To the Graduate Council:

I am submitting herewith a dissertation written by Laura Holcomb entitled "The Applicability of the Stage of Change Construct of the Transtheoretical Model of Behavior Change to the Problem of Type II Diabetic Adherence." I have examined the final copy of this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy, with a major in Psychology.

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THE APPLICABILITY OF THE STAGE OF CHANGE CONSTRUCT OF THE TRANSTHEORETICAL MODEL OF BEHAVIOR CHANGE TO THE PROBLEM OF TYPE II DIABETIC ADHERENCE

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ABSTRACT

The purpose of this study was to determine the applicability of the Stages of Change Construct of the Transtheoretical Model of Behavior Change to the problem of adherence of Type II diabetic patients to taking prescribed diabetes medications, monitoring blood glucose, diet, and exercise. Demographic questionnaires and Stage of Change Algorithms for each of the 4 treatment behaviors were administered to the 101 male Veteran outpatients who participated in the study. Composite Stage of Change scores were neither found to be significantly correlated with hemoglobin A_{1c} (HbA_{1c}) levels ($r=-0.031$; $p<.759$), nor to be predictive of attendance of a diabetes-related educational class (squared semi-partial $r=.165$, $p<.100$). There was no significant difference in HbA_{1c} levels depending upon diabetes class attendance for those with high Composite Stage of Change scores ($n=79$; $t=-0.992$, $df=77$, $p<.324$). There was no significant relationship found between the number of behaviors in Action or Maintenance and HbA_{1c} levels ($x^2=2.263$; $df=4$). Of the 4 diabetic treatment behaviors, only the Medication Stage of Change was significantly predictive of HbA1c levels (squared semi-partial $r=.039$, $p<.047$). The present study found no evidence of a significant relationship between the Stage of Change construct of the Transtheoretical Model of Behavior Change. However, the acceptance of a lack of relationship would be premature since this study identified many difficulties with the current design that might be resolved in future research, including a high probability of social desirability bias and/or self-report error, and problems with the current format of the Stage of Change Algorithms. Recommendations are made for further research to attempt to resolve these unexpected findings.

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The Impact of Diabetes

Diabetes is an incurable, chronic disease that affects 5.9 percent of the United States population, or 15.7 million people (American Diabetes Association, ADA, 2000). There are two major types of diabetes, I and II. Type I typically has its onset in childhood, and results from an inability of the pancreas to produce insulin. Type II diabetes, or adult onset, involves an impaired ability of the body to regulate insulin and glucose (Glasgow & Eakin, 1998). Over 90% of people with diabetes have type II. Of those with type II diabetes, about 90% are obese, a major risk factor for developing type II diabetes (Foreyt & Poston, 1999). Other risk factors for developing type II diabetes include age greater than 45, a family history of diabetes, sedentary lifestyle, high triglycerides, low HDL cholesterol, and hypertension (ADA, 2000; Stern, 1999). Persons of African American, Hispanic American, or Native American ethnicity are also at increased risk for type II diabetes (ADA, 2000).

Diabetes is one of the most costly health problems in America (Jacoby, Sena, & Fox, 1990; Leese, 1992; Olsson, Persson, Tollin, Nilsson, & Melander, 1994). Health care costs of people with diabetes have been estimated at as much as $138 billion in the United States each year (ADA, 2000). Veterans Health Administration data for the entire system for the fiscal year of 1998 (NCCC, 1999) indicated that 25% of their total

pharmacy expenditures in 1998 benefited veterans diagnosed with diabetes. The total cost of health care for the 349,400 veterans with diabetes was over $305 million.

Many of the health care costs for patients with diabetes are related to the numerous and severe potential complications associated with the disease. According to the American Diabetic Association (ADA, 2000), diabetes is the sixth-leading cause of death by disease in the United States. Diabetes is the leading cause of end stage renal disease (ESRD), which requires costly treatment by dialysis or kidney transplant. Persons with diabetes are 2 to 4 times more likely than those without diabetes to develop heart disease or to suffer a stroke. From 60% to 70% of people with diabetes have mild to severe forms of peripheral neuropathy, resulting from low blood flow through vessels damaged by diabetes-related peripheral vascular disease. Diabetes-related peripheral vascular disease results in more than 56,000 amputations performed in the United States each year. Diabetes can also lead to impotence from peripheral neuropathy or blood vessel blockage, affecting approximately 8% of men with type II diabetes.

The Management of Diabetes

The likelihood of diabetic complications can be reduced by control of blood glucose levels. There is not an exact threshold above which diabetic complications are certain. However, a patient is less likely to develop complications the closer that glycemic levels are to the normal, non-diabetic range (DCCT, 1996; UKPDS, 1998; Vaaler, 2000). Glycemic levels are commonly measured by the glycosylated hemoglobin assay (hemoglobin A_{1c}, HbA_{1c}), which reflects a patient's level of glycemic control over a 2 to 3 month period (Nathan, Singer, Hurxthal, & Goodson, 1984). Current American Diabetes Association guidelines (ADA, 1999) label hemoglobin A_{1c} (HbA_{1c}) levels

below 6 as *excellent*, from 6.0 to 6.9 as *good*, from 7.0 to 7.9 as *fair*, and 8.0 or above as *poor*. A goal hemoglobin A_{1c} (HbA_{1c}) of less than 7.0 was recommended for persons with diabetes. The average hemoglobin A_{1c} (HbA_{1c}) for all patients with diabetes in the Veterans Health Administration system in the 1998 fiscal year was 7.8 (NCCC, 1999), indicating a need for significant improvement in order to meet ADA recommendations.

Achieving glycemic control can be challenging because blood glucose levels are affected by several factors. These factors include the effectiveness of the diabetic treatment regimen prescribed by the physician (Johnson, 1992, 1993; McNabb, 1997), the degree of patient adherence to the diabetic treatment regimen (Glasgow & Eakin, 1998; Greenfield, Kaplan, Ware, Yano, & Frank, 1988; McNabb, 1997), physiological factors (Sims, 1986), and the direct effects of psychosocial stress through psychophysiologic processes (Halford, Cuddihy, & Mortimer, 1990; Peyrot, McMurry, & Kruger, 1999).

The Problem of Diabetic Adherence

The Role of the Patient in the Diabetic Treatment Regimen

The role of the patient in achieving glycemic control has been emphasized because it is the patient who carries the primary responsibility for executing the diabetic treatment regimen. Greenfield, Kaplan, Ware, Yano, & Frank (1988) stated, "No amount of technically competent, humanely delivered medical care will lead to effective management of chronic disease unless patients actively implement treatment regimens and minimize the impact of disease-related limitations on their usual activities. For patients with

diabetes mellitus, this means daily glucose monitoring and regulation of medications, exercise, and diet in the context of their work, home, and leisure routines" (p. 448).

Unfortunately, many patients with diabetes do not follow this diabetic treatment regimen. Even if a patient recognizes his or her responsibility for the management of diabetes, this recognition does not necessarily make him or her more likely to follow the diabetic treatment regimen (Coates & Boore, 1998). Approximately 75% of patients in one study admitted to making significant deviations from recommended dietary guidelines at least weekly (Christensen, Terry, Wyatt, Pichert, & Lorenz, 1983). Estimated percentages of diabetic patients who are adherent to exercise regimens have ranged from 19% to 30% (McNabb, 1997). One early study of diabetic patients found only 7% to be fully adherent to all aspects of their treatment regimen (Cerkoney & Hart, 1980).

Patients with diabetes are typically more adherent to certain parts of the diabetic treatment regimen than to others (Glasgow, McCaul, & Schafer, 1987; Kavanagh, Gooley, & Wilson, 1993; Peyrot & Rubin, 1994). Variations in adherence may be explained by the differing skills and levels of motivation required for different parts of the diabetic treatment regimen. When asked to specify the most burdensome aspect of the diabetic treatment regimen, patients in one study frequently responded with the most painful aspects of the diabetic regimen, such as insulin injections and blood glucose monitoring (Mollem, Snoek, & Heine, 1996). Patients in other studies have found diet and exercise to be the most difficult aspects of the diabetic treatment regimen to manage (Dietrich, 1996; Glasgow et al., 1987; Pham, Fortin, & Thibaudeau, 1996). Patient adherence to the diabetic treatment regimen may also vary depending upon the situation. For example, it may be easier to monitor glucose, eat right, exercise, and take diabetic

medications properly when at home than while traveling (McNabb, 1997). Also, patients with diabetes have been found to increase adherence closer to the date of a diabetes-related appointment with a health care professional (Amir, Rabin, and Galatzer, 1990).

Measurement of Diabetic Adherence

Achieving accurate measurement of patient adherence to the diabetic treatment regimen can be challenging. One obstacle to accurate measurement is that patients have not been found to be completely reliable sources of information about their adherence to the diabetic treatment regimen. Mazze, Lucido, and Sharnoon (1984) found that over 70% of patients with diabetes inflated the degree to which they performed blood glucose monitoring, and over 30% fabricated logbook entries of measured blood glucose levels. Self-report error and demand characteristics have also been found to explain some of the inaccuracies in reports of blood glucose levels (Gonder-Frederick, Julian, Cox, Clarke, & Carter, 1988). High levels of social desirability and a tendency to underestimate dietary intake have been associated with under reporting of dietary intake (Herbert, Clemow, Pbert, Ockene, I., & Ockene, J., 1995; Lowe, Kopyt, & Buchwald, 1996; O' Brien, Fries, & Bowen, 2000). Among a healthy population, under reporting of dietary intake occurred more often with women than with men, and was associated with greater adiposity (Johnson, Goran, & Poehlman, 1994).

McNabb (1997) has identified other obstacles to measuring adherence to the diabetic treatment regimen. First, the diabetic treatment regimen is complex, varying across patients and situations. It may include diet, medication, exercise, blood glucose monitoring, and making self-determined adjustments when appropriate. "Self-care in diabetes is fluid rather than static, and the regimen resembles more of a series of 'if-then'

statements rather than a standard medical prescription" (p. 215). A second difficulty is the specificity of the diabetes treatment regimen, which varies from patient to patient. A third difficulty is the variation in specificity of communication of the diabetic treatment regimen to patients. For example, some patients may simply be told to exercise or to lose weight while others may be given very specific guidelines or referred to structured treatment programs.

The use of the glycosylated hemoglobin assay (hemoglobin A_{1c}, HbA_{1c}) as an indicator of diabetic treatment regimen adherence is one possible solution to adherence measurement difficulties. The hemoglobin A_{1c} (HbA_{1c}) assay is an objective measure, involving a blood test, that reflects a patient's level of glycemic control over a 2 to 3 month period. This assay has been found to provide information beyond that which is available in the typical clinical setting (Nathan et al., 1984). Higher hemoglobin A_{1c} (HbA_{1c}) levels have been directly linked to such complications as neuropathy, nephropathy (renal impairment), and retinopathy, and to greater economic impact (Deichmann, Horswell, Castello, & Friday, 1999).

Factors Related to Diabetic Nonadherence

Several factors have been related to levels of patient nonadherence to the diabetic treatment regimen. The complexity of the diabetes treatment regimen and the capacity to follow such a complex regimen are two factors which have been considered relevant to the problem of nonadherence (Lo, 1999). Other factors include lack of education about diabetes, indirect factors, the number of patient-perceived barriers to adherence, quality of the provider-patient relationship, lack of patient involvement in medical decisions, lack of individualized diabetic treatment regimens, and motivational factors. First, lack of

knowledge and understanding about diabetes has been thought to be an important factor in nonadherence. Dyer, Lloyd, Lancashire, Bain, and Barnett (1998) found that patients who attended diabetes-related education classes had significantly lower mean hemoglobin A_{1c} (HbA_{1c}) levels than patients who did not attend the classes. Getting patients to attend diabetes-related education classes is not always an easy task, however (Dyer et al., 1998; Graziani, Rosenthal, & Diamond, 1999). Barriers to attendance of diabetes-related education classes may include lack of awareness of educational programs, misconceptions about what educational programs involve, structural barriers, and health beliefs (Graziani et al., 1999). A qualifier to the evidence that knowledge about diabetes is important, is that a substantial amount of evidence also exists which shows that knowledge alone is often not enough to result in greater adherence to the diabetic treatment regimen or in better metabolic control (Barth, Gosper, Jupp, Simons, & Chisholm, 1990; Chan & Molassiotis, 1999; Coates & Boore, 1998; Goodall & Halford, 1991; Greenfield et al., 1998; Krug, Haire, & Heady, 1991; Raz, Soskoline, & Stein, 1988; Rubin, Peyrot, & Saudek, 1991; Wierenga, 1994).

