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The Relationship of Metabolic Control to Hardiness, Self-Efficacy, and Perceived Medication Adherence in Adults with Diabetes Mellitus

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The Relationship of Metabolic Control to Hardiness, Self-Efficacy, and Perceived Medication Adherence in Adults with Diabetes Mellitus

A Dissertation submitted in partial fulfillment of the requirement
For the degree of Doctor of Philosophy
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By

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ABSTRACT

THE RELATIONSHIP OF METABOLIC CONTROL TO HARDINESS, SELF-EFFICACY, AND PERCEIVED MEDICATION ADHERENCE IN ADULTS WITH DIABETES MELLITUS

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Diabetes mellitus, a serious and costly disease, is a public health challenge. Diabetes is controllable, yet non-adherence to prescribed medications causes diabetes-related complications resulting in hospital admissions and readmissions that may be prevented. A cross-sectional, descriptive-correlational study was conducted to investigate the relationship of metabolic control (A1C) to hardiness, self-efficacy, and perceived medication adherence. Health-Related Hardiness Scale (Pollock, 1990); Long-Term Medication Behavior Self-Efficacy Scale (De Geest et al., 1994); and Perceived Medication Adherence Scale (Allison, 2000) were administered to 215 participants. Data analyses of correlation and multiple linear regression using SPSS 10.0 statistical software were performed. Metabolic control was not significantly predicted by hardiness, self-efficacy, and perceived medication adherence. However,

42% (n = 88) had A1C level < 7%. The Perceived Medication Adherence Scale was found to be of one factor structure and reliable. The findings indicate that physiological phenomena were not predicted by self-reported behavioral phenomena. Further research using an intervention study, such as patient education and/or telephone follow-up intervention in conjunction with diet and medication therapy needs to be conducted to determine whether metabolic control will be improved in adults with diabetes mellitus.

Chapter I: Introduction

Diabetes mellitus is a serious and complex disease. If left uncontrolled, diabetes can cause many complications – both microvascular (blindness as a result of retinopathy, end-stage renal disease, peripheral neuropathy, and non-traumatic lower-extremity amputations) and macrovascular complications (ischemic heart disease, stroke, and peripheral vascular disease). A high death rate from cardiovascular causes is due to high levels of risk factors for heart disease in individuals with diabetes. These risk factors are elevated fasting plasma glucose, blood pressure, cholesterol, triglycerides, obesity and cigarette smoking (Harris, 1998).

Despite the pending complications, patients with diabetes are often nonadherent (Kurtz, 1990). Adherence to the diabetes regimen varies from 7% in all aspects of the regimen (Cerkoney & Hart, 1980); 20% adherence with insulin injections (Watkins, Roberts, Williams, Martin & Coyle, 1967); to 57% (Cerkoney & Hart, 1980) to 70% of the monitoring regimen (Hopkins, Alford, Handelsman, Yue & Turtle, 1988). Nonadherence to the prescribed medication leads to poor diabetic control and infection, which are the cause of frequent hospital admissions and readmissions (Glasgow, McCaul & Schafer, 1987; Fishbein, 1985; Morris et al., 1997; Thompson, Cummings, Chalmers & Newton, 1995).

In a meta-analysis of 17,703 patients taking various medications for different medical conditions on a long-term medication regimen for treatment or cure, it was found that 50% of the patients did not take prescribed medications as instructed (Sackett & Snow, 1979; Wright, 1993). About 43% of the elderly population in a study were found to be prescription drug non-compliant for various reasons, including decreased comprehension and visual acuity, and inadequate labeling and medication changes (Kendrick & Bayne, 1982). A self-report survey of 341 female patients having diabetes who were 16 to 60 years of age found that insulin omission was common — 31% of the female subjects reported intentional insulin omission and 8.8% reported frequent omission (Polonsky et al., 1994). The practices of insulin injection and decision-making on insulin therapy among 100 persons, ages ranging from 17 to 64, with type 1 diabetes were studied. The study participants were asked a few open-ended questions and it was found that 31% of the study participants were skipping insulin injections for reasons varying from forgetfulness to intentional omission (Partanen & Rissanen, 2000). Poor compliance with insulin therapy in young insulin dependent diabetic patients was the major contributing factor to long-term poor glycemic control and diabetic ketoacidosis and, therefore, to increased hospital admissions (Morris et al., 1997; Thompson et al., 1995).

A 3-year retrospective case note review of all patients (N = 84) admitted with ketoacidosis to Ninewells Hospital between January 1991 and December 1993 found that non-adherence to the insulin regimen was 42% in young adult patients with hospital

admission for ketoacidosis (Thompson et al., 1995). In another study, 27% of the patients having diabetes had a specific educational deficit that was responsible for their hospitalization (Geller & Butler, 1981). Thus, from the literature, it can be seen that patients with diabetes have compliance problems with prescribed regimens like other patients with chronic illnesses.

Purpose

The purpose of the study was to investigate the relationships between the response variable, A1C (metabolic control), and three predictor variables (hardiness, self-efficacy, and perceived medication adherence) in adults with diabetes mellitus. Also, the Perceived Medication Adherence Scale used for this study was examined for further refinement, and retainment of factor structure and psychometric properties. The findings may become an impetus to conduct an experimental study in the future to determine how to improve management and control of diabetes.

Background and Significance

The prevalence of diabetes mellitus is increasing. It poses a significant public health challenge in terms of morbidity, mortality, and economic impact in the United States.

Prevalence

There are about 17 million (11.1 million people are diagnosed, and 5.9 million people are yet to be diagnosed) Americans - 6.2% of the population - who have diabetes (CDC, National Diabetes Fact Sheet, n.d., Retrieved February 23. 2003).

About 800,000 new cases are diagnosed each year, or 2,200 cases per day (Clark, 1998; Burke et al., 1999). Trends show that minority populations are disproportionately affected by diabetes. Between 1980 to 1999, the prevalence of diabetes was greater among blacks than whites; the age-adjusted prevalence was highest among black females (CDC, Statistics: Diabetes Surveillance System, n.d., Retrieved March 16, 2003). See Figure 1.

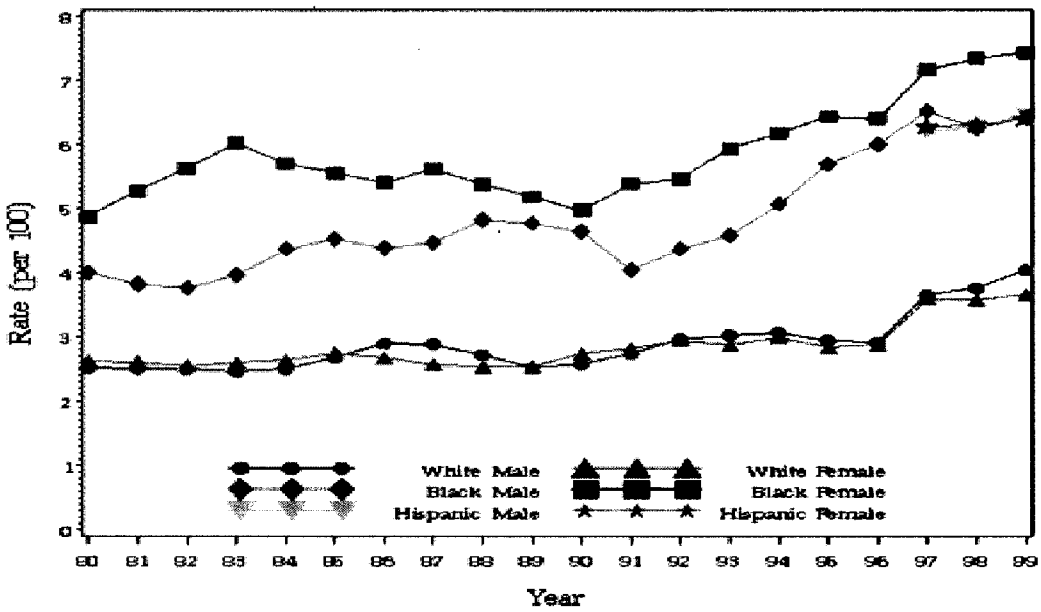


Figure 1. Age-Standardized Prevalence of Diagnosed Diabetes by Race/Ethnicity and Sex, United States, 1980-1999, CDC, Statistics: Diabetes Surveillance System, n.d., Retrieved March 16, 2003.

When age-specific prevalence of diagnosed diabetes by race/ethnicity and sex was examined, Black women had the highest prevalence among those aged less than 75 years and Hispanic men and women had the highest prevalence among those aged 75

years and older (CDC, Statistics: Diabetes Surveillance System, n.d. Retrieved March 16, 2003). See Figure 2.

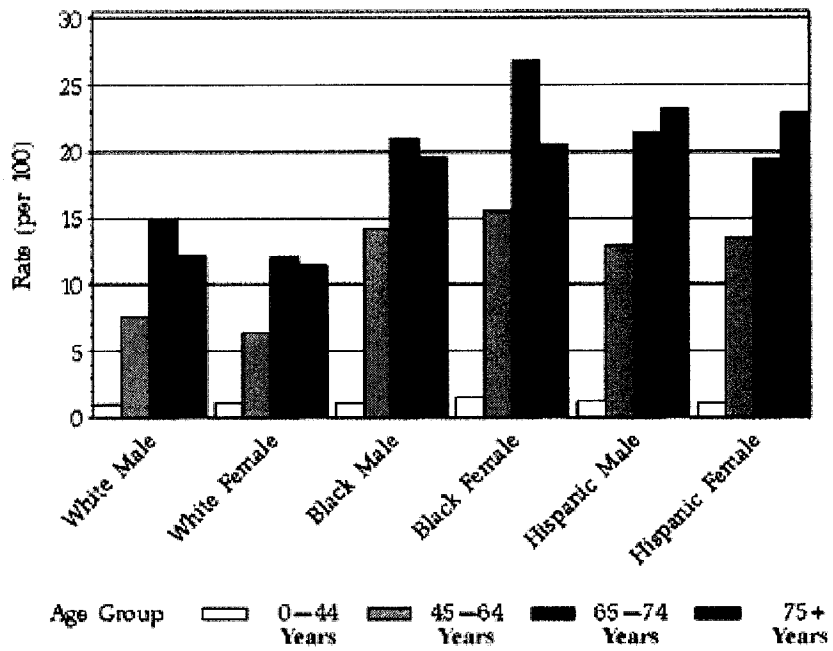


Figure 2. Age-Specific Prevalence of Diagnosed Diabetes, by Race/Ethnicity and Sex, United States, 1999, CDC, Statistics: Diabetes Surveillance System, n.d., Retrieved March 16, 2003)

Morbidity

Uncontrolled diabetes can cause infection, increased hospital admission and readmission. It further complicates the disease process affecting multi-organ systems. Heart disease is the leading cause of diabetes-related deaths; risk of stroke is 2 to 4 times higher in people with diabetes. High blood pressure is prevalent in 60% to 65% of people with diabetes. Blindness is caused by diabetes, which is the leading cause of new cases of blindness in adults 20 to 74 years old. Diabetic kidney disease causes end-

stage renal disease requiring dialysis or kidney transplant. Diabetes causes nervous system disease (impaired sensation or pain in the extremities, gastroparesis, carpal tunnel syndrome, etc.). The major contributing cause of lower extremity amputation is severe diabetic neuropathy (stepping on a nail leads to a nonhealing wound and then to amputation). Periodontal disease occurs with greater frequency and severity among people with diabetes. Complication of pregnancy contributes to congenital malformations in babies when preconception care is not received. Other devastating complications are diabetic ketoacidosis and hyperosmolar nonketotic coma that require hospitalizations. People with diabetes are more susceptible to and more likely to die of pneumonia or influenza than people without diabetes (CDC, National Diabetes Fact Sheet, n.d., Retrieved February 23, 2003). Diabetes was one of the top three recorded causes of 887,000 emergency room visits and one of three diagnoses for almost 2.2 million hospital outpatient visits in 1992 (Environmed Research Inc., 1999).

Type 2 diabetes mellitus may be the most rapidly growing chronic disease in the world (Nathan, 1995). Insulin resistance, a major cause of type 2 diabetes, is a condition of reduced sensitivity in both hepatic and peripheral tissues to the action of endogenous insulin (American Diabetes Association [ADA], 1998). Insulin resistance is strongly associated with obesity (Chatterjee & Scobie, 2002), defined as a Body Mass Index > 27 kg/m^2 (ADA, 1998). Insulin resistance is also known as syndrome X, or metabolic syndrome. It includes glucose intolerance leading to type 2 diabetes, hypertension, low HDL cholesterol, and elevated triglyceride levels leading to

atherosclerosis (Gavin, 2001), and obesity. One out of every four people in the U.S., (80 million Americans) have insulin resistance thereby increasing the risk for heart disease (The apple figure & insulin sensitivity, n.d., Retrived April 2, 2003). Furthermore, 80% of people with type 2 diabetes are either overweight or obese (Prescatore, 2003).

Mortality

Diabetes mellitus is a serious chronic disease that can cause premature death if uncontrolled. Diabetes is the 5th leading cause of death by disease in the U. S. (American Diabetes Association, 2003). The age-adjusted death rate was 13.5 deaths per 100,000 population in 1997. Diabetes was the seventh leading cause of death in the United States in 1997 (National Vital Statistics Reports, 1999). It was the sixth leading cause of death listed on U. S. death certificates in 1999 (CDC, National Diabetes Fact Sheet, n.d., Retrieved February 23, 2003). The crude and age-adjusted death rate was 19.4 deaths per 100,000 people in Virginia in 1998. Also, diabetes was the seventh leading cause of death in the Commonwealth of Virginia in 1998. The age adjusted death rate rose from 12.2 deaths per 100,000 population in 1940 to 21.8 deaths per 100,000 population in 2000 (Virginia Department of Health, 2000).

Economic Impact

Diabetes management is costly. Approximately $1 of every $6 - $7 spent on health care in the United States is spent on diabetes. Further, $1 of every $4 spent by Medicare on health care is spent on people with diabetes (Clark, 1998).

Total costs (direct and indirect) of diabetes in the United States in 2002 were estimated at $132 billion. Direct medical expenditures totaled $91.8 billion ($23.2 billion for diabetes care, $24.6 billion for chronic complications attributable to diabetes and over $44 billion for excess prevalence of general medical conditions [43.9% inpatient days and 15.1% nursing home, and 19.9% office visits]). Indirect expenditures totaled $39.8 billion resulting from lost workdays, restricted activity days, mortality, and permanent disability due to diabetes (American Diabetes Association, 2003).

Treatment of diabetic complications consumes a tremendous amount of health care resources. "From the perspective of a single-payer national health system, it was estimated that blindness costs approximately $2,000 per person per year in direct medical costs, end-stage renal disease costs approximately $45,000 per patient per year, and amputation costs approximately $31,000 per patient per episode" (Herman & Eastman, 1998, p. C21).

Diabetes mellitus is a serious and complex disease, but with intensive therapy it can be controlled and the rate of development and complications can be slowed. The Diabetes Control and Complication Trial (DCCT) Research Group (1993) reported that intensive insulin therapy for patients with insulin dependent diabetes (type 1 diabetes) reduced microvascular risk factors (retinopathy by 76%, nephropathy by 39% and neuropathy by 60%). The "Kumamoto" study revealed that intensive glycemic control by multiple insulin injection therapy delayed the onset and the progression of diabetic complications (retinopathy by 69% and nephropathy by 70%) in noninsulin dependent

(type 2) diabetic patients (Ohkubo et al., 1995). Patients with type 2 diabetes mellitus had improved blood glucose levels and reduced complications with intensive therapy with metformin, sulphonylurea or insulin (The United Kingdom Prospective Diabetes Study [UKPDS], 1995). The intensive treatment (sulphonylurea or with insulin, or conventional policy with diet) group had a 25% reduction in the risk of microvascular endpoint and a 16% risk reduction ($p = 0.052$) for myocardial infarction, including non-fatal and fatal myocardial infarction and sudden death. However, diabetes-related mortality and all-cause mortality did not differ between the intensive and conventional groups (UKPDS, 1998).

Empirically, there are knowledge gaps in ways to remedy the problems of non-adherence to the diabetes regimen (Watkins, Roberts, Williams, Martin, & Coyle, 1967; Polonsky et al., 1994; Partanen & Rissanen, 2000). Regimen non-adherence caused poor diabetic control and acquisition of infection that led to hospitalizations (Glasgow, McCaul, & Schafer, 1987; Fishbein, 1985; Morris et al., 1997; Thompson, Cummings, Chalmers & Newton, 1995) and long term complications (Harris, 1998). These findings are focused on finding non-adherent behaviors, rather than comprehensive solutions. The multi-center trials of DCCT (1993) and UKPDS (1995) showed that intensive hypoglycemic medication therapies reduced diabetes related complications. However, published evidence of a cross-sectional descriptive correlational study being conducted at small clinic settings looking for the relationship between one dependent variable,

metabolic control (A1C), and the three predictor variables (hardiness, self-efficacy and medication adherence) with adults having diabetes was not found.

Conceptual Definitions

Adherence

For the purpose of this study, *adherence* will be used. Adherence is defined as "the process in which a person follows rules, guidelines, or standards, especially as a patient follows prescription and recommendations for a regimen of care" (Mosby's Dictionary, 1990, p. 27). Also, adherence is defined as "the degree to which a patient follows a predetermined set of behaviors or actions (established cooperatively by the patient and provider) to care for diabetes on a daily basis" (McNabb, 1997, p. 217). Some of the literature uses the word *compliance*. Compliance is defined as "the extent to which a person's behavior (in terms of taking medications, following diets or executing lifestyle changes) coincides with medical or health advice" (Haynes, 1979, p. 1-2). Thus, the word compliance may be considered interchangeably with the adherence.

Medication Adherence

Medication adherence is adherence with prescribed medication regimens. This concept has three dimensions, self-care, self-efficacy and decision-making (Allison, 2000).

Self-Care. Self-care is the voluntary practice of activities that enables individuals to maintain life, health, and well being in a variety of states or to move from one state to another (Orem, 1995).

Self-Efficacy or Perceived Self-Efficacy. Self-efficacy is a central concept in Bandura's Social Cognitive Theory (Social Learning Theory) and it is defined as "people's judgments of their capabilities to organize and execute courses of action required to attain designated types of performances. It is concerned not with the skills one has but with judgments of what one can do with whatever skills one possesses" (Bandura, 1986, p. 391). Perceived Self-Efficacy is the estimation of a person's own efficacy. For the purpose of this study, perceived self-efficacy and self-efficacy are used interchangeably.

Decision-making. Decision-making is the process of deciding or making up one's mind for health promotion in this study.

Hardiness

Hardiness is defined as a personal constellation of attitudes, beliefs, and behavioral tendencies that consist of commitment, control and challenge (Lambert & Lambert, 1999).

Commitment. Hardy persons have an ability to feel deeply involved or committed to the activities of their lives (Kobasa, 1979). Appraisal and coping lead to involvement in health-related activities appropriate for dealing with the health stressors (Pollock, 1989a).

Challenge. Hardy persons see change as an exciting challenge for further development (Kobasa, 1979). Reappraisal of health stressors is potentially beneficial (Pollock, 1989a).

Medication Behavior Self-Efficacy

Medication behavior self-efficacy includes concepts used in the development of the long-term medication behavior self-efficacy scale that is based on Bandura's conceptualization of dimensions of self-efficacy (De Geest, Abraham, Gemoets, and Evers, 1994). The concepts used in the scale are personal attributes, environmental factors, and task related and behavioral factors.

Personal Attributes. Personal attributes are comprised of four themes. The themes are emotional distress, confidence in the physician, perceived health status, and normalcy.

Environmental Factors. Environmental factors consist of the themes of routine, distraction, social support and cost of medication.

Task-Related and Behavioral Factors. Task-related and behavioral factors are composed of the themes of side effects, drug delivery system, medication aids, medication schedule, and knowledge.

Metabolic Control

Metabolic control refers to glycemic status, or glucose level in the blood, which indicates the degree of diabetes control.

Overview of the Study

Diabetes mellitus is an increasingly common and serious chronic disease that poses a threat to individuals' health, finances and quality of life. Diabetes is a controllable disease, yet nonadherence with an appropriate hypoglycemic regimen causes an increase in morbidity and mortality. Diabetes-related complications cause hospitalization that may be prevented by education interventions. This study is a descriptive-correlational study investigating the relationship of metabolic control to hardiness, self-efficacy, and perceived medication adherence. The value of metabolic control was obtained by accessing the laboratory value of A1C, which was measured every visit the patient made to the diabetes and primary care clinics.

To measure some characteristics of persons with diabetes and their medication adherence and management behaviors, demographic data (Appendix A) were obtained, then, three scales were administered. The patients completed Health-Related Hardiness Scale (Appendix B) by Pollock (1986; Pollock & Duffy, 1990; Pollock, Christian, & Sands, 1990), and the Long-Term Medication Behavior Self-Efficacy Scale (Appendix C) by De Geest et al. (1995) to determine if high self-efficacy was related to metabolic control in participants' long-term medication regimens. Finally, the Perceived Medication Adherence Scale (Allison, 2000; Appendix D) was administered to determine how well the research participants practice their prescribed hypoglycemic medication adherence.

Surveys were stored in a locked filing cabinet accessible only to this co-investigator. Data were entered by this co-investigator manually. The design of the study was non-experimental, cross-sectional, descriptive-correlational study. For data analysis, correlation and multiple linear regressional analyses using SPSS 10.0 statistical software were performed.

