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Development and Validation of an Instrument to Predict Non-adherence to Medical Treatment Regimens

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DEVELOPMENT AND VALIDATION OF AN INSTRUMENT TO PREDICT NON-ADHERENCE TO MEDICAL TREATMENT REGIMENS

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Dissertation Approval

This is to certify that the thesis presented to us by Dorothy E. Parker on the 15th day of November, 2004, in partial fulfillment of the requirements for the degree of Doctor of Psychology, has been examined and is acceptable in both scholarship and literary quality.

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ABSTRACT

Development and Validation of an Instrument to Predict Non-Adherence to Medical Treatment Regimens

Evaluation of the Health Adherence Behavior Inventory (HABIT) is described with data pertaining to reliability and validity. The instrument was originally developed for use in a primary healthcare setting, to support the early identification of patients who are at risk for poor health outcomes and complications of chronic disease because of non-adherence to their healthcare provider's instructions. The items were refined from the original HABIT (DiTomasso, 1997) and drawn from various sources, including health risk assessments, health screening questionnaires, and nationally accepted standards for disease treatment and prevention.

The questionnaire consists of 50 items, 39 of which appear to load on one factor. Items were analyzed, revealing two clusters, which yielded one Main Factor (Prevention Factor). This factor represents positive health behaviors that have demonstrated a correlation with reduced risk for negative health outcomes. These behaviors address one domain of the multifaceted problem referred to as non-adherence.

With respect to construct validity, the questionnaire correlated significantly with the widely used and reliable Health Risk Assessment developed by Lifestyle Directions, Inc. The strong correlation with an established Health Risk Assessment suggests promise for further refinement of the scale, offering a briefer alternative to full risk assessment. Through additional research, it is anticipated that a more comprehensive set of questions may uncover other key domains that offer valuable insight into the prevention and the treatment of non-adherence.

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INTRODUCTION

The Cost of Non-Adherence

It is estimated that in 2003, over 3 billion prescriptions were written by physicians in the United States. Researchers estimate that between 12% and 22% of these prescriptions have never been filled. Another 12% were filled but were not taken, and of those taken, better than half would have been discontinued within 1 year. (Ellis, et al. 2001) The consequences of this problem are staggering, yet a single solution has yet to be clearly identified. Non-adherence with medical treatment regimens is recognized as a significant healthcare issue and a risk factor for poor health outcomes (McDermott, 1997). Creer (1996) refers to adherence as the "congruence between patient behaviors and advice or instructions provided by health care providers". For the purposes of this discussion, non-adherence will be defined as the absence of voluntary involvement by a patient in a mutually acceptable course of behavior to produce a desired preventive or therapeutic result (Meichenbaum & Turk, 1987). Examples of such behavior would include failure to enter into and/or to continue a treatment program, keeping appointments, taking correct medications, adopting life-style changes, and following physician's advice.

Non-adherence with long term medication regimens has been estimated as low as 42% and as high as 60% (some higher), with an average of approximately 50% across disease states (Sackett & Snow, 1979; Haynes, 1985; Bayer Institute for Health Care Communication, 1996; Meichenbaum & Turk, 1987; Dean & King, 1999). The Center for Health Policy Studies estimates that as many as 23% of nursing home admissions and 10% of hospital admissions in the United States each year may be due solely to non-adherence with prescribed medications. (Wegner, et al. 1995; Sung, et. al. 1998) Adherence to asthma regimens, for example, has been estimated as

standing between 2% and 100%, with an overall rate across studies at less than 50% (Milgrom, H., et al. 1996; Creer, 1996). This is even more distressing in the face of pharmacologic advancements in the treatment of this illness which should improve patient management; instead of improvement, there is the unexplained increase in morbidity and mortality, which experts suspect may be closely tied to poor adherence (Creer, 1996).

The impact of arthritis and related diseases is another example of enormous health care costs for individuals, their families, and the nation. Every year, arthritis results in over 39 million physician visits and hundreds of thousands of hospitalizations, at an estimated cost of $15 billion. By the year 2020, experts estimate that 60 million Americans, or nearly 20% of the population, will be affected, and some 11 million will be disabled as a result (U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, 1998). Much of this could be moderated through the adoption of healthier lifestyles or through the use of therapy, as prescribed by a physician.

The scenario is equally problematic in the area of heart disease. According to the Office of Inspector General (1990), drug non-adherence with treatment for cardiovascular disease results in 125,000 avoidable deaths each year in the United States alone. In this report, Daniel Gerner, chairman of the Healthcare Compliance Packaging Council in Washington, D.C., reported that rates of compliance are about 46% among asthmatics, 33.5% for patients on antibiotic therapies and 53% among hypertensive patients. Unfortunately, just over half of hypertensive patients are on any kind of therapy at all. The American Heart Association (AHA) reported that hypertension alone killed 42,565 Americans in 1997 and contributed to the deaths of about 210,000. (AHA, 1999). Since then these numbers have continued to rise. The cost of cardiovascular diseases and strokes in the United States in 2005 is projected at nearly $393.5 billion, more than 3 times the estimated costs in 1994. This figure includes health expenditures (direct costs, which include the cost of physicians

and other professionals, hospital and nursing home services, the cost of medications, home health and other medical durables) and lost productivity resulting from morbidity and mortality (indirect costs). In the case of hypertension the total cost is estimated at $59.7 billion. (AHA, 2003).

The cost of chronic illness in the United States is tremendous, in terms both of quantitative and qualitative consequences. The Task Force for Compliance in 1994 estimated that the combined direct and indirect costs of non-compliant patients for 1993 was over $100 billion, and in excess of $8.5 billion in hospitalization and physician costs; non-compliance was also responsible for over 10% of all hospital admissions (McCarthy, 1998). More recent studies reveal no significant improvements in this area. Experts conservatively estimate that half of the 2 billion prescription medicines dispensed in 1998 were not taken as prescribed (Clepper, 1992; McCarthy, 1998). Maintenance therapies for asymptomatic conditions are especially prone to non-adherence.

Other forms of non-adherence are not as well documented, but a 1985 study by Haynes found that 50% of patients did not follow referral advice, 7% did not keep follow-up appointments, and 50% suffering from chronic illnesses dropped out of treatment within one year. Some clinical studies suggest that patients who fail to adhere to treatment regimens increase health care spending in the U.S. by $7 billion to $10 billion per year simply in increased hospital and physician costs (Cramer & Spilker, 1991). In 1994, the direct annual costs attributed to noncompliance alone were estimated at $45 billion by Center for Health Policy Studies (Sung, et. al. 1998).

The medical community, health maintenance organizations, and payers have called for better ways to help patients adhere to prescribed regimens and behavior changes (Guico-Pabia, C. et al. 2001); (Eraker, Kirscht, and Becker, 1984). Many attempts have been made to develop methods to enhance compliance with various interventions. Unfortunately, the first evidence of non-adherence often occurs when the patient returns to the physician because the condition or illness has not improved or has worsened. Only then can the physician even begin to suspect non-compliance

(McCarthy, 1998). To date no comprehensive instrument is available to differentiate reliably, in advance of treatment, between patients who will be compliant and those who will not. Such an instrument would offer healthcare providers the opportunity to intervene earlier in the treatment process by providing insight about potential barriers to adherence. In anticipation of problems the patient may encounter, the physician could take immediate steps to lower, potentially, the patient's risk of complications, to reduce side effects and associated costs of additional or stronger medication, to raise the individual's quality of life, and improve therapeutic outcomes (Frederikson, 1995).

Non-adherence and Health Behavior Theories

Numerous studies which examine non-adherence have been conducted, with varying degrees of success. The overwhelming majority of these studies have been narrowly focused, examining between one to five specific factors, such as family or social support, patient education, provider/patient interaction, treatment complexity and dosing, access barriers, intelligence, and self-efficacy, among others.

Attempts to develop a theory of non-compliance have also generated several studies, including one example postulated by Fogarty (1997), which is referred to as the Reactance Theory. This theory draws upon the concept of psychological reactance to explain patient non-compliance with medical treatment. A perceived threat by an individual to his/her freedom generates a motivational state aimed at recapturing the affected freedom and preventing the loss of other freedoms. Thus the patients' perceptions of threats to their freedom or control may induce non-compliance. In her work, Fogarty proposed three macrolevel non-compliance patterns, including length, complexity, and type of medical regimen. She concluded that high rates of non-compliance

with complex and/or lengthy regimens may be at least partially explained by reactance theory, and she suggested, further, that there might be implications for examining the physician/patient encounters more closely. Interventions, she theorized, might be productive if the patients felt more in control of their conditions.

In their review of the relationship between Social Cognitive Theory and health behavior, Baranowski, Perry, and Parcel (1997) summarize the constructs of Mischel (1973) and Bandura (1977) in a discussion of non-adherence, together with proposed intervention strategies. Some examples of these constructs include environment, expectations, self-control, self-efficacy, reinforcements, and so forth. They speculate that through the systematic identification of relevant domains or constructs associated with non-adherence, and the application of these domains to individual responses and behaviors, healthcare providers are better positioned to facilitate positive changes within their patient populations, and are able to do so at an earlier point in the treatment process. The components of Social Learning Theory propose that the patient will not actively pursue change or positive health behaviors if he/she does not reasonably expect the ability to be successful. Thus self-efficacy is an important concept with respect to predictive change. Smoking is a negative health behavior that illustrates this concept. (Glanz, Lewis, & Rimer, 1990). Many people become discouraged after failed attempts to quit, which in turn decreases the likelihood of future attempts.

In a discussion on the origins of the Health Belief Model, Rosenstock (1990) suggests that it is important to differentiate between intrinsic (an internal reason) and extrinsic (an external reason) motivations for change. They hypothesize that self-efficacy is a stronger predictor of behavioral change among those with strong a perception of threat and a recognition of the benefits of taking recommended health actions. "Perceived threat", they stated, "is a sequential function of perceived severity and perceived susceptibility". People who deny their conditions will fail to acknowledge

the severity of the situations realistically, which in turn will affect their readiness to change. The Health Belief Model presumes that a trigger will initiate other variables and behaviors into motion (Quine, Rutter, and Arnold, 2000). One of the considerations believed to play a role in the patient's actions include not only the perceived benefits of the treatment or behaviors, but also the barriers to obtaining or performing the necessary behaviors. Barriers such as cost, convenience, and impact on self and family may negatively weigh in on the cost-benefit analysis of compliance.