Second, several indirect factors have been related to nonadherence to the diabetic treatment regimen. These factors include perceived stressors (Goodall & Halford, 1991; Lo, 1998, 1999; Peyrot et al., 1999), coping styles (Amir et al., 1990; Lo, 1998; Peyrot et al., 1999), personality characteristics (Hepburn, Deary, MacLeod, & Frier, 1994; Lo, 1998; Lustman, Frank, & McGill, 1991; Orlandini et al., 1995), locus of control (Lo, 1998; Peyrot & Rubin, 1994; Tillotson & Smith, 1996), lack of social and family support (Arnetz, 1984; Goodall & Halford, 1991; Griffith, Field, & Lustman, 1990; Lo, 1998, 1999; Pham et al., 1996; Swift, Armstrong, Beerman, Campbell, & Pond-Smith, 1995; Tillotson & Smith, 1996), depression and anxiety (Nagasawa, Smith, Barnes, &

Fincham, 1990), and health beliefs (Goodall & Halford, 1991; Lo, 1998; Nurymberg, Kreitler, & Weissler, 1996; Shoenberg, Amey, & Coward, 1998).

Third, patient-perceived barriers to adherence to the diabetic treatment regimen have been related to nonadherence. For example, obese patients may perceive significantly greater barriers to exercising than non-obese patients because they may be more likely to perceive even moderate exercise, such as walking, as painful (Foreyt & Poston, 1999). Patients with diabetes who report greater perceived barriers to adherence to the diabetic treatment regimen have been found to have higher hemoglobin A_{1c} (HbA_{1c}) levels, indicating less adherence to the diabetic treatment regimen over a 2 to 3 month period (Mollem et al., 1996). Patients with diabetes who perceive fewer barriers to adherence to the diabetic treatment regimen are more likely to report an intention to perform diabetic self-care behaviors (Lo, 1998; Pham et al., 1996). However, the perception that the benefits of adherence to the diabetic treatment regimen outweigh the barriers is not enough to result in adherence (Coates & Boore, 1998).

Fourth, the quality of the patient-provider relationship has been related to nonadherence to the diabetic treatment regimen. Amir et al. (1990) noted that criticism is frequently encountered by patients with diabetes, "because the medical team is constantly examining results of testing and dietary practices." (p. 150). They found that patients with diabetes are especially sensitive to criticism by health care professionals. Many diabetics in their study responded to criticism with defensive or aggressive behaviors. Also, the self-blame that frequently resulted from criticism paradoxically led to decreased adherence to the diabetic treatment regimen. Amir et al. (1990) recommended assertiveness training of both patients with diabetes and the medical team, to increase

effectiveness of communication about adherence issues and to encourage the use of active coping skills. Lo (1998, 1999) found that the quality of the rapport between patients and health care providers predicted the intention to perform diabetic self-care behaviors. She concluded that, "Health professionals have a role in engendering optimism, in maintaining enthusiasm, and facilitating and encouraging maintenance in health behaviours" (Lo, 1998, p. 418). Murphy and Kinmonth (1995) stated, "At the very least, a better understanding of patients' perspectives on diabetes could be expected to minimise the conflict and frustration which is generated when patients appear to behave in ways which show scant regard for their own health" (pp. 191-192). Ongoing contact between health care providers and patients is another important factor in establishing and maintaining a good relationship between patient and provider, and has been associated with better maintenance of dietary improvements in persons with diabetes (Smith & Wing, 1991).

Fifth, lack of patient involvement in medical decisions has been related to nonadherence to the diabetic treatment regimen. Lutfey and Wishner (1999) noted that patients may defer to physicians in the examination room, even when they don't agree with the treatment plan they are being asked to follow. They also suggested that Reactance Theory, the idea that perceived threats to freedom encourage a patient not to adhere to treatment recommendations in order to recapture that lost freedom, may play a role in nonadherence. Actively involving patients in decisions about their medical care may result in greater adherence to the diabetic treatment regimen (Golin, DiMatteo, & Gelberg, 1996). Kaplan, Greenfield, and Ware (1989) found that more controlling patient utterances, fewer controlling physician utterances, more effective patient information-seeking, and greater overall patient conversation relative to physician conversation were related to better hemoglobin A_{1c} (HbA_{1c}) levels. Greenfield et al. (1988) stated, "Ideally,

each patient would actively negotiate with the physician to arrive at the treatment plan that would best fit his or her psychology and life circumstances and thus would have the best chance for success" (p. 448). They found that an intervention to improve patient participation in medical care decisions resulted in improved blood sugar control and patient functioning in everyday life. This intervention helped patients to ask focused questions, and to negotiate treatment issues that could be affected by lifestyle and preferences. Patients also rehearsed simple techniques for overcoming such obstacles as embarrassment, forgetfulness, and intimidation by the physician. Providing ongoing feedback about a patient's health status is another way a health care provider can involve the patient. Cagliero, Levina, and Nathan (1999) found that immediate feedback of HbA_{1c} results at the time of a health care appointment resulted in significantly better glycemic control at 6 and 12 month follow up appointments.

Sixth, a lack of individualized diabetic treatment regimens has been related to nonadherence. Several studies have suggested that care for diabetic patients must be designed for individual patient needs (e.g.: Coates & Boore, 1998; Sadler, 1990; Travis, 1997). McNabb (1997) noted that an individualized treatment regimen may result in more patients with diabetes believing that they can and want to follow the treatment regimen. Lo (1998) suggested that a patient who feels that he or she is not ready to implement all of the recommended changes in diet and lifestyle may respond to an individualized treatment plan that involves an agreed upon, incremental sequence of steps.

Finally, motivational factors have been related to nonadherence to the diabetic treatment regimen. Nurymberg et al. (1996) stated that "if there is no adequate motivational tendency to support the behaviors necessary for implementing the diabetes

regimen no amount of education is likely to bring about adherence" (p. 27). They found that motivation for short-term adherence was related to beliefs about rules and norms, and to general beliefs about diabetes and the diabetes regimen. Motivation for long-term adherence required additional beliefs about goals and self, involving elaboration over time. "It is only when the patients have integrated the diabetes regimen into their personal goals and self-image that adherence becomes really strong" (p. 37).

Health Behavior Models Commonly Applied to Diabetic Adherence

The Health Belief Model (Becker, 1974; Rosenstock, 1966)

The Health Belief Model was based upon the theory that behavior depends upon the value placed upon a particular goal and the level of expectation that the goal can be achieved (Bernard & Krupat, 1994; Clark & Becker, 1998). There are five key elements of the Health Belief Model. *Perceived susceptibility* refers to the believed level of personal risk related to a particular health problem. *Perceived severity* refers to the believed seriousness of the health problem. *Perceived benefits* refers to beliefs about the effectiveness of taking various actions to reduce the threat of the health problem. *Perceived barriers* refers to the potential negative consequences of taking various actions to reduce the threat of the health problem. *Cues to action* refers to stimuli that trigger the decision-making process, such as messages from the media, advice from others, or an appointment reminder card from a physician.

Theory of Reasoned Action (Ajzen & Fishbein, 1977; 1980; Fishbein & Ajzen, 1975)

The Theory of Reasoned Action was developed in an attempt to understand the role of cognitive factors in the decision to take action. This model was based upon the idea that the best predictor of behavior is a person's behavioral intentions. Intentions

consist of three elements (Bernard & Krupat, 1994; Clark & Becker, 1998). The first element is *attitudes toward the behavior*, which are the result of beliefs about the expected outcomes of the behavior. The second element is *subjective norms*, which are perceptions of how a person is expected to behave combined with the motivation to comply with these expectations. The third element is *perceived control*, which is related to the resources and opportunities available for engaging in the behavior. The Theory of Planned Behavior (Ajzen, 1985) is an extension of the Theory of Reasoned Action which acknowledges the difference between perceived control and actual control (Clark & Becker, 1998).

Model of Illness Behavior (Fabrega, 1973)

The Model of Illness Behavior is a nine-stage, behavioral framework for studying social and cultural behavior influences on information processing about illness (Clark & Becker, 1998). This model focuses on the information a person must process when facing an illness. Four systems are involved in health-related processing of information, *biological*, *social*, *phenomenological*, and *memory*.

Social Cognitive Theory/Social Learning Theory (Bandura, 1986)

This theory explains behavior via several key concepts (Bernard & Krupat, 1994; Clark & Becker, 1998; Elder, Hovell, & Mayer, 1994; Lo, 1998). *Reciprocal determinism* is the idea that there is an interrelationship between people, their environment, and their behavior, with each influencing the other two. Behavior also depends upon the concepts of *self-efficacy* , a person's belief in his or her ability to perform the specific behaviors necessary to accomplish a particular goal, and *outcome expectations*, beliefs about whether specific behaviors will lead to the desired outcome.

Self-efficacy is thought to influence all aspects of behavior, including acquisition of new behaviors, inhibition of existing behaviors, disinhibition of behaviors, choices of behavioral settings, amount of effort expended on a behavior, persistence in a behavior, and emotional reactions to a behavior (Clark & Becker, 1998). Efficacy expectations are learned from *performance accomplishments*, personal experience of past performance, *vicarious experience*, observation of other events or people who may model behavior if perceived as similar enough to the observer and as demonstrating concerted effort with clear, rewarding outcomes, *verbal persuasion*, such as exhortation for continued behavior change by health care professionals or family members, and *physiological state*, with too high of an arousal state leading to impaired performance and low expectations of performance.

Not part of Bandura's theory are several other concepts that are often related to those of Social Learning Theory (Clark & Becker, 1998). *Locus of control* (Rotter, 1966; Rotter, Chance, & Phelps, 1972; Wallston & Wallston, 1984) refers to the perception of the source of control of an outcome as *internal*, controlled by a person's own behavior, or *external*, controlled by outside forces such as luck, fate, chance or other people (Bernard & Krupat, 1994; Clark & Becker, 1998; Lo, 1998; Tillotson & Smith, 1996). *Self-esteem* (Crandall, 1978) refers to realistic liking of and respect for oneself (Clark & Becker, 1998). *Coping* (Lazarus, 1981) refers to managing internal and external demands, and depends upon degree of health and energy, positive beliefs, problem-solving skills, and social skills (Lo, 1998). *Learned helplessness* (Seligman, 1975) refers to a situation where repeated failures result in a belief that a person's behaviors make no difference, and involves cognitive, affective, and motivational deficits (Bernard & Krupat, 1994; Clark & Becker, 1998).

Self-Regulation Model (Leventhal, E., Hansell, Deifenbach, Leventhal, H., & Glass, 1996)

This model consists of four components of a process in which the person, as scientist, processes information and regulates his or her relationship to the illness (Clark & Becker, 1998). The four components are extracting information from the environment, generating a representation of the danger of the illness to oneself, planning and acting, and monitoring the effects of actions on the problem. According to this model, adherence to a treatment regimen is related to perceptions of the presence or absence of symptoms.

The Transtheoretical Model of Behavior Change

Another health behavior change model that is potentially applicable to the problem of nonadherence to diabetic treatment regimen is the Transtheoretical Model of Behavior Change by Prochaska and DiClemente (DiClemente et al., 1991; Prochaska, 1991a; Prochaska & DiClemente, 1982, 1983; Prochaska et al., 1998). This model, "is an integrative framework for understanding how individuals and populations progress toward adopting and maintaining health behavior change for optimal health" (Prochaska et al., 1998, p. 59). The Transtheoretical Model gets its name because it emerged from a comparative analysis of more than 300 leading theories of psychotherapy and behavior change. Results of the comparative analysis pointed to several criteria that guided the development of the transtheoretical model (Prochaska & Norcross, 1994). First, the model had to, "respect both the fundamental diversity and the essential unity of psychotherapy systems" (p. 457). Second, fundamental variables had to be able to be empirically validated. Third, it had to be able to explain change both within and outside

of psychotherapy. Fourth, it had to generalize to both mental and physical health problems. Fifth, it had to encourage therapist innovation rather than merely borrowing from other systems.