Chapter II: Conceptual Framework

The conceptual framework for this study is presented in Figure 3. Unless adults with diabetes feel in control of their disease, managing diabetes can be stressful and it may not be controlled. A hardy personality type may influence day-to-day diabetes management decisions. Which personality constellation influences hypoglycemic medication adherence, and the level of adaptation as well as the role of self-efficacy in the management of diabetes needed to be determined. Once the medical providers know the pattern of medication adherence of their patients with diabetes, metabolic control will be predictable. The conceptual framework for this study was based on the concept of hardiness by Kobasa (1979), and health-related hardiness by Pollock (1986) in conjunction with her adaptation to chronic illness model (Pollock, 1989a), long-term medication behavior self-efficacy by DeGeest et al. (1994), self-efficacy concept by Bandura (1977), and perceived medication adherence based on Orem's Self-care (Orem, 1995).

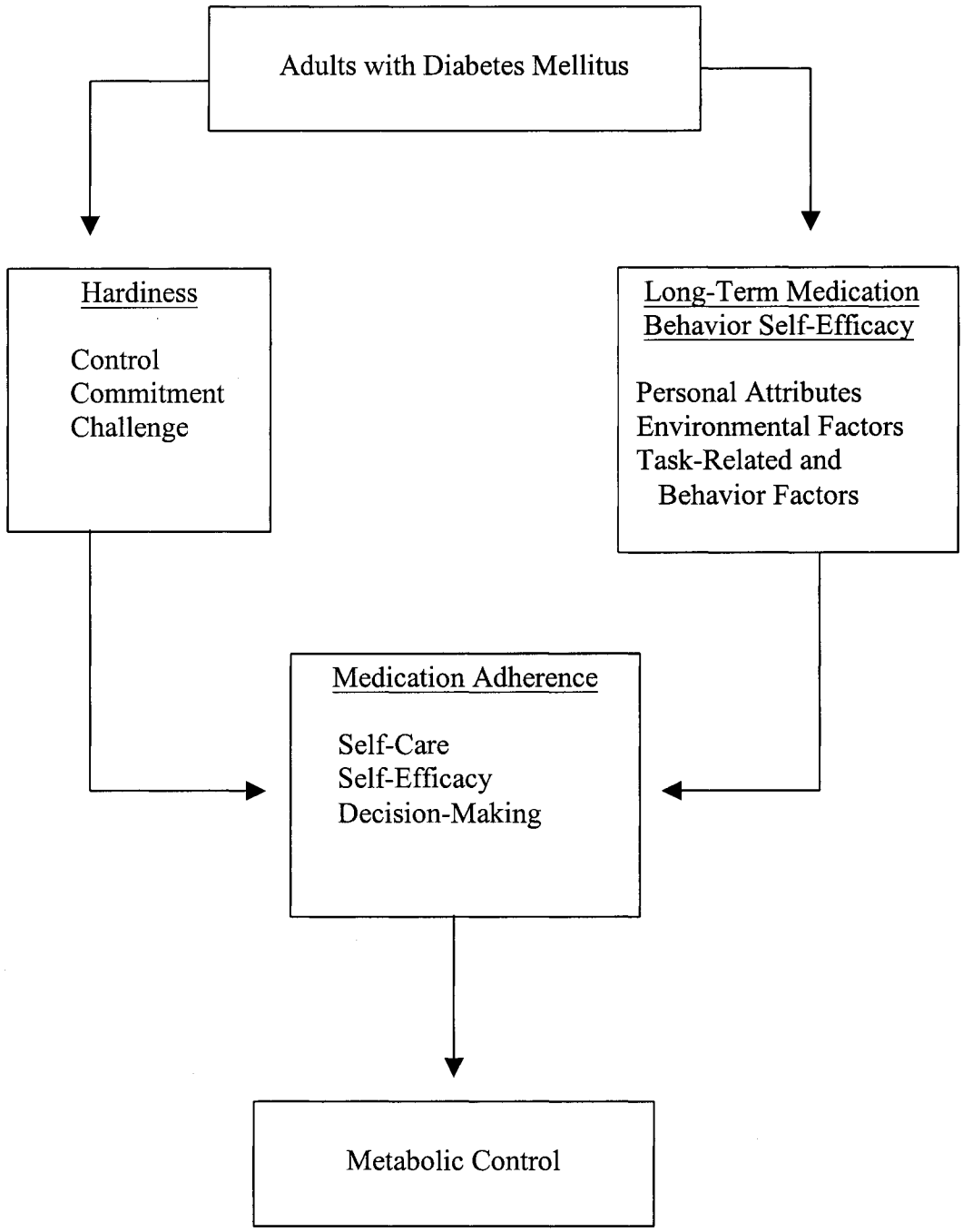


Figure 3. Conceptual Framework of Metabolic Control in Persons with Diabetes

Hardiness Concept

The concept of hardiness as a personality characteristic was developed by Kobasa (1979). Hardiness is a constellation of personality characteristics that function as a resistance resource in the encounter with stressful life events. According to Kobasa (1979), when people experience a high degree of stress, some fall ill, and some overcome the adversity by transforming themselves to cope with the situation and do not fall ill. Persons who can cope with the adversity and stay healthy have the personality characteristic of hardiness. Hardy persons possess three general characteristics: commitment, control, and challenge. They have the ability to feel deeply involved in or committed to the activities of their lives and anticipate change as an exciting challenge to further development. Persons low in hardiness might exaggerate constitutional predispositions by engaging in negative health practices - overeating and overdrinking (Kobasa, Maddi, & Kahn, 1982). Hardy persons believe that they can control or influence the events of their experience, and yet, when they recognize their inability to control the events, they ask others for help, thereby keeping the events under control. Kobasa (1979) developed three hypotheses related to health and illness. Among persons under stress: (a) Those who have a greater sense of control over events in their lives will remain healthier than those who feel powerless when facing external forces, (b) those who feel committed to the various areas of their lives will remain healthier than those who are alienated, and (c) those who view change as a challenge will remain healthier than those who view it as a threat.

On the basis of 670 completed stress and illness questionnaires from public utility male executives (middle and upper level), Kobasa (1979) asserts that hardiness is confirmed by the study. High stress/low illness executives are: (a) more in control, more committed, and more oriented to challenge than are high stress/high illness executives; (b) distinguished by their sense of commitment to (not alienated from) self, their sense of vigorousness and sense of meaningfulness and locus of control in life; and (c) viewing themselves as having less stress than high stress/high illness executives do. Results of Kobasa's study postulate that personality may have something to do with staying healthy. Further, hardiness has its greatest health-preserving effect when stressful life events mount (Lambert & Lambert, 1987).

Health-Related Hardiness (HRH):

The concept of HRH was developed on the basis of Roy's adaptation model, Kobasa's hardiness characteristics, Pollock's adaptation to chronic illness, and Lazarus' work on the concept of coping:

> The "health-related hardiness framework postulates that, when a hardy person is confronted with a health stressor, he or she possesses the confidence and self-mastery to appraise and modify responses appropriately (control). The framework, also, cognitively reappraises the health stressor so that it is viewed as stimulating and beneficial or an opportunity for growth (challenge), which, in turn, is evidenced by motivation and competence in promoting his or her health

and coping with the health stressor (commitment)" (Pollock, 1999, p. 1). Persons are challenged (rather than threatened) when confronted with a health stressor, which in turn, becomes a personal commitment. Hardy individuals dealing with a chronic health problem may not separate health into discrete categories but appraise the condition as a challenge, because they are committed to maintaining their health.

Adaptation to Chronic Illness

Adaptation to chronic illness is based on the integration of the major variables of chronicity, stress, hardiness, and physiological and psychosocial adaptation. The integration process is complex, and one is expected to go through both internal and external processes to achieve one's physiological and psychosocial adaptation to the chronic illness (Pollock, 1986), such as diabetes. The presence of the hardiness characteristic was significantly correlated with physiological adaptation in patients with diabetes (Pollock, 1986). Pollock (1989a) developed the moderating effect of hardiness (Figure 4) on adaptation to the chronic illness framework.

"Hardiness may indirectly affect adaptation to chronic illness by influencing the individual's perception of the stressor (chronic illness), the coping strategies chosen, or the social resources used" (p. 59). Unlike Kobasa, Pollock pointed out that an individual's perception and use of social resources were significantly related to the presence of hardiness in healthy adults.

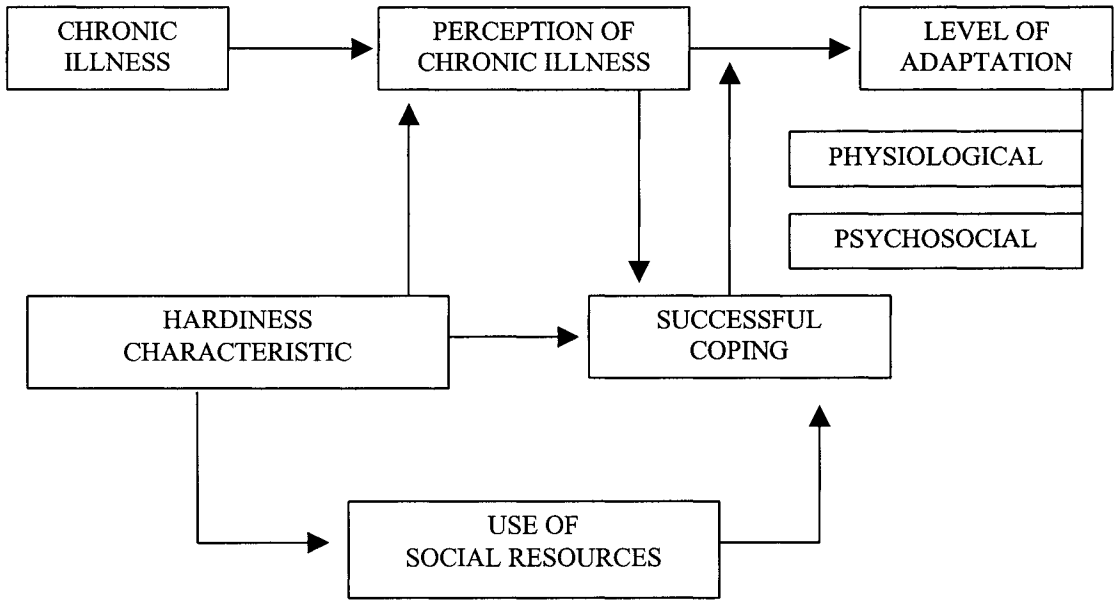


Figure 4. Moderating Effect of Hardiness (Indirect). Reprinted with permission (Appendix E) from Pollock, S. E.: The hardiness characteristic: A motivating factor in adaptation, 1989a.

Long-Term Medication Behavior Self-Efficacy

Self-Efficacy. Perceived self-efficacy is the central concept of the social cognitive theory by Bandura (1977). Expectations of personal efficacy (self-efficacy) "determine whether coping behavior will be initiated, how much effort will be expended, and how long it will be sustained in the face of obstacles and aversive experiences" (p. 191). Self-efficacy beliefs function as important determinants of human motivation, affect, and action (Bandura, 1989). Perceived self-efficacy proved to be an accurate predictor of performance in the inactive mode of treatment although subjects were engaged in no overt behavior. Also, it proved to be a better predictor of

behavior toward unfamiliar threats than did past performance (Bandura, 1977). Further, "perceived self-efficacy influenced performance both directly and through its strong effect on personal goal setting. Personal goals, in turn, enhanced organizational attainments directly and by means of the mediation of analytic strategies" (Bandura & Wood, 1989, p. 813). Therefore, the higher the level of one's self-efficacy, the higher the performance accomplishments and the lower the emotional arousal expected (Bandura, 1982) because those who have a high sense of self-efficacy visualize success scenarios that provide positive guides for performance (Bandura, 1989).

Understanding and promoting medication adherence are vital areas in nursing practice. The Long-Term Medication Behavior Self-Efficacy Scale (Appendix C) was developed by De Geest, Abraham, Gemoets and Evers (1994) based on Bandura's conceptualization of dimensions of self-efficacy. Dimensions and attributes of the scale are composed of:

1. Personal attributes with the themes of emotional distress, confidence in the physician, perceived health status, and normalcy affect the precision of medication intake.

2. Environmental factors include the themes of routine, distraction, social support and cost of medication influence medication-taking behavior.

3. Task-related and behavioral factors are composed of the themes of side effects, drug delivery system, medication aids, medication schedule, and knowledge.

Medication Adherence

Medication adherence is a health promoting behavior that is achieved when an individual practices self-care. Orem's Self-Care Deficit model relates medication adherence as a self-care activity in individuals with diabetes. The word, deficit, stands for the relationship between the action individuals should take and the action capabilities of individuals for self-care or dependent-care. "Deficit in this context should be interpreted as a relationship, not as a human disorder" (Orem, 1995, p. 177). Self-care is a learned activity and it is an action of mature and maturing individuals who are responsible and capable of performing the needed care deliberately or voluntarily, for themselves to maintain life, health and well being of their whole being. This, in turn, will affect their human functioning, human development, and human structural integrity (Orem, 1995).

To promote health, individuals play a critical role in the determination of their own health status. Every day, they make decisions that form lifestyle, social and physical environments. Health promotion at the individual level improves decision-making, and practicing health thereby improves self-care, which is the main mode of individual health care (Pender, 1996). Orem (1995) describes health as the state of wholeness (structurally and functionally). It also includes psychological, physical, interpersonal, and social aspects of living. In order for individuals to manage and keep diabetes under control, they must be motivated and responsible for medicating

themselves in fulfilling their self-care responsibilities in terms of adhering to the hypoglycemic medication(s) prescribed to them. To enhance the subject's self-care practice, Orem's self-care theory is appropriate for the development of the adult diabetes support group and diabetes education (Morris, 1998).

Medication adherence also requires individual decision-making strategies to promote health. There are four decision-making strategies that are conceptualized by Janis and Mann (1977). These are:

Optimizing and the perils of suboptimizing. "When an individual makes a vital decision bearing on his career, marriage, or health or on any other aspect of his personal welfare, he does not think only about the major utilitarian goals to be attained. He also takes account of a multiplicity of intangible considerations bearing on the probable effects of the chosen and unchosen courses of action on relatives and friends" (p. 24-25). The person's self-esteem with regard to living up to his personal standards of conduct also affects his decision-making.

Satisfying. This strategy is meeting a "good enough" outcome (minimal requirements).

Mixed scanning. To features of the optimizing strategies combined with essential features of the elimination-by-aspects approach and an incremental process approach followed for the minor decisions, ensue after the basic desired direction is set. This strategy is involved in the main cognitive activities, "vigilant information processing."

The decision-maker's repertoire. Every decision-maker has in his repertoire a variety of substrategies and orientations, and he uses the strategy deemed effective for the situation at that particular moment (Jannis & Mann, 1977).

Metabolic Control

Hemoglobin A_{1c} (A1C) is the biochemical test that is used for this study as the index of metabolic control. Erythrocytes are freely permeable to glucose and their average life span is 120 days. The level of A1C in a blood sample provides a glycemic history of the previous 120 days, the average erythrocyte life span, thus reflecting the previous 2-3 months of glycemic control.

Theory of the Study

The dependent variable of the study is the metabolic control of the biochemical measure, A1C. Predictor variables are hardiness, self-efficacy, and perceived medication adherence. Cofactor variables are demographics (age, education, and race) and disease situation (comorbid chronic illness, diabetes medications and duration of diabetes).

Adults with diabetes must make constant decisions on monitoring and management in order to control their chronic illness and to avoid the development of diabetes related complications. This includes adherence to their prescribed regimen, especially hypoglycemic medication. Hardiness characteristics, self-efficacy, and perceived hypoglycemic medication adherence are considered very important variables

that contribute to prescribed hypoglycemic medication adherence. Therefore, adults with diabetes who are hardy and/or who have self-efficacy (while controlling for demographics and disease situation) will be more likely to practice hypoglycemic medication adherence thereby achieving metabolic control. However, the relationship between hardiness characteristics and self-efficacy has not yet been established. Therefore, it is reasonable to test perceived medication adherence practice by administering scales that test hardiness, self-efficacy, and perceived medication adherence to obtain answers. See Figure 5.

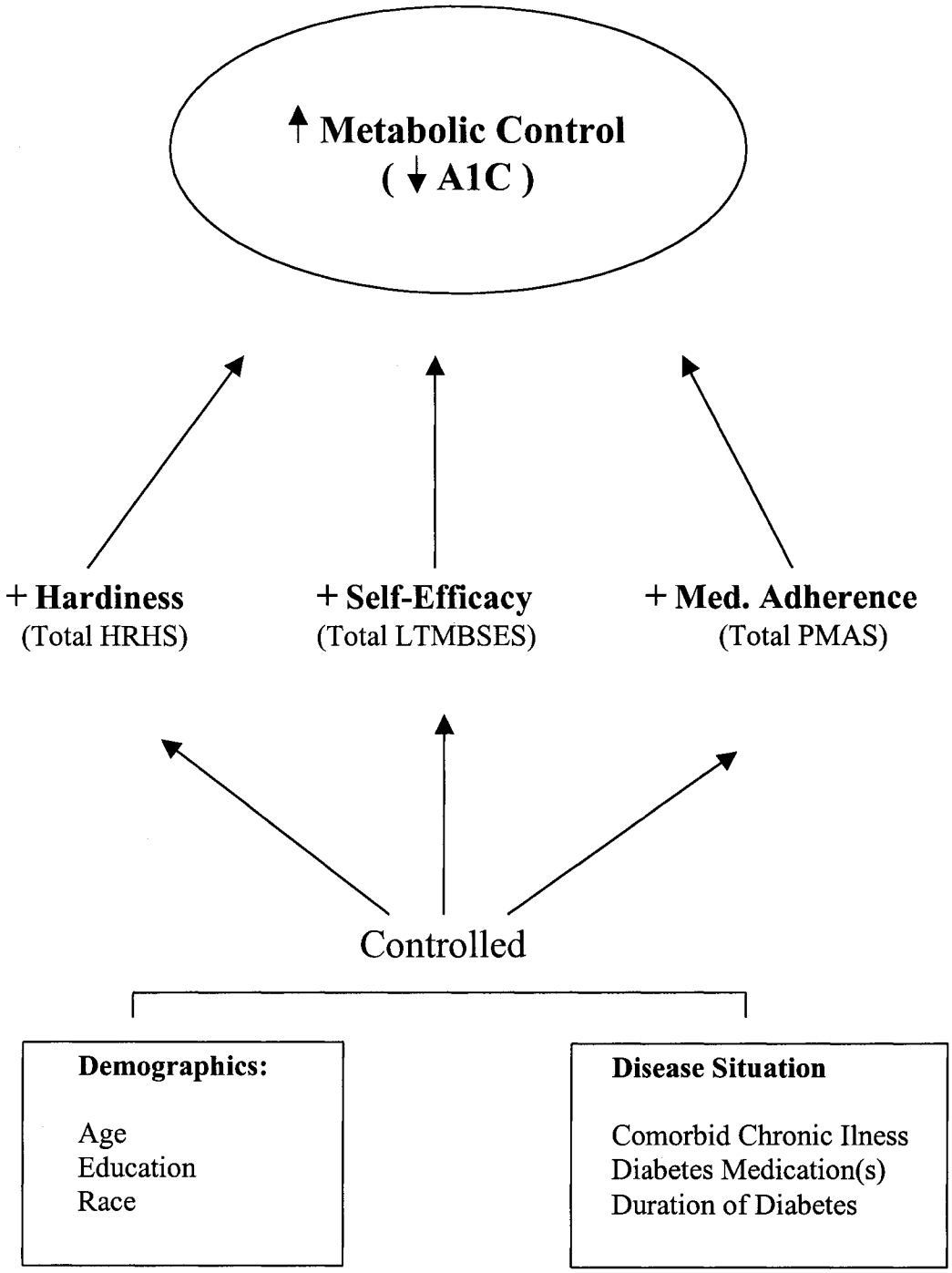


Figure 5. Theoretical Framework of Improved Metabolic Control

Achievement of Metabolic Control

Metabolic control can be achieved when adults with uncontrolled diabetes adhere to their prescribed regimens (hypoglycemic medications), when diet and exercise do not control their condition. A1C is a biochemical test that monitors the degree of metabolic control. The usefulness of A1C is further explored below.

A1C. The glycohemoglobin test is a useful test in assessing trends in response to therapy because it measures a patient's average glycemia over the preceding 2-3 months. The American Diabetes Association recommends that A1C testing should be performed routinely in all patients with diabetes at the initial visit to document the existing degree of glycemic control and approximately every 3 months thereafter for continuous care. For those patients who meet treatment goals, A1C should be performed at least two times a year. A1C should be performed quarterly in patients whose therapy has changed and in patients who are not meeting glycemic goals, in conjunction with the judgment of the clinician. A1C is a valuable tool for monitoring glycemia, but it is not currently recommended for the screening or diagnosing of diabetes (ADA, 2003). Depending on the assay method and laboratory used, the test may be called Hemoglobin A1C (A1C), Hemoglobin A_1, glycohemoglobin, glycated hemoglobin (GHb), or glycosylated hemoglobin. Glycated hemoglobin is expressed as a percentage (%) of total hemoglobin – the fraction of total hemoglobin that has glucose attached. Although the different measurements and different assay methods produce different

normal ranges, when properly performed, the readings correlate closely with each other. Though it is not used as a test for the diagnosis, A1C measurement improves the sensitivity of screening in high-risk individuals (Perry et al., 2001). Currently, efforts are underway to standardize the various assay methods world wide (American Diabetes Association, 1998). The combination of fasting plasma glucose (FPG) and A1C is recommended because it is more predictive than either parameter alone (Perry et al., 2001).

