The results of this study have provided the basis for future studies. Following are several recommendations for studies that should enhance or support the findings of this study.

1. Although the research findings supported the hypotheses, the effectiveness of this program for uninsured or underinsured Type 1 diabetics has not been determined. Only twenty percent (n = 4) of the sample were Type 1 diabetics, and only two experienced lower mean serum glucose after three months. This study should be repeated with equal groups of uninsured or underinsured Type 1 and Type 2 diabetics so the effectiveness of the program for each group can be evaluated separately.
2. The long-term effects of the program cannot be assumed since the dependent variables were only measured one time after the intervention. Similar studies that incorporate repeated measures of self-management skills and mean serum glucose will help determine if any "drop off effect" exists. If such a phenomenon is demonstrated, follow-up self-management education can then be incorporated into the program.
3. Reliability of measurements is the extent to which the measure yields the same results on repeated trials (Carmines & Zeller, 1990). Therefore, the previously untested Skills assessment instrument should be tested and reported in different populations. Once the consistency of the measure is established, researcher's can have more confidence in a study's outcome. According to Goodall and Halford (1991), a major difficulty in studying diabetes self-management is lack of reliable instruments.

4. This study demonstrated that supplying diabetes supplies and individualized one-to-one diabetes self-management education to at-risk diabetics was effective in lowering mean serum glucose and improving self-management skills. It is unknown if less costly group education sessions would demonstrate similar results. Finding similar results from group sessions would save time and money. Therefore, a study with a control group receiving group instruction with the same program would be helpful. However, obtaining sufficient numbers of uninsured or underinsured Type 1 diabetics from the same population may be challenging.
5. The same researcher conducted all the sessions which may have inadvertently biased the results. Offering the same program in similar populations with different educators would provide information about the effect of the educator on the outcomes.
6. Providing diabetes supplies eliminated the financial barrier to the implementation of self-management practices in uninsured or underinsured diabetics. A study that uses the same program with insured diabetics who have access to diabetic supplies would provide valuable information about the program's effectiveness in other populations.

Diabetic programs are expensive; however, the human and economic cost of not providing them is even greater. Research based on the above recommendations will provide valuable information to diabetes educators intent on planning and implementing diabetes education programs that improve health outcomes and are also cost effective.

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APPENDIX A

1998 Federal Poverty Guidelines

1998 Federal Poverty Guidelines for the 48 Contiguous
States and the District of Columbia

Size of family unit	Poverty guideline
1	$8,050
2	10,850
3	13,650
4	16,450
5	19,250
6	22,050
7	24,850
8	27,650

For families units with more that 8 members, add $2,800 for each additional member. (The same increment applies to smaller family sizes, as can be seen in the figures above.)

Source: Department of Health and Human Services. (February 24, 1998). Annual Update of the HHS Poverty Guidelines. Federal Register, 63 (36). [Guidelines posted on the World Wide Web]. Washington, DC: Author. Retrieved May 16, 1998 from the World Wide Web: http://aspe.os.dhhs.gov/poverty/98fedreg.htm.

APPENDIX B

Approval from Dissertation Committee for Prospectus

TEXAS WOMAN'S UNIVERSITY
DENTON DALLAS HOUSTON
COLLEGE OF NURSING, DENTON

PROSPECTUS FOR THE DISSERTATION

This prospectus proposed by: Helen Hansen, RN, MS

[redacted]

Titled: Health Outcomes of a Diabetes Supply and Diabetes Self-Management Education Program in an At-risk Population

Has been read and approved by the members of his/her research committee.

This research (check one):

__X__ involves human subjects (Student submits application materials to Human Subjects Review Committee);

_____ involves use of animals (Student submits application materials to Animal Care and Use Committee);

_____ does not involve either human subjects or animals.

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APPENDIX C

Approval Letter from the Graduate School for Prospectus

[redacted]

TEXAS WOMAN'S UNIVERSITY

DENTON / DALLAS / HOUSTON

[redacted]

THE GRADUATE SCHOOL
P.O. Box 425649
Denton, TX 76204-5649
Phone: 940/898-3400
Fax: 940/898-3412

February 2, 1999

Ms. Helen Hansen
6242 E. 100th St.
Tulsa, Ok 74137

Dear Ms. Hansen:

Thank you for providing the materials necessary for the final approval of your *Dissertation* prospectus in the Graduate School. I am pleased to approve the prospectus entitled **"Health Outcomes of a Diabetes Supply and Diabetes Selfmanagement Education Program in an At-risk Population"**, and I look forward to seeing the results of your study.