It is hypothesized that many factors can influence a patient's ability and willingness to comply with a specific treatment regimen. For example, adherence with medications is found to decrease under certain circumstances, such as the presence of side effects, perceived efficacy, the duration of medication use, the complexity of the regimen, and the relative cost of medications (Creer and Levstek, 1996). Inadvertently poor (??) interactions between physicians or medical staff and patients or parents may also result in incomplete or inadequate instruction, which in turn leads to failure to understand side effects or to misperceptions that foster non-adherence (Creer and Levstek, 1996). Other negative factors influencing patients may include lack of social support, memory decay, previous experiences, social stigma, apathy, co-morbidities (especially depression), lack of perceived benefits, and a general lack of reinforcement contingencies (Creer and Levstek, 1996). Research identifying causes of non-compliance attempts to reveal those who are liable to be non-compliant. Much of this research is based upon models which were developed to explain health behaviors. For example, the previously mentioned Health Belief Model (HBM) proposes that individuals are more or less likely to adhere to a treatment regimen if they believe that 1) there is a threat to their health, 2) they are personally susceptible to negative consequences, 3) they have some control in averting a negative health consequence, and 4) they do not perceive barriers to performing the desired behavior (Wiebe and Christensen, 1997; Tiedje and Kingry, 1992). The HBM, which dates back to the early 1950s, is one of the earliest models developed to

help explain health behavior and it is still one of the most influential and widely used approaches today. In 1993 DiMatteo, (et al.), studied the adherence of cancer patients; this was done in an effort to develop a scale to address elements of patients' adherence. The Adherence Determinants Questionnaire (ADQ) assessed 7 elements of patient's adherence to medical treatment and prevention, including perceptions of interpersonal care, beliefs about susceptibility, beliefs about severity, perceived utility of adhering, perceived subjective social norms for adhering, intentions to adhere, and perceptions of supports available, including absence of barriers. Past adherence and health value were also assessed. In field settings, intentions to adhere were most highly correlated with the perceived utility of adhering. Self-reported and objective measures of adherence were most strongly correlated with the presence of supports and the absence of barriers.

In a study of 597 women with early stage breast cancer, Fink, et al. (2004) found that 17% of the patients stopped taking tamoxifen during the 2 year follow-up period. Of these, 68% stopped taking it within the first 12 months. Examining the subjects' beliefs about therapy, the authors concluded that the ways in which the women perceived the risks and benefits of therapy were critical for sustaining adherence, and they recommended interventions designed to educate patients about the benefits and risks to discontinuance.

Although these models of beliefs and perceptions of severity and susceptibility have been frequently studied and show promise, to date they have not been shown to correlate consistently with variances in health related behaviors. (Abraham and Sheeran, 2000)

Another model, based upon structural theories of personality, is the Five-Factor Model (17), incorporated in the NEO Personality Inventory. This instrument has not been well studied, but purports to identify five dimensions of personality, including Extraversion, Agreeableness, Conscientiousness, Neuroticism, and Openness to Experience. Of these, only Conscientiousness appears to offer potential as a predictor of health behaviors, though this is still only speculation.

Other researchers have attempted to evaluate adherence by patients with chronic diseases, utilizing other personality questionnaires, such as the Sixteen Personality Factor Questionnaire (16PF). Such research has demonstrated limited success with similar constructs, such as Locus of Control and Self-Control (Wiebe and Christensen, 1997).

Self-Regulation Theory proposes that a patient's adherence behavior is closely tied to the physical symptoms and illness memories which interact in a way that triggers the compliance process. (Leventhal, 1984). To illustrate, in a study of kidney transplant patients, Siegal and Greenstein (1998) reported that the patients most likely to adhere to treatment regimens were "convinced" that their medications must never be delayed or missed, that they last in the body for less than 1 day, and that their physical symptoms interfered with the things they needed to do. In contrast, the low, or "partial-compliers", did not believe that the medication was essential, that it lasted longer in the body, and they perceived their physical symptoms to be milder than those in the "compliers" group.

The Multiattribute Utility Theory speculates that actions depend upon subjective values of specific outcomes. The individual considers the probabilities and consequences of alternative decisions, along with the relative importance of each consequence to the final decision. Ultimately these factors influence the person's actions. In the case of alternative health behaviors, it is speculated that the Multiattribute Utility Theory model has the ability to differentiate adherent and non-adherent patients. However few studies have been conducted to evaluate this theory in applied health decisions. (Carter, 1990) The Multiattribute Utility Theory is best illustrated in consumer purchasing behavior. Buying a car with airbags, for example, may cost more than the consumer would like to pay, and the purchaser must consider the probability and consequence of deciding to pay more or forego the option.

Yet another theory on behavior change is the Attribution Theory developed by Weiner in 1986. Similar in theme to other health psychology models, this theory focuses on the human need or desire to understand or explain adverse events. People want to make sense of their world and attempt to do so by looking for causal relationships. In 2000, Byrns studied low back pain in the garment workers industry. He found that those employees who attributed their pain to internal causes, such as knowledge of back safety, tended to feel less distress than those who believed the job itself was too difficult (external attributions). According to Byrns, this belief of the former that their pain could be reduced through their own actions reinforced the workers' motivation to adopt healthier behaviors based on a perception of their control of their particular circumstances.

Other theories that have been proposed to contribute greater understanding to the reasons for non-adherence include components similar to those already mentioned. For example, The Protection Motivation Theory framed by Rogers in 1975 underscores the persuasive value of fear communications; together with perceived self-efficacy, these may lead to cognitions and motivation for coping mechanisms and decisions to engage in protective behavior. A practical illustration of

this theory is the relatively higher treatment compliance rate believed by some to be observed in patients with HIV. In Western nations, the fear of HIV, along with mass communications related to prevention and treatment, were believed at one time to contribute to greater use of condoms in high risk populations and with better compliance with treatment among those already infected and diagnosed. (Catz, et al., 2000) Recent literature reveals mixed results.

Consumer Information Processing Theory (Rudd, et al. 1990) focuses on consumer choice and the availability of relevant information. This model supports the idea that consumers' decisions are directly related to each individual's ability to process information (capacity), in combination with motivation, attention, and decision rules and processes. The quality of the information and the consumer's internal cost-benefit analysis is tied to other constraints such as time, difficulty, etc. in the decision making process. At face value, this appears to make sense when applied to decisions such as financial investments, or the support of a particular political candidate. Unfortunately, when applied to decisions about healthcare, this model may not always serve the patient's best interests, particularly if he/she does not take the time necessary to make a fully informed decision. This may be related to perceived difficulty in understanding the choices in healthcare decisions, pointing again to the importance of the physician's role in properly educating his/her patient.

Within the last two-plus decades, revised versions of older theories have also surfaced. These include the Media Advocacy Theory (1990); the Precaution Adoption Model (1993); and the Transtheoretical Theory (1982-1983). Of these, the Transtheoretical Theory has received the most attention nationwide by stakeholders in the healthcare industry. DiClemente and Prochaska developed this model, with the initial focus primarily on how people change addictive behaviors (although precursors of this stage model can be found as early as 1966). (Prochaska, DiClemente and Norcross, 1992). The premise is that all individuals go through various phases when making changes and that this process has certain,(?) defined stages related specifically to the person's

readiness to change. These dimensions of the change process are delineated in five phases, beginning with precontemplation, contemplation, preparation, action, and maintenance. In the precontemplative stage the person has no intention to change in the foreseeable future. As individual awareness is raised and the person initially considers change, he/she has entered the contemplation stage. Thus in the case of health behaviors, a good illustration is the person who smokes cigarettes. This is the behavior most closely studied and most frequently referenced in literature on the transtheoretical model. According to proponents of the theory, the smoker who thinks seriously about quitting, and in fact begins to investigate methods to quit, has entered the contemplation phase. Once he/she joins a smoking cessation program, buys the nicotine patch, or other substitute, the person has entered the preparation phase. Actually using the patch or participating in smoking cessation classes and stopping this behavior constitute the action phase. (Norcross, et. al., 1989) A study by O'Connor, et al. (2004) was designed to test the hypothesis that patient readiness to change predicts future changes in glycemic control in adults with diabetes. The results presented readiness as an independent predictor of change in HbA(1c) for patients with high functional health status, but not for patients with low functional status. The authors recommended judicious use of the readiness to change assessment as a potential to improve care. Considerable controversy exists over the lack of standardization of measures, of timeframes for stages, and of the exact predictive value of the model. However, the theory has many supporters and several have adapted the model to specific uses, especially in healthcare, in which efforts to influence health behavior changes are becoming increasingly aggressive in response to rising costs. Examples include a variety of disease management programs which incorporate one-on-one counseling interventions, such as patient reminders and education, and low/no cost treatment, each designed for the patient's specific "phase" in the transtheoretical process of change.

Although specific factors are speculated as contributing to non-compliance, the issue is generally considered to be a multi-factorial phenomenon and to date no comprehensive assessment tool is available to identify prospective patients at risk for non-adherence. Various theories, including those underlying the development of models such as the Health Belief Model (HBM), provide a valuable foundation for examining the correlates of poor adherence; however, the problem is not consistent across patients, and numerous factors may operate simultaneously in any patient at any point in time. This is a significant challenge because the problems cannot be adequately or efficiently addressed until the underlying causes are identified and targeted.

Non-adherence and related Psychological, Social and Clinical Variables

From the Journal of Health Psychology, DiMatteo (2004) reported that a meta-analysis of patient adherence and social support has revealed a significant relationship between structural or functional social support and patient adherence to medical regimens. Factors such as practical, emotional and unidimensional social support, family cohesiveness and conflict, marital status, and living arrangements were examined. Practical support substantiated the highest correlation with adherence; marital status and living arrangements had modest correlations

Sanz, Constable, Lopez-Ibor, Kemp, and David (1998) studied insight scales and their relationship to psychopathological, social, and clinical variables. Their results supported the theory that psychopathology and clinical variables, particularly those related to insight, are related to attitudes towards treatment and subsequent compliance. The implications for those with mental health issues are evident.

In a recent study by Tucker, et al. (2004), the authors examined psychosocial mediators of antiretroviral non-adherence in HIV-positive adults with substance use and mental health problems. This challenging population included 1,889 HIV positive patients on antiretroviral therapy (ARV).