Measurement of A1C complements self-monitoring of blood glucose (SMBG) predictively and objectively. Discrepancies between SMBG and A1C results are considered more commonly due to problems with SMBG (Bardin, 1997). When A1C determinations are inconsistent with SMBG reports, concerns include the following: (a) The patient is misusing the SMBG equipment, (b) the patient is using a faulty or uncalibrated meter or (c) the patient is providing inaccurate data (ADA, 1998).

Metabolic control can be achieved and diabetes-related complications can be decreased with intensive management of diabetes. The Diabetes Control and Complications Trial (DCCT) research group found that patients with type 1 diabetes receiving intensive therapy had decreased diabetes-related complications — for every percentage decrease in glycated hemoglobin (A1C), there was a 25% decrease in diabetes-related deaths, a 7% decrease in mortality, and an 18% reduction in combined fatal and nonfatal myocardial infarction (Nicollerat, 2000). Further, the DCCT results indicate that the rate of progression of retinopathy is correlated with mean A1C levels;

successful efforts in lowering A1C corresponds with the lowering of the rate of complications. The United Kingdom Prospective Diabetes Study (UKPDS) group results showed that intensive therapy improves glucose control and reduces complications of persons with type 2 diabetes. The incidence of clinical complications was significantly associated with metabolic control as revealed in the UKPDS 35 prospective observational study. Each 1% reduction in updated mean A1C was associated with reductions in risk of 21% for any end point related to diabetes (17% to 24%, $p < 0.0001$). Twenty-one % for deaths related to diabetes (15% to 27%, $p < 0.0001$), 14% for myocardial infarction (8% to 21%, $p < 0.0001$), and 37% for microvascular complications (33% to 41%, $p < 0.0001$) (Stratton et al., 2000).

Metabolic control is achieved when A1C is less than 7 % (ADA, 2003), however, 6.5% or less is recommended by the American Association of Clinical Endocrinologists (AACE & the American College of Endocrinology, 2002). FPG level is 110 mg/dl or less; post prandal glucose of 140 mg/dl or less. The American Diabetes Association's recommendations for glycemic control for people with diabetes are illustrated in Table 1.

Table 1. Glycemic Control for People with Diabetes *

Biochemical Index	Nondiabetic	Goal	Additional Action Suggested
Preprandial glucose (mg/dl)+	< 110	80 - 120	< 80 > 140
Bedtime glucose (mg/dl)+	< 120	100 - 140	< 100 > 160
A1C (%)	< 6	< 7	>8

* The values shown in this table are by necessity generalized to the entire population of individuals with diabetes. Patients with co-morbid diseases, the very young and older adults, and others with unusual conditions or circumstances may warrant different treatment goals. These values are for nonpregant adults. "Additional action suggested" depends on individual patient circumstances. Such actions may include enhanced diabetes self-management education, comanagement with a diabetes team, in SMBG, or more frequent contact with the patient. A1C is referenced to a nondiabetic range of 4.0-6.0% (mean 5.0%, SD 0.5%). + Measurement of capillary blood glucose.

Reprinted with permission (Appendix F) from the American Diabetes Association (1998). Medical Management of Type 2 Diabetes (4th ed.), p.78.

Metabolic Control and Hardiness

Ross (1991) conducted research to determine if the presence of the hardiness personality characteristics influences compliance. She used the HRHS (total 40-items — 13 items measuring commitment, 13 items measuring challenge, and 14 items measuring control) and the Self-Management Compliance Questionnaire to test 50 hospitalized elderly participants with type 2 diabetes in a large metropolitan hospital in the United States. Alpha coefficients for the total HRHS in the study were 0.74. Reliabilities for subscales were 0.59 for control, 0.61 for commitment, and 0.49 for challenge. The study results revealed a significant correlation between the total HRHS ($r = -0.60$, $p < 0.05$) and compliance, although no significant correlations were found between the three subscales (control, commitment and challenge) of the HRHS and compliance. The study supported the notion that those who comply with their diabetic

regimen have the characteristics of hardiness. However, this study did not look at A1C levels.

To examine the influence of hardiness, self-efficacy, coping style, and psychosocial adaptation to illness on the metabolic control of insulin dependent and noninsulin dependent adults over the age of 17, Rapley (1990-1991) conducted an interview study of a total of 118 volunteers and administered four self-report instruments, including the HRHS, Psychosocial Adaptation to Illness Survey, Self-Efficacy scale and Ways of Coping Checklist. The reliability of the total HRHS alpha was 0.87, but subscales were 0.69 to 0.78. In this study, hardiness was a significant predictor of GHb (A1C) levels when adjusted for age, gender and diabetes type.

Metabolic Control and Self-Efficacy

Discussion of the conceptual issues related to self-efficacy for successful management of chronic illnesses like diabetes and rheumatoid arthritis relies on the individual's self-care ability to control symptoms and to avoid and/or prevent complications. Self-efficacy is central to an individual's view of self and it affects behavioral change. Managing chronic illness significantly requires individuals to improve confidence in a self-care regimen by increasing self-efficacy. Education is absolutely critical to avoid complications in diabetes management. Nurses should assess and tailor an education program focused on developing and strengthening an individual's sense of self-efficacy because people with strong efficacy beliefs are able to

withstand failures associated with mastering a complex task and are more likely to persist in their efforts with difficult tasks (Rapley & Fruin, 1999).

In a randomized, prospective, cross-over, one year study of 15 adults with type 1 diabetes to optimize insulin delivery, three intensive management strategies were used. The strategies were:

Simplified. This meal plan is based on food exchanges with no self-adjustments of insulin for food, exercise and stress.

Qualitative. This meal plan is based on food exchanges with qualitative adjustment of insulin.

Quantitative. This meal plan is based on using carbohydrate counting with quantitative adjustment of insulin for food and qualitative adjustment for exercise and stress. Adjustments of insulin were allowed for all three strategies based on preprandial blood glucose and the option of adjusting diet for exercise was allowed. Although there were no statistically significant differences in metabolic control, quality of life and self-efficacy among the three strategies, there was a clinically significant decrease in A1C levels with all strategies compared to baseline (baseline [10.9 $\pm$ 0.64]; simplified [9.7 $\pm$ 0.31]; qualitative [9.5 $\pm$ 0.44] and quantitative [10.2 $\pm$ 0.43]). There were no statistically significant differences in self-efficacy and quality of life between the strategies or in relation to time. The authors concluded that a strategy that is not very complex, such as "qualitative," and allows for flexibility of self-adjustments of insulin

may be the strategy of choice for intensive management programs (Kalergis et al., 2000).

A 12-month study was conducted to examine responses to continuous subcutaneous insulin infusion (CSII), known as insulin pump therapy, and multiple daily injections (MDI) of insulin in 75 adolescents (aged 12-20) with type 1 diabetes and to determine whether either treatment regimen more favorably affected clinical and psychosocial outcomes. The study found that the study participants' self-reported questionnaires demonstrated that there was improvement in self-efficacy, depression, and quality of life in both MDI and CSII treated patients. The average A1C levels were analyzed every 4-6 weeks and the results revealed improved metabolic control, initially, in both groups. The CSII group's A1C level continued to decrease during the 12-month study period (at 6 months A1C = 7.7, at 12 months A1C = 7.5) and the rate of severe hypoglycemic events was reduced by almost 50% in this group. The MDI group improved metabolic control initially, however, the group had more difficulty sustaining improvement for 12 months (at 6 months A1C = 8.1, at 12 months A1C = 8.3). The authors concluded that CSII is an alternative means to lower A1C levels and reduce the risk of hypoglycemia without compromising psychosocial outcomes in adolescents with type 1 diabetes (Boland, Grey, Oesterle, Fredrickson, & Tamborlane, 1999).

To determine whether a behavioral intervention, coping skills training (CST), combined with intensive diabetes management can improve the metabolic control and quality of life in adolescents, a randomized study was conducted with a total of 77

youths aged 12.5 to 20 years. The subjects were assigned into two groups: intensive management with coping skills training group or intensive management only group. Data were collected at pre-intervention and at 3 and 6 months post-intervention. At the conclusion of the study, the subjects who received CST had better metabolic control ($F = 3.89, p = .02$) and better general self-efficacy ($F = 4.54$, $p = .01$). They also reported fewer worries about diabetes and less negative impact of diabetes on their quality of life (Grey, Boland, Davidson, Yu, & Tamborlane, 1999).

Metabolic Control and Medication Adherence

Nonadherence to medication costs as much as $100 billion annually (Berf, 1993). Moreover, nonadherence with prescribed treatment may be the most serious obstacle to effective management of diabetes (Rosenstock, 1985).

A study was conducted to compare sulfonylurea adherence assessment by providers, patients' self-report, pill counts, and a medication event monitoring system (MEM-S-3 *R*) device, and to correlate the estimates of metabolic control by provider, patient, and laboratory. The study included 47 outpatient veterans with fair to poor metabolic control of type 2 diabetes mellitus receiving monthly refills of sulfonylurea in vials with a cap containing an electronic medication monitoring microprocessor. Outcome measures, including pill counts, monthly fasting plasma glucose, glycohemoglobin and a 24-hour diet recall, were obtained at the beginning of the study and at 60 days. The providers and patients were asked to assess adherence and metabolic control. The results revealed 47% were nonadherent to medication using

MEMS-*R*, 29% using pill counts, 29% using provider assessment, and 31% of patients assessed metabolic control differently than laboratory values. Metabolic control was not explained by medication adherence by provider, patient, and pill counts. Because sulfonylurea adherence and metabolic control both were influenced by numerous factors, it was not possible to accurately relate compliance and control (Mason, Matsuyama, & Jue, 1995). Adherence to insulin regimen did not correlate significantly with glycemic control (Boyer et al., 1996).

Based on the assumption that better regimen adherence produces better metabolic control of diabetes, a study investigating the degree of adherence to different aspects of the diabetic treatment regimen (insulin injections, glucose testing, diet, and exercise), adherence consistency across different regimens, and relationships between adherence and metabolic control was conducted. The prospective study included 93 adult outpatients with insulin dependent diabetes involving two series of home interviews at a 6-month interval. The measures of adherence included self-report, interview/recall, self-monitoring, and objective indices. The results revealed that the degree of adherence was higher for medication taking and glucose monitoring than a regimen requiring modification of lifestyle change, e.g., diet and exercise. There was no clear relationship between adherence and glycemic control. However, the glycemic control measures revealed that older subjects were in better glycemic control than younger subjects (A1C = 9.3% vs 11.2%, $t = 4.05, p < 0.001$). Duration of diabetes was related to several adherence measures, but not to glycemic control indices. Subjects

with diabetes longer than 10 years reported expending more time in work-related activities than subjects with a shorter diabetes history. However, subjects who had diabetes 10 years or less reported expending more time in recreational activities, and they exercised more days per week. Glucose testing adherence was very stable, but adherence to diet and to physical activity were less consistent over time. Recommendations for adherence to insulin injection and physical activity were not strongly related to adherence to other regimen areas. Males and persons with a longer duration of diabetes were less likely to control their eating patterns. "Younger subjects with a shorter history of diabetes and males seemed to be more physically active than females and persons who have had diabetes for a longer period of time" (Glasgow et al., 1987, p. 409).

Diabetes regimen adherence is a complex task and performance of any single self-care pattern is not strongly related to glycemic control. The authors concluded that there is not a straightforward relationship between adherence and control. Regimen adherence does not automatically lead to improved metabolic control. And yet, regimen adherence should be viewed as one of a variety of factors influencing glycemic control (Glasgow, McCaul & Schafer, 1987).

A cross-sectional study was conducted to investigate factors associated with adherence to diet and medication in 200 patients with type 2 diabetes mellitus from two hospitals in Leon, Mexico. Mean age of the participants in the study was 58.8 years. Using multiple regression analysis, the investigators found that adherence to diet was

associated with years since diagnosis of diabetes indicating that after years of having the disease, the participants had less denial and progressively accepted the diagnosis and treatment. On the other hand, the higher scores on adherence to medication were associated with having an older aged spouse which the authors believed that mature partners are more likely to give support to follow medical prescriptions. Adherence to medication was lower in patients from families with rigid control than in the group with Laissez-faire type of control. Further, rigid control may have an effect on decreased adaptation to change toward chronic disease within the family structure and may enhance the development of conflict with the authority, increasing the denial of the disease (Garay-Sevilla et al., 1995). The authors concluded that adherence to medication and diets in patients with type 2 diabetes mellitus are strongly associated with social support.

Schectman, Nadkarni, & Voss (2002) examined the relationship between adherence and diabetes metabolic control in a large indigent population hypothesizing that socioeconomic and minority populations have poorer diabetes outcomes and greater barriers to adherence. The study included 810 patients with type 2 diabetes who were on oral hypoglycemic medications (from the clinic pharmacy) and were receiving medical care from a university-based internal medicine clinic serving a low-income population in rural central Virginia. Using multiple linear regression, A1C level was examined to see whether there was any change in A1C level associated with medication adherence, demographics, and clinical characteristics. The findings were:

1. Adherence to hypoglycemic medication regimens was strongly associated with metabolic control in an indigent population. For each 10% increment in drug adherence, A1C level decreased by 0.16% at $p < 0.0001$. 2. African Americans (versus White race) had lower adherence and worse metabolic control; e.g., the mean A1C level was 0.29% higher than that of whites at $p = 0.04$ when other demographic and clinical variables were controlled (Schectman et al., 2002). Consequently, the authors emphasized the need for not only facilitating diabetes self-management behaviors of low-income populations but also fostering culturally sensitive and appropriate care for them.

Hardiness personal constellation has been studied on executives (Kobasa, 1979) and on patients with diabetes, but studies specifically looking for the relationship between hardiness and metabolic control, in terms of A1C level, on African American patients with diabetes are scarce. Rapley (1990-1991) conducted an interview study and administered self-report instruments, including the HRHS, to 49 patients with type 1 diabetes and 48 patients with type 2 diabetes. One of the findings was that "Hardiness was a significant predictor of GHb levels when adjusted for age, gender and diabetes type." (p. 44), however, the author did not specify the ethnicity of the study subjects. A study was conducted using the HRHS to predict compliance in 50 elderly participants with diabetes (Ross, 1991). Only 11 subjects were Black.

Summary

The prevalence of diabetes mellitus is increasing (CDC, National Diabetes Fact Sheet, n.d., Retrieved February 23. 2003; Clark, 1998; Burke et al., 1999). Diabetes poses a significant public health challenge because it is a serious, complex (Harris, 1998) and costly disease (Clark, 1998). If left uncontrolled, diabetes can cause many complications affecting all of an individual's body systems, prompting frequent hospitalizations, affecting quality of life and causing premature death. And yet, adherence to prescribed hypoglycemic agent is a challenge. Only 50% (across the board) of the people who need to take prescribed medications adhere to their regimens (Sackett & Snow, 1979; Wright, 1993). Although A1C is not used for screening or diagnosing of diabetes, it is a valuable tool (ADA, 2003) because A1C measurement improves the sensitivity of screening in high-risk individuals (Perry et al., 2001) and it measures a patient's average glycemia over the preceding 2 to 3 months (ADA, 2003). As mentioned in the previous study, A1C level is associated with medication adherence. Adherence to hypoglycemic medication regimens was strongly associated with metabolic control in an indigent population. For each 10% increment in drug adherence, A1C level decreased by 0.16% at $p < 0.0001$ (Schectman et al., 2002).

This study is different from other studies because this study was focused on behavioral manifestations that could contribute toward adherence, thereby improving metabolic control. Hence, self-reported behavioral measures were taken using PMAS, HRHS, and LTMBSES, then the most recent A1C levels were reviewed for the degree

of metabolic control. To measure the degrees of diabetes medication adherence, other studies relied on self-reported pill counts and a medication event monitoring system (MEM-S-3 *R*) device (Mason et al., 1995); self-reported log for glucose monitoring and insulin injections (Glasgow et al, 1987); and calculation using pharmacy prescription refill data (Schectman et al., 2002), then either monitoring A1C levels or reviewing the existing A1C laboratory values. Although controversial, adherence to hypoglycemic medication seems positively related to metabolic outcome. Thus, examining behavioral dispositions to determine whether they contribute to metabolic control may generate answers and implications for future research.

Hypotheses of the Study

Null Hypotheses

Hypothesis 1. There is no relationship of metabolic control to hardiness, self-efficacy, and hypoglycemic medication adherence.

Hypothesis 2. There is no relationship of metabolic control to cofactors (age, education, race, chronic illness, diabetes medications and duration of diabetes).

Operational Hypothesis

There are positive relationships among metabolic control with hardiness, self-efficacy, hypoglycemic medication adherence, and the cofactors (age, education, race, chronic illness, diabetes medications and duration of diabetes).

Chapter III: Methodology

Research Design

This study was a nonexperimental, cross-sectional descriptive-correlational design. Three instruments were used for data collection. This design was chosen because the purpose of the study was to identify relationships rather than to infer cause-and-effect among variables.

Population

The target population for this study was adults with diagnosed diabetes mellitus who were undergoing treatments with either oral or insulin hypoglycemic agents.

Sampling Strategy

Sample Selection and Setting

After permission was obtained from the Institutional Review Board (IRB permission #2778, Appendix G) to conduct a study involving human subjects, 242 patients with type 1 or type 2 diabetes from the Diabetes and Primary Care Clinics at Virginia Commonwealth University Health System were recruited. The recruitment strategies included: (a) discussing the research project with the medical care providers and obtaining their help in identifying the potential participants, (b) showing the letter of introduction (Appendix H) to the potential participants at the clinic in order to recruit

them, and (c) asking patients while they were being seen at the Diabetes and Primary Care Clinics if they would be willing to participate in the study.

Selection criteria included being adults at least 18 years of age who were currently treated with hypoglycemic medication(s) for diabetes; being capable of providing self-care; and being able to understand, speak, and write English. Potential subjects were screened for selection criteria prior to consent and enrollment.

Every attempt was made to insure that this study included a representative sample of adults of all available races and of both genders. However, the overriding consideration in assessing a sample in a quantitative study is its representativeness — the sample behaves like or has characteristics similar to the population. "Unfortunately, there is no method for ensuring absolutely that a sample is representative without obtaining the information from the entire population" (Polit & Hungler, 1999, p. 279). Once a potential study subject was identified, the co-investigator or a facilitator explained the purpose of the study, answered questions, and obtained consent (Appendix I) from the potential subject. A study facilitator was hired to assist the co-investigator with data collection. The study facilitator was trained before data collection began. When the study subjects had any questions during the data collection, the co-investigator or a facilitator answered questions.

Sample Size Determination by Power Analysis

In using multiple regression, the sample size should be large enough to support the data analysis and to decrease the risk of Type II errors. Power analysis was done using the following formula to obtain estimated effect size (γ):

$$\gamma = \frac{R^2}{1 - R^2} = \frac{0.13}{1 - 0.13} = \frac{0.13}{0.87} = 0.15$$

Then, determined N, the sample size, using

$N = \frac{L}{\gamma} + K + 1$ (Polit, 1996, p. 285).

$$N = \frac{15.65}{0.15} + 9 + 1 = 114$$

$R^2 = .13$ (moderate effect, Cohen, 1988)

L = tabled value (15.65) for a specified $\alpha = 0.05$ and a power of 0.80 (Polit, 1996, p. 286).

γ = estimated effect size (Medium effect size, 0.15, Cohen, 1988).

K = number of predictor variables (Polit, 1996). There are nine predictor (hardiness, self-efficacy, perceived medication adherence) and cofactor variables (age, education, race, co-morbid chronic illness, diabetes medication, duration of diabetes).

A medium effect size of 0.15 was selected because of the assumption that a higher score on the Health-Related Hardiness, Long-Term Medication Behavior Self-Efficacy, and Perceived Medication Adherence scales would have a medium sized effect on the outcome (A1C).

Considering dropouts, missing data, and inappropriate answers, 242 subjects were recruited for the successful completion of the study.

Human Subjects

Permission to conduct the research was obtained from the IRB, Virginia Commonwealth University. The patient consent form was used in recruitment of subjects. All completed consent forms were stored in a locked cabinet accessible only to the co-investigator.

Procedure

Research participants who were diagnosed with diabetes mellitus and were taking hypoglycemic medication(s) were recruited from the Diabetes and Primary Care Clinics at Virginia Commonwealth University Health System (VCUHS). Only those meeting the selection criteria were enrolled. After obtaining consent to participate in the study and permission to check their latest laboratory test of A1C, data collection occurred at the time of recruitment. Data were collected from the subjects individually in a private setting. Health-Related Hardiness, Long-Term Medication Behavior Self-Efficacy, and Perceived Medication Adherence Scales were administered at the beginning of the study. Additional data obtained were medical record number, A1C laboratory value, blood pressure, height, weight, gender, age, race, education, marital status, religion, type of diabetes, duration of the diabetes, diabetes medication regimen, chronic illness, and information about their health care provider and communication patterns (Appendix A).

Operational Definitions

Diabetes Control

Diabetes control was expressed in terms of metabolic control, which was measured by A1C (nondiabetic range of 4.0-6.0%, American Diabetes Association, 1998).