If I can be of further assistance, please let me know.

Sincerely yours,

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

APPENDIX D

Approval Letters from Human Subjects Review Committee

[redacted]

TEXAS WOMAN'S UNIVERSITY

DENTON / DALLAS / HOUSTON

HUMAN SUBJECTS
REVIEW COMMITTEE
P.O. Box 425619
Denton, TX 76204-5619
Phone: 940/898-3377
Fax: 940/898-3416

January 4, 1999

Ms. Helen Hansen
6242 East 100th St.
Tulsa, OK 74137

Dear Ms. Hansen: [redacted]

Your study entitled "Health Outcomes of a Diabetes Supply and Diabetes Self-management Education Program in an At-risk Population" has been reviewed by a committee of the Human Subjects Review Committee and appears to meet our requirements in regard to protection of individuals' rights.

If applicable, agency approval letters obtained should be submitted to the HSRC upon receipt. **The signed consent forms and an annual/final report (attached) are to be filed with the Human Subjects Review Committee at the completion of the study.**

This approval is valid one year from the date of this letter. Furthermore, according to HHS regulations, another review by the Committee is required if your project changes. If you have any questions, please feel free to call the Human Subjects Review Committee at the phone number listed above.

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

TEXAS WOMAN'S UNIVERSITY

HUMAN SUBJECTS REVIEW COMMITTEE
P.O. Box 425619
Denton, TX 76204-5619
Phone: (940) 898-3377
Fax: (940) 898-3416
e-mail: HSRC@twu.edu

December 10, 1999

Ms. Helen Hansen
6242 East 100th St.
Tulsa, OK 74137

[redacted]

Dear Ms. Hansen:

Re: *Health Outcomes of a Diabetes Supply and Diabetes Self-management Education Program in an At-risk Population*

The request for an extension for the above referenced study has been reviewed by a committee of the Human Subjects Review Committee and appears to meet our requirements in regard to protection of individuals' rights.

If applicable, agency approval letters obtained should be submitted to the HSRC upon receipt prior to any data collection at that agency. The signed consent forms and an annual/final report are to be filed with the Human Subjects Review Committee at the completion of the study.

This extension is valid one year from January 4, 2000. Furthermore, according to HHS regulations, another review by the Committee is required if your project changes. If you have any questions, please feel free to call the Human Subjects Review Committee at the phone number listed above.

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

APPENDIX E

Agency Consent Form

TEXAS WOMAN'S UNIVERSITY
COLLEGE OF NURSING

AGENCY PERMISSION FOR CONDUCTING RESEARCH

THE Community Action Project (Project-Get-Together)

GRANTS TO Helen L. Hansen, RN, MS

a student enrolled in a program of nursing leading to a Master's/Doctoral Degree at Texas Woman's University, the privilege of its facilities in order to study the following problem.

Health Outcomes of a Diabetes Supply and Diabetes Self-Management Education Program in an At-Risk Population

The conditions mutually agreed upon are as follows:

1. The agency (may) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) (may not) be identified in the final report.
3. The agency (wants) (does not want) a conference with the student when the report is completed.
4. The agency is (willing) (unwilling) to allow the completed report to be circulated through interlibrary loan.
5. Other ______________________________

Dissertation/Theses signature page is here.

To protect individuals we have covered their signatures.

APPENDIX F

Subject Consent to Participate in Research

TEXAS WOMAN'S UNIVERSITY

SUBJECT CONSENT TO PARTICIPATE IN RESEARCH

Study Title: "Health Outcomes of a Diabetes Supply and Diabetes Self-management Program for At-Risk Diabetics"

Researcher: Helen L. Hansen, RN, MS, doctoral candidate, Texas Woman's University

Phone numbers: 918-631-2918 (Office) or 918-632-6638 (Pager)

Research Advisor: Maisie Kashka, Ph.D. Phone number: 940-898-2401 (Office)

I understand that this is a research study and the purpose is to determine if a diabetes supply and diabetes self-management program will improve my health. The researcher has explained that I will meet with her every two weeks for five sessions. A sixth session will be one month after the fifth session. The sessions will take no more than sixty to ninety minutes. At the first session I will have my blood sugar checked and fill out three forms One form is a questionnaire about how I take care of my diabetes, and two forms will provide information about me. The last form will be filled out by my doctor so I can get the free insulin each month. I will also have a sample of blood taken by the researcher at the first and last session. It will be taken from a fingerprick and will test my average blood sugar over the last three weeks.