The Transtheoretical Model of Behavior Change is the most widely used stage model in health psychology (Weinstein, Rothman, & Sutton, 1998). The Transtheoretical Model has proven applicable to many types of health behaviors. These behaviors include smoking cessation (DiClemente et al., 1991; LaForge, Velicer, Richmond, & Owen, 1999; O'Connor, Carbonari, & DiClemente, 1996; Prochaska & DiClemente, 1983; Prochaska, DiClemente, & Norcross, 1992; Prochaska et al., 1994), weight loss (Laforge et al., 1999; Prochaska, DiClemente, & Norcross, 1992; Prochaska, Norcross, Fowler, Follick, & Abrams, 1992; Prochaska et al., 1994), dietary fat reduction (Curry, Kristal, & Bowen, 1992; Greene, Rossi, Reed, Willey, & Prochaska, 1994; Laforge et al., 1999; Marcus, Ross, Selby, Niaura, & Abrams, 1992; Prochaska et al., 1994), exercising (Cardinal, 1995, 1997; Laforge et al., 1999; Prochaska et al., 1994; Reed, Velicer, Prochaska, Rossi, & Marcus, 1997), sunscreen use (Prochaska et al., 1994; Rossi, Blais, Redding, & Weinstock, 1995), alcohol and substance abuse (DiClemente & Hughes, 1990; Prochaska et al., 1994), cessation of adolescent delinquent behaviors, practice of safer sex, radon testing, mammography screening, physicians practicing preventive medicine with smokers (Prochaska et al., 1994), participation in psychotherapy (Brogan, Prochaska, J. O., & Prochaska, J. M., 1999; McConnaughy, Prochaska, & Velicer, 1983), stress reduction (Laforge et al., 1999), and overcoming phobias (Prochaska, 1991b).

Components of the Transtheoretical Model

The first component of the transtheoretical model is *Processes of Change.* Processes of change, "are the covert or overt activities that people engage in to alter affect, thinking, behavior, or relationships related to particular problems or patterns of living" (Prochaska & Norcross, 1994, p. 457). Processes of change, "represent a middle level of abstraction between global theories (such as psychoanalysis, behaviorism, systems) and specific techniques (such as dream analysis, progressive muscle relaxation, family sculpting), in which meaningful points of both convergence and contention may be found among psychotherapy systems" (Prochaska & Norcross, 1994, p. 12). The ten processes of change with the most empirical support, identified in the comparative analysis of major systems of psychotherapy, were included in the transtheoretical model. They include *consciousness-raising* (such as observations, confrontations, interpretations), *catharsis/dramatic relief* (such as psychodrama or Gestalt empty chair), *self-reevaluation* (assessment of values possibly leading to change in sense of self), *environmental reevaluation* (effects of behavior on environment), *self-liberation* (sense of autonomy and self-efficacy), *social liberation, counterconditioning* (substituting healthier alternatives), *stimulus control* (managing situations or cues that can elicit problems), *contingency management*, and *helping relationship*. The process of change included most often among the major systems of psychotherapy as a major factor of behavior change is consciousness-raising.

The second component of the transtheoretical model is *Stages of Change.* "Stages of change represent specific constellations of attitudes, intentions, and behaviors related to an individual's status in the cycle of change" (Prochaska & Norcross, 1994, p. 461). Stages of change also, "represent the temporal, motivational, and constancy aspects of

change" (DiClemente et al., 1991, p. 295). Psychotherapy patients of Prochaska and DiClemente were asked how often they applied each of the ten processes of change in attempts at change both within and outside of therapy. Patients said they used different processes at different points in the course of change (Prochaska & DiClemente, 1982). Through a study of the processes of change used by smokers while quitting smoking, Prochaska and DiClemente (1983) empirically identified a series of stages through which a person progresses in making a behavioral change.

In the first stage of change, *Precontemplation*, a person does not intend to make a behavioral change within the next six months. Six months was chosen, "because that seems to be about as far out in time that people seriously plan health behavior changes" (Prochaska, 1991a, p. 806). People in this stage "tend to avoid reading, talking, or thinking about their high-risk behaviors" (Prochaska et al., 1998, p. 59). They may be either completely unaware or lacking adequate awareness of their problems (Prochaska, DiClemente, & Norcross, 1992).

In the second stage of change, *Contemplation*, a person intends to make a behavioral change within the next six months. An important task occurring in this stage is weighing the costs and benefits of making a behavior change (Prochaska et al., 1998). A person may stall while in this stage, experiencing ambivalence while weighing the balance between the costs and benefits.

In the third stage of change, Preparation, a person intends to make a behavioral change within one month. People in this stage "have a plan of action, such as joining a health education class, consulting a counselor, talking to their physician, buying a self-

help book, or relying on a self-change approach" (Prochaska et al., 1998, p. 61). They may also have already made some small behavior changes (Prochaska et al., 1992).

In the fourth stage of change, Action, a person has made a "specific overt modification" (Prochaska et al., 1998, p. 61) in his or her lifestyle within the past six months. This behavior modification must be recognized by the scientific and professional community as being adequate for reducing the risk of disease. For example, total abstinence from cigarettes as opposed to simply cutting down would be necessary to indicate the Action stage. During the action stage, social support becomes especially important in coping with the stress of change (Prochaska et al., 1992).

In the fifth stage of change, Maintenance, a person is "working to prevent relapse" (Prochaska et al., 1998, p. 61). Six months is the most common time frame used for differentiating the Action stage from the Maintenance stage (Prochaska et al., 1984). However, this time frame was originally decided upon based upon research on smoking cessation (Prochaska et al., 1994). Therefore, time frames other than six months have been substituted when considered more appropriate (Donovan, Jones, Holman, C., Holman, J. & Corti, 1998).

Finally, Termination is a stage when a person has "zero temptation and 100% self-efficacy" (Prochaska et al., 1998, p. 61). Termination may not be a realistic goal for most people, who at best may remain in the Maintenance phase for life. Relapse occurs when a person discontinues action or maintenance behavior, and results in the person cycling back through the stages (DiClemente et al., 1991).

The Transtheoretical Model is considered to be a *spiral* model (Prochaska, 1991a). People tend to make a spiral progression through the stages, cycling back through with each relapse. Very few people progress linearly from Precontemplation to Maintenance without relapsing, but most people do not relapse all the way back to Precontemplation (Prochaska, 1991a). "This spiral pattern suggests that people learn from their relapse experiences" (p. 806).

Use of the processes of change have been found to vary according to stage of change (Prochaska, 1991b; Prochaska & Norcross, 1994). In other words, "efficient self-change depends on doing the right things (processes) at the right times (stages)" (Prochaska et al., 1992, p. 1110). During the precontemplation stage, patients use processes of change the least of any stage. They are less open about their problems and have fewer emotional reactions to them. This may result in being labeled resistant. To help a patient move from precontemplation to contemplation, consciousness-raising interventions, catharsis/dramatic relief, and environmental reevaluation have been found to be most helpful. Helping patients to become aware of defenses may be necessary in order to help them see the negative consequences of their behavior and to release the corresponding emotions.

Patients in contemplation are most open to consciousness-raising interventions, and are typically in the process of self-reevaluation and environmental reevaluation. These processes help to move the patient to the preparation stage, when self-liberation becomes important. This process involves a cognitive and affective foundation of self-efficacy (Bandura, 1986), and requires that the patient begin to master behavioral

processes of counterconditioning, contingency management, and stimulus control in order to prepare for success in action.

During the action phase, the behavioral processes continue to be important in order to prevent relapse. The helping relationship involves consultation about errors in change attempts, and support and understanding. Moving to the maintenance stage requires considering the conditions under which relapse might be more likely and planning alternatives for coping with these conditions. Change processes are not applied as frequently in the Maintenance stage as in the Action stage (Prochaska et al., 1994).

The third component of the transtheoretical model is *Levels of Change* (Prochaska, 1991a; Prochaska & Norcross, 1994). Levels of change is a hierarchy of five types of psychological problems including level one-*symptom/situational problems*, level two-*maladaptive cognitions*, level three-*current interpersonal conflicts*, level four-*family/systems conflicts*, and level five-*intrapersonal conflicts*. With each successive level comes a decrease in conscious awareness of the problem, greater removal of the problem from the present time, a greater amount of time to resolve the problem, increased resistance of the problem to change, and a greater threat of the problem to self-esteem.

Three strategies are used for intervention across levels of change (Prochaska & Norcross, 1994). The first strategy, *shifting levels*, involves beginning therapy at the highest level of change justifiable (closest to level one), and working to deeper levels only as necessary to reach the maintenance stage of change. The second strategy, *key levels*, involves focus on the level of change most related to the problem to be changed. This strategy works only for cases where a single level of change is clearly the only level

related to the problem. The third strategy, *maximum impact*, involves engaging a patient at each level of change simultaneously. This strategy should be applied in complex cases.

Advantages of the Transtheoretical Model Over Other Common Health Behavior Models

There are several advantages that the Transtheoretical Model has over some of the other common health behavior models that have been applied to the problem of diabetic adherence. First, the Transtheoretical Model is a more comprehensive model than some of the other health behavior models. For example, The Health Belief Model is limited to attitudes and beliefs, to the exclusion of environmental and social influences on behavior (Bernard & Krupat, 1994). Also, the Theory of Reasoned Action is limited to the role of cognitive factors in the decision to take action, to the exclusion of all other factors (Clark & Becker, 1988). Second, the Transtheoretical Model is widely applicable, regardless of the value placed on health, the prevalence of cues to action, attitudes about illness, or the basis of illness decisions. The Health Belief Model is only relevant and useful if health is a highly valued goal (Pham et al., 1996) and if cues to action are widely prevalent (Clark & Becker, 1988). The Model of Illness Behavior is only operable if illness is seen by the patient as present, undesirable, and discrete, and if illness decisions are based upon rational evaluations of optimal treatment actions (Clark & Becker, 1998). Third, the Transtheoretical Model is more clearly organized than some of the other leading health behavior models. For example, the Health Belief Model has been criticized for having unclear relationships between variables (Clark & Becker, 1988). Fourth, the key variables of the Transtheoretical Model are clearly operationalized. The Model of Illness Behavior, for example, has been criticized for lack of clearly operationalized variables (Clark & Becker, 1988). Finally, the Transtheoretical Model considers motivational factors, which have been largely overlooked among other health behavior models (Nurymberg et al.,

1996). It should also be noted that the Transtheoretical Model incorporates Bandura's self-efficacy, which serves as an intermediate outcome variable in the model (Clark, Abrams, Niaura, Eaton, & Rossi, 1991).

A key benefit of applying the Transtheoretical Model to health behaviors is that the Stages of Change point to methods of intervention that may best help people to progress to the next stage (DiClemente et al., 1991; Prochaska, 1991). For example, people in the Action stage have been found to benefit most from behavioral techniques, while people in the Precontemplation stage have been found to benefit most from experiential processes such as consciousness-raising or self-reevaluation. One critical assumption of the Transtheoretical Model is that the majority of persons are not ready to take action and, therefore, will not benefit from the traditional action-oriented health promotion programs (Prochaska, Johnson, & Lee, 1998). Randomized trials have proven the usefulness of stage-matched interventions for smoking cessation, exercising, condom use, dietary fat reduction, sun exposure, mammography screening, and alcohol abuse (Laforge et al., 1999). Stages of change have also been found to predict attendance of weight control therapy sessions (Prochaska et al., 1992)

Previous Research Applying the Transtheoretical Model to Diabetic Adherence

There is little existing research that applies or addresses the appropriateness of applying the Transtheoretical Model of Behavior Change to the problem of patient adherence to the diabetic treatment regimen. Ruggiero and Prochaska emphasized this fact when they served as guest editors of a 1993 issue of *Diabetes Spectrum* entitled, "Readiness for Change: Application of the Transtheoretical Model to Diabetes." In this edition were a number of articles that applied the Transtheoretical Model to the problem

of diabetes regimen adherence. However, they merely extrapolated from findings of research with other populations and other problem behaviors. Ruggiero and Prochaska also emphasized that no research has been published that examines application of the Transtheoretical Model to more than one behavior change at a time. They also noted that it is not known whether recommending sequential change of behaviors in the diabetic treatment regimen might be more effective than the currently common practice of recommending simultaneous change and, if so, in what order the behaviors should be targeted for change.