Hardiness Measurement

Hardiness was measured as a total score of the Health-Related Hardiness Scale, which included 3 subscales (control, commitment, and challenge). The total score (34 to 204) was the hardiness predictor variable.

Self-Efficacy Measurement

Self-efficacy was measured by the Long-Term Medication Behavior Self-Efficacy Scale, which included 3 subscales (personal attributes, environmental factors and task-related and behavior factors). The total score (27 to 135) was the self-efficacy predictor variable.

Perceived Medication Adherence Measurement

Medication adherence was measured by the Perceived Medication Adherence Scale, which included 3 subscales (self-care, self-efficacy, and decision-making). The total score (18 to 90) was the perceived medication adherence predictor variable.

Demographic Variables

Demographic cofactors included in this study were age, education and race. Education was coded as number of years of education. Race was dummy coded as 1 = African American and 0 = other.

Disease Situation Variables

Disease situation cofactors were comorbid chronic illness, diabetes medications prescribed and duration of diabetes. Duration of diabetes was expressed in years. Duration of diabetes is a predictor variable.

Instruments

Instruments for the study were the Health-Related Hardiness Scale (Appendix J. Permission to use HRHS), the Long-Term Medication Behavior Self-Efficacy Scale (Appendix K. Permission to Use LTMBSES) and the Perceived Medication Adherence Scale. The instruments are described in Appendix L.

Health-Related Hardiness Scale

The compiled Hardiness Scales rather than a single scale were used to test hardiness personalities of public utility male executives in middle to upper levels (Kobasa, 1979). Lambert and Lambert (1999) contend that because not all of the studies measuring hardiness have used the same instrument, it is difficult to generalize findings. It does not seem appropriate to use the same scales to test persons with chronic illness, such as persons with diabetes, who require daily management decisions,

skills, and monitoring as those who are well. Thus, the HRHS by Pollock (1984b; Pollock & Duffy, 1990) was developed. This scale is more appropriate for this study.

The HRHS was developed by Pollock (1990) to measure the hardiness construct in health-related research. The HRHS, which measures the effect of hardiness personality on adaptation to chronic illness, was developed following her in-depth evaluation of the concept of stress and adaptation as the stress response. Since its inception, the instrument has been used in a variety of health-related and health promotion research studies with adults (Pollock, 1999). The current version contains 34 items on a six-point Likert-type scale ranging from 1 (strongly disagree) to 6 (strongly agree) (Pollock, 1990). Scores for the total HRHS range from 34 to 204 with high scores indicating presence of hardiness (Pollock, 1993). Scoring for the negatively worded items need to be reversed. Depending on the purpose of the investigation, the scale can be used to measure the unitary construct of health-related hardiness and/or the two dimensions of commitment/challenge (20 items) or control (14 items).

Results of a principal component analysis with chronically ill subjects (N=389) supported these two dimensions. The first factor (20 items) encompassed the dimensions of commitment and challenge, while the second factor (14 items) accounted for the control dimension. The two factors explained 32.1% of the initially extracted common variance. The total 34-item HRHS had a standardized alpha coefficient of .91, demonstrating high internal consistency. Cronbach's alphas were .87 for both the 20-item commitment/challenge subscale and the 14-item control scale.

Commitment and challenge items loading together suggested that they were more closely related and not discrete dimensions in a health-specific context. In other words, commitment to adjusting to a health stressor such as chronic illness is also the challenge. The HRHS has been used internationally. It has been translated into seven languages, and has been used in Africa, Australia, Korea, and Taiwan (Pollock, 1999).

From the refinement process of the scale development, Pollock & Duffy (1990) concluded that the HRHS has three main advantages over Kobasa's hardiness measure for health-related research. The advantages are: "health specificity, measurement of the presence of the factors (commitment/challenge and control) rather than the absence to determine hardiness and the easy scoring method" (Pollock & Duffy, 1990, p. 222). In other words, although the concept of the HRHS development was based on Kobasa's hardiness, the scale construct differs from Kobasa's (1979) in three areas. The differences are: (a) the use of health-specific definitions for measuring the concepts of control, commitment, and challenge; (b) the measurement of the presence, rather than absence, of the three concepts to determine hardiness; and (c) the introduction of the concept of health stressor to facilitate health-related research.

Using the adaptation to chronic illness model (Pollock, 1984a) as the theoretical framework for integrating the major variables of chronicity, stress, hardiness, and physiological and psychosocial adaptation, Pollock (1986) conducted a research study with 60 (N = 20 in each group) adults with diabetes mellitus, essential hypertension, or rheumatoid arthritis for at least one year. Pollock tested three hypotheses:

Hypothesis 1. Among persons with rheumatoid arthritis, those who have the hardiness characteristic will exhibit more adaptive behavior.

Hypothesis 2. Among persons with insulin-dependent diabetes mellitus, those who have the hardiness characteristic will exhibit more adaptive behavior.

Hypothesis 3. Among persons with hypertension, those who have the hardiness characteristic will exhibit more adaptive behavior (p. 91).

Pollock (1986) used the HRHS to measure hardiness and physiologic adaptation instrument for each diagnostic group. The HRHS contained 48 items on a 6-point Likert scale with 15 items measuring commitment, 15 items measuring challenge, and 18 items measuring control. Reliabilities for the total HRHS (Cronbach's alpha 0.81), and for subscales (alpha coefficients 0.84 for control, 0.78 for commitment, and 0.82 for challenge) indicated good internal consistency. Findings supported hypothesis 2, that physiological and psychosocial adaptations were significantly related for the diabetic group, but not in the arthritic or hypertensive groups (Pollock, 1986).

Pollock (1989b) studied 30 adults with type 1 diabetes mellitus, ages ranging from 21 to 55, to investigate whether or not the presence of hardiness was related to physiological adaptation to chronic illness. Further, she was interested in knowing if the presence of the hardiness characteristic was related to better physiological adaptation, although Pollock did not present findings on physiological adaptation. "Hardiness also was related to how one perceives the situation and what one does about the situation" (p. 273).

Long-Term Medication Behavior Self-Efficacy Scale

The Long-Term Medication Behavior Self-Efficacy Scale is a 27-item scale (revised version) on a five-point Likert-type scale that measures the patient's confidence level of self-efficacy from very little (1) to quite a lot (5). The self-efficacy scores range from 1 to 5, with higher scores indicating higher levels of self-efficacy. Self-efficacy is calculated by summing the scores of all items, then dividing by 27. Because the scale was developed as part of a research project in transplant recipients, the item numbers 8, 9, and 14 are related to side effects of immunosuppressive medication. Per recommendation of the author (personal communication, July 16, 2000), the items are substituted with questions related to hypoglycemic medication side effects. The Cronbach's alpha for the scale is 0.88, reflecting good reliability (De Geest et al., 1998). Validity of the scale has been established based on results of 1042 subjects who were included in several transplant compliance research projects and other studies in chronic illness patient populations worldwide.

This scale was used in two separate studies. The first study included a sample of 150 renal transplant recipients (De Geest et al., 1995) and the second study included a sample of 101 heart transplant recipients (De Geest et al., 1998). Self-efficacy was a determinant of medication compliance behavior in both studies.

The scale, related to medication behavior, was developed by De Geest et al. (1994) following the conduct of a qualitative study using a phenomenological method of analysis. The study was focused on exploring patient perception, experiences, and

practices associated with long-term medication behaviors. In-depth interviews were conducted on 14 patients with lifelong dependency on medicine. The themes were identified based on Bandura's conceptualization of three dimensions of self-efficacy. Dimensions of personal attributes include the themes of emotional distress, confidence in the physician, perceived health status, and normalcy. The dimensions of the environmental factors identified are the themes of routine, distraction, social support and cost of medication. The third dimension of self-efficacy, task-related and behavioral factors, was composed of the themes of side effects, drug delivery system, medication aids, medication schedule, and knowledge.

Perceived Medication Adherence Scale

The current Perceived Medication Adherence Scale (PMAS) is an 18-item instrument with a Likert scale (Allison, 2000) with a format ranging from 5 (Strongly agree) to 1 (Strongly disagree) for the positive response items. The scale was refined from 19 items to 18 items. The negative response items (83 and 84) were recorded ranging from 1 (strongly agree) and 5 (strongly disagree). Each item in the scale is a short question reflecting medication adherence. The possible range of scores for the current scale is 18 to 90 with a high score indicating the affinity to adhere to prescribed medication(s). There are three subscales in the instrument; they are self-care, self-efficacy, and decision making. All three subscales contribute to the performance of medication adherence. The scale was developed following a literature review, which identified the need for such an instrument to measure medication adherence globally.

The 19-item scale was administered to 200 participants aged 18 to 61 years. A total of 152 females (78%) and 48 males (24%) completed the instrument. The subjects' willingness to participate and their completion of the instrument were considered as an indication of their consent.

Eighty-two percent (n = 164) of the participants were White, non-Hispanic; 8.5% were African Americans (n = 17); 4.0% (n = 8) were Asians; 2% (n = 4) were Hispanic; and the rest of the participants (3.5%, n = 7) were of other races. Fifty-four percent (n = 108) of the participants were master's degree or above educated and 28 % (n = 56) were college graduates; 15.5% (n = 31) had some college education; 2% (n = 4) were high school graduates; and 0.5% (n = 1) had some high school education. Sixty-nine percent (n = 138) were married and 14.5 % (n = 29) were single; 10.5% (n = 21) were either divorced or separated; 3% (n = 6) each were widowed and were in a committed relationship; 75.5% (n = 151) had children. Fifty-nine percent (n = 118) reported their religion as Protestant and the remainder had other religions. Approximately 63% (n = 127) were employed as health care professionals and 30% (n = 60) had chronic illness. Approximately 89% (n = 177) had physicians as their primary care providers and 10 % (n = 20) reported nurse practitioners as their primary care providers.

The participants were recruited from various settings including offices, hospitals, conference sites, schools, and churches in Washington, D.C., Virginia, and Tennessee. Some of the surveys were completed in the presence of the investigator, and some were completed at the participant's home and mailed to the investigator later. The factor

analysis, utilizing principal component analysis, as the extraction method showed extraction of communalities ranging 0.347 to 0.611. "Communality is the sum of squared loadings (SSL) for a variable across factors" (Tabachnick & Fidell, 1996, p. 648). Three factors were extracted using Varimax with Kaiser Normalization as the rotation method to increase interpretability were extracted. Each factor signifies a subscale – self-care, self-efficacy and decision-making. Factor loadings for the self-care subscale were 0.323 to 0.913, for the self-efficacy subscale 0.309 to 0.314, and the decision making subscale were -0.539 to 0.749. The negative (-0.539) factor loading was for the item that reads, "I decide whether I should take my medications." This item is the only negative factor loading which may represent lack of similarity among the subscale component matrix. Scree plots also supported the existence of three components within the PMAS.

Regression analysis on the three subscales revealed a Mahalanobis distance of 23.514 which is within the maximum range at n = 195, df = 194 and x^2 (between 122.7 to 168.3). This means that there were no subjects who responded erratically. Reliability analysis on each of the subscales was performed. For the self-care subscale, item-total correlations ranged from 0.51 to 0.85, and the Cronbach's alpha was 0.92. For the self-efficacy subscale, item-total correlations ranged from -0.0085 (the item that reads, "I decide whether I should take my medications.") to 0.46, and the Cronbach's alpha was 0.42. During the data cleaning process, the scale was recoded. However, the same item consistently showed negative correlations. Therefore, the reliability of the

self-efficacy subscale was analyzed again, and at this time, the item was omitted to see whether the correlations were affected. Item-total correlations for the self-efficacy subscale without the item ranged from 0.38 to 0.57, and the Cronbach's alpha was 0.65. This is a notable change. For item-total correlations, subscale decision-making, ranged from 0.09 to 0.45, and the Cronbach's alpha was 0.46. Two subscales, self-care and self-efficacy, met the inter-item correlations criteria, which are between 0.30 to 0.70. The subscale, decision-making did not meet the criteria because its lower range was -0.0085.

Correlations between subscales to total were between .60 to .70, which meet the criteria. Correlations between total PMAS and subscales were – self-care 0.94; self-efficacy 0.67; and decision-making 0.51 (p=0.01). This shows the correlations between total PMAS and self-care and total PMAS and self-efficacy both met the criteria. Although the correlation between the subscale decision-making was less than the correlation criteria, Cronbach's alpha for the total scale (19 items) was 0.85. This indicates that the total PMAS meets the criteria for a new scale since Cronbach's alpha is greater than 0.70. Validity of the Medication Adherence Scale (PMAS) is established through literature reviews and by the examination of the items by nurse experts.

Content validity of the MAS was established through literature reviews and through item examinations by six expert registered nurses – three nurse practitioners and three nursing school faculty who have encountered issues of patient medication adherence frequently at their nursing practice sites. The original 31-item instrument

was reviewed item by item by the experts for item clarification, relevancy, congruence, wording, and accuracy. Items that were less clear and irrelevant were deleted during the review process. A total of 19 items were retained as the final instrument and was administered to the 200 subjects. However, this scale was further refined to an 18 item scale. Variable, the total scores of the 18 items, for the Medication Adherence Scale is 90.

Factor analysis, Pearson's correlations, regression, and reliability analysis were performed. The highest loading (0.913) item in factor analysis on the self-care subscale is the item that states, "I take my medications by the prescribed method." The highest loading (0.805) item on the self-efficacy subscale states, "I know why I take each medication."

Construct validity was established by examination of correlations between items, total PMAS to subscales, and between subscales. Positive correlations were found. Concurrent validity examining correlations with another instrument was not done because there is no other scale that measures medication adherence based on similar subscales of self-care, self-efficacy and decision-making.

Reading Difficulty Levels of the Instruments

Reading difficulty levels were determined based on Fry (1977) and DeVellis (1991) methods. See Table 2.

Table 2. Reading Difficulty Levels of HRHS, LTMBSES and PMAS*

Instrument	Sentences	Words (T: 100)	Syllables	Grade Level
Health-Related Hardiness Scale	24	21	28	8th Grade
	25	24	30	
	26	18	22	
	27	18	19	
	28	19 (18 +1)	27	
Average	N/A	20	25.2	
Instrument	Sentences	Words (T: 100)	Syllables	Grade Level
Long-Term Medication Behavior Self-Efficacy Scale	10	10	30	6th to 8th Grade
	11	15	27	
	12	17	28	
	13	16	26	
	14	12	20	
	15	19	34	
	16	11 (12-1)	21	
Average	N/A	14.3	26.6	
Instrument	Sentences	Words (T: 100)	Syllables	Grade Level
Perceived Medication Adherence Scale	6	16	27	6th Grade
	7	12	16	
	8	16	20	
	9	17	24	
	10	14	17	
	11	12	16	
	12	13	17	
Average	N/A	14.3	19.6	

* Reading levels: 5th-grade with 14 words & 18 syllables; 6th-grade with 15/16 words & 20 syllables; and 7th-grade with 18 words and 24 syllables per sentence.

Data Analysis

The SPSS 10.0 Windows statistical software program (SPSS Inc., 1999) was used to analyze data. Data were entered as they were collected and surveys were stored in a locked cabinet accessible only to the co-investigator, who conducted the data analysis. Data were entered and were checked manually for out of range variables and outliers.

For the analysis of data, multiple regression statistical technique was applied to predict the relationships, but not imply causal relationships, among one dependent variable, metabolic control, 3 predictor variables (hardiness, self-efficacy and perceived medication adherence) and 6 cofactors (age, education, race, co-morbid chronic illness, diabetes medications and duration of diabetes). In this regression analysis, continuous and dummy coded predictor variables were used because the variables were expressed in numbers.

Hierarchical (sequential) regression was used. Cofactors entered the equation in an order of age, education and race as the first set and comorbid chronic illness, diabetes medications and duration of diabetes as the second set. Then, hierarchical order of the predictor variables were entered, total scores of the HRHS as the 3rd set, total scores of the LTMBSES as the 4th set and total scores of the PMAS as the 5th and final set according to theoretical considerations. This created 5 models. Initial differences in age, education, race, duration of diabetes, comorbid chronic illness and diabetes medications were held constant. The purpose of this process was to hold constant the demographic and disease variations while considering the variables of interest: hardiness, self-efficacy,

and perceived medication adherence. Regression coefficients, the value of R^2, and the results of correlation and analysis of variance (ANOVA) were reported. Information on the changes to R^2 at each step of the analysis and the significance of the changes were also presented. The tolerances of predictors were examined to detect multicollinearity. Residual scatter-plots were inspected, and assessed to determine whether the assumptions for multiple regression were violated.

Limitations

This study used a nonexperimental, cross-sectional descriptive-correlational design, therefore, conclusions cannot be drawn about causality between the dependent variable and the predictor variables. There was no observation of adherence, thus, the findings are limited to self-report.

Social desirability response set bias refers to misrepresentation of personal attitudes or traits by providing answers in accordance to the social milieu (Polit & Hungler, 1997). The study subjects knew they would be paid $10 upon completion of the study as a recruitment incentive. That may have interfered with the subjects' responses on the questionnaires because they may have subconsciously selected answers that would please the coinvestigator who was at the study site.

Chapter IV: Results

The results of the study are presented in this chapter in the order of description of the sample, demographics, description of the variables, and data transformation. Following that, the relationships of the response and the predictor variables are examined to determine whether assumptions of the multiple regressions were met by examining normality, linearity, multicollinearity, and homoscedasticity. The psychometric properties of the scales used for this study are evaluated. The PMAS is examined for further refinement and retainment of factor structure and psychometric properties as observed in the previous study in Summer, 2000. Finally, hypotheses testing, discussion, implications and conclusions will follow.

Descriptive Statistics

Description of the Sample

A convenience sample of the study subjects was recruited to participate in the study from the Primary Care Clinics of the Virginia Commonwealth University Health System. The study data were collected from 242 patients from A. D. Williams Primary Care Clinics (239 patients) including two patients from the Ambulatory Care (ACC) Diabetes Clinic and one patient from the private side of the Primary Care Clinic. Of the 242 study participants, 27 patients were excluded from the data analysis for the following

reasons: Eleven patients did not complete the questionnaires, one patient was not on any hypoglycemic medication, one patient who completed the questionnaires did not have diabetes mellitus, and five patients received their diabetes care from sources other than the study sites. One patient was not proficient in English. Eight participants with responses that reflected inaccurate readings of the questionnaires were excluded from the analysis as well. Thus, data from 215 participants were used for analysis.

Demographics

Demographic data of the 215 adult subjects with diabetes who were taking one or more hypoglycemic agents revealed the following: More females, 73.5% (n = 158), than males, 26.5% (n = 57), participated in the study. The age of the subjects ranged from 19 to 81 with a mean of 55.5 years. Eleven (5.1%) subjects, were 60 years of age. Nine patients (4.2%) from each age group 46, 58, 63 and 64 years of age. Of the 215 subjects in the study, 73.5% (n = 158) were African Americans, 20.5% (n = 44) were White, 2.8% (n = 6) Hispanics, 1.4% (n = 3) Asians, 1.4% (n = 3) were identified as other, and .5% (n = 1) gave an invalid response. Education levels ranged from 4 (n = 6, 2.8%) years to 21 (n = 1, .5%) years. The majority, 67% (n = 144), of the subjects had 10^{th} to 12^{th} grade educations. Marital status data showed that 26% (n = 56) were either divorced or separated, 25.6% (n = 56) of the subjects were single, 23.7% (n = 51) were married, and 21.9% (47) of the subjects were widowed. Almost half (48.8%, n = 105) subjects were Protestant, 40.5% (n = 87) reported other religions, 7.4% (n = 16) were Catholic, 1.4% (n = 3) were Islam, .9% (n = 2) reported no religion, and .5% (n = 1) was Jewish.

In terms of type of diabetes, 94.4% (n = 203) reported having type 2 diabetes and 5.6% (n = 12) marked as having type 1 diabetes. This finding is congruent with the national statistics indicating that 5% to 10% of the patients with diabetes having type 1 diabetes and 90% to 95% have type 2 diabetes (Centers for Disease Control and Prevention Diabetes and Public Health Resource, 1998). Duration of diabetes ranged from 0.5 month to 42 years; the highest percent (10.2%, n = 22) had diabetes for 10 years. Fifty-three percent (n = 114) of the subjects were on oral hypoglycemic agents, 24.7% (n = 53) were on insulin only, and 22.3% (n = 48) were on a combination of insulin and oral agents.

The subjects were asked what other chronic illnesses they had besides diabetes. Of the 215 subjects, only 7% (n = 15) had no other chronic illness. Twenty-six percent (n = 56) had hypertension, 19.1% (n = 41) had hypertension and high cholesterol, 12.1% (n = 26) had hypertension, heart conditions and high cholesterol. The majority of subjects' health care providers were physicians (79.5%, n = 171). Other providers reported were nurse practitioners (NP), 12.1% (n = 26); other 2.8% (n = 6); combination of physician and NP 3.3% (n = 7); and combination of physician and other licensed practitioner, physician and other provider, or NP and other provider 1.5% (n = 3). The subjects' responses on their providers' calls to check on their medication adherence were 48.8% (n = 105) for every 3 months, 18.6% (n = 40) for never, 12.6% (n = 27) for every month, 11.2% (n = 24) for rarely, and .5% (n = 1) for weekly. Overall,

81% (n = 174) of the subjects reported that they receive follow-up calls from their providers checking on their medication-taking practices.