At the first session I will be given a month's supply of glucose testing strips, syringes, insulin, lancets, and a small booklet to keep records. These supplies will be replaced each month, for three months, when I meet with the researcher. I understand that I can keep the supplies if I am unable to complete the study. I will also try to record my blood sugars and exercise times in a record book and bring it to each session. The researcher gave me her phone and pager number so I can call her with any questions between meeting times.

The researcher explained that the possible risks of the study are: pain when the finger is pricked to get the blood sample, loss of my time, fatigue, emotional distress from the information I am given about diabetes, and improper release of information. Although the pain from the fingerstick is minimal, the researcher will minimize this by following the proper procedure. The loss of time and fatigue will be minimized by meeting with me at convenient times, having short questionnaires, and getting the blood sugar test results in four minutes. I know some of the information may scare me, but the researcher will answer my questions. To prevent improper release of information, the researcher will keep my files in a locked file cabinet, and shred them after three years. Information stored on the computer will be in a secured file and deleted after three years.

I understand that there are benefits to the study. I will receive free insulin and diabetes supplies for three months. The sessions with the researcher will help me to better understand and manage my diabetes. I can have a copy of the results when the study is done.

My participation is voluntary and I can withdraw at any time without it affecting any of the services that I am eligible for at Community Action Project (Project-Get-Together) either now, or in the future. I will be given a signed and dated copy of this consent form to keep.

The researchers will try to prevent any problem that could happen because of this research. I should let the researcher know at once if there is a problem and they will help me. I understand, however, that TWU does not provide medical services or financial assistance for injuries that might happen because I am taking part in this research.

If I have any questions about the research or about my rights as a subject, I should ask the researchers: their phone numbers are at the top of this form. If I have questions later, or wish to report a problem, I may call the researchers or the Office of Research and Grants Administration at 940-898-3375.

I have read this consent form and understand the contents. I freely consent to participate in this study under the conditions described.

______________________ ______________________ ______________
Signature of Participant Phone Number Date

______________________ ______________
Signature of Researcher Date

APPENDIX G

"Diabetes Survey" Data Collection Form

Project-Get-Together Diabetes Supply Program
Diabetes Survey

1. Who answers your questions about diabetes? ____________________

2. When was the last time you went to a class about diabetes? __________
   How long were the classes?____________________
   How many days were the classes?____________________
   Where were the classes?____________________

3. What is the hardest thing about having diabetes?
____

4. How many times in the past year have you seen a doctor for your diabetes? ____________________

5. Have you been in the hospital in the past year for your diabetes?________
   How many times?____________________

6. What does your blood sugar usually run?____________________

7. What was your blood sugar this morning?________

8. Do you have time to exercise?__________
   How many minutes a day do you exercise?__________
   How many times a week do you exercise?__________
   How do you exercise? __________

9. What is your age?_______ 10. What is your race?________

11. What was the last year of school you attended?________

12. Are there any diabetes medicines that you do without because they cost too much? ____________________

13. Are there any diabetes supplies that you do without because they cost too much? ____________________

Appendix H

Diabetes Supply Program Patient Information Form

PROJECT GET TOGETHER

Diabetes Supply Program

Patient Information

Patient's Name:______________________________

Address:______________________________

City:__________ County__________ State:__________ Zip:__________

Telephone:_____/__________ Age:__________ Race:__________

INCOME: Weekly$__________ Monthly$__________ Yearly$__________
Food Stamps__________ SSI__________ MED. SS__________ TANF__________
Voc. Rehab__________ Work Income__________ Other__________

MONTHLY EXPENSES: RENT__________ HOUSE PAYMENT__________
Groceries__________ Other Payments__________

Employment:______________________________ Phone__________
Address:______________________________ City__________
Unemployed: Yes__________ No__________ Retired: Yes__________ No__________
Are you registered with the State Employment Services? Yes__________ NO__________
How long have you been unemployed?______________________________
Medicaid #__________ Medicare #__________

WHAT SUPPLIES DO YOU NEED HELP WITH AT THIS TIME?