Sullivan and Joseph (1998) performed a qualitative analysis of telephone interviews and a focus group session with 5 male and 5 female clients who had been diagnosed with type II diabetes for at least one year. Participants were asked a series of questions about the difficulty of the behavior changes they had been asked to make since the diagnosis of diabetes. The terms *easy*, *difficult*, and *impossible* were loosely defined to correspond with the stages of Action/Maintenance, Contemplation, and Precontemplation. Most of the participants considered the changes of diet, exercise, and blood glucose monitoring to be *difficult*, meaning that they had tried to make the changes at least once but had reverted to old behaviors. Participants considered periods of action to be attainable but they rarely achieved maintenance for 6 months or more.

Wells (1988) performed correlations between glycosylated hemoglobin A_{1c} (HbA_{1c}) assay levels and scores on self-report measures of diabetes self-care and stages of change of overall adherence to the diabetes treatment regimen, for 59 male and 43 female health center outpatients with type II diabetes. Diabetes self-care was measured by the Diabetes Regimen Adherence Questionnaire (DRAQ, Brownlee-Duffeck &

Peterson, 1987) with a Chronbach coefficient alpha of .87. Stage of change of overall diabetes treatment adherence was measured by the University of Rhode Island Change Assessment (URICA, McConnaughy, DiClemente, Prochaska, & Velicer, 1989), with a Chronbach coefficient alpha of .90. Results included a significant negative correlation between hemoglobin A_{1c} (HbA_{1c}) levels and scores on the DRAQ ($r=-.56$, $p<.0001$), a positive correlation between hemoglobin A_{1c} (HbA_{1c}) levels and questions on the URICA corresponding to the Precontemplation stage of behavior change ($r=.53$, $p<.0001$), and negative correlations between hemoglobin A_{1c} (HbA_{1c}) levels and questions on the URICA corresponding to the Contemplation ($r=-.37$, $p<.0001$), Action ($r=-.55$, $p<.0001$), and Maintenance ($r=-.40$, $p<.0001$) stages of behavior change. DRAQ scores were negatively correlated with questions on the URICA corresponding to the Precontemplation stage ($r=-.59$, $p<.0001$), and positively correlated with questions on the URICA corresponding to the Contemplation ($r=.40$, $p<.0001$), Action ($r=.70$, $p<.0001$), and Maintenance ($r=.48$, $p<.0001$) stages of behavior change. DRAQ scores were positively correlated with age ($r=.25$, $p<.01$) and with education level ($r=.36$, $p<.001$).

Wells' (1988) results seem to support the validity of the stages of change construct for adherence to the diabetic treatment regimen. However, there are some problems with interpreting the results of the Wells study. First, it was unclear when hemoglobin A_{1c} (HbA_{1c}) levels were drawn in relation to the time of participation in the study. This is an important factor to consider, as participants would not necessarily be expected to remain in the same stage of behavior change over long periods of time. Therefore, conclusions based upon the correlation of hemoglobin A_{1c} (HbA_{1c}) levels with other measures could be erroneous.

Second, an unmodified University of Rhode Island Change Assessment (URICA, McConnaughy et al., 1989) was used to determine participants' stage of change for overall diabetes treatment regimen adherence. The authors of the URICA have recommended modification of item content when necessary to reflect the problem behavior being studied, as this instrument was originally designed for use in measuring stages of change with psychotherapy clients (McConnaughy et al., 1983, 1989). Though Wells (1988) acknowledged this recommendation, participants were merely asked to respond to items, "in reference to your diabetes" (p. 83). Wells reported that several of the participants complained about the difficulty of interpreting URICA items in relation to their diabetes. She also acknowledged that this difficulty may have skewed results of the study. A more important problem with the use of the URICA, however, is that its authors have discouraged its use for identifying discrete stages of change for any problem behavior. They stated, "The motivation to do this is understandable, but the practice is not well justified from a measurement point of view and should be discouraged" (CPRC, 2000). They explained that the URICA is designed to reflect the possibility that a patient may have attitudes and behaviors characteristic of multiple stages, with adjacent stages being more highly correlated than nonadjacent stages. Therefore, the URICA is best suited to reflect typologies of transitions between stages, subtypes within stages, and progress in treatment. Sutton (2001) has also determined that the URICA does not measure discrete stages of change.

The Stage of Change Algorithm is considered to be the appropriate measure of discrete stages of change (CPRC, 2000). No study published to date has used the Stage of Change Algorithm to determine patient stage of adherence to the diabetic treatment regimen. Determining stages of change with the algorithm appears to be an important

step in answering the question of the applicability of the stage of change construct to the problem of adherence to the diabetic treatment regimen. Ruggiero and Prochaska (1993) have recommended the use of separate Stage of Change Algorithms for measuring stage of change for adherence to each of the behaviors in the diabetes treatment regimen, as opposed to using a single Stage of Change Algorithm for overall diabetes treatment regimen adherence.

CHAPTER II

PURPOSE OF THE PRESENT STUDY

Prochaska stated that, "The vast majority of our behavior change programs are designed for the small minority of the people who are ready to take action on their health behavior problems" (Prochaska, 1991a, p. 806). If this premise of the Transtheoretical Model of Behavior Change proves to have scientific merit, it will mean that money and resources are being wasted on the current diabetes-related educational classes. Also, it will suggest that patients with Type II diabetes are being done a disservice by the current system of treatment which is a "one treatment fits all" system.

The present study will examine the applicability of the stage of change construct of the Transtheoretical Model of Behavior Change to the problem of patient adherence to the diabetic treatment regimen. Adherence to the diabetic treatment regimen is important to glycemic control and to reducing the likelihood of complications from diabetes. If the stage of change construct proves applicable to the problem of diabetic adherence, this would suggest that interventions to increase adherence to the diabetic treatment regimen should be stage specific. Use of stage specific interventions would then allow for more effective utilization of funding and professional skills. For example, patients in later stages might be targeted for attendance of the type of action-oriented diabetes skill-training classes currently common in today's health care system. Patients in earlier stages could be offered less action-oriented interventions, such as consciousness-raising and assistance in self-reevaluation, which would more effectively help them to progress to

later stages. Also, by determining individual behaviors for which patients are consistently falling into lower stages, priorities for planning and implementing interventions can also be determined (Ruggiero & Prochaska, 1993).

CHAPTER III

HYPOTHESES

1. Composite Stage of Change scores, computed by summing individual Stage of Change Scores for all 4 diabetic treatment behaviors being studied (Medication, Blood Glucose Monitoring, Diet, and Exercise) will be negatively and significantly correlated with hemoglobin A_{1c} (HbA_{1c}) levels.

2. Composite Stage of Change scores will be positively and significantly predictive of attendance of a diabetes-related educational class.

3. For patients with Composite Stage of Change scores between 12 and 16, roughly corresponding to those in Action and/or Maintenance stages on all 4 diabetic treatment behaviors being studied, those who have attended a diabetes-related educational class will have significantly lower (better) hemoglobin A_{1c} (HbA_{1c}) levels than those who have not attended a diabetes-related educational class.

4. For patients with Composite Stage of Change scores between 0 and 4, roughly corresponding to those in Precontemplation and/or Contemplation stages on all 4 behaviors being studied, there will be no significant difference in hemoglobin A_{1c} (HbA_{1c}) levels between those who have attended a diabetes-related educational class and those who have not attended a diabetes-related educational class.

CHAPTER IV

METHODS

Participants

A total of 101 Veterans being treated for Type II Diabetes at a Veterans hospital in a large urban area participated in the study. Potential participants were initially identified by inclusion on a list of patients having received blood glucose monitors from the hospital's Diabetes Clinical Nurse Specialist and on a computer generated list of patients with appointments scheduled in the outpatient clinics at the hospital within the data collection time period. Patients participating in the study then met the following inclusion and exclusion criteria, verified by patients' individual computer charts or by answers to questions about these criteria asked as part of the questionnaire packet:

Inclusion Criteria

1. Diagnosis of Type II diabetes for at least one year
2. HbA_{1c} test performed within one month of participation
3. Documented to have received a blood glucose monitor
4. Outpatient status

Exclusion Criteria

1. Diagnosis of substance abuse or dependence
2. Diagnosis of a DSM-IV (American Psychiatric Association, 1994) psychological disorder
3. Diagnosis of dementia or other cognitive impairment

Participants were either recruited in conjunction with outpatient medical appointments (76.2%) or via 176 mailed questionnaire packets with prepaid return postage (23.8%). Of the 116 patients invited to participate in conjunction with medical appointments, 10 patients refused to participate, including 6 African Americans and 4 Caucasians. The return rate of the mailed questionnaires was 23.3%. Forty-six additional potential subjects who returned questionnaires, either by mail or in person, were subsequently disqualified for not meeting all inclusion and exclusion criteria or for failing to fully complete the questionnaire or the consent form. Ten of these subjects were disqualified because they did not report to the lab for an HbA_{1c} test.

All of the participants were male. There were several reasons for the lack of female participation. First, there were fewer than 10 females on the list of patients having received blood glucose monitors. Second, there were only 5 females who also met all of the other inclusion and exclusion criteria. Third, no qualifying females came to the hospital for appointments and also received hemoglobin A_{1c} (HbA_{1c}) tests, or had received hemoglobin A_{1c} (HbA_{1c}) tests within one month. Finally, neither of the two females who had received hemoglobin A_{1c} (HbA_{1c}) tests within one month and were sent questionnaire packets via mail returned them.

Ages of participants ranged from 41 to 86, with a mean age of 65.51 (std. dev.= 9.4). Participants included 41.58% Caucasians and 58.42% African Americans. Education levels of participants ranged from less than high school (24.75%), to high school diploma/GED (36.63%), to some college or higher education (23.76%), to college diploma (10.89%), to some graduate school (0.99%), to graduate school diploma (2.97%).

Time since participants' onset of Type II Diabetes was from one to five years (34.65%), to 6-10 years (20.79%), to over 10 years (44.55%). Participants' diabetes treatment by medication ranged from no medication/diet only (4.95%), to oral medication (59.41%), to insulin (16.83%), to a combination of oral medications and insulin (18.81%). Incidence of complications from Type II Diabetes are listed in Table 1. Body Mass Index (BMI) of participants ranged from 21.8 to 51.1, with a mean of 31.46 (std. dev. =5.74). 8 participants were morbidly obese (BMI>40). 48.51% of the participants had either been to a diabetes-related educational class within the hospital, as recorded in participants' hospital charts, or reported having attended a diabetes-related educational class outside the hospital. 3.96% had been to diabetes-related educational classes both within and outside of the hospital where this study is based.

Procedures

Participation was requested and questionnaire packets were distributed and collected by the researcher or an informed health care provider, in conjunction with a scheduled health care appointment. Alternatively, potential participants received questionnaire packets through the U. S. Postal Service, including prepaid return postage.

Table 1. Participant Incidence of Type II Diabetic Complications

Health Condition	Incidence
Peripheral Neuropathy	27.72%
Foot Ulceration	10.89%
Retinopathy	4.95%
Diabetes-Related Hospitalization in Past Year	3.96%
Toe Amputation	2.97%
Cataracts	2.97%
Renal Impairment	3.96%

Patients receiving mailed questionnaire packets who chose not to participate were informed that they should dispose of the questionnaire packets. Questionnaire packets included demographic questions (Appendix A) about education level, years since onset of Type II Diabetes, smoking status, and attendance of a diabetes-related educational class outside of the Veterans hospital where the present study was based. Stages of change measures were also included for each of the following behaviors within the diabetic treatment regimen: taking prescribed diabetic medications, performing blood-glucose monitoring at least twice per week, limiting dietary fat and calories, and exercising at least three times per week for at least 20 minutes each time. Questionnaire packets were easily completed in less than 10 minutes. Of those participants who completed questionnaires in conjunction with medical appointments, 30.69% self-administered the questionnaires with the researcher available for questions, while 48.51% requested oral administration.

Other information was collected by review of patients' computerized hospital records. This information included the patients' age, gender, race, whether taking prescribed insulin, oral agents, or a combination of the two, number of hospitalizations in the past year for diabetes-related medical conditions, Body Mass Index (ratio of weight to height), incidence of diabetic complications (peripheral neuropathy, foot ulcers, amputations, renal impairment, retinopathy, and cataracts), last Hemoglobin A_{1c} (HbA_{1c}) level, and attendance of a diabetes-related educational class at the Veterans hospital where the present study was based.