The subjects' heights, weights and blood pressures were obtained by chart reviews. Height ranged from 51 inches to 75 inches with a mean of 65.7 inches. Their weight ranged from 105 pounds to 417.9 pounds with a mean of 211.3 pounds (a median of 207 pounds). Body mass index (BMI) ranged from 15.5 to 59.6 with a mean of 34.3 kg/m^2. In this study, 16% (n = 35) of the subjects were obese (BMI > 27 kg/m^2) and 65% (n = 140) of the subjects were morbidly obese (BMI > 30 kg/m^2). When these subjects were counted together, 81% (n = 175) of the total study participants were either obese or morbidly obese. According to the ADA specification, systolic blood pressure (SBP) should be under 130 mmHg and diastolic blood pressure (DBP) less than 85 mmHg as a goal to achieve for patients with diabetes. In this study, SBP ranged from 82 to 231 with a mean of 141 mmHg, and DBP ranged from 53 to 130 with a mean of 77 mmHg. Seventy percent (n = 150) of the subjects had SBP > 130 mmHg and 21% (n = 45) of the subjects had DBP > 85 mmHg.

Nearly 38% (n = 81) of the subjects were receiving their diabetes care from the A.D. Williams Primary Care Clinic (ADWPCC), West, 36.7% (n = 79) from the ADWPCC, Central, and 24.2% (n = 52) were from the ADWPCC, East. Two (.9%) patients were from the Ambulatory Care Clinic (ACC) Diabetes Clinic, and one patient (.5%) who participated in the study was from the ACC Primary Care Clinic.

The variables, race and religion, were recoded for better distribution for the analysis. Race was recoded as 1= African American and 0 = other. Religion was recoded as 1 = Protestant and 0 = other. See Table 3 for Demographic Characteristics of the sample (n = 215).

Table 3. Demographic Characteristics of the Sample (n = 215)

Variables	Subject Characteristics
Gender	Female (n = 158, 73.5%); Male (n = 57, 26.5%)
Age	Mean: 55.5; Range: 19 to 81
Race	African American (n = 158, 73.5%); White (n = 44, 20.5%); Hispanic (n = 6, 2.8%); Asian (n = 3, 1.4%); Other (n = 3, 1.4%); Invalid (n = 1, 0.5%)
Education	Mean: 11 years, Range: 4 to 21 years
Marital Status	Divorced/Separated (n = 56, 26 %); Single (n = 55, 25.6%); Married (n = 51, 23.7%); Widowed (n = 47, 21.9%); Missing (n = 6, 2.8%)
Religion	Protestant (n = 105, 48.8%); Other (n = 87, 40.5%); Catholic (n = 16, 7.4%); Islam (n = 3, 1.4%); None (n = 2, 0.9%); Jewish (n = 1, 0.5%); Invalid (n = 1, 0.5%)
Type of Diabetes	Type 1 (n = 12, 5.6%); Type 2 (n = 203, 94.4%)
Duration of Diabetes	Mean: 9.9 years; Range: 0.04 to 42 years
Diabetes Medication	Oral (n = 114, 53%); Insulin only (n = 53, 24.7%); Insulin & oral (n = 48, 22.3%)
Chronic Illness Beside Diabetes	HTN (n = 56, 26%); HTN & high cholesterol (n = 41, 19.1%); HTN, heart condition & high cholesterol (n = 26, 12.1%); None (n = 15, 7.0%); HTN & Heart condition (n = 11, 5.1%); HTN & other (n = 11, 5.1%); HTN, heart condition, high cholesterol & other (n = 10, 4.7%); High cholesterol (n = 8, 3.7%); HTN, high cholesterol & other (n = 8, 3.7%); heart condition (n = 7, 3.3%); heart cond. & high cholesterol (n = 4, 1.9%); HTN, heart condition & kidney failure (n = 3, 1.4%); kidney failure (n = 1, 0.5%); heart condition & other (n = 1, 0.5%); high cholesterol & other (n = 1, 0.5%); heart condition, high cholesterol & other (n = 1, 0.5%); HTN, high cholesterol kidney failure & other (n = 1, 0.5%)

Health Care Provider	Physician (n = 171, 79.5%); NP (n = 26, 12.1%); Physican & NP (n = 7, 3.3%); other (n = 6, 2.8%); OLP (n = 2, 0.9%); Physician & OLP (n = 1, 0.5%); Physician & other (n = 1, 0.5%); NP & other (n = 1, 0.5%)
Provider(s) Call	Q3months (n = 105, 48.8%); never (n = 40, 18.6%); Qmonth (n = 27, 12.6%); rarely (n = 24, 11.2%); Q6months (n = 17, 7.9%); N/A (n = 1, 0.5%); weekly (n = 1, 0.5%)
Height (inches)	Mean: 65.7; range: 51 to 75 inches
Weight (lbs)	Mean: 211.3; range: 105 (A1C: 7.5) to 417.90 (A1C: 6.2); weight between 200 to 417.9 pounds (n = 124, 58.8%)
BMI	Mean: 34.3; range: 15.5 (A1C: 5.8) to 59.6 (A1C: 6.3)
SBP	Mean: 141; range: 82 to 231 mm/Hg
DBP	Mean: 77; range: 53 to 130 mm/Hg
Clinic Location	ADWPCC West (n = 81, 37.7%); ADWPCC Central (n = 79, 36. 7%); ADWPCC East (n = 52, 24.2%); ACC Diabetes Clinic (n = 2, 0.9%); ACCPCC (n = 1, 0.5%)

Description of Variables

The subjects' age ranged from 19 to 81 years of age with a mean of 55.5 (*SD* 11.46); skewness (asymmetrical distribution) was -.36 and Kurtosis (peakedness of a distribution) was .03. The histogram of age distribution appears to be fairly normal, although a slight and not obvious skewness to the right was noted. The majority (73.5%, n = 158) of the subjects were African Americans. Education levels ranged from 4 (n = 6, 2.8%) years to 21 (n = 1, .5%) years with a mean of 11 years with skewness of .20 and kurtosis of 2.41. Duration of diabetes ranged from .04 to 42 years with a mean of 9.9 years, skewness of 1.511 and kurtosis of 2.405. The majority, 53% (n = 114), of the subjects were on oral agents, 24.7% (n = 53) were on insulin only, and 22.3% (n = 48) were on a combination of insulin and oral agents. Only 7% (n = 15) of the subjects had

no chronic illness other than diabetes. The remaining 93% (n = 200) of the subjects had chronic illnesses. Hypertension (26%, n = 56) was the predominant chronic condition, and hypertension with the combination of a heart condition and/or high cholesterol problems were the next most common chronic conditions that the subjects reported in addition to diabetes.

The response variable, A1C (laboratory value), and the predictor variables, Hardiness, measured by the HRHS, Self-Efficacy, measured by the LTMBSES, and Perceived Medication Adherence, measured by the PMAS were examined to determine the distributions of normality. Further, linearity, multicollinearity (interrelatedness of the independent variables) and homoscedasticity (distribution variability between response and predictor variables) of relationships between the predictor and response variables were examined to determine whether assumptions of multiple regression were met. The response variable, A1C value, was obtained from the patients' laboratory record by accessing the hospital computer system or by reviewing the patients' medical records after obtaining the patients' consents (Appendix I). The Primus CLC 385 Glycated Hemoglobin Analysis was the test for A1C at the chemistry laboratory of the VCUHS. The cofactors, demographics (age, education, race) and disease situation (comorbid chronic illness, diabetes medication, and duration of diabetes) were also examined. Thus, variable statistics included were age, race, education, duration of diabetes, diabetes medications, total HRHS (n = 215), total LTMBSES (n = 215), total PMAS (n = 215), and A1C (n = 211).

The total score of HRHS can range from 34 to 204. In this study, it ranged from 94 to 185 with a mean of 145, *SD* 16.81, skewness of -.35 and kurtosis of -.05. A histogram of HRHS appears to be normally distributed (Figure 6).

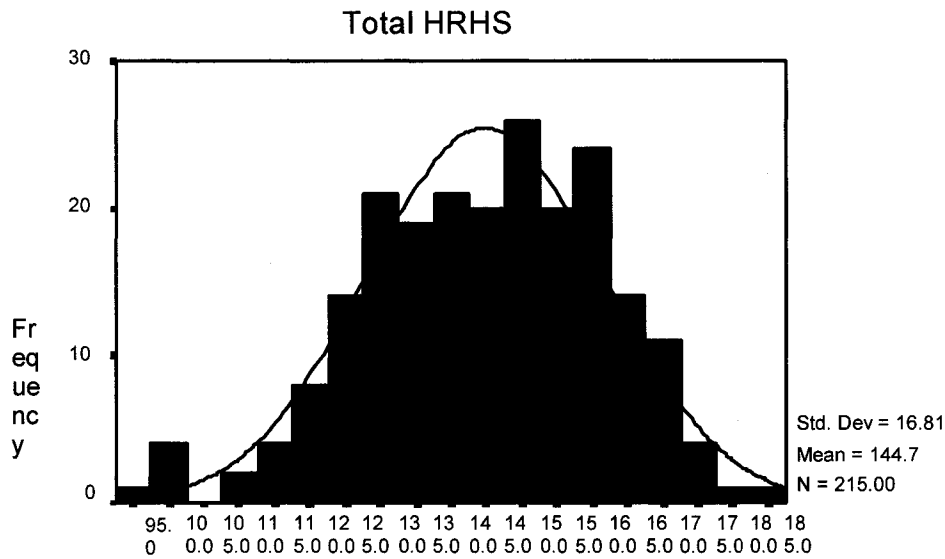


Figure 6. Total HRHS with Fit Line

The score of the total LTMBSES can range from 27 to 135 and in this study it ranged from 51 to 135 with a mean of 102.56, *SD* 18.53, skewness of -.65 and kurtosis of -.62. A histogram of LTMBSES shows some kurtosis (Figure 7).

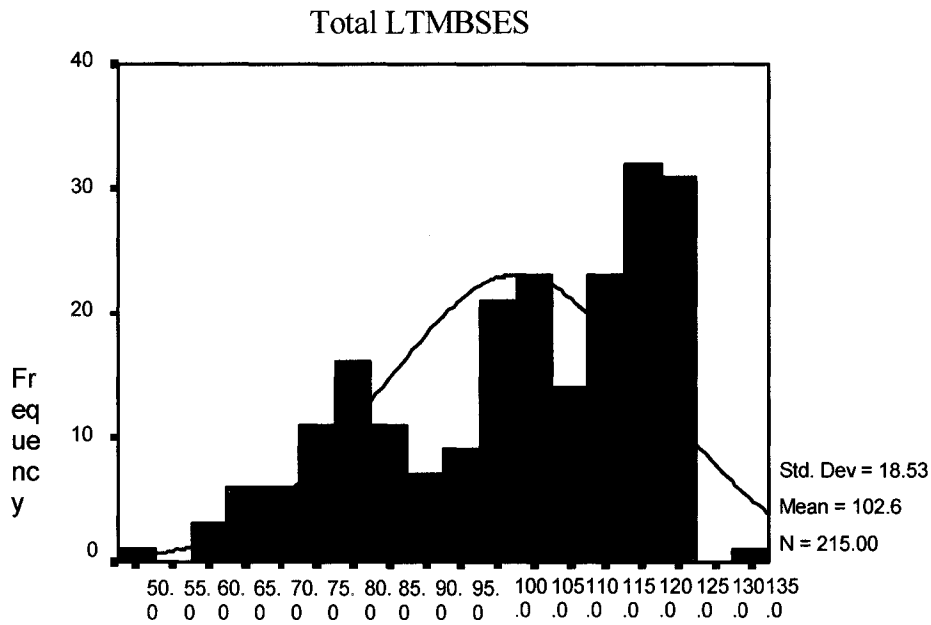


Figure 7. Total LTMBSES with Fit Line

The scores of the total PMAS can range from 18 to 90 and in this study it ranged from 59 to 90 with a mean of 82, *SD* 7.40, skewness of -1.00 and kurtosis of .04. A histogram of PMAS shows some skewness to the right and minimal kurtosis (Figure 8).

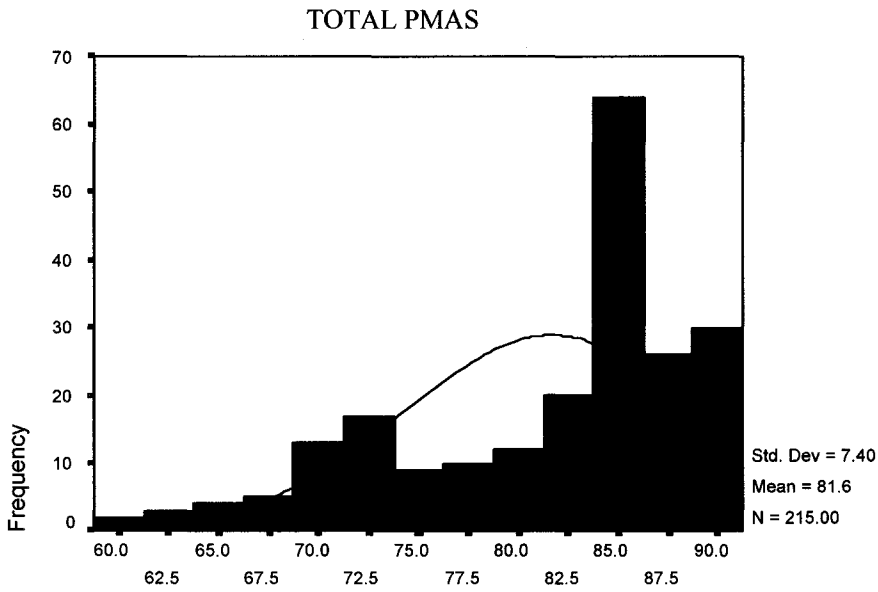


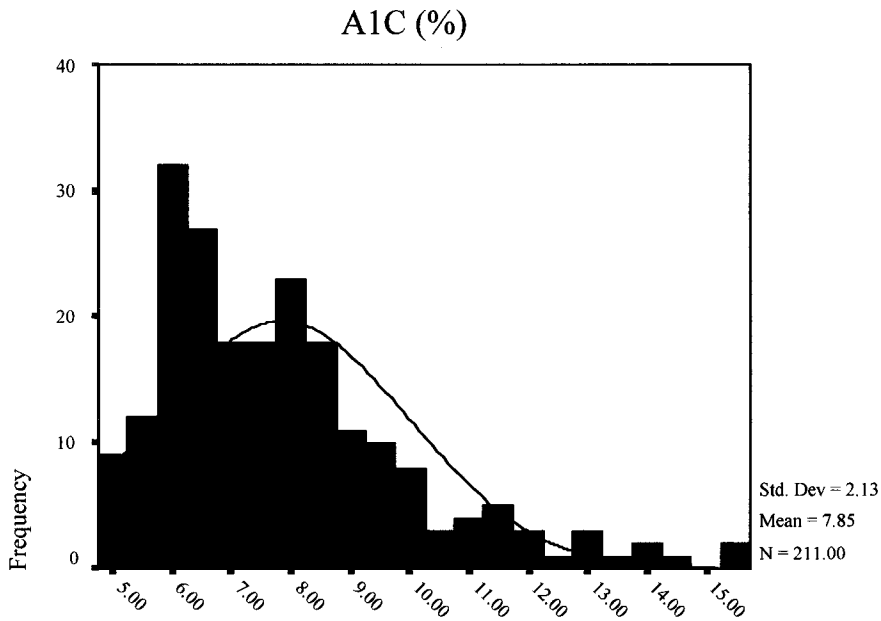
Figure 8. Total PMAS with Fit Line

The response variable, A1C, ranged from 4.8 to 15.7 (Table 4, A1C Distribution) with a mean of 7.8%, *SD* 2.13, skewness of 1.24 and kurtosis of 1.58. See Table 4 for Variable Statistics.

Table 4. A1C Distribution

A1C Range	Number of Subjects	Percent
4.8 to 6.9	88	41.71
7.0 to 8.0	44	20.85
8.1 to 9.0	35	16.59
9.1 to 10.0	16	7.58
10.1 to 11.0	9	4.27
11.0 to 12.0	7	3.32
12.1 to 13.0	4	1.90
13.1 to 14.0	5	2.37
14.1 to 15.0	1	0.47
15.1 to 15.7	2	0.94
Total	211	100%

The histogram of A1C shows some skewness and kurtosis in distribution. See Figure 9.



Figuire 9. Distribution of A1C with Fit Line

Studentized deleted residuals were used to examine normality because they make it easier to spot unusual points. When sample size is much larger than 30, the distribution of the studentized deleted residuals should be approximately normal (Norusis, 2000). Residuals statistics show that the Mahalanobis distance ranges from 1.63 to 38.41 with a mean of 8.96 (*SD* 6.22). Mahalanobis distance is a measure of the distance of a case from the average values of all the independent variables (Norsusis, 2000). For this study, Mahalanobis distance was calculated (SPSS Inc., 1999) using the formula, (N-1) (leverage) = (215 -1) (0.13) = 27.82. N being the number of case, leverage = 3P/N, P being the number of variables which is 9 for this case. The maximum distance of the

Mahalanobis distance, 38.41, is much higher than expected (27.82). The high Mahalanobis distance is because of five subjects (ID 63, 79, 99, 102 and 137) with A1C values 15.7, 13.2, 14.6, 15.4, and 13.3, which were detected by the casewise diagnostics. These are the multivariate outliers, however, the laboratory values of A1C are each subject's physiological measure of metabolic control and cannot be substituted. Thus, the high A1C levels should not be eliminated from the data or be transformed in attempt to reduce the influence of outliers for the analysis.

Table 5. Variable Statistics

	Age	Race	Edu	Dur/ Diab (yrs.)	Diab/ Med	Chr/ ill	Total HRHS	Total LTMBSES	Total PMAS	A1C (mg/dl)
N	215	215	215	215	215	215	215	215	215	211
Mean	55.51	-	10.96	9.88	-	-	144.70	102.56	81.64	7.85
SD	11.46	-	2.64	8.83	-	-	16.81	18.53	7.40	2.13
Skew-nesss	-.36	-	.20	1.51	-	-	-.35	-.65	-1.00	1.24
Kurtosis	.03	-	2.41	2.41	-	-	-.05	-.62	.04	1.58
Range	19 - 81	-	4 - 21	.04 -4	-	-	94 - 18	51 - 135	59 - 90	4.8 - 15.7

Data Transformation

Data Cleaning

Data were entered manually. Then, the data were reviewed for accuracy and any discrepancies compared to the original data were corrected. The negatively worded item numbers 15, 16, 17, 21, 22, 23, 25, 27, 32, 34, 35, 37, 38, 46, 54, 55, 60, 83 and 84 were recoded. There were 17 missing values - items 17, 23, 30, 40, 52 (3 subjects missed) 54, 55, 56, 63, 69, 71, 72 (considered as missing value because one subject marked 2 responses for this item), 78 and 83 (2 subjects missed).

Missing Value Mean Substitutions

In order to avoid loss of subjects and maintain all cases with complete data (Munro, 2001), mean substitutions were conducted because "if cases with missing values are not randomly distributed through the data, distortions of the sample occur if they are deleted" (Tabachnick & Fidell, 1996, p. 63). The missing values were estimated using regression and frequency means, and it was found that the estimations from these two

methods were comparable, mostly higher points from regression means. The rounded values of the regression means were substituted for the missing values (Table 6).

Table 6. Regression Mean Values

Varibles	Std. Deviation	Mean	Substitution	N
v17. H-my efforts.	1.82	2.91	3	196
v23. H-eat & exercise.	1.86	3.07	3	196
v30. H-sick-get well.	1.94	4.09	4	196
v40. H-excited-improving.	1.29	5.29	5	196
v52. S-taking meds at work.	1.50	3.84	4	196
v54. S-taking meds cause hungry.	1.29	4.11	4	196
v55. S-taking meds drop BP<50.	1.48	3.41	3	196
v56. S-taking meds when healthy.	1.02	4.40	4	196
v63. S-taking meds angry at friend.	1.46	3.80	4	196
v69. S-taking meds sick stomach.	1.42	3.60	4	196
v71. S-taking meds at party.	1.63	4.48	4	196
v72. S-taking meds long walk.	1.59	3.37	3	196
v78. M-I complete rx as directed.	3.63	4.99	5	196
v83. I skip my meds when busy.	1.41	2.10	2	196

Normality, Linearity, Multicollinearity, and Homoscedasticity

A test of assumptions of normality, linearity, multicollinearity, and homoscedasticity can be assessed by examination of residuals scatterplots between predicted dependent variable scores and errors of prediction. When the residuals (differences between obtained and predicted dependent variable scores) are normally distributed about the predicted dependent variable scores, residuals have a straight line relationship with the predicted dependent scores (Tabachnick & Fidell, 1996). Scatterplot of studentized deleted residuals in the plots are preferred by many researchers because with use of a valid application of the model to compute the

residuals, they have a mean of 0 and a variance of 1. Further, if the errors are normally distributed, and the form of the model is correct, then about 95% of the residuals should fall between -2 and +2. When the residuals are from a normal distribution, the plotted values fall roughly along the line (SPSS Inc., 1999). For this study, looking at the plots of the normal probability plots (Figure 10) and regression studentized deleted residual with fit line (Figure 11) of the response variable, A1C, normality and linearity are evident.