INSULIN: Human__________ Reg__________ NPH__________ OTHER__________
Conventional__________ Reg__________ NPH__________ OTHER__________
Beef__________ Beef/Pork__________ Pork__________

MONITORING STRIPS: Brand Name of Machine______________________________
Name of Strips if Visual Method is used______________________________

SYRINGES: 1cc__________ 1/2__________ 3/10cc__________

THE ABOVE INFORMATION IS TRUE AND CORRECT:

SIGNED______________________________ DATE__________

Referred to PGT by:______________________________ Phone__________
Address______________________________ City__________ Zip__________

Name of Attending Physician:______________________________
Address______________________________ Phone__________

APPENDIX I

Physician Prescription Form

PROJECT GET TOGETHER

Diabetes Supply Program

Physician Prescription

Patient's Name:______________________________

Diabetes Diagnosis:

Type 1 - Insulin Dependent ______________________________

Type 2 - Non-Insulin Dependent ______________________________

Gestational ______________________________

insulin:

Human:

Would you approve a change to Novolin if Project Get Together could not furnish Humulin to your patient?

Yes__________ No__________

Action of Insulin: Regular__________ NPH__________ Lente__________
Other__________

Conventional:

Action of Insulin: Regular__________ NPH__________ Lente__________
Semi-Lente__________ Ultra-Lente__________

Source: Beef__________ Beef/Pork__________ Pork__________

I certify that the medication described above is correct and that the patient named above is in need of Emergency Medical Assistance.

Physician's signature:______________________________

Print/Type Name:______________________________

RETURN FORM TO: PROJECT GET TOGETHER
2020 South Maplewood
Tulsa, Oklahoma 74112

APPENDIX J

"I'm in Control" Patient Information Form

I'm In Control – Patient Information Form

Name____ Date______________

Address______________________ City______________ State_____ ZIP__________

Phone: Home (   )______________________ Daytime (   )______________

Physician ______________________________ phone______________________

Support person ___________________________ Relationship ______________

Health Assessment

Diabetes: ☐type 1, or ☐type 2, or other_____ Date Diagnosed________________

Height______ Weight_______ Recent weight change _______ Blood pressure______

Other health history____

____

____

Current Medications-Diabetes	Dose	Times to take

Other Medications	Dose	Times to take

Allergies ____

Lab tests	Last test date	Result (normal range)	Next scheduled date
Glycohemoglobin			
Lipid's			
Other			

Educational Instruction and Outcomes

Barriers to learning or special learning needs - Planned instructional approaches

____

____

____

Participation in *I'm In Control* Classes:	Date Attended	Comments
Module I: I'M IN CONTROL: Covers basic information on the types of diabetes and goals for control. Reviews methods to monitor diabetes control.		
Module II: DIABETES LIFESTYLE: Covers basic information on healthy meal planning, exercise and managing stress.		
Module III: YOUR DIABETES MEDICINES: Reviews medications from orals to insulin and combinations. Instructs on administration and safety guidelines.		
Module IV: PREVENTING DIABETES COMPLICATIONS: Reviews the possible complications of diabetes and a plan for preventing complications and staying healthy.		

Outcomes of Each Class (Participant is able to:) Mastery	Yes	No
Module I: I'M IN CONTROL:		
Identify type of diabetes		
Describes goal blood glucose levels fasting, and before meals		
Demonstrate self blood glucose monitoring		
List members of the care team		
Module II: DIABETES LIFESTYLE:		
Reads a food label		
Creates a healthy meal plan with 5 fruits & vegetable daily		
Creates a physical activity plan to improve glucose control		
Identifies stresses in life and ways to cope		
Module III: YOUR DIABETES MEDICINES:		
Identify names and doses of personal diabetes medicines		
Describes actions of diabetes medicines		
Designs a plan of action of blood glucose is too low		
Designs a plan of action of blood glucose is too high		
List safety guidelines for current medicines		
Module IV: PREVENTING DIABETES COMPLICATIONS:		
Make an appointment for an annual dilated eye exam		
Do a foot check and able to care for one's own feet		
Make an appointment for an annual physical with recommended tests		
State the near normal blood glucose ranges to prevent complications		

APPENDIX K

"I'm in Control" Skills Assessment

I'M In Control Skills Assessment

Name____ **Date**____________

Please circle the number on the scale where you feel you are now able to do the following diabetes management skills. In areas where you need help, we will assist you with setting a goal. At the end of the education program you will score your goals again to check your progress.