All participants received full written informed consent, including information about the nature of the study, and potential risks and benefits of participation (Appendix C). Patient confidentiality was and will be assured by storing all questionnaires and information collected from patient charts in a locked filing cabinet in the office of the supervising researcher at the Veterans hospital where the present study was based. Once patient information was compiled from patients' hospital charts and the completed questionnaire packets, names and social security numbers were removed from questionnaires so that patients cannot be identified with their data. Each patient's signed informed consent form was also separated from his research data.

Measures

Attendance of Diabetes Education Class

Patient records were reviewed to determine if each participant had attended a diabetes-related educational class regularly offered at the Veterans hospital where the

present study was based. These classes are one session in length, and are focused on skills training for diabetes self-care, including taking of medications, glucose monitoring, diet, and exercise. Patients were also asked to indicate on the demographic questionnaire if they had attended a diabetes-related educational class outside the Veterans hospital where the present study was based.

Glycosylated Hemoglobin Assay Level (Hemoglobin A_{1c}, HbA_{1c})

Patients' computerized hospital records were reviewed to determine each patient's most current HbA_{1c} level. All HbA_{1c} levels were assessed within one month of patient participation in the study. Patient HbA_{1c} Assays are determined by blood test as a routine part of monitoring treatment for diabetes. The Hemoglobin A_{1c} (HbA_{1c}) assay reflects a patient's level of glycemic control over a two to three month period (Nathan et al., 1984). Current American Diabetes Association (ADA, 1999) guidelines label hemoglobin A_{1c}, (HbA_{1c}) levels below 6 as excellent, from 6.0 to 6.9 as good, from 7.0 to 7.9 as fair, and 8.0 or above as poor. A goal HbA_{1c} of less than 7.0 was recommended for persons with diabetes.

Stage of Change Algorithms

The Stage of Change Algorithm is a self-report measure designed to determine a person's stage of change (i.e.: Precontemplation, Contemplation, Preparation, Action, or Maintenance) for a specified behavior. The Algorithm was based upon the stage of change construct, developed by Prochaska and DiClemente (1983) through their research on the Transtheoretical Model of Behavior Change. The Stage of Change algorithm has been well validated across a diverse set of problem behaviors (CPRC, 2000; Reed et al., 1997). External validation includes consistently replicated patterns of increasing pros of

behavior change, decreasing cons of behavior change, and increasing self-efficacy/confidence from the Precontemplation stage to the Maintenance stage. These patterns have been demonstrated across at least 12 different problem behaviors (Prochaska et al., 1994). The Algorithm has also differentiated people by stages on numerous other measures, consistent with theory, including objective measures of cardiorespiratory fitness (VO2 max) and body mass index (BMI) (Cardinal, 1997) and self-report measures of exercise barriers (Cardinal, 1995, 1997) and dietary fat intake (Curry et al., 1992). Specificity of the Algorithm has ranged from 87% to 93% and predictive validity has ranged from 58% to 64% in research on dietary fat reduction (Greene et al., 1994). Other evidence of predictive validity has been supported in research by J. O. Prochaska (personal communication, September 28, 2000) that will soon be in press. Stage of change and social desirability have been found to be unrelated in a study of exercise behavior ($rs = -.09$, $p > .05$) (Cardinal, 1997).

Short-term (3 to 4 day) test-retest reliability of the algorithm has been demonstrated, ranging from .52 to 1.0 in studies of exercise behavior (Cardinal, 1997) and dietary fat intake (Donovan et al., 1998). Long-term test-retest reliability is not an appropriate measure because persons may progress from one stage to another at any time (Donovan et al., 1998; J. O. Prochaska, personal communication, September 28, 2000; Prochaska, 1991a). Internal reliability cannot be measured because the Stage of Change Algorithm is essentially a single-item measure (Donovan et al., 1998; J. O. Prochaska, personal communication, 2000). In spite of this problem, the Algorithm has been widely accepted, and is considered to be a more appropriate measure for stage of change assignment than the multiple item University of Rhode Island Change Assessment

instrument (URICA) (CPRC, 2000). The brevity and easy administration of the Stage of Change Algorithm have contributed to its popularity (Laforge et al., 1999).

Versions of the Stage of Change Algorithm (Appendix B) were used to determine stages of change for each of the following key behaviors in the diabetic treatment regimen: taking prescribed diabetic medications, performing blood-glucose monitoring at least twice each week, limiting dietary fat and calories, and exercising at least 3 days each week for a total of at least 20 minutes each day. These are the behaviors recommended to patients by the Diabetes Clinical Nurse Specialist at the Veterans hospital where the present study is based (M. Asberry, personal communication, October 18, 2000). The versions of the Stage of Change Algorithm used in this study followed recommended standards for stage of change algorithms, including a well-defined description of each stage of change, a complete definition of the criterion behavior, easily understandable measurement criteria, and a true/false response format that has been determined to be one of the preferred formats for the Algorithm (J. O. Prochaska, personal communication, September 28, 2000; Reed et al., 1997). Three months was the time period required for assignment to the Maintenance stage, as the Hemoglobin A_{1c} (HbA_{1c}) assay is a measure of glycemic control over a two to three month period.

CHAPTER V

RESULTS

All statistics were conducted using the Statistica statistical package, Version 4.1. (Statsoft, 1994). Descriptive statistics for key variables are listed in Table 2. Stage of Change distributions for each of the diabetic treatment behaviors are listed in Table 3.

There were several significant correlations between participant characteristics and key study variables. First, age was significantly, negatively correlated with hemoglobin A_{1c} (HbA_{1c}) levels ($r=-.26$; $p<.01$). Second, smoking status was significantly correlated with hemoglobin A_{1c} (HbA_{1c}) levels ($r=.20$; $p<.05$). Third, history of hospitalization within the past year for diabetes-related conditions was significantly correlated with Composite Stage of Change scores ($r=.19$; $p<.05$). Fourth, history of amputation was significantly, negatively correlated with Medication Stage of Change scores ($r=-.20$; $p<.04$). Finally, history of retinopathy was signficantly correlated with Exercise Stage of Change scores ($r=.23$; $p<.02$). Also, the correlation between Body Mass Index (BMI) and Exercise Stage of Change scores approached significance ($r=-.19$; $p<.07$).

In Hypothesis 1, Composite Stage of Change scores were predicted to be significantly negatively correlated with hemoglobin A_{1c} (HbA_{1c}) levels. The Pearson product moment correlation between Composite Stage of Change scores and hemoglobin A_{1c} (HbA_{1c}) levels was not significant ($r=-0.031$; $p<.759$). In Hypothesis 2, Composite Stage of Change scores were predicted to be significantly, negatively

Table 2. Descriptive Statistics of Key Variables

Variable	Min	Max	Mean	Std. Dev.
HbA_{1c} Level	4.7	15.4	8.17	1.89
Medication Stage Score	2.0	4.0	3.89	0.40
Monitoring Stage Score	0.0	4.0	3.48	0.94
Diet Stage Score	0.0	4.0	2.67	1.42
Exercise Stage Score	0.0	4.0	2.92	1.31
Composite Stage Score	5.0	16.0	12.96	2.41
#Behaviors in Action or Maintenance	0.0	4.0	2.93	0.92

Table 3. Stage of Change Distributions

Stage	% in Stage
MEDICATION	
Precontemplation	0.00%
Contemplation	0.00%
Preparation	2.97%
Action	4.95%
Maintenance	92.08%
BLOOD GLUCOSE MONITORING	
Precontemplation	1.98%
Contemplation	0.99%
Preparation	15.84%
Action	9.90%
Maintenance	71.29%

Table 3, Cont'd. Stage of Change Distributions

Stage	% in Stage
DIET	
Precontemplation	12.87%
Contemplation	5.94%
Preparation	26.73%
Action	9.90%
Maintenance	44.55%
EXERCISE	
Precontemplation	7.92%
Contemplation	4.95%
Preparation	26.73%
Action	7.92%
Maintenance	52.48%

correlated with attendance of a diabetes class. The Pearson product moment correlation between Composite Stage of Change Scores and diabetes class attendance was -0.165 ($p<.100$). A Pearson product moment correlation matrix of all key variables is listed in Table 4. In Hypothesis 3, for participants with Composite Stage of Change scores between 12 and 16 (roughly corresponding to those in action and/or maintenance on all 4 behaviors), hemoglobin A_{1c} (HbA_{1c}) levels were predicted to be significantly lower (better) for those participants who have attended a diabetes class than for those who haven't. An independent samples t-test ($n=79$; $t = -0.992$, $df=77$, $p<.324$) indicated that there was not a significant difference in HbA_{1c} levels depending upon diabetes class attendance for those with Composite Stage of Change scores between 12 and 16. In Hypothesis 4 it was predicted that for participants with Composite Stage of Change scores between 0 and 4 (roughly corresponding to those in precontemplation and contemplation on all 4 behaviors), there would be no significant difference in HbA_{1c} levels between those who have attended a diabetes class and those who have not attended a diabetes class. This hypothesis was unable to be tested because there were no participants with Composite Stage of Change scores between 0 and 4. The lowest Composite Stage of Change score was 5. Frequencies of Composite Stage of Change scores appear in Table 5.

In addition to the main hypotheses were two other planned analyses. First, the number of behaviors in which a participant is in action or maintenance was crosstabulated with whether a participant's hemoglobin A_{1c} (HbA_{1c}) level was greater or less than 7.0. A chi-square analysis was then performed to determine the number of behaviors which are necessary for a participant to be in either Action or Maintenance stages of change in order to achieve a hemoglobin A_{1c} (HbA_{1c}) level below 7.0. The result of the chi-square

Table 4. Pearson Product Moment Correlation Matrix of Key Variables

	HbA_{1c}	Med Stage	Monitor Stage	Diet Stage	Exercise Stage	Composite Stage	#Behav Act/Maint	Diabetes Class
HbA_{1c}	1.00**	-.20*	-.06	.06	.02	.03	-.15	-.16
Med Stage	-.20*	1.00**	.18	-.03	.02	.22*	.25**	.03
Monitor Stage	-.06	.18	1.00**	.08	-.02	.45**	.45**	-.02
Diet Stage	.06	-.03	.08	1.00**	.21*	.73**	.57**	-.24*
Exercise Stage	-.02	.02	-.02	.21*	1.00**	.66**	.59**	-.04
Composite Stage	.03	.22*	.45**	.73**	.66**	1.00**	.87**	-.16
#Behav Act/Maint	-.15	.25**	.45**	.57**	.59**	.87**	1.00**	-.03
Diabetes Class	-.16	.03	-.02	-.24*	-.04	-.16	-.03	1.00**

*p<.05 **p<.01

Table 5. Frequencies of Composite Stage of Change scores

Composite Stage of Change Score	Frequency	Percent	Cumulative Frequency	Cumulative Percent
5	1	.99	1	.99
8	5	4.95	6	5.94
9	5	4.95	11	10.89
10	4	3.96	15	14.85
11	7	6.93	22	21.78
12	21	20.79	43	42.57
13	9	8.91	52	51.49
14	21	20.79	73	72.28
15	9	8.91	82	81.19
16	19	18.81	101	100.00

analysis (x^2=2.263; df=4) was that a significant relationship was not found between the number of behaviors in action or maintenance and hemoglobin A_{1c} level greater or less than 7.0. The percentage of participants assigned to either Action or Maintenance on at least three of the four diabetic treatment behaviors being studied was 67.32%. Frequencies of participants assigned to Action or Maintenance for 0 to 4 behaviors are listed in Table 6. Finally, a stepwise regression analysis was performed to determine the collective contribution of the 4 diabetic treatment behaviors (medications, monitoring, diet, and exercise) to the overall variance in hemoglobin A_{1c} (HbA_{1c}) levels, as well as to determine the unique variance contributed by each of the treatment behaviors individually. The results of this regression analysis were that the contribution of the collective diabetic treatment behaviors to the variance in hemoglobin A_{1c} (HbA_{1c}) levels was not significant (squared semi-partial r =.039, p<.358). Results of this regression analysis appear in Table 7. Also, the Medication Stage of Change was the only diabetic treatment behavior that significantly contibuted to the variance of hemoglobin A_{1c} (HbA_{1c}) levels (squared semi-partial r =.039, p<.047). Results of this regression analysis appear in Table 8.