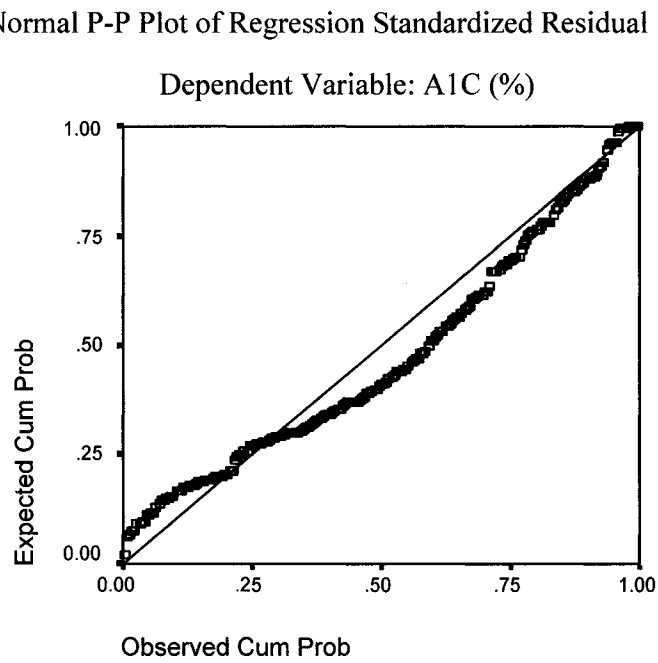


Figure 10. Normal P-P Plot of Regression Standardized Residual of A1C with Fit Line Cum Prob = Cumulative Probability.

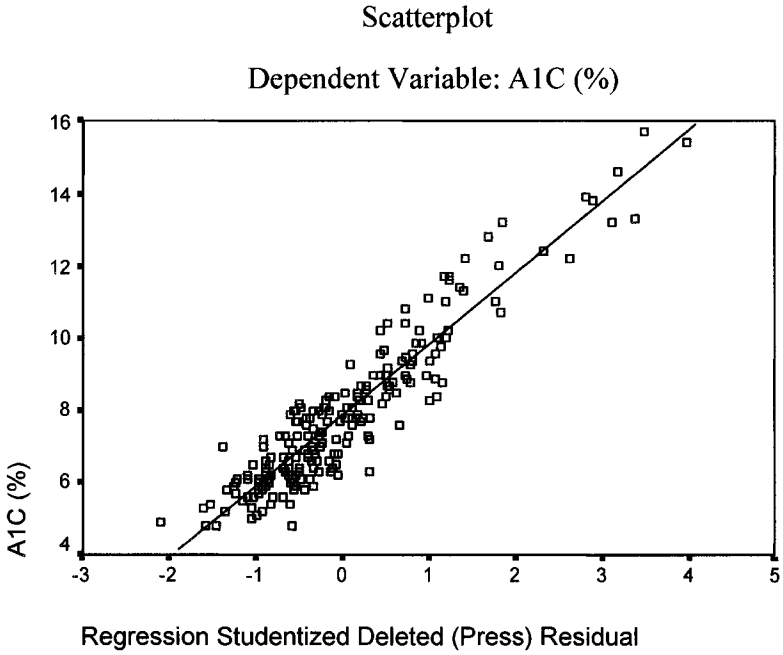


Figure 11. Regression Studentized Deleted Residual with Fit Line of A1C

Multicollinearity (interrelatedness of independent variables) can be detected by examining the tolerance of predictors (Polit, 1996). A tolerance ($1 - R^2$) of 0 ($1 - 1 = 0$) indicates perfect collinearity (Munro, 2001). Values for tolerance for this study are .97 to 1.00 for model 1; .90 to .97 for models 2; .90 to .96 for model 3; .88 to .96 for model 4 and .70 to .96 for model 5. Therefore, multicollinearity is not a problem for this study, indicating that there is no interrelatedness between independent variables. When the assumption of multivariate normality is met, the relationships between variables are homoscedastic (Tabachnick & Fidell, 1996). Thus, the relationships among variables for this study are homoscedastic (for each value of X, the variability of Y scores is approximately the same, Polit, 1996).

Psychometric Analysis of the Study Instruments

Psychometric analysis of the three study scales, Health-Related Hardiness Scale (HRHS), Long-Term Medication Behavior Self-Efficacy Scale (LTMBSES) and Perceived Medication Adherence Scale (PMAS), were performed to determine their reliabilities and validities.

Health-Related Hardiness Scale (HRHS)

HRHS measures the hardiness construct that is used to measure the unitary construct of health-related hardiness by using the total score for this study in 215 adults with diabetes mellitus. The scale contains 34-items on a six-point Likert-type scale, "strongly disagree to strongly agree", with high scores indicating presence of hardiness. The possible total score of the scale ranges from 34 to 204. For this study the score ranged from 94 to 185. Item mean is 4.26, ranging from 2.04 to 5.47, with a variance of .88.

The reliability coefficient, Cronbach's alpha, is .67 and standardized item alpha is .71 (Table 7).

Table 7. Reliability Scale of HRHS

34 Item (HRHS) Means	Mean	Min.	Max.	Range	Variance	Alpha	Stand. Alpha
Values	4.26	2.04	5.47	3.44	.88	.67	.71

The author of the HRHS developed an instrument that can be used to measure the unitary construct of health-related hardiness and/or the two dimensions of

commitment/challenge. Factor analysis using varimax rotation was performed. The principal component analysis extraction method of scree plot of HRHS shows two factors (*Figure* 12) present within the scale with initial Eigenvalues (variances of the components) (SPSS, Inc., 1999); the total amount of variance explained by a factor (Munro, 2001) of 6.01 and 4.05 accounting for variance of 29.60 %.

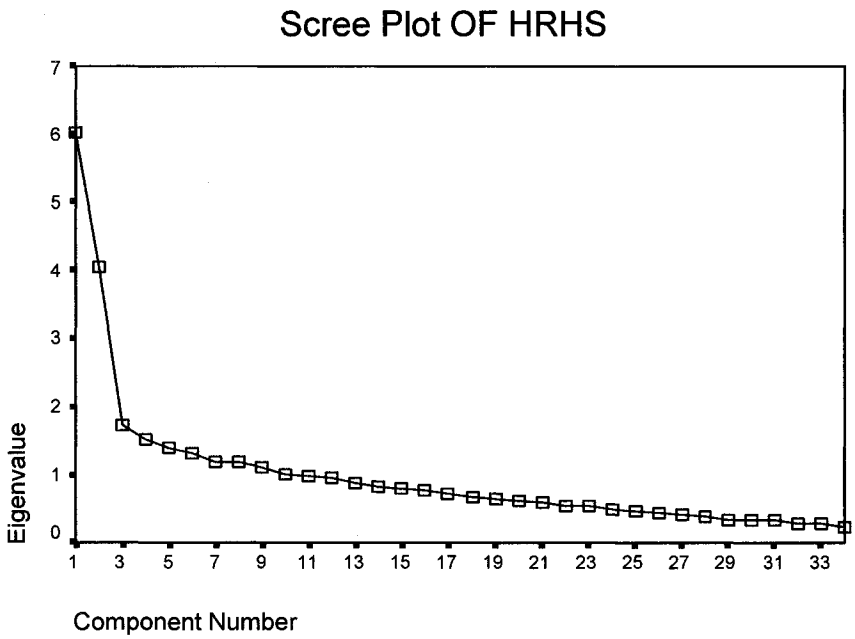


Figure 12. Scree Plot of HRHS

Long-Term Medication Behavior Self-Efficacy Scale (LTMBSES)

LTMBSES measures self-efficacy as a determinant of medication compliance behavior. This scale contains 27-items on a five-point Likert-type scale, "very little to quite a lot", with higher scores indicating higher levels of self-efficacy. The possible total score of the scale ranges from 27 to 135. For this study, the score ranged from 51

to 135 with a mean of 102.56 (SD 18.53) based on N = 215. The item mean is 3.80, ranged from 1.95 to 4.51 with a variance of .43.

The reliability coefficient, Cronbach's alpha = .90 and the standardized item alpha = .91 are reported. See Table 8.

Table 8. Reliability Scale of LTMBSES

27 Item (LTMBSES) Means	Mean	Min.	Max.	Range	Variance	Alpha	Stand. Alpha
Values	3.80	1.95	4.51	2.56	.43	.90	.91

Factor analysis using varimax rotation was performed. Principal component analysis extraction method of the scree plot shows two factors (Figure 13) present within the scale with initial Eigenvalues of 11.73, and 2.24 accounting for variance of 51.70%.

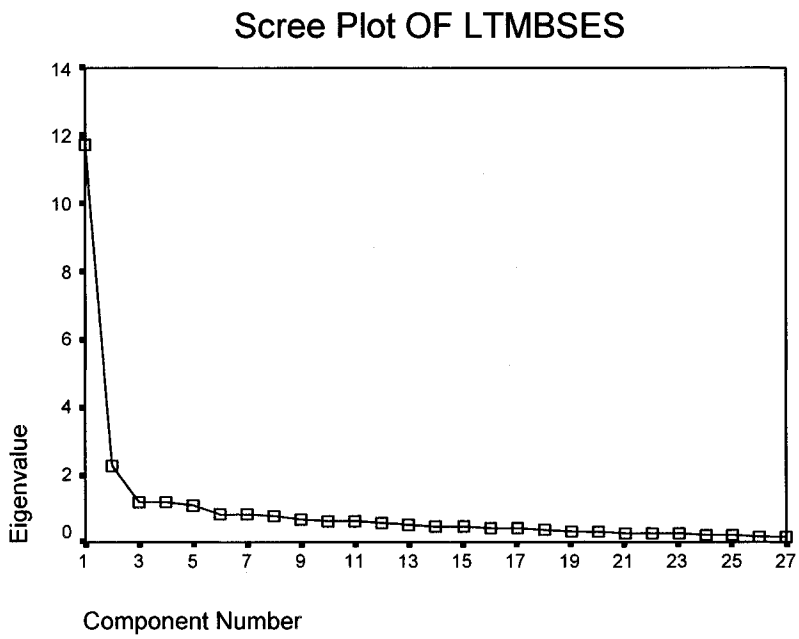


Figure 13. Scree Plot of LTMBSES

Perceived Medication Adherence Scale (PMAS)

PMAS measures perceived medication adherence. The scale contains 18 items on a five-point Likert-type scale, "strongly disagree to strongly agree", with higher scores indicating higher levels of perceived medication adherence. The total possible score of the scale ranges from 18 to 90. For this study, the score ranged from 59 to 90 with a mean of 81.64 (SD 7.40) based on $n = 215$. The item mean was 4.54, ranging from 3.36 to 4.77 with a variance of .13. The reliability coefficient was .83 (Cronbach's alpha) and the standardized item alpha = .90 (Table 9).

Table 9. Reliability Scale of PMAS

18 Item (PMAS)	Mean	Min.	Max.	Range	Variance	Alpha	Stand. Alpha
Values	4.54	3.36	4.77	1.41	.13	.83	.90

Factor analysis using varimax rotation was performed. The principal component analysis extraction method of the scree plot shows one factor present (*Figure* 14) within the scale with initial Eigenvalues of 7.39 and 1.58, accounting for variance of 49.82%.

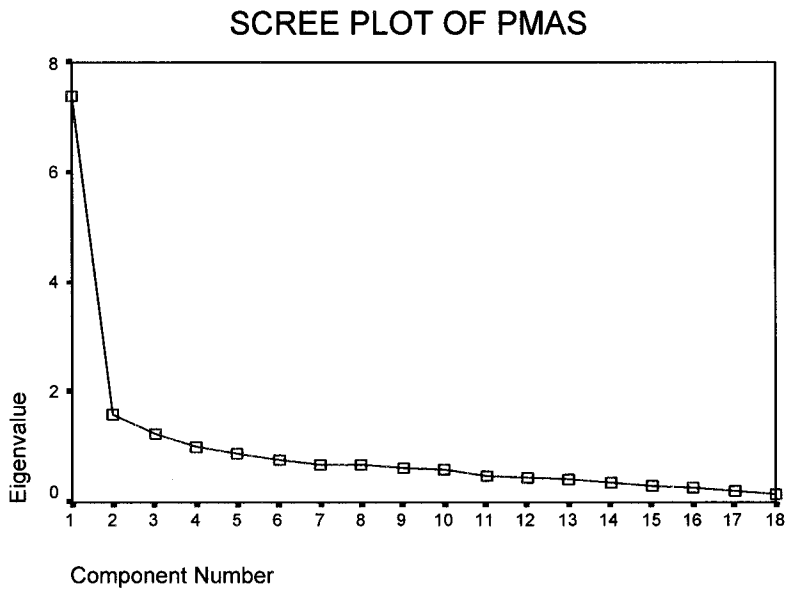


Figure 14. Scree Plot of PMAS

The PMAS scale used for this study was examined for further refinement, and for retainment of factor structure and psychometric properties as observed in the previous study in Summer, 2000 (Medication Adherence Scale). Correlations of PMAS with other variables (HRHS, LTMBSES, and A1C) revealed .26 with HRHS (p = .000), .50 with LTMBSES (p = 000), and -.09 with A1C (p = .193). This means that the

correlations of the PMAS with other predictor variables is substantial for LTMBSES because the correlations between the variables are between .30 and .70 (Munro, 2001), a = .01, p = .00, but only with one scale, LTMBSES.

Principal component analysis extraction method of communalities showed that the highest loading (.84) in the scale was item #80, "I take my medications as prescribed." The factor loadings ranged from .44 to .84. A two-tailed Pearson's correlation was performed on the 18-item PMAS scale (N=215). Of the 318 inter-item correlations, 216 were significant at p = 0.01 level, 16 were significant at p = 0.05 level, and 86 were not significant. The Pearson's correlations ranged from .01 to .76. See Table 10. Reliability of the total PMAS was .83, and standardized item a = .90.

Table 10. Comparison of PMAS and MAS

Scale	N	Item	Communalities	Alpha	IIC *	Mean	SD
PMAS, 2003	215	18	.44 to .84	.83	.01 to .76	81.64	7.40
MAS, 2000	200	19	.35 to .61	.85	-.01 to .86	80.00	8.18

* IIC: Inter-Item Correlation

Hypotheses Testing

Null Hypothesis 1

"There is no relationship of metabolic control to hardiness, self-efficacy and hypoglycemic medication adherence."

To examine the relationships and predictability of A1C (metabolic control) between A1C and total scores of HRHS, LTMBSES and PMAS, Pearson's correlations (significance, 2-tailed), regression, and ANOVA were performed. "Beta reflects the weight associated with standardized scores (z-scores) on the variables. It is a partial correlation coefficient, a measure of the relationship between an independent and a dependent variable with the influence of the other independent variables held constant" (Munro, 2001, p. 256). HRHS had a correlation of .10 with A1C level, which is not statistically significant ($p = .14$), moreover, when the other predictor variables are accounted for, the partial correlation coefficient, Beta, between A1C level and HRHS is only .12 ($p = .09$), which also is not significant. LTMBSES had a correlation of -.07 with A1C level, which is not statistically significant ($p = .28$). Further, when the other predictor variables are accounted for, the partial correlation, Beta, between A1C level and LTMBSES is only -.01 ($p = .95$), which also is not significant. PMAS had a correlation of -.09, which is not statistically significant ($p = .19$), moreover, when the other predictor variables are accounted for, the partial correlation, Beta, between A1C level and PMAS is -.11, which also is not significant ($p = .15$). See Table 11 for correlations of the variables.

Table 11. Correlations of HRHS, LTMBSES, PMAS and A1C

Correlations

		Total HRHS	Total LTMBSES	Total PMAS	A1C (%)
Total HRHS	Pearson Correlation	1.000	.258**	.261**	.102
	Sig. (2-tailed)	.	.000	.000	.140
	N	215	215	215	211
Total LTMBSES	Pearson Correlation	.258**	1.000	.498**	-.074
	Sig. (2-tailed)	.000	.	.000	.283
	N	215	215	215	211
Total PMAS	Pearson Correlation	.261**	.498**	1.000	-.090
	Sig. (2-tailed)	.000	.000	.	.193
	N	215	215	215	211
A1C (%)	Pearson Correlation	.102	-.074	-.090	1.000
	Sig. (2-tailed)	.140	.283	.193	.
	N	211	211	211	211

**. Correlation is significant at the 0.01 level (2-tailed).

For this analysis, the regression of A1C (metabolic control) on three predictor variables (total scores of HRHS, LTMBSES, and PMAS) accounted for 13% of the variance (See Table 12). This finding was significant at the .001 level (see Table 13 ANOVA Table.

Table 12. Model Summary

Model Summary[f]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.275[a]	.076	.062	2.066	.076	5.657	3	207	.001
2	.329[b]	.108	.082	2.044	.032	2.469	3	204	.063
3	.340[c]	.115	.085	2.041	.007	1.669	1	203	.198
4	.344[d]	.118	.083	2.043	.003	.651	1	202	.421
5	.357[e]	.127	.088	2.037	.009	2.093	1	201	.149

a. Predictors: (Constant), edu, race, age

b. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill

c. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill, Total HRHS

d. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill, Total HRHS, Total LTMBSES

e. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill, Total HRHS, Total LTMBSES, Total PMAS

f. Dependent Variable: A1C (mg/dl)

Table 13. ANOVA Table Showing Significance of A1C Outcome

ANOVA[f]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	72.442	3	24.147	5.657	.001[a]
	Residual	883.661	207	4.269		
	Total	956.102	210			
2	Regression	103.407	6	17.234	4.123	.001[b]
	Residual	852.695	204	4.180		
	Total	956.102	210			
3	Regression	110.359	7	15.766	3.784	.001[c]
	Residual	845.743	203	4.166		
	Total	956.102	210			
4	Regression	113.076	8	14.134	3.387	.001[d]
	Residual	843.027	202	4.173		
	Total	956.102	210			
5	Regression	121.765	9	13.529	3.259	.001[e]
	Residual	834.337	201	4.151		
	Total	956.102	210			

a. Predictors: (Constant), edu, race, age

b. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill

c. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill, Total HRHS

d. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill, Total HRHS, Total LTMBSES

e. Predictors: (Constant), edu, race, age, diabe/med, dura/diabe, chronic/ill, Total HRHS, Total LTMBSES, Total PMAS

f. Dependent Variable: A1C (mg/dl)

Hardiness was not significantly related to metabolic control. There was a negative relationship between self-efficacy and metabolic control, indicating that adults with diabetes mellitus having high self-efficacy will have better metabolic control but it was statistically not significant. There was a negative relationship between perceived medication adherence and metabolic control, indicating that adults with diabetes mellitus

having higher perceived medication adherence will have better metabolic control but it was statistically not significant.

The prediction equation for this analysis by using *b*-weights is (Table 14): Predicted level on A1C (metabolic control) = 9.20 + 1.52E-02 (hardiness) - 5.33E-04 (self-efficacy) - 3.25E-02 (perceived medication adherence). To calculate the predicted A1C, the mean values of hardiness, self-efficacy and perceived medication adherence were plugged in, yielding: A1C (predicted) = 9.20 + 0.0152 (144.79) - 0.000533 (102.56) - 0.0325 (81.64) = 9.20 + 2.20 - 0.055 - 2.65 = 8.70 (%). The actual mean A1C is 7.85.

Table 14 Coefficients

Model 5 Variables	U.std. Coeff *b*-weight	U.std.Coef Std. Error	Std.Coef Beta	*t*	Sig.
Constant	9.20	2.02		4.56	.00
Age	-4.720E-02	.01	-.25	-3.66	.00
Race	.41	.34	.08	1.20	.23
Edu	4.303E-02	.06	.05	.78	.44
Dura/diab	2.422E-02	.02	.10	1.46	.15
Diab/med	.43	.21	.14	2.03	.04
Chronic/ill	-8.301E-04	.00	-.11	-1.53	.13
Total HRHS	1.515E-02	.01	.12	1.69	.09
T.LTMBSES	-5.328E-04	.01	-.01	-.06	.95
Total PMAS	-3.246E-02	.02	-.11	-1.45	.15

These results failed to reject hypothesis 1 that there is no relationship of metabolic control to hardiness, self-efficacy and perceived medication adherence.

Null Hypothesis 2

"There is no relationship of metabolic control to cofactors (age, education, race, chronic illness, diabetes medications and duration of diabetes)."

To examine the relationships and predictability of metabolic control between A1C and cofactor variables (age, race, education, duration of diabetes, diabetes medications, and chronic illnesses other than diabetes), Pearson's correlations (significance, 2-tailed), regression and ANOVA were performed. Age had a correlation of -.25 with A1C level, which is significant (p = .00). When the other predictor variables are accounted for, the partial correlation (Beta) between A1C level and age is -.25 (p = .00), which also is significant. Education level had a correlation of .11 with A1C level, which is not significant (p = .11). When the other predictor variables are accounted for, the partial correlation (Beta) between A1C level and educational level is .05, which also is not significant (p = .44). Race had a correlation of .09 with A1C level, which is not significant (p = .20). When the other predictor variables are accounted for, the partial correlation (Beta) between A1C level and race is .08, which also is not significant (p = .20). Duration of diabetes had a correlation of .03 with A1C level, which is not significant (p = .63). When the other predictor variables are accounted for, the partial correlation (Beta) between A1C level and duration of diabetes is .10, which also is not significant

(p = .15). Diabetes medication had a correlation of .10 with A1C level, which is not significant (p = .17), but when the other predictor variables are accounted for, the partial correlation (Beta) between A1C level and diabetes medication is .14, which is significant (p = .04). Chronic illness other than diabetes had a correlation of -.12 with A1C, which is not significant (p = .09). When the other predictor variables are accounted for, the partial correlation (Beta) between A1C level and chronic illness is -.11, which also is not significant (p = .13).