1. I understand my goals for control and why blood glucose control is important. My goal for glucose control is:________________before breakfast.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score___________ date:________________
Reason for your score?

2. I am monitoring my blood glucose as instructed by my health care team. I test my blood glucose ______ times a day with the following meter___________________.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score___________ date:________________
Reason for your score?

3. I understand the results of my glycosylated hemoglobin test, done every _____months. My goal for this test is: __________ My last test result was __________.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score____________ date:__________________
Reason for your score?

4. I take my insulin or pills as instructed by my physician, my dose and times to take are:

____

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score____________ date:__________________
Reason for your score?

5. I am able to adjust my medication, diet and exercise to get good glucose control.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score____________ date:__________________
Reason for your score?

6. I am comfortable with following my meal plan. What meal plan do you follow?____

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score__________ date:________________
Reason for your score?

7. I understand my exercise plan and am able to follow it. Exercise plan:_Type of activity______________ How often______________ How much time?__________.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score__________ date:________________
Reason for your score?

8. I am having my eyes checked by an ophthalmologist (eye doctor) every year. Last check: ____________________ next appointment____________________

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score__________ date:________________
Reason for your score?

9. I am getting regular foot care. Who does it? ______________ When?

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score__________ date:_______________
Reason for your score?

10. I see my Diabetes Doctor at least every 3 to 6 months for a check-up. Last visit:______________ next visit______________________________.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score__________ date:_______________
Reason for your score?

11. I am coping with my diabetes and managing stress in life.

Not at all	Somewhat	OK	Fairly well	Completely
1	2	3	4	5

Personal Goal:

Evaluation of personal goal achievement, score__________ date:_______________
Reason for your score?

APPENDIX L

Personal Communication from Dr. R. Glasgow

From: Russ Glasgow [russkpf@earthlink.net]
Sent: Thursday, September 28, 2000 9:23 AM
To: Kathryn Madden
Cc: helen-hansen@utulsa.edu
Subject: RE: Dr. Glasgow

Dear Helen-

You are certainly welcome to use the model figure discussed below, or any modification of it in your dissertation.

Best wishes for your project- (FYI-.to possibly save you additional time and communications)- it is my understanding that for something like a disseration you are certainly free to include whatever you would like, as long as the source is acknowledged...if/when you decide to publish results in a journal or book, my understanding is that if you are using precise figure that someone else published, you need to get permission, but that if you are modifying it...appropriate thing would just be to refer to the original, but that you do not really need permission.

Sincerely,

Russ Glasgow

-----Original Message-----
From: Kathryn Madden [mailto:Kathryn@ori.org]
Sent: Monday, September 25, 2000 8:49 AM
To: 'russkpf@earthlink.net'
Subject: FW: Dr. Glasgow

-----Original Message-----
From: Helen Hansen [mailto:helen-hansen@utulsa.edu]
Sent: Monday, September 25, 2000 7:12 AM
To: kathryn@ori.org
Subject: Dr. Glasgow

I have tried to send this several times so I apologize if it is a duplicate.
I am trying to find out how to get in touch with Dr. Glasgow by email. I would like to use his model in my dissertation in a pictorial form. I also want to make a minor addition. I mailed him a letter and example today but think it would be easier to do by fax or email. Could you please forward this to Dr. Glasgow? My email is helen-hansen@utulsa.edu. My fax is 918-631-2068 Thank you for expediting this for me. Helen Hansen

APPENDIX M

Oklahoma State Department of Health
Skills Assessment and Health Form Permission Letter

Oklahoma State Department of Health
Creating a State of Health
Jerry Regier, Acting Director and
Secretary of Health and Human Services

October 9, 2000

Helen Hansen, RN, MS
6242 East 100th Street
Tulsa, Oklahoma 74137

Dear Ms. Hansen,

This letter is to verify that authorization has been given to include the "I'm In Control" Skills Assessment and Health Form in the appendix of your doctoral dissertation.

Thank you for promoting the "I'm in Control" diabetes education program of the Oklahoma State Department of Health. If you have any questions, please contact me at (405) 271-4072 extension 57106. Good luck in your dissertation defense.

Sincerely,

Myrna Rae Page

Myrna Rae Page, MPH, CHES
Coordinator, Diabetes Control and Prevention Program