The purpose of the study was to investigate whether or not non-adherence to ARV could be explained by difficulty in getting the treatment and/or negative attitudes toward ARV medications. Difficulty in getting the medications and a poor fit with lifestyle were documented as the two most significant mediators. Poor fit with lifestyle referred to heavy use of alcohol and narcotics, which compromised memory, motivation, and social support.

With the advent of Medicaid and Behavioral Managed Care, physicians and mental health professionals have more aggressively sought ways to increase patient compliance and appropriate utilization of services. One area of focus studied by Moore-Greene (2000) involved an attempt to standardize social indicators to enhance medical case management, including compliance. The result was the development of what the author referred to as "life indicators", which she loosely defined as bio-psychosocial problems, with emphasis on environmental situations such as poor access, and lower SES; these appeared to be moderately correlated with poor compliance and other negative health measures. She concluded that life indicators could be readily incorporated into a medical case management model to target noncompliance and inappropriate utilization. More recent research suggests that doubling co-payments for prescriptions leads to increased use of emergency department visits (17%) and increased hospital days (10%) for the sentinel conditions of diabetes, asthma, and gastric acid disorder. (Goldman, et al., 2004).

In addition to financial barriers, patient characteristics such as age and education have also been studied. Huyser, et al. (1997) examined factors affecting adherence to rehabilitation interventions for individuals with fibromyalgia. The subjects were followed through a six-week training program, with questionnaires and physical exams. Although treatment factors revealed a modest correlation with overall adherence, the best model for predicting adherence suggested that a subject's age and education were the strongest influences.

In a study to evaluate the correlates of compliance with follow-up appointments and the filling of prescriptions following an emergency room visit, only 45% of more than1300 patients at an urban hospital could recall being advised to take a medication; of these, 12% reported that they did not obtain the medication. Of those who indicated that they were given follow-up appointments, 33% said they missed their appointments. Although lack of insurance was an independent correlate, dissatisfaction with discharge instructions was also identified as a correlate of not filling prescriptions (Thomas, et al., 1996). Extensive evaluation of the data to assess the underlying causes of dissatisfaction was not presented.

At the University of Pittsburgh, a recent study to explore the relationships between adherence with a medication regimen for lowering serum cholesterol and several domains of psychological and cognitive functioning, researchers found that conscientiousness and IQ were robust predictors of adherence in hierarchical regression analyses. Depression and anxiety, mental flexibility, and visuospatial-constructional ability were less robust but still statistically significant correlates of adherence. (Stilley, et al. 2004)

As healthcare costs continue to rise, Health Insurance Organizations (HMOs, PPOs, etc.) and other payers (employers) continue efforts to understand human behavior more fully and to discover ways to influence individuals to reduce health risk factors. Many studies have looked at specific interventions designed to motivate individuals to practice preventive health care. One such study was conducted to evaluate the effect of a cash incentive to improve adherence to preventive health behaviors, specifically to encourage obtaining an annual physical. For 3 consecutive years a cash incentive of $60 was offered to each individual in a small insured population (1500 people) who received a complete physical examination within the previous 12 months. On average, 26% of the eligible participants took advantage of the screening and the $60 incentive. (Manatee County Government, 2002).

In a study on compliance, Haynes (1985) also reported that adherence to treatment regimens was found to be associated positively with the physician's ability to make the patient feel understood; there was also a positive association with the patient's perceived support and ability to negotiate, feeling as if he or she were collaborating with the physician in the treatment. This adds credence to the importance of self efficacy in the patient's general motivation for adherence. In several studies involving patients with cancer, schizophrenia, and diabetes, the physician-patient relationship has also been demonstrated as an important factor in therapeutic outcomes (Smith and Thompson, 1993).

Steiner (1994) examined several aspects of non-compliance to help understand essential factors that influence this behavior. The results noted many opportunities for misunderstandings that can and do occur during a healthcare episode. They reported that the essential factors influencing compliance included patient/provider interaction and thorough drug education, usually focused on benefits and disadvantages (particularly where side effects were also fully explained).

In another study on understanding communication as a variable, Enguidanos (1997) studied language as a factor which affects compliance following an emergency room visit. The objective was to focus on the English language versus the Spanish language as significant variables. Four additional socioeconomic factors were also compared. They found no correlation between language and compliance, but they did report that having a primary medical doctor prior to the Emergency Department visit was positively correlated with follow-up compliance; this was the only significant socioeconomic variable irrespective of language ability.

In a similar attempt, Thomas, et al. (1996) found that not having made an appointment before leaving the Emergency Department was an independent correlate of missing follow-up appointments. In addition, the absence of insurance and dissatisfaction with discharge instructions were reported as independent correlates of not filling prescriptions. These studies are similar to

other studies which underscore the value of consistent and reliable information sharing between providers in order to offer a more cohesive approach to individual care.

Putnam, et al. (1994) found that a commitment-based intervention was effective in significantly improving patient adherence to medical regimens. Based upon a 10 week antibiotic regimen, subjects were asked to give verbal and written commitments for adherence and they completed tasks designed to increase their investments in a medication program. The concept resembles patient contracting in psychological counseling treatments. During treatment, unannounced pill counts were conducted and structured tasks were assigned. The authors concluded that the conscientiousness of the participants was triggered by the verbal and written commitment, thereby decreasing the likelihood of premature termination of therapy.

Although many studies have analyzed self efficacy, patient education, and provider communication, other studies which examine a patient's mental status have also revealed some interesting outcomes. DiMatteo (2000) evaluated the associations between anxiety and non-compliance and depression and non-compliance, as potentially independent factors. Anxiety proved to be relatively insignificant as the subjects' averages were low; however, the relationship between depression and non-compliance was substantial and significant. They concluded that compared with non-depressed patients, the odds are 3 times greater that depressed patients will be non-compliant with medical treatment recommendations. The authors suggested that further research is warranted among patients who might not be adhering to medical advice in order to explore the value of early recognition of depression as a risk factor for poor outcomes. In similar work, Delgado (2000) concluded that the complex nature of noncompliance includes rational and intentional decisions based on many beliefs, which in turn may be significantly colored by depression. The author concluded with recommendations to develop strategies directed towards the effective education and treatment of depression, emphasizing collaboration between the patient and the physician.

Researchers at the Washington University School of Medicine in St. Louis, Missouri also found that elderly patients with coronary artery disease who were depressed were significantly less likely to adhere to their treatment regimens than their non-depressed counterparts (Carney, et al., 1995).

Non-adherence, Depression, and the Elderly

Nikolaus (1996) structured a study on the elderly to identify problems with medication compliance during and after hospital stays. They concluded that logistical problems such as difficulty opening and removing tablets from commercial packages presented serious challenges for these patients and recommended routine testing of packages during a hospital stay. They also reported that management of medication should be taught and supervised within the first few days after discharge from the hospital. Similar results were found by Cramer (1998), in a study to understand the role of packaging aids and the monitoring of compliance in the elderly.

A data analysis by a large health insurance organization on members over 50 years of age revealed that age, existing health status, and education seemed to be correlated with adherence to multiple healthy lifestyle factors. For individuals 50-64 years of age, all three factors appeared to be statistically significant. For seniors 65 years and older, having a college degree was the only statistic(?) significant with healthy lifestyles.

Because seniors are the largest single demographic group of healthcare consumers, extensive research has been invested into ways to improve long-term compliance for chronic diseases. Liu and Park, (2004) conducted a study to examine whether or not forming detailed implementation plans for achieving a goal improved older adults' adherence to a health behavior. They concluded that continued reinforcement, practice, and training significantly improved the subject's adoption of positive health behaviors.

Franson and Smith (1998) published an article which reviewed the extent of non-compliance in older adults who take psychotherapeutic agents. Their review found that, in addition to the patient/provider relationship, belief in the efficacy of the medication, patient education, and the type of psychotherapy were also influential factors. Although it was not formally assessed, the authors inferred the importance of a positive therapeutic alliance.

In a separate study of older adults, compliance with adult preventive care guidelines was conducted, revealing that high knowledge scores, accompanied by recommendations based on patient history, knowledge of preventive care guidelines, and high self-perceived effectiveness were independently associated with self-reported preventive care efforts. Female gender also appeared to be modestly associated with greater attention to preventive care (Ely, et. al., 1998). Recently, many more studies have been undertaken to focus on senior Americans. A rapidly aging population, coupled with double digit healthcare inflation has drawn much attention in the political arena. In a more recent study conducted by Hughes (2004), the author found that older patients may deliberately choose not to adhere to medication (intentional non-adherence) to avoid adverse effects of the medication. In addition, when further questioned it became apparent that the patients selected which medication to skip based upon symptoms; consequently, non-symptomatic conditions such as hypertension were less likely to be addressed than more painful or symptomatic conditions, such as migraine or arthritis.

Inappropriate Use of Medications

Misuse of medications is another major cause of morbidity and mortality. Few studies have examined the frequency of, and factors associated with, discrepancies between what doctors prescribe and what patients actually take. Bedell, et al. (2000) conducted a 4 month study in private

practices affiliated with an academic medical center in Boston. A population of 312 patients from practices of 5 cardiologists and 2 internists were compared by examining medication bottles with medical records. Although findings could not consistently identify discrepancies across classes of medications, the types of errors included: patients taking medications that were not recorded, patients not taking enough of a prescribed medication, and patients taking more medication than indicated. The authors concluded that discrepancies among recorded and reported medications were quite common, across all drug classifications. Older age and polypharmacy (complexity of treatment regimen) were reported as the most significant correlates of discrepancies in general. The article concluded with an urgent recommendation to address these causes. Disease management companies understand the dynamics of these issues and those who work with seriously ill populations employ numerous practical interventions, such as patient diaries, alarm watches, and pill holders, which reflect recent learnings in this field.

Conditions or treatments which are generally considered non-life threatening or palliative in nature are less (often)?? (seriously)??? studied. For example, though not generally considered life-threatening, non adherence with Hormone Replacement Therapy is estimated to be between 70% and 91% for women from 40 to 60 years of age (Hurley, et al., 1998). The problem resides not so much in who takes it versus who does not, but who begins and then stops abruptly without telling her physician. This type of behavior supports susceptibility theories such as the Self-Regulation Theory and the Health Belief Model, suggesting the perceived severity of the condition and relative susceptibility to negative consequences is relatively low.