For this analysis, the regression of A1C (metabolic control) on six cofactor, predictor variables (age, educational level, race, duration of diabetes, diabetes medications and chronic illness) accounted for 13% of the variance and was significant at the .001 level (ANOVA table). There was a negative relationship (-.25, p = .00) between age and A1C, indicating that the older the adult with diabetes, the better his/her metabolic control. Educational level was not significantly related to metabolic control. Race, duration of diabetes, diabetes medication, and chronic illness were not significantly related to metabolic control.

The prediction equation based on this analysis by using beta weights (B) is: Predicted level on A1C (metabolic control) = 9.20 - 4.72E-02 (age) + 4.30E-02 (education) + .41 (race) + 2.42E-02 (duration of diabetes) + .43 (diabetes medication) - 8.30E-04 (chronic illness).

These results failed to reject the null hypothesis that there is no relationship of metabolic control to cofactors (education, race, chronic illness, diabetes medications and duration of diabetes), except for the cofactor, age.

There were no statistically significant relationships between A1C level and gender, marital status, religion, type of diabetes, health care provider's call, height, weight, body mass index, blood pressures and the location of clinics where the subjects received their diabetes care.

Chapter V: Discussion, Implications and Conclusion

The purpose of the study was to investigate the relationships between the response variable, A1C (metabolic control), and three predictor variables (hardiness, self-efficacy and perceived medication adherence). Another purpose was to examine for further refinement and for retainment of factor construct and psychometric property of the Perceived Medication Adherence Scale (PMAS), which was initially developed in summer, 2000.

The results revealed that hardiness, self-efficacy and perceived medication adherence were not significantly related to metabolic control. The study also further refined and retained the factor construct and psychometric property of the PMAS. The scale was found to be a one factor scale and reliable. It had good correlations with the HRHS and the LTMBSES.

Discussion

A1C

Of the total subjects (n = 211), 41.71% (n = 88) had A1C levels less than 7.0 %, which is the goal, according to the ADA (1998). This means the 58.29% (n = 123) of the subjects had uncontrolled diabetes. In this study, weight and BMI were not associated with A1C levels. The subject who weighed 105 pounds had an A1C level of

7.5, whereas the subject who weighed 417.9 pounds had an A1C level of 6.2. The subject who had a BMI of 15.5 had an A1C level of 5.8 and the subject who had a BMI of 59.6 had an A1C of 6.3. The subject who had the highest A1C level (15.7) had overall low scores of HRHS 128, LTMBSES 76, and PMAS 75. This subject was 70 inches tall, and weighed 187.8 pounds with a BMI of 27.

The observed mean A1C level was 7.85, whereas the predicted A1C level in the prediction equation was 8.70, which is higher than the observed value. This may explain the insignificant relationships of A1C to hardiness, self-efficacy and perceived medication adherence observed in the present study. A more normal distribution of A1C values might have supported the hypothesis that metabolic control is related to measures of hardiness, self-efficacy and perceived medication adherence. Although some subjects had good metabolic control, the majority of the subjects had uncontrolled A1C levels because of insulin resistance. The majority of subjects were either obese or morbidly obese (81%, $n = 175$) and had numerous chronic illnesses, such as hypertension, high cholesterol levels, coronary heart disease or combination of these abnormalities totaling 93% ($n = 200$).

A study similar to this study, was conducted by Schectman et al. (2002), included African Americans as the majority of subjects, and these subjects had a mean A1C level of 8.1%. In this study, the mean A1C level was 7.85, which is lower than the study by Schectman et al. (2002). This finding could be due to the contribution made

by the providers' follow-up telephone calls to check on their patients and medication adherence – 81% (n = 174) of the subjects reported receiving the calls.

Hardiness

In this study, the subject who scored 185 (highest) on the HRHS had an A1C level of 5.9 % whereas the subject who scored 180 on the HRHS had an A1C level of 9.0%. The subject who scored 94 (lowest) on the HRHS had the best metabolic control, A1C level of 4.8%. Thus, self-report does not support the theoretical stance.

Self-Efficacy

According to previous studies, self-efficacy seemed to have a positive effect on metabolic control in patients with diabetes mellitus. In this study, the subject who scored 135 (highest score) on LTMBSES had an A1C of 5.8% while the subject who scored 51 (lowest score) on the scale had an A1C of 8.4%. Twenty-one subjects scored 123 on LTMBSES, and their A1C levels ranged from 5.1 to 13.2. In view of this finding, it is tempting to conclude that self-efficacy can be transitory or has some other effect that has little to do with metabolic control in adults with diabetes mellitus. An individual's self-efficacy is related to specific situations and tasks, rather than a general nature (van der Bijl, van Poelgeest-Eeltink, & Shortridge-Baggett, 1999).

To examine the effect of the perceived self-efficacy and confidence in outcomes, selected demographic variables, and disease characteristics on an individual's adherence over time to a diabetes regimen (home glucose testing, medication administration, diet, and exercise) were studied. The study found that self-efficacy had no effect on taking

medication, although it affected exercise, diet, and home glucose testing at different times. Self-efficacy appeared to be an important variable in terms of the diabetes self-care regimen at specific points in time, although self-efficacy appears to be unstable over time (Skelly et al., 1995).

Medication Adherence

The means of the PMAS (2003) score and MAS (2000) score were comparable. The mean of the PMAS score was 82 (SD 7.40) whereas the mean of the MAS score was 80 (SD 8.18). Adherence to hypoglycemic medication regimens was associated with metabolic control in an indigent population in the study by Schectman et al. (2002). For each 10% increment in drug adherence, the A1C level decreased by 0.16% at $p < 0.0001$ (Schectman et al., 2002). However, in the present study, 21 subjects scored 90 (highest score) on the PMAS and the A1C levels were from 5.2 to 12.4; the subject who scored 59 on the scale had an A1C level of 12.8. Possibly, this result is related to insulin resistance. Another explanation might be a social desirability factor. Indeed, findings from this study revealed the apparent difficulties in correlating medication adherence to metabolic outcome.

Diabetes regimen adherence is a complex task and performance of any single self-care pattern is not strongly related to glycemic control. Further, there is no straightforward relationship between adherence and control. Regimen adherence does not automatically lead to improved metabolic control. And yet, regimen adherence

should be viewed as one of a variety of factors influencing glycemic control (Glasgow et al., 1987).

Metabolic control was not explained by medication adherence by provider, patient, and pill counts. Because sulfonylurea adherence and metabolic control both are influenced by numerous factors, it is not possible to accurately relate compliance and control (Mason et al., 1995). Adherence to the insulin regimen did not correlate significantly with glycemic control (Boyer et al., 1996).

Relevant Findings

There was a negative correlation between age and A1C, indicating that the older the adult with diabetes, the better his/her metabolic control. This finding is the same finding in the study conducted by (Glasgow et al., 1987). It can be postulated that after years of having diabetes, the older adults became accustomed to their self-care of diabetes, leading to better control. The positive correlation between age and duration of diabetes is understandable; the older the subject, the longer the duration of diabetes. In term of age and blood pressures, older subjects had higher systolic, and lower diastolic blood pressures, however, when the relationship of systolic and diastolic blood pressures were considered, the correlation was positive. That is, the older the subject, the higher the blood pressure. Older subjects reported having a religious affiliation more often than younger subjects. The subjects with type 2 diabetes had more hypoglycemic agents, both oral agents and insulin, than the subjects with type 1

diabetes because subjects with type 1 diabetes take insulin only. The male subjects were taller than the female subjects, and the older subjects were shorter than the younger subjects. Heavy subjects had higher BMIs than their counterparts.

Implications

Nursing Implications

Participants in this study were mostly African Americans with type 2 diabetes mellitus. As seen in Figure 1, from the Centers for Disease Control and Prevention, minority populations are disproportionately affected by diabetes. Between 1980 and 1999, the age-adjusted prevalence of diagnosed diabetes increased, and the increase was at a greater rate among Blacks than Whites; the age-adjusted prevalence was highest among black females. Furthermore, between 1997 and 1999, the age-adjusted prevalence of diagnosed diabetes for Hispanic males and females was similar to that of black males (CDC, Statistics: Diabetes Surveillance System, n.d., Retrieved March 16, 2003) and higher in both Blacks and Hispanics than for Whites. Thus, it is reasonable to say that nurses taking care of patients with diabetes should pay particular attention in assessing the needs of patients, providing culturally sensitive education tailored to the patients' needs, and also providing care geared toward the prevention, and early detection of diabetes-related complications. Further, nurses need to actively participate in diabetes-related research and implement the study findings.

Conclusion

The prevalence of diabetes mellitus is increasing. It poses a significant public health challenge because diabetes mellitus is a serious, complex, and costly disease. If left uncontrolled, diabetes can cause many complications that can lead to frequent hospitalizations, decreased quality of life, and premature death.

The purpose of this study was to investigate the relationships between the response variable, A1C (metabolic control), and three predictor variables (hardiness, self-efficacy, and perceived medication adherence) in adults with diabetes mellitus. A cross-sectional correlation study was conducted. Data analyses were performed using correlation and multiple linear regression with hierarchical procedure. The relationships between A1C and the predictor variables were not statistically significant, indicating that each predictor variable did not contribute toward the metabolic control. The findings indicate that physiological phenomena were not predicted by self-reported behavioral phenomena.

The PMAS scale used for this study was examined for further refinement, and retainment of factor structure and psychometric properties. This scale was found to be of one factor structure and reliable.

Interestingly, age, a cofactor, was found to be correlated with metabolic control. Older subjects had better metabolic control than younger subjects. When age was compared to blood pressures, older subjects had high systolic and low diastolic blood pressures, however, when the blood pressures were compared with each other, a positive

correlation was found, indicating that those who had high systolic blood pressure also had high diastolic blood pressure.

The study participants were mainly African Americans with type 2 diabetes mellitus. Research has been shown that African Americans have low adherence and self-management behaviors (Schectman et al., 2002). Further, the age-adjusted prevalence of diagnosed diabetes was higher, and increased at a greater rate among African Americans than Whites between 1990 and 1999 (CDC, 1998). Therefore, it is crucial to foster patient specific and culturally sensitive care for African Americans. Moreover, further testing of instruments is needed to determine if a different norm exists for African Americans.

Further research is needed at different sites with different populations and multi-center clinical trials before any generalizations are made. A randomized clinical trial providing diabetes regimen education and/or telephone follow-up intervention in conjunction with diet and medication therapy is one study project that may shed light on the improvement of metabolic control in adults with diabetes mellitus.

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Appendix A: Demographic Information

MRN: _____ HbA_{1c}: _____ Date: _____ ID #_____

BP: _____ Height: _____ Weight: _____ Clinic: (DC, ACCPCC, ADWPCC)

1. Gender: 1) Female _____ 2) Male _____
2. Age: _____
3. Race: 1) African American _____ 2) Asian _____
   3) Hispanic _____ 4) Other _____ 5) White _____
4. Education completed (# of years): _____ years.
5. Marital status: 1) Single _____ 2) Married _____
   3) Divorced/Separated _____ 4) Widowed _____
   5) Committed relationship _____
6. Religion: 1) Protestant _____ 2) Catholic _____
   3) Jewish _____ 4) Islam _____ 5) Other _____
7. Type of Diabetes: 1) Type 1 _____ 2) Type 2 _____
8. My duration of diabetes is in years: _____ years
9. Diabetes medication(s) I take is(are): 1) Insulin only _____
   2) Oral medication _____ 3) Insulin and oral medication _____
10. Chronic illness(es), in addition to diabetes, I have is (are):
    1) High blood pressure _____ 2) Heart condition _____
    3) High cholesterol _____ 4) Kidney Failure _____
    5) Other _____
11. My health care provider is:
    1) Physician _____ 2) Nurse Practitioner _____
    3) Other licensed provider _____ 4) Alternative healer _____
    5) Other _____
12. How often does/do your provider(s) call you to check on you for medication taking?
    1) Never _____ 2) Rarely _____ 3) Every 6 months _____
    4) Every 3 months _____ 5) Once a month _____

Appendix B: HEALTH-RELATED HARDINESS SCALE

Instructions: ID #:

This is a questionnaire designed to determine the way in which different people view certain important issues related to their health. Each item is a belief statement with which you may agree or disagree. Beside each statement is a scale, which ranges from strongly disagree (1) to strongly agree (6). For each item, we would like you to circle the number that represents the extent to which you disagree or agree with the statement. Please make sure that you answer each item and that you circle only one number per item. Thank you for taking the time to complete this questionnaire.

1. Strongly Disagree
2. Moderately Disagree
3. Slightly Disagree
4. Slightly Agree
5. Moderately Agree
6. Strongly Agree

	Circle Your Answers					
13. Involvement in health promotion activities are stimulating.	1	2	3	4	5	6
14. I can avoid illness if I take care of myself.	1	2	3	4	5	6
15. I find it difficult to be enthusiastic about good health.	1	2	3	4	5	6
16. Luck plays a big part in determining how soon I will recover from an illness.	1	2	3	4	5	6
17. No matter how hard I try to maintain my health, my efforts will accomplish very little.	1	2	3	4	5	6
18. I am in control of my health.	1	2	3	4	5	6
19. I admire people who work hard to improve their health.	1	2	3	4	5	6
20. Good health is more important to me than financial security.	1	2	3	4	5	6

1. Strongly Disagree
2. Moderately Disagree
3. Slightly Disagree
4. Slightly Agree
5. Moderately Agree
6. Strongly Agree

Circle Your Answers

21. My good health is largely a matter of good fortune.	1	2	3	4	5	6
22. No matter what I do, I'm likely to get sick.	1	2	3	4	5	6
23. I find it boring to eat and exercise properly to maintain my health.	1	2	3	4	5	6
24. The main thing which affects my health is what I myself do.	1	2	3	4	5	6
25. Changes taking place in health care are not exciting to me.	1	2	3	4	5	6
26. I find people who are involved in health promotion interesting.	1	2	3	4	5	6
27. Setting goals for health is unrealistic.	1	2	3	4	5	6
28. Most things that affect my health happen to me by accident.	1	2	3	4	5	6
29. Changes taking place in health care will have no effect on me.	1	2	3	4	5	6
30. If I get sick, it is my own behavior that determines how soon I get well.	1	2	3	4	5	6
31. I do not find it interesting to learn about health.	1	2	3	4	5	6
32. I will stay healthy if it's meant to be.	1	2	3	4	5	6

1. Strongly Disagree
2. Moderately Disagree
3. Slightly Disagree
4. Slightly Agree
5. Moderately Agree
6. Strongly Agree

	Circle Your Answers					
33. I am not interested in exploring new ways to improve my health.	1	2	3	4	5	6
34. No matter what I do, if I am going to get sick, I will get sick.	1	2	3	4	5	6
35. I feel no need to try to maintain my health because it makes no difference anyway.	1	2	3	4	5	6
36. The current focus on health promotion is a fad that will probably disappear.	1	2	3	4	5	6
37. No matter how hard I work to promote health for society, it never seems to improve.	1	2	3	4	5	6
38. Our society holds no worthwhile goals or values about health.	1	2	3	4	5	6
39. If I take the right actions, I can stay healthy.	1	2	3	4	5	6
40. I get excited about the possibility of improving my health.	1	2	3	4	5	6
41. I am determined to be as healthy as I can be.	1	2	3	4	5	6

1. Strongly Disagree
2. Moderately Disagree
3. Slightly Disagree
4. Slightly Agree
5. Moderately Agree
6. Strongly Agree

	Circle Your Answers					
42. When my health is threatened, I view it as a challenge that must be overcome.	1	2	3	4	5	6
43. I read everything I can about health.	1	2	3	4	5	6
44. I can be as healthy as I want to be.	1	2	3	4	5	6
45. When something goes wrong with my health, I do everything I can to get at the root of the problem.	1	2	3	4	5	6
46. I have little influence over my health.	1	2	3	4	5	6

Appendix C: LONG-TERM MEDICATION BEHAVIOUR SELF-EFFICACYSCALE© (De Geest et al., 1994)

ID #:

We would like to know how much confidence you have about doing each of the behaviours listed below. For each of the following statements, please circle the number that most closely represents your level of confidence in performing the behaviour.

1. Very Little
2. Little
3. Neutral
4. A Lot
5. Quite A Lot

	Circle Your Answers				
47. Taking my medication when I am at home.	1	2	3	4	5
48. Taking my medication even though the pills are big and difficult to swallow.	1	2	3	4	5
49. Taking my medication even though it is very expensive.	1	2	3	4	5
50. Taking my medication in the absence of medication aids (e.g. pill box, calender,...).	1	2	3	4	5
51. Taking my medication when nobody helps me getting ready.	1	2	3	4	5
52. Taking my medication while at work.	1	2	3	4	5
53. Taking my medication during the weekend.	1	2	3	4	5
54. Taking my medication when it may cause me to feel very hungry.	1	2	3	4	5
55. Taking my medication even if it drops my blood sugar levels very low < 50.	1	2	3	4	5

1. Very Little
2. Little
3. Neutral
4. A Lot
5. Quite A Lot

		Circle Your Answers				
56.	Taking my medication when I feel very healthy.	1	2	3	4	5
57.	Taking my medication when it is prescribed to be taken every other day.	1	2	3	4	5
58.	Taking my medication when the time of intake does not coincide with my meal times.	1	2	3	4	5
59.	Taking my medication when I am in the middle of a project at home.	1	2	3	4	5
60.	Taking my medication when it may make me feel weak.	1	2	3	4	5
61.	Taking my medication when nobody reminds me about the time at which I should take the medication.	1	2	3	4	5
62.	Taking my medication when I have visitors at my home.	1	2	3	4	5
63.	Taking my medication after I have gotten very angry at a friend.	1	2	3	4	5
64.	Taking my medication when I am in pain.	1	2	3	4	5
65.	Taking my medication while watching an exiting programme on T.V.	1	2	3	4	5
66.	Taking my medication when I feel very ill.	1	2	3	4	5
67.	Taking my medication when I feel very sad.	1	2	3	4	5

1. Very Little
2. Little
3. Neutral
4. A Lot
5. Quite A Lot

	Circle Your Answers				
68. Taking my medication while unknown people are watching me (e.g. in a restaurant).	1	2	3	4	5
69. Taking my medication when I feel sick in my stomach.	1	2	3	4	5
70. Taking my medication when I am having an argument with my partner.	1	2	3	4	5
71. Taking my medication when I am at a party.	1	2	3	4	5
72. Taking my medication while taking a long walk.	1	2	3	4	5
73. Taking my medication while visiting a bar.	1	2	3	4	5

Appendix D: Perceived Medication Adherence Scale

ID #:

Instruction: The following questions relate to hypoglycemic medication adherence. Please answer the questions in accordance to the scale below:

1 = Strongly disagree
2 = Disagree
3 = Slightly agree
4 = Agree
5 = Strongly agree

	Circle Your Answers				
74. I take my medications at the right time.	1	2	3	4	5
75. I take the right medications.	1	2	3	4	5
76. I take the right dosage of my medications.	1	2	3	4	5
77. I take my medications by the prescribed method.	1	2	3	4	5
78. I complete the prescription as directed.	1	2	3	4	5
78. I comply with my health care provider's directions regarding medications.	1	2	3	4	5
80. I take my medications as prescribed.	1	2	3	4	5
81. I know how I am supposed to take my medications.	1	2	3	4	5
82. I refill my prescription before I run out of my medications.	1	2	3	4	5
83. I skip my medications when I am busy.	1	2	3	4	5

1 = Strongly disagree
2 = Disagree
3 = Slightly agree
4 = Agree
5 = Strongly agree

	Circle Your Answers				
84. I share my medications with others.	1	2	3	4	5
84. I read the directions on the prescription.	1	2	3	4	5
85. I stop taking my medications if I develop side effects.	1	2	3	4	5
87. I follow the directions on the prescription.	1	2	3	4	5
88. I know why I take each medication.	1	2	3	4	5
89. I take my medications to control my illness.	1	2	3	4	5
90. I adhere to my prescribed medication routines.	1	2	3	4	5
91. I store all my medications as recommended.	1	2	3	4	5

Thank you for your participation!

Subject: Re: HRHS Scales and Instructions
Date: Fri, 16 Feb 2001 08:17:05 -0600
From: Susan Pollock <sonsep@ttuhsc.edu>
To: Ok Chon Allison <oallison@vcu.org>

Appendix E.

Permission to Reprint Moderating Effect of Hardiness

Ms. Allison: You have permission to use diagrams related to Adaptation to Chronic Illness framework. Susan E. Pollock
At 12:49 AM 2/16/01 -0500, you wrote:
>Dear Dr. Pollock:
>
>Thank you so much for the HRHS Scales and Instructions. I received >them. In my letter of January 27, 2001, I mentioned that "I would like >to obtain your permission for the use of your diagrams in many of your >articles related to the "Adaptation to Chronic Illnesses" in my >theoretical framework." May I have your permission to use them? Of >course, I will mention that I received your permission in the context. >Thank you.
>
>Ok Chon Allison

Appendix F.