Table 6. Frequencies of Participants in Action or Maintenance For 0-4 Behaviors (Medication, Monitoring, Diet, and Exercise)

# of Behaviors	% in Action or Maintenance Stages
0	0.99%
1	3.96%
2	27.72%
3	35.64%
4	31.68%

Table 7. Results of Stepwise Multiple Regression for the Collective Contribution of Diabetic Treatment Behavior (Medication, Monitoring, Diet, and Exercise) Stage Scores to Variance in HbA_{1c} Levels

Step	Variable	Multiple R	Rsquared	Beta	Squared Semi-Partial Correlation
1	Medication	.176	.031	.191	.035
	Monitoring	.192	.037	.062	.001
	Diet	.228	.052	.064	.004
	Exercise	.212	.045	.031	.001
	Total	.210	.044		.041

*p<.05 **p<.01

Table 8. Results of Stepwise Multiple Regression for the Contribution of Individual Diabetic Treatment Behavior (Medication, Monitoring, Diet, and Exercise) Stage Scores to Variance in HbA_{1c} Levels

Step	Variable	Multiple R	Rsquared	Beta	Squared Semi-Partial Correlation
1	Medication	.198	.039	.039	.039*

*p<.05 **p<.01

CHAPTER VI

DISCUSSION

The Stage of Change distributions for each of the diabetic treatment behaviors showed that the behavior with the highest percentage of participants in Maintenance was taking diabetic medications (92.08%). Taking medications was followed by monitoring blood glucose (71.29%), exercising (52.48%), and diet (44.55%). The diabetic treatment behavior with the highest percentage of participants in Precontemplation was diet (12.87%), followed by exercise (7.92%), blood glucose monitoring (1.98%), and taking diabetic medications (0.00%). It can be inferred that these participants have the most difficulty following their diabetic diet and exercise regimens, consistent with previous research by Dietrich (1996), Glasgow et al. (1987), and Pham, et al. (1996).

There were significant correlations between several participant characteristics and key study variables. First, hemoglobin A_{1c} (HbA_{1c}) levels were negatively correlated with age, suggesting that the older the participant was the better was his blood glucose regulation. Second, smoking status was positively correlated with hemoglobin A_{1c} (HbA_{1c}) levels, suggesting that the more a participant smoked the poorer was his blood glucose regulation. Third, history of hospitalization within the past year for diabetes-related conditions was significantly correlated with Composite Stage of Change scores, suggesting that recent hospitalization for diabetes is associated with less reported adherence to the diabetic treatment regimen. Fourth, history of amputation was significantly, negatively correlated with Medication Stage of Change scores, suggesting that those who have had diabetes-related amputations are less likely to report following their diabetic treatment regimen. Finally, history of retinopathy was signficantly

correlated with Exercise Stage of Change scores, suggesting that participants with retinopathy are more likely to report following their exercise regimen. Also, a negative correlation between Body Mass Index (BMI) and Exercise Stage of Change scores approached significance, possibly suggesting that participants with higher ratios of weight to height are less likely to report following their exercise regimen. No other significant correlational relationships were found between key study variables and participant characteristics.

None of the first three hypotheses in the present study were supported by the data analyses. The data showed no relationship between Composite Stage of Change scores and either hemoglobin A_{1c} (HbA_{1c}) levels or attendance of a diabetes-related educational class. There also was no relationship found between hemoglobin A_{1c} (HbA_{1c}) levels and attendance of a diabetes-related educational class for participants with higher Composite Stages of Change scores.

The fourth hypothesis, that participants with lower Composite Stage of Change scores would not differ significantly on hemoglobin A_{1c} (HbA_{1c}) scores depending upon whether or not they had attended a diabetes-related educational class, was unable to be tested because there were no subjects with Composite Stage of Change scores below 5. This lack of low Composite Stage of Change scores was reflected in a much higher mean Composite Stage of Change score than expected. This mean resulted from the fact that many of the participants reported being in Action and/or Maintenance stages of change on at least three of the four behaviors in the diabetic treatment regimen that were examined in this study.

In addition to the main hypotheses were two other planned analyses. First, there was an attempt to determine the number of behaviors in which a participant must be in either action or maintenance stages of change to achieve a hemoglobin A_{1c} (HbA_{1c}) level less than 7.0, in order to meet American Diabetes Association recommendations (1999). The number of behaviors for which a participant was either in the action or maintenance stages of change was crosstabulated with a participant having a hemoglobin A_{1c} (HbA_{1c}) level of either greater than 7 or less than 7, and then a chi-square analysis was performed. The chi-square analysis indicated that there was not a significant relationship between the number of behaviors in action or maintenance and hemoglobin A_{1c} level greater or less than 7.0. The percentage of participants assigned to either Action or Maintenance on at least three of the four diabetic treatment behaviors being studied was 67.32%, which was much higher than anticipated. Second, in a planned regression analysis, the Medication Stage was the only diabetic treatment behavior stage found to be significantly predictive of hemoglobin A_{1c} (HbA_{1c}) levels. This finding suggests that a diabetic patient's stage of change for taking medications accounts for a modest amount of variance in maintenance of blood glucose levels. In both this individual and a collective regression analysis, the stages of the other diabetic treatment behaviors did not contribute significantly to the variance.

The results of this study did not correspond with expected results. It is clear in the diabetes literature that monitoring blood glucose, following the proper diet, and exercise are important to the diabetic regimen. However, stage of change for each of these behaviors and the Composite Stage of Change, as measured in this study, were unrelated to blood glucose regulation.

The first possibility in interpreting these results is that the Stage of Change construct of the Transtheoretical Model of Behavior Change is simply not a valid way of understanding the problem of Type II diabetic adherence. This interpretation would be in line with the arguments of several critics of the Stage of Change construct who have questioned its validity and utility. Davidson (1992), for example, has criticized the validity of the stage of change construct, attributing its popularity to a *weltanschauung* which is a world view that is resistant to change even with evidence to the contrary.

Many other criticisms have been made against the Stage of Change construct of the Transtheoretical Model of Behavior Change. First, critics have noted that the stage a person is assigned to largely depends upon the questionnaire used (Etter & Perneger, 1999). Second, critics have argued that available data do not prove that behavior follows a stage process rather than a continuous process (Etter and Perneger, 1999; Sutton, 2001). Third, some authors have criticized what they view as arbitrary time points used to distinguish stages (Etter and Perneger, 1999; Sutton, 1996, 2001; Weinstein, Rothman, & Sutton, 1998). Fourth, the stage of change concept has been criticized for not adequately accounting for people who occasionally engage in a behavior (Etter & Perneger, 1999). Fifth, it has been argued that stage of change is thought of as one concept but in practice involves several discrete variables which have been combined haphazardly, such as current behavior, intention to change, and duration of the current behavior (Etter & Perneger, 1999). Six, some studies have shown only minor differences between stages on some variables, leading critics to suggest that either the stages of change are not as useful as proponents claim or that the scales used are not sufficiently reliable (Donovan et al., 1998). Seventh, it has been argued that although research has shown that people at different stages of change use different techniques and have differing beliefs about the

behavior that cause them to move from stage to stage, these techniques and beliefs have not yet been well defined (Weinstein, Rothman, and Sutton, 1998). Eighth, critics have found the measure of intention used in the stages of change classification system to be inadequate (Etter & Perneger, 1999; Pierce, Farkas, Zhu, Berry, & Kaplan, 1996; Stockwell, 1996). Finally, critics have cited one study by Farkas et al. (1996), in which the authors concluded that factors other than stage of change better predict long-term smoking cessation than stage of change.

While the overall findings of the present study may suggest that there is not a significant relationship between the Stage of Change Construct of the Transtheoretical Model of Behavior Change and maintenance of blood glucose levels, there are other possible explanations for the findings of this study that must be considered. These possible explanations include demand characteristics, social desirability bias, self-report error, self-selection bias, problems with measurement and sampling, problems with the complexity of the diabetic treatment regimen and the influences on hemoglobin A_{1c} (HbA_{1c}), and conflicting instructions from health care professionals.

First, it is possible that demand characteristics affected the outcome of the study. It is difficult to know how the majority of participants interpreted the purpose of the study or the expectations of the researcher. But from the comments made and questions asked by some of the participants, it appeared that participants may not have understood the distinction between asking about their behaviors for the purpose of testing the applicability of a new approach to diabetic behavior change and asking about their behaviors for the purpose of criticizing their individual performance. Diabetic patients have been found to be extremely sensitive to the criticism about their treatment-related

behaviors which they frequently encounter in communication with health care professionals (Amir et al., 1990). Therefore, participants may have been less than frank about their diabetic treatment behaviors in order to avoid feared criticism.

It is also probably characteristic of this patient population to be acquiescent to health care professionals. Many patients have been noted to defer to physicians in the examination room but then to fail to adhere to treatment recommendations because they did not actually agree with the treatment plan (Lutfey and Wishner, 1999; Street, 1991). Less educated patients, such as the 61.38% of the participants in this study who had a high school education or less, have been found to be less inclined to express concerns, to be less opinionated, and to be less effectively expressive with health care professionals (Street, 1991). This Veteran population may also be even more acquiescent than the typical patient population, given the strict hierarchy and undisputed following of orders in the military system in which these patients were trained. While health care professionals are not military superiors, they nevertheless may be seen as authority figures deserving of similar respect and deference. A tendency to defer to health care professionals could have resulted in participants being more likely to express interest in changing their diabetic treatment behaviors, even if their actual levels of motivation for and intention to change were low. As Weinstein et al. (1998) stated, "A tendency to exaggerate interest in action would weaken predictions from stage models because people who appear to be in a particular stage would be a mixture of those who actually belong in that stage and those who belong in earlier stages" (p. 294).

Closely related to demand characteristics are the issues of social desirability bias and self-report error. Participants in the present study may have responded to questions about their behavior in a way that they perceived to be favorable rather than in an accurate way. Participants may also overestimate or underestimate their own behaviors in a socially favorable way. Patients with diabetes have been found to be especially disposed to both problems (Gonder-Frederick et al., 1988), with over 70% overreporting of the degree to which they perform blood glucose monitoring (Mazze et al., 1984) and many underreporting and underestimating dietary intake (Herbert et al., 1995; Lowe et al., 1996), resulting in less perceived need for change (O'Brien, Fries, & Bowen, 2000).

There are several reasons why the results of the present study suggest that social desirability and self-report error should be considered when interpreting the results of the present study. First, participants assigned to the Action or Maintenance stages of change for exercise, 60.40% greatly exceeded the 19% to 30% (McNabb, 1997) of diabetic patients who have been found to be adherent to exercise regimens. Second, 67.32% of participants were assigned to Action or Maintenance stages of change on three of the four diabetic treatment behaviors, far exceeding the 7% of diabetic patients found to be fully adherent to all aspects of their treatment regimen in one early study (Cerkoney & Hart, 1980). Third, several of the participants' wives who were present during questionnaire administration verbally contradicted their Veteran husbands' reports of behaviors and intentions consistent with Action or Maintenance stages of change. Although these Veterans typically changed their answers to coincide with the views of their wives, it suggests that other Veterans not accompanied by their wives may not have answered questions in line with their actual behaviors, whether intentionally or because of faulty estimation. Finally, there were several participants for whom hospital chart notes or

verbal accounts from health care providers indicated that actual diabetic treatment behaviors were not characteristic of Action or Maintenance, as the participants had reported to the researcher. No systematic attempt was made to exclude these patients from the analyses.

Another possible problem with interpreting the results of the present study is that it appears that some self-selection bias may have occurred. There were 20 participants who either refused participation in conjunction with an outpatient clinic appointment or did not follow up by going to the lab for their ordered HbA_{1c} test, and 76.7% of the participants who were mailed questionnaire packets failed to return them. The lack of a greater number of participants being assigned to the Precontemplation and Contemplation stages of change for the four diabetic treatment behaviors suggests that participants in these stages of change may either not follow up with appointments and lab tests at the outpatient clinics or may have chosen not to return the questionnaire packets.

The lack of expected results of the present study could also be accounted for by problems with measurement. Weinstein et al. (1998) emphasized that measurement of stages can be imperfect. There were several potential hazards in the selection of the format and wording of the Staging Algorithms for each of the diabetic treatment behaviors. An attempt was made to incorporate information and recommendations from past research in the design of the Staging Algorithms. However, the Staging Algorithms used may still have resulted in incorrect assignment of participants to stages.