Non-adherence and Asthma

Data from the National Health Interview Survey (1980 – 1990) reported that the age-adjusted prevalence rate of self-reported asthma increased by 38% over this time period.

Additionally, Taylor found a significant increase in the prevalence of asthma in children younger than 18 years of age (from 3.2% in 1981 to 4.3% in 1988) (Creer & Levstek, 1997). There are many thoughts about the cause of this increase, such as air pollution, inner-city congestion, and the need for better identification and diagnosis. The corresponding physician visits for asthma increased from 6.5 million to 7.1 million during the same timeframe. What is more alarming, however, is the sharp increase in deaths from asthma, which rose 46% between 1980 and 1989 (Creer & Levstek, 1997). Given the rapid development of newer and more effective treatments for asthma, the increase in deaths is particularly distressing and underscores the importance of treatment adherence, specifically in manageable conditions such as asthma. Non-compliance with prescribed medical regimens and an inability to use medications properly, especially inhalers, has been identified as possible causes of increased morbidity and mortality associated with asthma (Legorreta, 1998).

In a study of health beliefs and compliance with asthmatics, Chambers, Markson, Diamond, Lasch, and Berger (1999) found that patients were more likely to report regular use of inhaled corticosteroids if they saw themselves as active participants, meaning that they collaborated with their physician in treatment and they viewed asthma as a serious illness. Their beliefs about the consequences and their perspective on personal control over the disease supported the concept and importance of patient education and of shared decision making to achieve better outcomes in the treatment of asthma. This also lends credibility to the concept of self-efficacy and the constructs of Social Cognitive Theory as applied to patient adherence.

Non-adherence and Kidney Disease

Much of the literature on treatment compliance has focused on attributions, health beliefs, and emotions as influencers of adherence. In a separate study on these variables with hemodialysis patients, Friend, et al. (1998), found that of these three potential factors, attributions appeared to

play a more significant role than either health beliefs or emotions, though none significantly predicted both absolute fluid levels and fluid adherence. Health beliefs predicted changes in fluid adherence, but attributions predicted absolute fluid adherence. Negative emotions showed no correlation with absolute fluid levels or changes in fluid adherence.

Non-adherence, Heart Disease and Hypertension

A study involving cardiac patients found that physicians ranked hospital recommendations as one of the most important sources of patient information and one of the most important influences on patient compliance, stating that patients who were recently hospitalized were much more likely to follow treatment regimens, post-discharge, than those who had not been hospitalized. The results did not follow the length of time that patients followed treatment post-discharge nor was further investigation conducted to evaluate the patient's interpretation of the significance of hospitalization, nor whether the hospitalization was the primary influential factor. Nevertheless, the physician's perceptions of the patient's attitudes regarding compliance are recognized as fertile ground for research. (Feely, J. 1999).

Steiner (1994) conducted a three-part review on patient compliance in an effort to outline the term compliance. The results focused on the complexity of medical regimens, and emphasized the fact that it is the patient and physician interaction which seems to determine more heavily the likelihood of compliance, especially when (?) symptoms are not evident. Similar results were found by Sung, et al. (1998) in a study of patients with hyperlipidemia. In this asymptomatic condition, factors that appeared related to poor adherence included gender (females were lower in compliance), patient/physician communication, complexity of regimen, side-effects, perceived health status, and comorbidities. Patients who reported previous histories of good compliance were also more likely to adhere to their treatment regimens. The data did not offer an explanation for the differences in

gender, although it is worth noting that many medications for hypertension and other heart conditions are contraindicated in women of child bearing age.

In a study at the University of Southern California, 86% of new antihypertensive drug therapy patients interrupted or stopped purchasing medication during the first year. Each of the patients who interrupted therapy used an additional $873 for health care in that 12 month period. The higher costs were primarily due to increased hospital expenditures (Cramer, 1997). Ischemic heart disease is one of the major causes of morbidity and mortality in the United States, representing over 20% of all deaths in 1996 (Sung, et al., 1998). Many of the risk factors for this chronic condition are well established and preventable, i.e. diets high in cholesterol, hypertension, smoking, physical inactivity, obesity, depression, and diabetes. Moreover, the Multiple Risk Factor Intervention Trial (MRFIT, 1998) has documented the fact that persons with combinations of risk factors such as hypertension, hyperlipidemia, and diabetes are at higher risk for cardiovascular disease and associated mortality (Chang, et al., 2001). If physicians were able to influence patients to adopt positive health behavior changes, the necessity for medication could be significantly reduced, as would unnecessary hospitalizations and physician visits.

One in four adult Americans has high blood pressure and nearly a third do not know they have the condition. Nearly 15 percent of individuals with hypertension are not on any type of therapy (special diet or drugs) and 25 percent of those on therapy are not taking adequate medication nor are they using measures to achieve desired blood pressure goals. Roughly 50% of hypertensive patients who have experienced a cardiovascular event discontinue cardiovascular rehabilitation within the first year of the event; between 16% and 50% discontinue medication within the first year; and greater than 79% relapse and begin to smoke again within the first six months of an event (Burke and Dunbar-Jacob, 1997). Hypertension is easily detected and usually controllable. Non-Hispanic blacks (particularly males) and Mexican Americans are more liable to

suffer from high blood pressure and have a greater mortality rate, than are non-Hispanics. People with lower educational and income levels also tend to have higher levels of blood pressure. The use of medication and lifestyle modification (including diet, smoking cessation, and exercise) are well-established behavior changes that can help control high blood pressure. Controlled hypertension reduces the risk of other cardiovascular disease and resulting healthcare utilization. However this is only true for patients who are cooperative and responsive to treatment, i.e. adherent to treatment and/or medication. Research has revealed that patients have high adherence if they sustain their routine for at least 6 months (American Heart Association, 1999).

Meta-analyses indicate that patients with mild-to-moderate hypertension can benefit significantly from even modest blood pressure reductions. A reduction of 5mm Hg in diastolic pressure would reduce mortality from stroke by 40% and from coronary heart disease by 14%, (Rudd, Ahmed, Zachary, Barton, and Bonduelle, 1990). One of the key challenges with hypertension is to convey the severity of the condition in terms that influence the patient's attitude and motivation.

Non-adherence and Communicable Diseases

Numerous studies have linked social support to better medication adherence among illness groups, but few have examined potential mechanisms for this relationship. Gonzalez, et al. (2004), in their research on social support, positive states of mind (PSOM), and HIV treatment adherence in men and women, found that depression and PSOM were highly correlated with better adherence, whereas higher depression scores related to non-adherence.

It is widely recognized that adherence to antiretroviral therapy is critical to long-term treatment success, yet rates of adherence to antiretroviral medications are also frequently subtherapeutic. In a United States study of HIV patients, compliance with a complex treatment

regimen was assessed to determine modifiable conditions associated with suboptimal adherence, including how well clinicians predict patient adherence. The findings (Patterson, et. al. 2000) indicated that a clear and significant relationship between compliance and clinical outcomes was evident, (i.e. virologic failure and treatment compliance); however, the underlying cause for poor compliance was not apparent. Moreover, physicians and nurses could predict adherence correctly in fewer than 50% of the cases. Existing studies on compliance suggest an inverse correlation between the number of medications that patients take and the degree to which they comply with their treatment regimens.

Bedell, et al. (2000), studied compliance with complex regimens of HIV patients and also concluded that dosing is a relevant consideration, with greater compliance typically associated with fewer doses per day in some subsets of patients. This may offer some explanation about the reasons that some individuals with complex diagnoses fail to adhere to medication treatment regimens. However, this behavior pattern is not consistently observed in HIV patients who are generally still more compliant than average, yet maintain very complex treatment regimens. This may lend credence to the Health Belief Model, which attributes, to some degree, adherence to the individual's perceived threat (HIV is viewed as a very deadly disease) compared with their perceived ability to manage it (medication is seen as the only hope of slowing disease progression).

A study was conducted by the University of California, San Francisco (UCSF), Center for AIDS Prevention to learn more about the factors that motivate or deter patients from multi-drug therapy. Through in-depth interviews the researchers learned that patients who were not on therapy most often indicated they would be motivated to start treatments if they experienced a decline in their health status (fear) and/or if they received strong recommendations from their physicians to do so (Key, 1998). Here again, the patient/physician relationship appears to be critical, although

perceived loss of freedom (patient denial) and co-morbidities such as depression may also be very important factors.

Similar research results were reported in a 2004 study by Reynolds, et al., which examined beliefs about antiretroviral therapy and psychosocial characteristics of HIV-positive persons. Among a subset of 325 patients reporting current use of medications (nonantiretrovirals) during the prior month, depression was the strongest correlate of non-adherence. The most common reasons given for non-adherence to the medications, in descending order, were "simply forgot", "away from home", and "busy". The authors concluded that personal and situational factors such as depression, stress, and lower education were associated with less certainty about the potential for treatment success and with the perceived ability to adhere.

In the March, 2000 issue of Health Psychology, Catz, et al. published their study on patterns, correlates, and barriers to medication adherence among persons who were prescribed new treatments for HIV disease. The study included 63 men and 9 women on highly active antiretroviral therapy. Subjects completed measures of medication adherence, of psychological characteristics, and of barriers to adherence. After 3 months, nearly 33% of the subjects had missed doses during the previous 5 days. Depression, side-effect severity, self-efficacy, and social support were the most significant correlates of poor adherence.

Another study with a homeless population examined the effect of cash incentives to improve adherence to tuberculosis preventive therapy. An intervention group was compared with "usual care", and the results showed a significantly better compliance rate in the group that received the monetary incentive ($5 biweekly cash) (Tulsky, et al., 2000). Although the results of this kind of intervention may be intuitive in this unique population, these kinds of studies offer useful information and lay the foundation for continued research on the domains of non-adherence and the interventions that show promise.

Non-adherence and Preventive Care

In addition to researchers, employers have also attempted to understand how and why people comply with healthy behavior regimens, particularly with respect to preventive care. Weinberg (1997) reported that eliminating a common barrier, specifically access, played a significant role in facilitating a higher compliance rate with recommended mammography guidelines. Employees were offered mammograms at the work-site, resulting in 89.5% of women receiving at least one mammogram, and 44.6% practicing monthly self-exams. Though not significant, the compliance rate favored Caucasians and women with a family history of breast cancer, suggesting that the relevance (perceived threat) of the disease was also a factor. In 1995, Friedman, et al. found that utilizing the Health Belief Model, analyses of behaviors and intentions to obtain mammograms suggested two strong predictors of breast cancer screening – physician recommendations and perceived barriers.