Permission to Reprint Glycemic Control for People with Diabetes

August 29, 2001

Permission Editor
American Diabetes Association
ADA National Service Center
1660 Duke Street
Alexandria, Virginia 22314

Dear Permission Editor:

I am writing this letter to obtain your permission to reprint a table -- "Table 3.15 Glycemic Control for People with Diabetes" on page 78 from Medical Management of Type 2 Diabetes (4th. Ed.). I currently work as a Nurse Practitioner and am a Certified Diabetes Educator. Additionally, I am a Ph.D. student in Nursing at the Virginia Commonwealth University, Richmond, Virginia. I am writing my dissertation proposal and want to include the table in the proposal. My dissertation research will focus on hypoglycemic medication education and adherence of persons with diabetes.

Thank you in advance for your permission. I look forward hearing from you soon.

Sincerely,

[redacted]

Ok Chon Allison, MSN, ANP, CDE
8737 Shadymist Drive
Richmond, VA 23235
Tel & Fax: 804-745-4376
E-mail: oallison@vcu.org or ocalliso@hsc.vcu.edu

[redacted]

9/20/01

Appendix G.

IRB Letter of Permission

VCU
MCV CAMPUS
Virginia Commonwealth University

OFFICE OF RESEARCH
SUBJECTS PROTECTION

SANGER HALL
1101 EAST MARSHALL STREET
P.O. BOX 980568
RICHMOND, VIRGINIA 23298-0568

ROOM 1-023: 804 828-0868
FAX: 804 828-5917

ROOM B1-001: 804 828-0868
FAX: 804 827-1448
TDD: 1-800 828-1120

DATE: October 15, 2002

TO: Janet B. Younger, PhD
School of Nursing
PO Box 980567

FROM: Deborah L. Haller, PhD, ABBP
Chairperson, VCU IRB Panel B
Box 980568

RE: **VCU IRB #: 02778**
Title: The Relationship of Metabolic Control to Hardiness, Self-Efficacy and Medication Adherence in Adults with Diabetes Mellitus

On October 1, 2002, the following research study was ***approved*** by expedited review according to 45 CFR 46.110 Category 7. This approval reflects the revisions as received on September 30, 2002. This approval includes the following items reviewed by this Panel:

PROTOCOL: The Relationship of Metabolic Control to Hardiness, Self-Efficacy and Medication Adherence in Adults with Diabetes Mellitus, received September 30, 2002

CONSENT/ASSENT:

- Research Participant Information and Consent Form, received September 30, 2002

ADDITIONAL DOCUMENTS:

- Appendix E: Letter of Introduction, received September 30, 2002

In order to comply with federal regulations, industry standards, and the terms of this approval, the investigator must *(as applicable):*

1) Conduct the research as described in and required by the approved protocol.

2) Obtain informed consent from all subjects without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate (unless Waiver of Consent is specifically approved).

3) Document informed consent using only the most recently dated consent form bearing the VCU IRB "APPROVED" stamp (unless Waiver of Consent Documentation is specifically approved).

4) Provide non-English speaking subjects with a translation of the approved consent form in the subject's first language. The panel must approve the translated version.

5) Obtain prior approval from the VCU IRB before implementing any changes whatsoever in the approved protocol or consent form, unless such changes are necessary to protect the safety of human research subjects.

6) Adverse Event Reporting Timeline:

CLASS	SEVERITY	EXPECTEDNESS/ RELATEDNESS	LOCATION	REPORTING TIMELINE
1(a)	Serious	Unexpected Related or possibly related	VCU or VCU IRB-approved site	2 business days from *occurrence*
1(b)	Serious	Unexpected Related or possibly related	Non-VCU site	2 business days from *receipt*
2	Non-Serious	Unexpected Related or possibly related	All	Not required
3	Non-Serious Serious	Expected	All	Not required

7) Other Reporting Timelines:

- Report in writing to the VCU IRB within 10 days of any such changes made to protect the safety of human subjects enrolled on this study.
- Report to the VCU IRB within 10 days the receipt of any new information that may adversely affect the safety of the subjects or the conduct of the trial.

8) Obtain prior approval from the VCU IRB before use of any advertisement or other material for recruitment of study subjects.

9) Promptly report and/or respond to all inquiries by the VCU IRB concerning the conduct of the approved research when so requested.

This approval expires on September 30, 2003. Federal Regulations/VCU Policy and Procedures require continuing review prior to continuation of approval past that date. Continuing Review report forms will be mailed to you prior to the scheduled review.

This Institutional Review Board is in compliance with good clinical practices (GCP) as defined under the U.S. Food and Drug Administration (FDA) regulations and the International Conference on Harmonization (ICH) guidelines. Virginia Commonwealth University is approved by DHHS to conduct human subjects research under a Multiple Project Assurance #M1315. **All correspondence related to this research study must include the IRB protocol number and the investigator's name(s) to assist us in locating your file. Please note that the CCHR number is no longer valid, if applicable.**

The Primary Reviewer assigned to your research study is Stephanie Fox, Psy.D. If you have any questions, please contact Dr. Fox at sfox@vcu.edu or 827-1561; or you may contact Brenda Innis, IRB Coordinator, VCU Office of Research Subjects Protection, at binnis@hsc.vcu.edu or 828-3992.

Appendix H. LETTER OF INTRODUCTION

INTRODUCTION

Hello, My name is Ok Chon Allison. I have been a nurse practitioner for over 15 years, am a certified diabetes educator, and I currently am a doctoral (Ph.D.) student in Nursing at Virginia Commonwealth University, School of Nursing. As part of my dissertation work, I would like to learn about the relationship of diabetes control to hardiness personal characteristics, self-efficacy and medication adherence practice in adults with diabetes mellitus. This letter is to recruit adults with diabetes mellitus who are taking medication(s) for the condition to participate in a research project. Participation in this study involves giving permission to the researcher to review chart data and completing questionnaires. You are not being asked to participate in the educational intervention study and telephone follow-up.

BENEFITS

Your participation may also benefit you and other adults with diabetes by helping clinicians find out ways of promoting medication adherence. The findings of this study will be the foundation of conducting an interventional research project that will be focused on educational intervention and telephone follow-up in an attempt to facilitate diabetes medication adherence, thereby improving the diabetic condition and quality of lives of adults with diabetes. You will receive $10.00 as a recruitment incentive.

RISKS, INCONVENIENCES, DISCOMFORTS

Although there are no known physical risks to you, there is a minimal risk due to disruption of your flow of normal activities of daily living while you are participating in the study. The researcher will make every effort to create a safe environment while you complete the research questionnaires.

COST OF PARTICIPATION

There are no costs to you for participating in this study.

CONFIDENTIALITY

The information provided by you will remain confidential. You will be assigned a number so that your name will not be used in any records of the research. Absolute confidentiality cannot be guaranteed because of the need to give information to the sponsors, agents for the sponsors and an agent for the researchers and for research or regulatory purposes. The results of this study may be presented at meetings or in professional publications. Your identity will not be disclosed in those presentations.

QUESTIONS OR WITHDRAWAL

Your participation in this study is entirely voluntary. If you do participate, you may freely withdraw from the study at any time by notifying one of the investigators. Further, if you have any questions regarding to this study now or in the future you may contact the investigators:

Janet B. Younger, Ph.D., RN, CPNP
Principal Investigator
E-mail: younger@hsc.vcu.edu
Tel: (804)-828-3968
Virginia Commonwealth University
School of Nursing
1220 East Broad Street
Richmond, VA 23298-0567

or

Ok Chon Allison, MSN, ANP, CDE,
Co-investigator
ocalliso@hsc.vcu.edu
(804)-827-0100 or Cell: (804)-543-2218
Internal Medicine, VCU Health System
GI, Nutrition, West Hospital, 14th Floor.
1200 East Broad Street
Richmond, VA 23298-0711

APPROVED
10/01/02 [redacted]

Appendix I.

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

TITLE: **THE RELATIONSHIP OF METABOLIC CONTROL TO HARDINESS, SELF-EFFICACY AND MEDICATION ADHERENCE IN ADULTS WITH DIABETES MELLITUS**

PROTOCOL NUNBER: VCU IRB #2778

SPONSORS:

1) **VCU SCHOOL OF NURSING, PHD PROGRAM**
2) **SIGMA THETA TAU INTERNATIONAL NURSING HONOR SOCIETY, GAMMA OMEGA, VCU CHAPTER**
3) **AMERICAN ACADEMY OF NURSE PRACTITIONERS, FOUNDATION, DEMPSTER 2001 DOCTORAL EDUCATION NP RESEARCH GRANT**

INVESTIGATORS:

1) **JANET B. YOUNGER, PHD, RN, CPNP, PRINCIPAL INVESTIGATOR**
2) **OK CHON ALLISON, MSN, RN,CS, ANP, CDE, CO-INVESTIGATOR**

This consent form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. You may keep an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY:

The purpose of this research study is to investigate the relationship between metabolic control, and three predictor variables - hardiness personal constellations, self-efficacy orientation and medication adherence practice in adults with diabetes mellitus. The findings may become an impetus to conduct an experimental study in the future to improve management and control of diabetes, which, in turn, will decrease diabetes-related complications, prevent or reduce hospitalizations and improve the quality of life. You are being asked to participate because you have been diagnosed with diabetes mellitus, taking medication(s) for the condition, and may meet the study entry requirements. You are not being asked to participate in the educational intervention study and telephone follow-up.

DESCRIPTION OF THE STUDY:

If you have agreed to participate by signing and returning the consent form, you will be enrolled in this study. You will then be asked to provide demographic data and answer three questionnaires. Your participation in this study will require up to one hour to answer questionnaires. There will be no follow-ups for the study. Approximately 100 to 120 adults with diagnosed diabetes mellitus who are taking medication(s) for the condition will participate in this study.

APPROVED
10/01/02 [redacted]

APPROVED
10/01/02 [redacted]

PROCEDURES:
If you decide to be in this research study, you will be asked to sign this consent form after you have had all your questions answered. Also, your permission form will be provided for you to sign so that the study researchers can have access to your hospital laboratory Hemoglobin A_{1c} test result and your medical record. Your blood pressure, height, and weight will be taken, or reviewed from your medical record. You will then be asked to provide demographic data and answer three questionnaires (Health-Related Hardiness Scale, Long-Term Medication Behavior Self-Efficacy Scale and Medication Adherence Scale). Each questionnaire will take about 10 to 20 minutes to complete.

RISKS AND DISCOMFORTS:
The potential risks to the participants will be minimal. There is a potential for some emotional discomfort for you in being asked personal questions about your background (age, gender, education, marital status, religion and your diabetes, etc.). If you are uncomfortable about answering these questions and would like to talk about them, please let the research investigator(s) or facilitator know. You do not have to answer any question(s) that you feel uncomfortable about answering. There is a minimal risk due to disruption of your flow of normal activities of daily living while you are participating in the study. The researchers will make every effort to create a safe environment while you complete the research questionnaires and to make sure no one sees your answers to the questionnaires, other than the researchers, facilitator(s) and study sponsors.

BENEFITS:
This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. Your participation may benefit you and other adults with diabetes by helping clinicians find out ways of promoting medication adherence. The findings of this study will be the foundation of conducting an interventional research project that will be focused on educational intervention and telephone follow-up in an attempt to facilitate diabetes medication adherence, thereby improving the diabetic condition and quality of lives of adults with diabetes.

COSTS: There are no costs to you for participating in this study.

PAYMENT FOR PARTICIPATION:
You will be paid $10.00 if you complete all questionnaires.

ALTERNATIVE:
This is not a treatment study and that the alternative is not to participate.

CONFIDENTIALITY:
The information provided by you will remain confidential. Your name will not be used. You will be assigned a number so that your name will not be used in any records of the research. Information from this study will be given to the sponsor(s). Medical records

APPROVED
10/01/02 [redacted]

which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- The sponsors
- An agent for the sponsor(s)
- An agent for the researchers

And may be looked at and/or copied for research or regulatory purposes by:

- The US Office of Human Research Protections and
- Virginia Commonwealth University.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this study may be presented at meetings or in professional publications. Your identity will not be disclosed in those presentations.

COMPENSATION FOR INJURY:
Virginia Commonwealth University and the VCU Health System (formerly known as Medical College of Virginia Hospitals) have no plan for providing long-term care or compensation in the event that you suffer injury as a result of your participation in this research study. If injury occurs, medical treatment will be available at the MCV Hospitals. Fees for such treatment will be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment injuries as a result of your participation in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL:
Your participation in this study is voluntary. You may decide to not participate in this study. If you do participate, you may freely withdraw from the study at any time by notifying one of the researchers during daytime hours. Your decision will not change your future medical care at this site or institution.

Your participation in this study may be stopped at any time by one of the study researchers or the sponsor(s) without your consent for medical or administrative reasons.

QUESTIONS:
In the future, you may have questions about your study participation. If you have any questions about the study, you may contact the investigators:

Janet B. Younger, Ph.D., RN, CPNP
E-mail: younger@hsc.vcu.edu
Tel: (804)-828-3968
Virginia Commonwealth University
School of Nursing
1220 East Broad Street

or

Ok Chon Allison, MSN, ANP, CDE,
ocalliso@hsc.vcu.edu
(804)-827-0100 or Cell: 804-543-2218
Internal Medicine, GI, Nutrition
VCU Health System
West Hosp., 14th Floor

APPROVED
10/01/02 [redacted]

Richmond, VA 23298-0567

1200 East Broad Street
Richmond, VA 23298-0711

If you have questions about your rights as a research participant, you may contact:

Office for Research Subjects Protection
Virginia Commonwealth University
1101 E. Marshall St., Room 1-023
P. O. Box 980568
Richmond, VA 23298
Telephone: 804-828-0868
Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

CONSENT:
I have read this consent form. I understand the information about this study. All my questions about the study and my participation in it have been answered; I freely consent to participate in this research study.

I understand that I will receive a signed and dated copy of this consent form for my records.

I authorize the release of my medical records for research or regulatory purposes to the sponsor(s), and VCU Internal Review Board.

By signing this consent form, I have not waived any of the legal rights, which I otherwise would have as a subject in a research study.

Subject name, printed _____ Date _____

Subject Signature _____ Date _____

[redacted] 10-16-02
Signature of Person conducting informed consent discussion (Co-Investigator) Date

[redacted] 10-16-02
Principal Investigator's Signature Date

APPROVED
10/01/02 AF/BT

Appendix J.

Permission to use Health Related Hardiness Scale

TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

School of Nursing
Office of the Dean

Lubbock, Texas 79430
(806) 743-2749

Dear Colleague:

Thank you for your interest in the Health Related Hardiness Scale (HRHS). I am happy to make this instrument available to you for research as a way of collecting data from various populations. The requirements for using this instrument are listed below. After I receive this form and a copy of your abstract, I will mail you a copy of the instrument.

My policy is to grant permission to use the HRHS for research purposes if I:

1. receive an abstract of the proposed research;
2. am assured of receiving the results of the study;
3. receive a copy of the reliability and validity estimates obtained;
4. am assured that no further psychometric analyses will be done; and
5. am credited with authorship in any use, associated report, or publication involving the instrument.

I agree to the above requirements and have enclosed an abstract of my proposed research.

Signed: [redacted] Date: January 27, 2001

Name Ok Chon Allison, MSN, ANP, CDE

Address: 8737 Shadymist Drive

City & State: Richmond, VA 23235

Telephone: (work) _____ (home) 804-745-4376

Sincerely

[redacted]

Susan E. Pollock, PhD, RN, FAAN
Professor and Associate Dean for Research
School of Nursing
Texas Tech Health Sciences Center
3601 4th Street
Lubbock, Texas 79430

m:\winword\research\hrhs\contract.406

An EEO / Affirmative Action Institution

Appendix K.

Permission to use Long-Term Medication Behavior Self-Efficacy Scale

CENTRUM VOOR ZIEKENHUIS- EN VERPLEGINGSWETENSCHAP
DEPT. MAATSCHAPPELIJKE GEZONDHEIDSZORG
FACULTEIT GENEESKUNDE
KAPUCIJNENVOER 35
B-3000 LEUVEN

Ok Chon Allison
8737 Shadymist Drive
Richmond, VA 23235
USA
Email: oallison@vcu.org
Tel: +1-804-7454376
Fax:' +1 804 7454369

KATHOLIEKE
UNIVERSITEIT
LEUVEN

ONS KENMERK
UW KENMERK
LEUVEN, 16/07/00

Dear Dr. Ok Chon Allison,

Thank you for interest in the Long-Term Medication Behavior Self-Efficacy Scale for your research in diabetes mellitus patients.

The Long-Term Medication Behavior Self-Efficacy Scale has been used in two completed research projects on "Prevalence, determinants, and consequences of non-compliance with immunosuppressive therapy in transplant recipients". The first study included a sample of 150 renal transplant recipients (De Geest et al., Transplantation 1995; 59: 340-347) and the second study consisted of 101 heart transplant recipients (De Geest et al., Journal of Heart and Lung Transplantation, 1998; 17: 854-863). Self-efficacy was a determinant of medication compliance behavior in both studies.

The Long-Term Medication Behavior Self-Efficacy Scale has been adjusted, based on results of factor analysis and correlation analysis. The initial 33-item instrument has been reduced to a 27-item instrument. The Cronbach's alpha for the 27-item instrument is 0.88, reflecting good reliability (De Geest et al., Journal of Heart and Lung Transplantation, 1998; 17: 854-863). Please find enclosed the English version of the scale.

The self-efficacy score is calculated by summing the scores of all items divided by 27. Thus, the self-efficacy scores range between 1 and 5, with higher scores indicating higher levels of self-efficacy.

Items 8, 9, and 14 are related to side-effects of medication. Because the Long-Term Medication Behavior Self-Efficacy Scale was developed as part of a research-project in transplant recipients, the side-effects included are side-effects of immunosuppressive medication. We enclosed distressing symptoms related to side-effects of immunosuppressive therapy because these side-effects are most likely to trigger noncompliance (cf. Common Sense Model, Leventhal et al., Cognitive Therapy and Research 1992; 16: 143-463 & Moons, De Geest et al., Heart and Lung, 1998; 27: 315-325). Because these side-effects are probably not relevant for your study you could replace them with distressing side-effects related to the diabetes treatment under study in your research.

The Long-Term Medication Behavior Self-Efficacy Scale has been further validated based on results of 1042 subjects who where included in several transplant compliance research projects and other studies in chronic patient populations worldwide. Results confirm the predictive validity of the scale. The manuscript reporting these findings is in preparation (Denhaerynck et al.). We are currently also in the data analysis phase of a study that assesses different scaling methods when using the The Long-Term Medication Behavior Self-Efficacy Scale.

Because the validation process is ongoing, I would appreciate it if you could send me your full address and the details of your study. Upon completion of your study I would appreciate it if you could send me the results concerning the Long-Term Medication Behavior Self-Efficacy Scale in case you would decide to use the scale in your study. This would allow us to further study psychometric properties of the instrument. I will send a copy of this letter to Kris Denhaerynck, one of my collaborators, who is involved in the validation studies of the LTMBSE-scale. He will inform you what kind of data we would need for further validation of the scale should we receive confirmation from you that you will validate the scale.

PROF. DR. S. DE GEEST
TEL. +32-16-33 69 81 / 33 69 75FAX (016)33 69 70
E-mail: sabina.degeest@med.kuleuven.ac.be

16/07/00

I wish you all success with your research. Please, do not hesitate if you have any further questions.
Yours sincerely,

Sabina De Geest, Ph.D., RN, NFESC
Professor of Nursing
Director
Institute of Nursing Science
University of Basel
Kollegienhaus 1st Floor
Petersplatz 1
4003 Basel
Switzerland
Tel: +41-61- 2673040
Fax: +41-61- 2670955
Email: Sabina.DeGeest@unibas.ch
&
Center for Health Services and Nursing Research
School of Public Health
Catholic University of Leuven
Kapucijnenvoer 35/4, B-3000 Leuven, Belgium
Tel: +32-16-336975 Fax: +32-16-336970
E-mail: Sabina.DeGeest@med.kuleuven.ac.be or SdeGeest@compuserve.com

Appendix L: Description of Measurements

Instrument	Measures	Items & Range	Variable	Reliability	Validity
Health-Related Hardiness Scale by Susan E. Pollock, 1990	Measures the hardiness construct in health-related research and/or the 2 dimensions of commitment/ challenge (20 items) or control (14 items).	34 items. The score ranges from 34 to 204 on a six-point Likert-type scale. Strongly disagree to strongly agree with high scores indicating presence of hardiness.	204 Total Scores of 34 items	.91 (34 item HRHS) .87 for both the 20-item commit-ment/ challenge subscale and the 14-item control scale.	Strong support for the validity of the HRHS, which is, used more than 250 studies internationally has been established (Pollock, 1999)
Long-Term Medication Behaviour Self-Efficacy Scale by De Geest et al., 1994	Measures Self-efficacy as a determinant of medication compliance behavior.	27 items. The score ranges from 27 to 135 very little to quite a lot with higher scores indicating higher levels of self-efficacy.	135 Total Scores of 27 items	.88	Based on transplant compliance research projects (N = 1042) & other studies in chronic patients worldwide.
Medication Adherence Scale (2000). The name of the scale is changed to Perceived Medication Adherence Scale by Allison, 2003.	Measures perceived medication adherence.	18 items (19 items originally). scores range from 18 to 90 (19 to 95 original) on a five-point Likert-type scale. Strongly disagree to Strongly agree.	90 Total Scores of 18 items	.92 (Based on the original 19 item scale) for total PMAS scale.	Construct validity: Pos. Corr. between total PMAS & subscales. Content validity: Lit. reviews and exam. By 6 nurse experts.