It was difficult to decide upon the criteria to use in the Staging Algorithm for each of the diabetic treatment behaviors examined. While there are commonalities among health care providers in recommendations for diabetic treatment behaviors, there is some variation which depends either upon practitioner preference or perceived patient need. Because most of the participants received their blood glucose monitors from the Diabetes Clinical Nurse Specialist, it seemed appropriate to use the standards that she recommends to patients. For a few participants, their primary care provider recommended that they monitor blood glucose less than the recommendation of twice per week given by the Diabetes Clinical Nurse Specialist. These participants were still assigned stages using the twice per week standard, as even this is a very low amount of monitoring compared to what the average Type II Diabetic is asked to perform. On the other hand, many of the participants commented or added a note on their questionnaires that they monitor their blood glucose daily, typically more than once per day.

The present study used longer and more precise definitions of both exercise and diet than found in some previous research using staging algorithms. In a study comparing different formats of exercising staging algorithms, Reed et al. (1997) found that algorithms using longer, more complete definitions of exercise resulted in more participants being assigned to earlier stages of change than algorithms using short definitions of exercise. The longer definition is important perhaps because the term, "exercise" can have different connotations to different people (Donovan et al., 1998). A common misconception among severely obese diabetic patients that small amounts of low-intensity activity are of no health benefit (Foreyt & Poston, 1999). The reality is that for the Type II Diabetic population, many of whom are obese, a low-intensity activity may raise their heart rate and definitely burns more calories than sitting or lying down. The importance of longer

definitions was demonstrated during data collection in the present study when many of the participants who received oral administration reacted to the announcement that "the next set of questions concerns exercising..." saying, "I don't exercise." When many of these participants heard the full, detailed description of exercise used in the present study, they realized that they did indeed meet the specified criteria.

While the decision to use longer definitions of diet and exercise appears to have been a good one, it seems likely that the choice of wording for the staging questions may have been problematic. Specifically, the use of the term "consistently" may have caused some subjects to be assigned into the wrong stage for the various diabetic treatment behaviors. Weinstein et al. (1998) found that small changes in the wording of a staging algorithm can make a large difference in the distribution of stages. They pointed to the evidence of an unpublished study by Weinstein, Lyon, and Sandman (cited in Weinstein et al., 1998) in which, "400 participants in a study of radon testing, 23.7% said that they 'planned' to test, but only 13.7% said they had 'decided' to test" (p. 294). The choice of the term "consistently" in the present study was based upon previous staging algorithms for following a low fat diet (Greene et al., 1994; Laforge et al, 1999) and protecting oneself from sun exposure (Rossi et al, 1995). From the questions and comments of some of the participants who were recruited in conjunction with primary care outpatient appointments, it appeared that either they were unsure of the definition of "consistently" or that they interpreted it loosely and much more liberally than intended. The correct interpretation of *never or almost never deviating from the specified criteria for each of the diabetic treatment behaviors* was communicated to those who asked or made comments indicating that they were interpreting it differently than intended. However, there were many participants with whom there was no opportunity for clarification of the term.

Another problem with the measurement of the stages of diabetic treatment behaviors in the present study is that the reliability of the Staging Algorithm is difficult to assess. First, the Staging Algorithm is essentially a one-item measure. This prevents testing the reliability of the measure with an internal consistency measure. Second, test-retest reliability of the Staging Algorithm is difficult to assess, given that patients may move forward or backward in stages in less than the two weeks that are the customary least amount of time between testings in order to avoid measurement effects (Donovan et al., 1998).

Another potential problem with measurement in the present study concerns the measurement of the hemoglobin A_{1c} (HbA_{1c}) levels. One month was the time limit chosen for the maximum lapse between the measurement of hemoglobin A_{1c} (HbA_{1c}) levels and administration of the questionnaire. This time limit was chosen with the objective of having the participant's questionnaire answers to be reflective of their behaviors and intentions during the 2 to 3 months reflected by the hemoglobin A_{1c} (HbA_{1c}) level. However, one month may still have been enough time for participants to move forward or backward into a different stage than they were in at the time the HbA_{1c} was taken.

A final potential problem with measurement in this study concerns the methodology. Weinstein, Rothman, & Sutton (1998) have argued that the most commonly used methodology, the type of cross-sectional comparison which was used in this study, is at best a weak test of a stage idea. They suggested that experimental studies testing the matching of interventions to stage are preferable.

Given the lack of expected results in the present study, it is difficult to interpret the finding of the extra planned analysis, that the Medication Stage was the only diabetic treatment behavior stage found to be significantly predictive of hemoglobin A_{1c} (HbA_{1c}) levels. It is undeniable that the effectiveness of the medication regimen is a critical factor in glucose regulation (Johnson, 1992, 1993; McNabb, 1997). It may be that a patient who strictly follows an effective diabetic medication regimen may be able to achieve blood glucose regulation without strictly following a diet or exercise regimen, while a patient with an inadequate diabetic medication regimen may strictly follow diet and exercise regimens but still not achieve adequate blood glucose regulation. However, the results could also be erroneous, attributable to the same types of problems that might account for the overall lack of expected findings. Unfortunately, there is no medical research to date which might shed further light on these findings by indicating the relative proportions of variance expected to be accounted for by each of the elements of the diabetic treatment regimen (Goodall & Halford, 1991). This type of research would also be helpful in deciding how to interpret the lack of the overall hypothesized results of the present study. Knowing the relative contributions of various parts of the diabetic treatment regimen to the overall picture of the hemoglobin A_{1c} (HbA_{1c}) would help in deciding whether or not the Composite Stage of Change scores used as the standard in the present study were the appropriate measures to use in testing the applicability of the Stage of Change Construct to the problem of Type II Diabetic adherence.

In addition to the potential problems with this study that were discussed in the previous section, the sample of patients with Type II Diabetes in the present study may not be representative of all persons with Type II Diabetes. This sample was limited to

male Veterans, meaning that the results may not generalize to women or nonveterans with Type II Diabetes.

Recommendations for Further Research

To improve the current study, there are several possibilities for combating the difficulties associated with self-report of diabetic treatment behaviors. Although still prey to self-report bias, the use of food and exercise diaries might be helpful in increasing the accuracy of patients' perceptions of the performance of these behaviors. Having patients to bring medications for direct determination of medication adherence might also increase accuracy of staging, though patients could still simply remove medication without having taken it. Systematic collection of collateral reports from family members might also be fruitful (McNabb, 1997), since the reports of several of the participants in the present study were contradicted by wives. Collateral reports from health care professionals are less certain, since for participants in this study hospital chart notes and verbal reports from primary care providers more often overestimated adherence rates as compared to what patients were reporting in the context of the research. Instead of relying only on self-report of blood glucose monitoring frequency, it may be useful to modify the Staging Algorithm to use readings of blood glucose monitoring dates that can be downloaded from the majority of the blood glucose monitors used by the diabetic patients in the Veterans hospital where this study was based. As more sophisticated technology becomes commonplace, patients could also phone into systems such as HumaLink (Harris & Blonde, 1998) or log on to online sites that would allow them to enter dietary intake throughout the day which would be registered for the researcher.

Activity monitoring is another more high tech possibility that could increase the reliability of future research findings.

To improve the accuracy of stage assignments for the diabetic treatment behaviors, the wording of the questions about the performance of each behavior should be made even more specific in order to resolve the apparent problems with the use of the word "consistently" in the present study. Asking about actual behaviors within the past week might be considered. For example, recommended wording for the first question in each of the Staging Algorithms might be as follows: "In the past week, did you miss any doses of your prescribed diabetes medication?" "In the past week, did you monitor your blood glucose at least twice?" "In the past week, did you cheat on the low fat, low calorie diet described above?" "In the past week, did you exercise for a total of at least 20 minutes on at least 3 different days?" It might also be beneficial to develop a structured interview format for the Staging Algorithm. Hemoglobin A_{1c} (HbA_{1c}) levels might also be taken on the day of administration of the Staging Algorithms.

Another highly recommended strategy for further research would be to perform an experimental study to see if matching intervention to stage results in better adherence than the "one class fits all" approach currently used. Weinstein et al. (1998) stated that, "the added complexity of implementing a stage-based intervention can be justified only if it significantly outperforms an effective standardized treatment" (p. 298). An experimental study would be more labor intensive, however, and would require participants who were willing to come for more than one session. This would not be easy with the Veteran population in the current study, as many of the participants made a point of clarifying

that they would not have to return for additional sessions, indicating that would be too burdensome.

The results of this study were briefly discussed with Dr. Prochaska, author of the Transtheoretical Model of Behavior Change (J. O. Prochaska, personal communication, June 6, 2001). He reported that he has also recently completed some unpublished research applying the stages of change construct to the problem of Type II diabetic adherence. He suggested that the diet algorithm needed to be supplemented with questions about the specific key dietary practices, such as those included in the definition of diet in this study, adjusting the stage of change accordingly. He also suggested using a stricter gold standard for glucose monitoring, as opposed to the minimal behavior being recommended to patients or using "as your doctor has told you to." He agreed that using a structured interview might also be helpful, as might using collateral reports to adjust stages. Contrary to the literature, he also said that if social desirability was thought to be an insurmountable obstacle, using the profile obtained by the URICA might be warranted. But he agreed that part of the problem seemed to be patients' misperceptions of their own behaviors.

Conclusions

The present study found no evidence of a significant relationship between the Stage of Change construct of the Transtheoretical Model of Behavior Change. Therefore, there continues to be no scientific justification for matching intervention to stage with Type II Diabetics. However, the acceptance of a lack of relationship would be

premature, since this study also identified many difficulties with the current design that might be resolved in future attempts. Experimental research matching patients with Type II diabetes to treatment conditions is also highly encouraged.

The results of this study are in line with some previous research suggesting that diet and exercise are the diabetic treatment behaviors which Type II diabetic patients may have the most difficulty following (Dietrich, 1996; Glasgow et al., 1987; Pham, Fortin, & Thibaudeau, 1996). Therefore, available skills and resources might be best used for interventions with this patient population which target diet and exercise.

This is a new area of research in the application of the Stage of Change Construct of the Transtheoretical Model of Behavior Change. Never before have the Stages of Change been applied to a problem that involved more than one simultaneous behavior. Examination of the possible ways in which the Transtheoretical Model of Behavior Change might be applicable to the problem of diabetic adherence continues to be a worthwhile pusuit, since the Transtheoretical Model offers such advantages over other common health behavior models.

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APPENDICES

APPENDIX A

Demographic Questionnaire

Please answer EACH of the following questions by circling the letter next to your answer:

1. What is the highest level of education you have completed?
   A. Less than high school
   B. High school diploma or GED
   C. Some college or other higher education
   D. College or other higher education diploma
   E. Some graduate school
   F. Graduate school diploma

2. How many years has it been since you were diagnosed as having diabetes?
   A. Less than 1 year
   B. From 1 to 5 years
   C. From 6 to 10 years
   D. More than 10 years

3. Do you smoke cigarettes?
   A. No, I do not smoke
   B. Yes, I smoke less than one pack each day
   C. Yes, I smoke 1 to 2 packs each day
   D. Yes, I smoke 2 to 3 packs each day
   E. Yes, I smoke 3 or more packs each day

4. Have you attended a diabetes-related educational class OTHER THAN one at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center?
   A. No, I have not attended a diabetes-related educational class outside this hospital
   B. Yes, I have attended a diabetes-related educational class outside this hospital
      *If yes, please circle how long ago: a) 6 months to 1 year
      b) 1 year to 2 years
      c) 2 years to 5 years
      d) Over 5 years

APPENDIX B

Stage of Change Algorithm Versions

(Note: Headings and scoring keys did not appear on patient version)

Medication Algorithm

The next set of questions concerns taking your prescribed diabetes medication(s).