A meta-analysis of studies evaluating the effect of patient education and counseling for preventive health behaviors conducted in 1997 by Mullen, et al., revealed that education and counseling conducted by the primary care provider does help patients adopt healthier lifestyles across many behaviors; however, emphasis was placed upon the types of behaviors changed, and recognized that addictive behaviors such as smoking and alcohol abuse were more challenging issues.

In summary, there is significant and relevant literature which indicates the degree of concern surrounding the issue of non-adherence, including the magnitude of the problem. This problem contributes substantially to the high costs of healthcare in the United States, not only through poorer health outcomes, morbidity, and death, but also indirectly in reduced quality of life, disability, and intangible measures of productivity. A better understanding of the fundamental issues of non-

adherence as well as their key contributing factors is essential to improving the long term health status of Americans.

Rationale

The primary point of care in the healthcare delivery system takes place in the physician's office. The principal provider/patient interaction represents the initial step in each unique episode of care. What the physician does within practice is really involved with behavior prescriptions, such as eating, sleeping, exercise, and medication. However, the physician usually does not target non-adherence and often underestimates it. This may be due to the fact that there are so many possible factors contributing to non-adherence that it is difficult to know which factors are operating for any given patient at a given point in time. (Claydon, Efron and Woods, 1997). For example, in a meta-analysis conducted by Lisper, Isacson, Sjoden, and Bingefors (1997), the effects of patient education revealed that behavior-oriented instructions concerning the use of drugs (based on the patient's own daily routines) were more likely associated with better compliance because the information was personal and specific. Without delineating possible reasons for compliance, however, therapy becomes less focused and may be only partially effective, if effective at all. If the constraints placed upon a physician's time within our fractured healthcare system are included, the ability to identify prospectively or to react to patient's behavior is even further compromised. To the extent that the patient does not comply with his/her prescribed regimen, numerous, additional outpatient visits and/or hospitalizations may be necessary, compromising the quality of life for the patient, while adding to increased financial burden for the patient and healthcare system alike. The result is significant and additional, but often avoidable, costs to society, to families, and to the individual's quality of life. As previously stated, non-adherence is a serious problem with potentially lethal

consequences. Non-adherent patients may allow a disease to progress, and may require more invasive procedures, and more aggressive medications. When a physician understands the adherence issues that may affect a specific patient's likelihood of complying with the treatment regimen, he/she is better prepared to offer the appropriate support at the beginning of the treatment process in order to facilitate better outcomes. Approaches to improve adherence, such as those outlined by Creer (1996) and Chambers et al. (1999), suggest that by identifying patient's issues, by altering treatment regimens and by applying behavioral techniques, the physician is able to influence outcomes positively.

In the absence of reliable and practical methods to predict which patients will not adhere to their recommended treatments, physicians and other healthcare providers are left with their own judgments. Frequently these judgments are based upon experience, either with those particular patients, or in general over time with multiple patients and conditions. This approach leaves both the provider and patient vulnerable to the consequences of non-adherence. An instrument that reliably predicts patients' health behavior problems would provide a profile of factors contributing to non-adherence. A tool of this nature would be invaluable in aiding the physician in the selection and implementation of appropriate interventions, which could ultimately lead to lower healthcare costs, higher quality of life, and a lighter burden of illness for all those who share the costs of poor health outcomes.

Purpose of the Study

The purpose of this study is to develop and validate a self-report screening instrument with valid and reliable psychometric properties so that it may be useful to identify those prospective patients with chronic disease who are less likely to comply with their medical treatment regimens. The framework for this instrument is the Health Adherence Behavior Inventory (HABIT) developed

by DiTomasso in 1997. The original questionnaire was initially used by DiTomasso and colleagues to assess medical patients in an urban medical center. Patients who failed to progress as well as anticipated in their treatments, and who were less compliant with their physicians' instructions, appeared to exhibit similarly poor lifestyle habits. The need to address these issues earlier in the treatment process inspired the use of screening questions to elicit relevant information for the primary care and mental healthcare providers. This information proved useful in the early identification of problematic issues surrounding the patients' behavior and ultimate health outcomes. The questions evolved from observations made by the healthcare team regarding patients who were observed to be or who were suspected to be non-compliant. Specifically, the original items were intended to provide a brief but useful screening for positive health behaviors that were consistent with adherence and with better health outcomes. Hypotheses concerning the utility of this instrument suggested that it would ultimately be brief, reliable, and be able to differentiate the non-compliant patient from the compliant patient. This led to further refinement of the items and a consideration for more rigorous evaluation and empirical study. The present study was proposed to examine the psychometric properties of the HABIT, specifically to assess the construct validity, the internal consistency, and the factor structure of the questionnaire. Construct validity was assessed by comparing the HABIT with a well documented and validated Health Risk Assessment by Lifestyle Directions, Inc. For the purposes of this study, medical treatment regimen was confined to treatment protocols involving medication, exercise, and diet, with emphasis on medication. Chronic disease was limited to specific diagnoses indicative of hypertension.

Research Question/Hypotheses

The research question for this study was based on the idea that it is possible to predict non-adherence in a medical patient population. The hypothesis for this study presumed that individuals who are routinely non-adherent with medical treatment regimens tend to possess similar state/trait characteristics so that they can be identified in a practical and efficient manner (i.e. Questionnaire) to facilitate interventions by a professional healthcare provider.

The research hypotheses were as follows:

1. The HABIT would possess content validity as established by an expert panel of healthcare professionals.

2. The HABIT would possess construct validity as demonstrated through factor analysis.

3. The HABIT would demonstrate internal consistency reliability.

4. People who were rated as less likely to comply with a prescribed treatment regimen would score significantly differently on the HABIT from those who were rated as more likely to comply with similar treatment regimens. The degree of compliance would be measured by the following possession ratio calculation:

$$\text{Days Fill Ratio} = \frac{\text{\# of days in the previous 6-12 months for which the subject had recorded filled Rx}}{\text{\# of days in the previous 6-12 months for which the subject had a recorded Rx}}$$

The closer this ratio to "1", the greater the degree of compliance with medication (a ratio of "1" would indicate that the subject had sufficient medication for an entire prescribed period). It was anticipated that the results of this study would reflect a positive correlation between the scores on the Health Adherence Behavior Inventory (HABIT) and the Days Fill Ratio/Possession Rate.

5. There would be a negative correlation between the number of self-reported, positive health behaviors on the HABIT and blood pressure level.

CHAPTER 2

METHOLODOGY

Subjects

The subjects for this study were randomly selected from a population of eligible volunteers who presented at one of three pharmacies to receive a prescription for the treatment of hypertension. Subjects could be male or female and between the ages of 18 and 65.

A total of 300 subjects with completed surveys and screenings were required to complete this study as designed. Only subjects who had been diagnosed with hypertension within at least the prior 6 months *and* were currently being prescribed medication to treat hypertension were accepted into the study. The subjects were queried to confirm the fact that they consistently filled their prescriptions with the same pharmacy.

Subjects may have had other concomitant conditions, provided these conditions did not preclude the subject from voluntary participation or render the subject housebound or bedridden. Participation was voluntary and subjects had to be willing to provide consent in writing by returning a signed consent form. Subjects were free to withdraw from the study at any time. Participants were also required to understand and respond in English, utilizing, at a minimum, language ability at an 8th grade reading level.

Interested volunteers who were participating in other studies, including, but not limited to, clinical research trials, behavior modification studies, health surveys, or disease management studies, were not accepted into the study. Patients who were institutionalized or hospitalized were also excluded from the study.

Design

This study employed a correlational research design to assess the psychometric properties of the Health Adherence Behavior Inventory (HABIT).

Description of Instruments and Measures

Health Adherence Behavior Inventory (HABIT) The Health Adherence Behavior Inventory, (DiTomasso, 1997), is a 50 item, dichotomous questionnaire, developed by DiTomasso for use in primary care settings. (see Appendix B) The original questions were designed and delivered by healthcare providers in an ambulatory setting in an effort to uncover useful information to support an individual patient's treatment progress. The HABIT includes items that describe ordinary health-related behaviors, "habits", such as following physician's advice, getting prescriptions filled as soon as they are received, limiting intake of fatty foods, avoiding smoking, etc. The respondents are asked if the described behavior is generally true or not true of their own behavior. Responses correspond with a numerical value: (True = 1, False = 0). A total score is then calculated by adding the response values from all completed items. Most of the items are presented in the affirmative, such as "I limit the amount of sugar I consume", or "I eat enough fruits and vegetables". Three of the 50 items are framed in the negative, meaning that the item describes a negative behavior or attitude, such as "People tell me I am a couch potato". These items are reverse scored. It was anticipated that a higher score on the HABIT (indicating frequent practice of positive health behaviors) would correlate to a lower score on the Health Risk Assessment (reflecting lower risk of developing a disease).

Health Risk Assessment. (HRA) The Lifestyle Directions (LDI) HRA is an established health risk assessment that has been widely used for more than 20 years to measure risk of disease. The questionnaire has been well studied and correlates highly with direct medical costs and

utilization claims data. (see Appendix C) The HRA includes 113 items that solicit health-related history, behaviors and attitudes, as well as biometric screening values (to be entered by a clinician upon completion of blood screening and biometric measures). The number of questions and categories are broken down (?) as follows: (demographics = 3), (medical history = 38), (physical health = 9), (dietary habits = 10), (lab values = 7), (screening history = 3), (personal habits = 11), (attitudes on health = 6), (medications/drug use = 15), (exercise attitude = 1), (women only health = 7), and (men only health = 3). The HRA is a validated instrument with a proprietary algorithm (owned by Lifestyle Directions, Inc.) which is applied to all responses. The analysis of responses yields a percentile score of "Overall Health Risk". The percentiles range from minimal risk (0% - 25%), to moderate risk (26% - 50%), to major risk (51% - 75%), to severe risk (76% - 100%). It was anticipated that a lower Overall Health Risk score (percentile %) would correlate with a higher numerical score on the HABIT.

The LifeStyle Directions, Inc. HRA is one of the oldest and most frequently utilized HRAs on the market. A substantial study comparing HRAs was published in 1987 by Smith, et al. in the American Journal of Public Health, in which 41 HRAs were compared in terms of their validity in predicting risk of future coronary heart disease. The study classified the HRAs into five categories, depending on their science-base and method of scoring. The morbidity and mortality based HRAs required computer scoring. The others could be scored by hand. The correlation of true risk of cardiac death and HRA-based estimates of risk of cardiac death ranged from 0.145 to 0.800, with 0.000 being worthless, and 1.000 being perfect. The two morbidity- (illness) based HRAs had correlation scores of 0.800 and 0.763, respectively. LDI-HRA is a morbidity-based system. Thus, in a crowded HRA marketplace, the morbidity-based HRAs distinguished themselves in terms of validity. The LDI-HRA, the first of the morbidity-based HRAs, has also distinguished itself by its documented efficacy and its sensibly balanced approach to the needs of participants, physicians, and

payers. The HRA includes age specific and gender specific questions from which the response data generates an individualized Personal Health and Vitality Guide. Complementary tools include Health Risk Summary Sheet, Report Card and aggregate Corporate Vitality Reports for the group. These components are serial, both for the individual and the group, and are designed to track changes over time. Subsequent response data is measured, compared and linked with the prior data. Changes are shown in percentile risk scores and in the individualized paragraphs. Over 15 essential categories such as biometrics, screenings, lifestyle health habits, etc. are analyzed to create participants' risk profiles based upon diet, exercise, stress and other factors that inhibit current physical and mental activities and increase risk of future illnesses. It is important to note that although sequential administrations are useful measures of individual change, baseline administrations (or once only analyses) also offer meaningful opportunities to assess individual and group risk factors. The information can also be very valuable to respondents who are unaware of the severity of their current health status.

Biometrics: Blood Pressure, Glucose, and Lipids Biometric tests are important measures of health status and are routinely performed by licensed healthcare practitioners. For this study, a licensed Pharmacist conducted the assessments in the pharmacies during the interview and testing process. These lab values/readings are important components of the overall health risk assessment algorithm.

Blood Pressure was measured using the Auscultatory Method. A mercury-gravity reader and blood compression cuff was used with a stethoscope over the brachial artery to read systolic and diastolic blood pressure. Current JNC VII and American Diabetes Association (ADA) blood pressure goals are <140/90 mm Hg or <130/80 mm Hg for patients with diabetes or chronic kidney disease.

Hypertension, most commonly referred to as high blood pressure, is a major determinant of cardiovascular disease. The relationship between blood pressure and risk of cardiovascular events is continuous, consistent, and independent of other risk factors. The Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (current JNC VII) guidelines report that for individuals 40-70 years of age, each increment of 20 mm Hg in SBP (Systolic Blood Pressure) or 10 mm Hg in DBP (Diastolic Blood Pressure) doubles the risk of CVD (Cardiovascular Disease) across the entire blood pressure range from 115/75 to 185/115mm Hg. In persons older than 50 years, Systolic Blood Pressure (SBP) >140 mm Hg is a much more important CVD risk factor than Diastolic Blood Pressure (DBP).

Glucose and lipid values are obtained directly from a blood sample. Cholestek kits, which were used in this study, are among the most widely used population based testing products currently on the market. Blood samples are collected from the subject's fingertip, requiring only a small drop of blood to calculate glucose, LDL, HDL, and Triglycerides. Normal glucose concentration in the blood is 80 to 120 mg/dl. Normal/desirable total cholesterol value is <200 mg/dL. Normal/desirable LDL value is <130 mg/dL. Normal/desirable HDL value is >35 mg/dL. Normal/desirable triglyceride value is <150 mg/dL. These measures were recorded by the Pharmacist who conducted the screenings and were communicated privately to the subjects for sharing with their doctors.

Weight and Height Weight and height measures are variables assessed for inclusion in the health risk assessment, (Physical Health Section of the HRA, items 2 and 3). These measures are utilized in the Lifestyle Directions (LDI) algorithm to assess overall risk. Individuals who are 20% to 30% over average weight for their age, sex, and height are considered obese. This information is desirable but not essential for accurate assessment of risk.

Rating of adherence pharmacy record By agreeing to participate in this study, each subject provided consent for his/her pharmacy profile/history to be examined and documented within the parameters specified in the consent form. This entailed a chart review of the subject's pharmacy record to determine the prescriptions indicated for the control of hypertension that the subject had received within the previous 6 to 12 months. Because there is more than one class of drugs used for this purpose, it was necessary for the pharmacist to identify the universe of appropriate medications for examination. A list of the NDC codes for those medications with a documented, FDA approved indication for lowering blood pressure was compiled and used by the pharmacist who was conducting the chart reviews. The pharmacist asked the subjects if they were currently taking medications for blood pressure control (antihypertensive), and if so, which medications. The subjects were also asked to indicate the time when they were told initially by their physicians that they had high blood pressure (hypertension) as well as the time when they were first prescribed medications to control their blood pressure. The pharmacist recorded the subjects' responses on the spreadsheet and examined the patients' medication refill histories to determine the fulfillment ratio for their hypertension medications. The ratio was calculated by dividing the number of days dispensed (# of pills ÷ dosage) since first prescription by the number of days since first prescription. For purposes of this study, a ratio = 1 was interpreted as 100% adherence. Any ratio of <1 was interpreted as less than fully compliant. It was anticipated that the lower the fulfillment ratio, the higher the relative Blood Pressure of the subjects would be.

Procedure

Assembly of packets

Measures and forms were assembled into identical packets, consisting of the following materials necessary for each subject: (1) Informed Consent; (2) Health Adherence Behavior Inventory (HABIT); (3) Health Risk Assessment (HRA); (4) Subject Ticket for incentive drawing; and (5) Investigator assistant checklist of all necessary measures and dates of completion. (see Appendices A, B, C, and E) The checklist was provided for the pharmacist's benefit so that he and/or his assistants could quickly review each subject's packet for completion prior to data entry. Each packet, including all papers within the packet, was sequentially numbered to ensure that each respondent's data was confidential, yet were accurately captured and recorded in a consistent and ethical manner. A total of 300 packets were prepared.

Questionnaire Development

Through a comprehensive collection and review of relevant literature, the authors of the HABIT identified and selected the appropriate domains which were to be used. Items were chosen to represent the universe of non-adherent risk behaviors affecting health outcomes. The investigator solicited independent expert review to ensure that the domains adequately represented the universe of non-adherence. The expert panel was composed of two psychologists and two physicians, including an internist and a family physician. The final item pool of all potentially relevant and appropriate questions were refined and developed. (Appendix B) Experts were asked to place items in clear and understandable domains, (e.g., verbal monitoring) retaining only those items upon which 100% agreement was achieved. The questionnaire was developed and the items were randomly ordered.

Site Selection

A suitable population in which pharmacy claims data was accessible (such as a pharmacy) was identified, and three pharmacies were selected to screen and assess subjects. It was essential that the selected sites offered private screening areas where subjects could be interviewed and tested. It was also important that the subjects received all of their hypertension medications from the same pharmacy. The three pharmacies were owned and operated by a licensed Pharmacist in the State of Georgia, with additional licensure to perform cholesterol and glucose screening tests. Approval and cooperation by the identified organization was obtained to solicit subjects for participation in this study prior to initiating the study. The pharmacy was responsible for soliciting patients for participation, explaining the informed consent, performing the appropriate blood screening, weight and height measurements, ensuring that all questionnaires were completed, and examining and recording the subjects' prescription refill records.

The investigator developed a poster (Appendix D) to solicit participation and enrollment, as well as a Question and Answer Instruction Sheet (Appendix E) to which the pharmacist might refer when answering questions from interested patients. A consent form (Appendix A) was also developed to ensure informed consent was documented. A health risk assessment was selected for inclusion in the data (Appendix C). To facilitate participation, the investigator selected and offered an incentive to be offered to study participants.

IRB approval from Philadelphia College of Osteopathic Medicine was obtained.

Subject Recruitment

Two weeks prior to beginning the study, the principal investigator met with the pharmacist and his assistant in order to train them on the administration of the surveys; this was done to ensure complete understanding of the procedure. At that time, 300 packets which were prepared by the

investigator were provided to the Pharmacist (100 packets per pharmacy) ; a recruitment poster (Appendix D) was placed in each pharmacy indicating the nature, requirements, and timing of the study, along with a description of the incentive to participate. During this two week period, the pharmacist was instructed to use the Question and Answer Instruction Sheet (Appendix E) to respond to questions from prospective subjects. This form helped to ensure a consistent recruitment process by enabling the pharmacist and assistants to answer similar questions in the same manner. Within 2 weeks of placing the posters in the pharmacies, the Pharmacist advised the Investigator that pharmacy customers asked numerous questions, indicating that the posters and communication about the study were achieving the objective of generating interest about the study.

Once the study officially began, the potential subjects were randomly recruited (every 3rd eligible patient) from all patients who presented at the pharmacy with a prescription for hypertension over a 5 month period.(LASTING OVER A 5 MONTH PERIOD? HAD BEEN GETTING THE PRESCRIPTION FOR 5 MONTHS?) When a patient presented at one of the three pharmacies with an appropriate prescription, the individual was asked by the pharmacist or assistant if he/she would be interested in participating in the study. If the patient responded positively, the pharmacist/assistant probed the patient with additional questions to determine the individual's appropriateness for inclusion in the study. Interviews and tests were conducted in a private room within the pharmacy.

Subject Testing

After the pharmacist/assistant was assured that the subject met the study inclusion criteria, the subject received one of the packets with an Informed Consent Form explaining the study, a Health Risk Assessment, a Health Adherence Behavior Inventory (HABIT), a ticket for the incentive drawing, and biometric screenings (lab work). Each subject who agreed to participate in

the study was required to complete the HABIT and the Health Risk Assessment (HRA) questionnaire after signing the consent form. The investigator at the pharmacy site was responsible for ensuring that the questionnaires were answered completely. All data was gathered by the pharmacist and an assistant who was blinded to the study. Following completion of the questionnaires, the subject submitted to a full lipid panel and blood pressure screening, as well as height and weight measurement. The cholesterol test involved a tiny prick of the subject's finger to obtain a small blood sample. The sample was analyzed for cholesterol, glucose, and triglycerides. All blood testing, weight, and blood pressure measures were performed by a licensed healthcare provider at the pharmacy (satisfactory licensure documentation was provided to the principal investigator prior to initiation of the study). The healthcare provider shared results of the screening with the subject and offered general interpretation of the results. Subjects were provided with a hardcopy of their lab values and encouraged to share these results with their primary care physicians. Specific questions concerning lab results were referred to the subjects' physicians. Although all subjects were encouraged to share the results of their screening with their physicians, any subject whose results indicated that an urgent referral to a physician was warranted, would have been asked permission for the pharmacist to communicate directly with the subject's physician by telephone to communicate their results. No results were obtained which warranted such actions. Completion both of questionnaires and lab work took approximately 30 minutes for each subject.