Please answer EACH of the next two questions:

1. At this time, are you carefully and consistently taking your prescribed diabetes medication(s)? (please circle your answer below)

   1 = Yes 2 = No

2. Have you carefully and consistently taken your prescribed diabetes medication(s) for at least the past 3 months? (please circle your answer below)

   1 = Yes 2 = No

Please answer the next 2 questions ONLY if you are NOT carefully and consistently taking your prescribed diabetes medication(s) AT THIS TIME:

3. Are you planning to begin to carefully and consistently take your prescribed diabetes medication(s) within the next 30 days? (please circle your answer below)

   1 = Yes 2 = No

4. Are you planning to begin to carefully and consistently take your prescribed diabetes medication(s) within the next 6 months? (please circle your answer below)

   1 = Yes 2 = No

Medication Stage Assignment:

Precontemplation:	No on questions 1, 2, 3, 4
Contemplation:	No on questions 1, 2, 3; Yes on question 4
Preparation:	No on questions 1, 2; Yes on question 3
Action:	Yes on question 1; No on question 2
Maintenance:	Yes on questions 1 and 2

Glucose Monitoring Algorithm

The next set of questions concerns checking your blood sugar (glucose) at least twice each week.

Please answer EACH of the next two questions:

1. At this time, are you carefully and consistently checking your blood sugar (glucose) at least twice each week? (please circle your answer below)

   1 = Yes 2 = No

2. Have you carefully and consistently checked your blood sugar (glucose) at least twice each week for at least the past 3 months? (please circle your answer below)

   1 = Yes 2 = No

Please answer the next 2 questions ONLY if you are NOT carefully and consistently checking your blood sugar (glucose) at least twice each week AT THIS TIME:

3. Are you planning to begin to carefully and consistently check your blood sugar (glucose) at least twice each week within the next 30 days? (please circle your answer below)

   1 = Yes 2 = No

4. Are you planning to begin to carefully and consistently check your blood sugar (glucose) at least twice each week within the next 6 months? (please circle your answer below)

   1 = Yes 2 = No

Blood Glucose Monitoring Stage Assignment:

Precontemplation:	No on questions 1, 2, 3, 4
Contemplation:	No on questions 1, 2, 3; Yes on question 4
Preparation:	No on questions 1, 2; Yes on question 3
Action:	Yes on question 1; No on question 2
Maintenance:	Yes on questions 1 and 2

Diet Algorithm

The next set of questions concerns limiting the amount of fat and calories in your diet. Some examples of ways to do this are eating smaller portions, eating reduced fat salad dressing or cheese, eating chicken without skin, limiting butter/margarine/other fats in your diet, eating fruits and vegetables for snacks, limiting red meat, etc.

Please answer EACH of the next two questions:

1. At this time, are you carefully and consistently limiting the amount of fat and calories in your diet? (please circle your answer below)

   1 = Yes 2 = No

2. Have you carefully and consistently limited the amount of fat and calories in your diet for at least the past 3 months? (please circle your answer below)

   1 = Yes 2 = No

Please answer the next 2 questions ONLY if you are NOT carefully and consistently limiting the amount of fat and calories in your diet AT THIS TIME:

3. Are you planning to begin to carefully and consistently limit the amount of fat and calories in your diet within the next 30 days? (please circle your answer below)

   1 = Yes 2 = No

4. Are you planning to begin to carefully and consistently limit the amount of fat and calories in your diet within the next 6 months? (please circle your answer below)

   1 = Yes 2 = No

Diet Stage Assignment:

Precontemplation:	No on questions 1, 2, 3, 4
Contemplation:	No on questions 1, 2, 3; Yes on question 4
Preparation:	No on questions 1, 2; Yes on question 3
Action:	Yes on question 1; No on question 2
Maintenance:	Yes on questions 1 and 2

Exercise Algorithm

The next set of questions concerns exercising for a total of at least 20 minutes, at least 3 days each week. You do not have to complete the whole 20 minutes at one time. Exercise could include any activity where you notice that your heart is beating faster or that you are breathing with a little more effort. Some examples of exercise might be walking, vacuuming, mowing the lawn, pushing a grocery cart, gardening, mopping the floor, etc.

Please answer EACH of the next two questions:

1. At this time, are you consistently exercising for a total of at least 20 minutes, at least 3 days each week? (please circle your answer below)

   1 = Yes 2 = No

2. Have you consistently exercised for a total of at least 20 minutes, at least 3 days each week for at least the past 3 months? (please circle your answer below)

   1 = Yes 2 = No

Please answer the next 2 questions ONLY if you are NOT consistently exercising for a total of at least 20 minutes, at least 3 times each week AT THIS TIME:

3. Are you planning to begin to consistently exercise for a total of at least 20 minutes, at least 3 days each week within the next 30 days? (please circle your answer below)

   1 = Yes 2 = No

4. Are you planning to begin to consistently exercise for a total of at least 20 minutes, at least 3 days each week within the next 6 months? (please circle your answer below)

   1 = Yes 2 = No

Exercise Stage Assignment:

Precontemplation:	No on questions 1, 2, 3, 4
Contemplation:	No on questions 1, 2, 3; Yes on question 4
Preparation:	No on questions 1, 2; Yes on question 3
Action:	Yes on question 1; No on question 2
Maintenance:	Yes on questions 1 and 2

APPENDIX C

Informed Consent Form

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Subject Name: _____ Date:

Title of Study: Stages of Change and Type II Diabetic Adherence

Principal Investigator: Laura E. Holcomb, B.A. VAMC: Cleveland (541)

DESCRIPTION OF RESEARCH BY INVESTIGATOR

NOTE: The consent form should include the following section headings:

I. Purpose of the Study
II. Description of the Study
III. Inconveniences
IV. Discomforts/Risks/Side Effects
V. Benefits
VI. Alternative Procedure(s)/Treatment(s)
VII. Use of Research Results
VIII. Special Circumstances

TO POTENTIAL PARTICIPANTS: Federal regulations require written informed consent before participation in a research study. This is to be certain that research subjects know the nature and risks of the study as they make a decision to participate or not to participate. You are asked to read the following information and discuss it with the investigator, so that you will be fully informed about this research study and how it may affect you. Your signature on this form means that you have been fully informed and that you freely give your consent to participate.

I. PURPOSE OF THE STUDY:

The purpose of this research study is to see if using a special model of the steps a person goes through in changing his or her behavior can help us to better understand how to help patients with type II diabetes to manage their illness.

You have been invited to participate in this research study because you are currently being treated for type II diabetes.

This study is also in the partial fulfillment of the requirements for the PhD degree at the University of Tennessee, Knoxville.

If you choose to participate, you will be one of approximately 50 to 100 patients in this research study.

CLEVELAND VA MEDICAL CENTER INSTITUTIONAL REVIEW BOARD APPROVED 10.2.2001

SUBJECT IDENTIFICATION: ID plate or name (last, first, mid)

_____
Subject's Initials

VA FORM 10-1086 JUNE 1990 (revised 9/93

Subject Name: _____ Date:

Title of Study: : Stages of Change and Type II Diabetic Adherence

Principal Investigator: Laura E. Holcomb, B.A. VAMC: Cleveland (541)

II. DESCRIPTION OF STUDY:

This research study is being conducted only at the *Louis Stokes Cleveland Department of Veterans Affairs Medical Center - Wade Park (LSVAMC)..*

STUDY PROCEDURES

QUESTIONNAIRE COMPLETION
This study involves filling out a short questionnaire about your management of type II diabetes. If you choose to participate you will be asked to fill out the questionnaire either now or following your appointment with your health provider, whichever is more convenient. If you received this in the mail, you are asked to fill it out and return in the provided prepaid postage envelope and to keep the extra copy of the informed consent for your information.

The questionnaire should take you no more than 10 minutes to complete.

FOLLOWING QUESTIONNAIRE COMPLETION
Once you have completed and returned the questionnaire, you are finished with your part in this research study.

After you complete and return the questionnaire, Laura Holcomb, B.A. will add the following information from your LSVAMC records:

- age
- gender
- race
- whether you have been prescribed insulin or oral medication
- the number of times you have been hospitalized in the past year for diabetes-related conditions
- Body Mass Index (relationship between height, weight, and total body fat)
- whether you have experienced any other health conditions associated with having type II diabetes (such as renal disease, retinopathy-eye damage, cataracts, amputations, peripheral neuropathy-numbness and/or pain in hands or feet, foot ulcers, etc.)
- whether you have attended a diabetes-related educational class offered here at the LSVAMC
- your last hemoglobin A_1c level (test indicating average blood glucose over the last 2 to 3 months)

Your combined questionnaire and LSVAMC chart information will then be separated from this informed consent so that you cannot be directly identified with your research data.

III. INCONVENIENCES:

There are no expected inconveniences related to participating in this study, other than the time it takes to fill out the questionnaire.

IV. DISCOMFORTS / RISKS / SIDE EFFECTS:

UNCOMFORTABLE THOUGHTS OR FEELINGS
Though it is not expected, filling out this questionnaire could possibly lead to uncomfortable thoughts or feelings associated with your type II diabetes. If you experience any such feelings and need assistance, please inform the principal investigator.

V. BENEFITS:

You will not directly benefit from participating in this study. Your participation will help medical research determine if using a special stage model of behavior change can help us to better understand how to help patients with type II diabetes to manage their illness.

VI. ALTERNATIVE PROCEDURE(S) / TREATMENT(S):

You have the alternative to not participate in this research study.

VII. USE OF RESEARCH RESULTS:

The results of this research study may be published in scientific or medical journals or presented at scientific meetings, but your name and identity will not be used. Any information connecting you to the study will be kept strictly confidential, except as provided by law. This signed informed consent sheet will be stored in a locked filing cabinet in the office of the responsible investigator, Dr. Gerald Strauss, and will only be accessible by him and the principal investigator, Ms. Laura Holcomb.

By participating in this research study, you give the investigators your permission for them to collect data from your medical records, as described above.

The Institutional Review Board of the Cleveland VA Medical Center may review your medical records as they pertain to this study.

CLEVELAND VA MEDICAL CENTER INSTITUTIONAL REVIEW BOARD APPROVED Feb 2 2001

Subject Name: _____ Date:

Title of Study: : Stages of Change and Type II Diabetic Adherence

Principal Investigator: Laura E. Holcomb, B.A. VAMC: Cleveland (541)

VIII. SPECIAL CIRCUMSTANCES:

Financial Considerations

Your participation in this research study will be done at no cost to you, nor will you receive any payment for your participation.

VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM (Continuation Page 5 of 5)

Subject Name: _____ Date:

Title of Study: : Stages of Change and Type II Diabetic Adherence

Principal Investigator: Laura E. Holcomb, B.A. VAMC: Cleveland (541)

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the preceding information. Dr./Mr./Ms _____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but I will not be identified in publications by name, photograph, or other identifiers. My records, including my name and results of my participation, may be revealed as required by laws and regulations of state and federal agencies.

If I have any questions about this study or if any problems arise during the study, I can call:

Ms. Laura Holcomb at 216-791-3800 ext 5368 or Dr. Gerald Strauss at 216-791-3800 ext 5852 DURING THE DAY and Dr. Gerald Strauss at (pager) 216-736-9087 AFTER HOURS. If any medical problems occur in connection with this study, the Cleveland VA Medical Center will provide emergency care.

If I have concerns or questions about this research study that the investigator has not answered, I can contact an official of the Institutional Review Board for Human Studies through J. Blume, at 216-791-3800, ext 4659.

I understand my rights as a subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed consent form or a photocopy of it. I understand that in signing this consent form I do not waive my legal rights nor release the Cleveland VA Medical Center from liability for negligence.

Subject's Signature	Date
*Signature of Subject's Guardian, Representative, or Parent — Date	Guardian/Representative/Parent (print)
Signature of Witness — Date	Witness (print)
Signature of Investigator — Date *Only required if subject is under age or mentally incompetent	I have received a copy of this consent form _____ Subject's Initials

VA FORM **10-1086** JUNE 1990 **(revised 9/93)**

APPROVED
JED. 2 2001
CLEVELAND VA MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

VITA

Laura Elizabeth Holcomb was born in Memphis, Tennessee on April 15, 1968. She received a B. A. in Psychology (Health and Premedicine Track) from Rhodes College in Memphis in 1990. Laura is first author, with Dr. Robert Neimeyer and Dr. Marlin Moore as co-authors, of a research article published in *Death Studies* entitled, "Personal Meanings of Death: A Content Analysis of Free Response Narratives" (Vol. 17, number 4, 1993). After receiving her doctoral degree in Clinical Psychology from the University of Tennessee, Knoxville, Laura has accepted a postdoctoral fellowship in behavioral medicine at Dartmouth Medical School.