Upon the receipt of completed materials, the pharmacist / assistant reviewed the responses for completeness, segregating those that were incomplete from completed questionnaires. When the pharmacist or assistant was satisfied that all items were complete, the subject was thanked for his or her cooperation and given a copy of the lab results.

Data Entry and Reporting

All data from completed questionnaires and lab work was entered into a spreadsheet database by an assistant blinded to the study. The HABIT and the Health Risk Assessment (HRA) were pre-numbered to correspond with each other (one unique identifier per questionnaire per subject which was administered at the same time). Responses from the HABIT and the HRA were entered by the pharmacy investigator assistant into a spreadsheet template which was provided to the pharmacy study site prior to the beginning of the study. Upon completion of the study, the pharmacist investigator assistant made copies of all questionnaires as well as copies of the completed spreadsheet containing all responses. One copy of all materials remained with the pharmacy until completion of the study, at which time they were to be destroyed. Each subject who agreed to participate in the study was required to complete both the HABIT questionnaire and the Health Risk Assessment after signing the consent form.

Completed HRA questionnaires were bulk shipped from the Pharmacy to LDI (Lifestyle Directions, Inc, Pittsburgh, PA.) for analysis. The vendor processed each HRA and provided the pharmacy assistant with individual HRA (%) scores for each participant. The subject was identified only by subject number. The HRA percentile (%) risk scores given by LDI to the pharmacy assistant were added to the spreadsheet database. LDI also generated individual reports for the study participants. This report, "the Personal Health and Vitality Guide", provided a customized health status report for each subject based upon his or her responses to the HRA. The health status reports were sealed in confidential envelopes and bulk shipped to the pharmacy for confidential distribution by the pharmacist during the patient's next visit to the pharmacy. The envelopes containing the personalized health status reports were opened only by the study participant. No identifiable personal information from these questionnaires or reports was shared with the pharmacist or his staff. This completed all data collection for this study.

The completed spreadsheet database was provided to the study investigator for final analysis. Responses from both questionnaires were compared with each other and with biometric measures of hypertension, cholesterol, glucose, and weight, as well as with the pharmacy records of refill for the identified prescription.

Statistical Analysis

Data for this psychometric study were collected and entered into a database (SPSS, Version 12.0). Descriptive statistics were examined. All data was analyzed, including frequency distribution, mean, median, standard deviation, and standard error. A Principal components varimax rotated factor analysis, and Cronbach's coefficient alpha reliability analysis, including corrected item total score correlation, correlation of scores on instrument, and various psychometric parameters were calculated.

CHAPTER 3

RESULTS

This study was conducted over the 5 month period, from January 1, 2004 through May 30th, 2004. A total of 93 subjects completed all requisite questionnaires and biometric screenings. All subjects were randomly selected from a population of hypertensive patients who presented with an antihypertensive prescription to be filled at one of 3 pharmacies in the metro Atlanta, Georgia area. Each subject was currently diagnosed with hypertension and fulfilled the study inclusion criteria of having an existing prescription for antihypertensive medication for a minimum of 6 months prior to entering the study. In all, 89 (95.6%) of the subjects had been diagnosed with hypertension for more than 12 months and 4 subjects had been diagnosed with hypertension for between 6 and 12 months. English was the first language of each subject and all subjects were able to read at a minimum 8th grade reading level, in accordance with study inclusion criteria. Participation was voluntary, and a signed, informed consent was obtained from each subject. Subjects could remove themselves from the study at any time. Also, in accordance with exclusion criteria, none of the subjects who completed the study was institutionalized, hospitalized, or currently participating in any other studies or disease management programs.

Data collected for this study were entered into the statistical software SPSS (Statistical Program for the Social Sciences, version 12.0). The database was doubled keyed to ensure accuracy and statistics were computed for all variables. The following tables and discussion represent the final results and include the descriptive statistics and relevant factor analyses which address the variables of interest and hypotheses of this study.

Descriptive Statistics

Of the 93 subjects who volunteered to participate in this study, 17 subjects were males (18.3%) and 76 subjects were females (81.7%). A total of 73 (78.5%) of the subjects were Caucasian, 12 (12.9%) were African-American, and 8 (8.6%) were classified as "Other". The average age of this population was 59.5 years. The majority of subjects, 62 (66.6%), had completed at least a high school education and within this group 28 (30.1%) also completed some level of college or beyond. Of those who reported marital status, there were 20 (21.5%) married individuals in the study, 18 (19.4%) divorced subjects, 22 (23.7%) single subjects, and 29 (31.2%) widows/widowers. Three of the subjects (3.2%) were working on a full-time, permanent basis. The majority of subjects (58.1%) had previously retired and the remaining (38.79%) participants were otherwise employed or disabled. All 93 subjects were insured with both medical and pharmaceutical health benefits. Of these, 48 (51.6%) had a benefit that required less than a $30 co-pay to fill a prescription; 36 (38.7%) had a co-pay benefit requiring less than a $20 co-pay per prescription refill. The remaining 9 subjects had no co-pay for prescription drugs.

Responses to the HABIT

All 93 subjects (100%) in this study fully completed the Health Behavior Inventory (HABIT), as well as biometric screenings. The HABIT consists of 50 items that describe ordinary health behavior "habits", such as getting annual physical exams, wearing sunscreen, exercising and using seatbelts. Subjects responded "true" if the described behavior generally matched their own behavior and "false" if they disagreed that the described behavior was similar to their own. Table 1 represents the frequency distribution of all variables (50 items) included on the HABIT. Three

items identified are reverse scored, meaning that for a particular behavior, a positive response is "false". These statements/behaviors include "People tell me I am a Couch Potato"; I do not take prescribed medicines as directed"; and "I eat meals while doing other things." If a subject agreed with these statements and responded "true", the behavior would not be considered a "positive health behavior". Rather, this would be considered a "negative health behavior", and analyzed accordingly.

All items are presented in descending order of positively endorsed response. From this data it is clear that nearly all (96.8%) of the subjects reported that they followed their physicians' advice. Specifically, they reported that they tended to keep their physician appointments, were punctual, obtained ordered medical tests, and filled their prescriptions promptly. Items less frequently endorsed included behaviors related to exercise, such as taking stairs over elevators/escalators (25.8%); practicing relaxation or meditation exercises (32.3%); lifting weights (10.8%); and jogging (3.2%). This may be related to the relatively older average age of the study group (59.5 years), which implications are discussed later in more detail.

Biometric Results

Biometric screenings were conducted by a licensed healthcare practitioner for each subject, including blood pressure, total blood cholesterol, high-density lipoproteins (HDL), low-density lipoproteins (LDL), triglycerides, and glucose (random or fasting). These values were immediately communicated to the subject by the practitioner. There were 10 subjects in whom the systolic blood pressure was above 160 and/or the diastolic blood pressure was above 90; these subjects were queried thoroughly about their "normal" blood pressure readings, their medications, and the frequency of their physician visits. Similarly, in 36 subjects whose total blood cholesterol measures exceeded 200, and/or LDL values were obtained higher than 170, participants were asked additional

questions to assess urgent risk. This additional assessment involved questions related to diet (in particular, immediately prior to the screening to assess accuracy of reading), as well as to existing medication regimen, and to the patient's last physician encounter. If, in the pharmacist's professional opinion, the lab results warranted immediate follow-up for the patient, the pharmacist would have asked the patient for permission to speak with his/her physician. However, based upon these subjects' responses, it was determined that none of the lab values obtained by the healthcare provider were considered to present an immediate danger to the subjects; therefore, no call from the pharmacist to the subject's physician was warranted. However all subjects were strongly encouraged to share their lab results with their primary care physicians for follow-up.

Tables 2 and 3 provide the Systolic and Diastolic blood pressure values, frequency distributions, and cumulative percentages for all subjects tested. The Systolic Blood Pressure was found to be significantly negatively correlated to the HABIT , (-.177*), i.e., the lower the systolic blood pressure the higher the HABIT score.

The additional biometric measures referenced in Table 4 were not specific to the study hypotheses. Only hypertension, (blood pressure ratios), were metrics of interest for this adherence study. However, the lab values for cholesterol, triglycerides, and glucose were important metrics for calculating the subject's overall health risk and were desirable for more accurate processing of the Health Risk Assessment. Table 4 provides the minimum, maximum, mean, and standard deviation for all biometric measures.

Table 1
Health Adherence Behavior Inventory, Frequency Distribution

Behavior	Percentage with positive response
Keep doctor's appointments I make	98.9%
Arrive on time for physician appointments	98.9%
Obtain tests when ordered by a physician	96.8%
Get medication prescriptions from physician filled promptly	96.8%
Take a logical approach to problem solving	94.6%
Take prescribed medications for recommended period	94.6%
Follow advice of physicians	93.5%
Follow doctor's advice on health matters	93.5%
Wear seat belts in cars	92.5%
Take all medications as directed by doctor	92.5%
Get routine physical exams	92.5%
Sit in non-smoking public places	90.3%
Avoid excessive use of alcohol	89.2%
Able to keep a realistic view of stresses	89.2%
Do not chew tobacco	88.2%
Successfully cope with most stresses	88.2%
Routinely examine skin for unusual markings	83.9%
Limit amount of fat in diet	83.9%
Try to eat low cholesterol foods	83.9%
Avoid cigarette smoke	82.8%
Limit amount of caffeine consumed	82.8%
Limit salt intake	82.8%
Avoid people who smoke	81.7%
Eat enough fruits and vegetables	79.6%
Examine breasts or testicles for lumps	79.6%
Limit amount of sugar in diet	78.5%
Try to sleep at least 8 hours each night	76.3%
Get enough emotional support if stressed	76.3%
Usually eat 3 meals a day	73.1%
Drink low fat or skimmed milk	72.0%
Watch calories carefully	71.0%
Go to bed at a regular time each night	69.9%
Get enough rest each night	69.9%
Test smoke alarms regularly	68.8%
Ask friends not to smoke in my presence	66.7%
Avoid napping during the day	64.5%
Am physically active	62.4%
Avoid fast food restaurants	60.2%
Weigh myself on a regular basis	60.2%
Avoid snacking between meals	53.8%
Exercise on a regular basis	50.5%
Prefer to walk rather than drive if possible	47.3%
Wear sun screen on sunny days	35.5%
Eat meals while doing other things	34.4%
Practice formal relaxation or meditation exercises	32.3%
Take stairs over elevator/escalator	25.8%
Do not take prescribed medicines as instructed	14.0%
Lift weights	10.8%
Am told by people that I am a "couch potato"	9.7%

Jog or run	3.2%

Table 2
Systolic Blood Pressure Values, Frequency Distributions, and Cumulative Percentages

Systolic Blood Pressure	Frequency	Percentage	Cumulative Percent
108	2	2.1%	2.1%
110	2	2.1%	4.2%
118	6	6.5%	10.7%
120	2	2.1%	12.8%
122	5	5.4%	18.2%
124	2	2.1%	20.3%
126	1	1.1%	21.4%
128	3	3.3%	24.7%
130	6	6.5%	31.2%
132	7	7.5%	38.7%
134	1	1.1%	39.8%
136	2	2.1%	41.9%
138	9	9.7%	51.6%
140	9	9.7%	61.3%
142	4	4.3%	65.6%
148	4	4.3%	69.9%
150	4	4.3%	74.2%
152	3	3.3%	77.5%
154	2	2.1%	79.6%
158	5	5.4%	85.0%
160	2	2.1%	87.1%
162	2	2.1%	89.2%
164	2	2.1%	91.3%
168	2	2.1%	93.4%
170	3	3.3%	96.7%
172	1	1.1%	97.8%
185	1	1.1%	98.9%
189	1	1.1%	100.0%

Table 3
Diastolic Blood Pressure Values, Frequency Distributions, and Cumulative Percentages

Diastolic Blood Pressure	Frequency	Percentage	Cumulative Percent
50	2	2.2%	2.2%
60	2	2.2%	4.4%
62	2	2.2%	6.6%
64	3	3.2%	9.8%
68	2	2.2%	12.0%
70	4	4.3%	16.3%
72	9	9.7%	26.0%
74	5	5.3%	31.3%
75	3	3.2%	34.5%
76	4	4.3%	38.8%
78	7	7.6%	46.4%
80	16	17.1%	63.5%
82	11	11.7%	75.2%
84	4	4.3%	79.5%
86	4	4.3%	83.8%
88	5	5.3%	89.1%
90	4	4.3%	93.4%
94	2	2.2%	95.6%
96	2	2.2%	97.8%
100	2	2.2%	100.0%

Table 4
Biometric measures of Blood Pressure, Cholesterol, Triglycerides and Glucose, Minimum, Maximum, Mean and Standard Deviation

Measure	Minimum	Maximum	Mean	Standard Deviation
Systolic BP	108	189	138.2	21.2
Diastolic BP	50	100	78.8	8.6
Total Cholesterol	109	460	195.9	47.8
HDL	20	91	49.6	15.4
LDL	31	209	100.8	36.1
Triglycerides	30	650	224.8	101.5
Glucose	64	284	130.0	44.8

Responses to the Health Risk Assessment (HRA)

As previously mentioned, the validated Health Risk Assessment by Lifestyle Directions, Inc. (LDI) was utilized in this study to establish construct validity for the HABIT questionnaire. Individuals who are at greater risk for disease score higher on the HRA than low risk respondents. This is reflected in an "Overall Health Risk" percentile score. The questionnaire includes 113 items, including a comprehensive medical history, dietary habits, personal habits, laboratory values, medication usage, and attitudes on health. The overall "health risk" score is calculated using the Lifestyle Directions proprietary algorithm, which provides a relative measure of the respondent's likelihood of developing or exacerbating serious health conditions and compromising quality of life. A total of 89 subjects (95.7%) completed all items on the HRA. A few individuals did not respond to all items. The items most frequently missed included waist and hip measurements, attitudes on exercise, and attitudes towards health in general. These missing data do not compromise the integrity of the overall health risk score. The algorithm is designed to account for these missing responses.

Table 5 provides the frequency distribution of all subjects' responses to the medical history portion of the HRA. In this section subjects are asked if they or anyone in their immediate families (parents or siblings) has/had the specified diseases or conditions, which may predispose the individual to develop similar symptom(s) or condition(s). Consistent with national averages, the most prevalent conditions included various forms of heart disease, diabetes, and musculoskeletal disorders. This is particularly noticeable in a population such as this in which the average age was 59.5 years. Over 33% (31) of the subjects also reported depression, for themselves and/or in their immediate families, including 24 subjects (25.8%) who indicated that they were depressed themselves. Data is presented in descending order of frequency of overall prevalence within families. Although hypertension is not specifically referenced in the Health Risk Assessment as an independent diagnosis, the association between hypertension and other conditions such as

hyperlipidemia, heart disease and stroke is well established. Thus the prevalence of these conditions would not be unexpected in a population which was designed to include subjects with a diagnosis of hypertension.

Table 6 provides, in descending order, the frequency distribution of all subjects' responses to the HRA questions related to dietary habits. Subjects were asked to report how many servings of the listed foods they ate in a typical day; the possibilities ranged from 1 to 5 servings. Greater consumption of fruits, vegetables and fiber, combined with lesser consumption of fats, oil, salt and sweets, contributes to a reduced risk for serious disease. A minimum of 2 servings per day per category is considered significant in the HRA algorithm.

Table 5 Health Risk Assessment (HRA)
Medical History, Frequency Distributions, and Percentages

Disease	Subject who reported Disease in Self, Parent or Sibling	Percentage	Subject reported condition in self	Percentage
Heart Attack	88	94.6%	85	91.4%
Arthritis	66	70.9%	55	59.1%
High Cholesterol	48	51.6%	43	46.2%
Diabetes	42	45.2%	24	25.8%
Heart Disease	41	44.1%	17	18.3%
Back Pain	40	43.0%	36	38.7%
Stroke	36	38.7%	16	17.2%
Allergies	33	35.5%	28	30.1%
Depression	31	33.3%	24	25.8%
Thyroid Disease	31	33.3%	24	25.8%
Osteoporosis	26	27.9%	23	24.7%
Gallstones	23	24.7%	15	16.1%
Skin Cancer	22	23.6%	14	15.1%
Heart Failure	21	22.5%	6	06.5%
Lung Cancer	16	17.2%	1	01.1%
Migraine	16	17.3%	10	10.8%
Alcoholism	15	16.1%	6	06.5%
Emphysema	14	15.1%	4	04.3%
Alzheimers	12	13.0%	2	02.2%
Asthma	11	11.8%	7	07.5%
Breast Cancer	10	10.7%	3	03.2%
Kidney Disease	10	10.7%	4	04.3%
COPD	9	9.7%	5	05.4%
Hepatitis	9	9.6%	6	06.5%
Rectal Polyps	9	9.6%	6	06.5%
Other Cancer	8	8.6%	3	03.2%
Colon Cancer	7	7.5%	3	03.2%
Seizures	7	7.5%	3	03.2%
Stomach Cancer	6	6.4%	1	01.1%
Drug Dependency	5	5.4%	3	03.2%
Parkinsons	4	4.3%	0	0%
Liver Disease	3	3.2%	2	02.2%
Uterine Cancer	3	3.3%	2	02.2%
Prostate Cancer	2	2.2%	1	01.1%
Ovarian Cancer	1	1.1%	0	0%
AIDS	0	0%	0	0%
Liver Cancer	0	0%	0	0%

Table 6 Health Risk Assessment (HRA)
Dietary Habits, Frequency Distributions, and Percentages

Food Category	Minimum 2 servings/day	Percentage
Fiber	76	81.7%
Vegetables	61	65.6%
Meat, Fish, Poultry, Beans	48	51.6%
Fruits	48	51.6%
Breads, Cereals, Rice, Pasta	45	48.4%
Dairy (milk, yogurt, cheese)	43	46.2%
Fats, Butter, Oils, Sweets	40	43.0%
Salt	12	12.9%

In addition to dietary habits, subjects were asked on the HRA to report their use of tobacco, including cigarettes and all other forms, such as chewing tobacco, pipe, etc. Reported tobacco use was minimal, with 71 (88.8%) subjects reporting no tobacco use of any kind and 9 (9.6%) respondents indicating less than one/half a pack per day. When asked about former habits, 24 subjects (25.8%) reported being former smokers; the average time since quitting was 13.5 years (across all 24 subjects).

Other information captured on the HRA included details related to existing medications taken by the subjects. Table 7 presents, in descending order, data on medication usage; it also includes a list of chronic diseases, and the medications necessary to control those diseases. Subjects were asked to check all conditions for which they currently take (or are advised to take) medications.

Table 7
Health Risk Assessment (HRA) Medication Usage Frequencies and Percentages

Disease/Condition	Number of Patients current taking medication	Percentage
Hypertension	93	100.0%
High Cholesterol	37	39.8%
Arthritis	31	33.3%
Calcium Supplement	27	30.3%
Diabetes	23	24.7%
Thyroid Condition	21	22.8%
Back Pain	18	19.4%
Digestive Problems	15	16.3%
Heart Problems	15	16.1%
Osteoporosis	12	13.0%
Allergies	7	7.5%
Asthma	7	7.5%
Lung Problems	5	5.4%
Seizure	4	4.3%
Weight Control	2	2.2%

Items which focused on stress levels, exercise, sleep, and preventive health habits were also included on the HRA. Because this instrument is designed to project an accurate assessment of the respondents' risks for negative health consequences, the level of detail and questioning concerning adherence to preventive health tests is extensive. The HRA section which captures preventive screening exams includes periodic tests such as mammograms, prostate exams, colonoscopies, etc. Table 8 displays the respondents' self-reported history of preventive exams for colorectal disease.

Table 8 Health Risk Assessment (HRA)

Frequency of screening, percentage, and cumulative percent of exams for colorectal disease

Colorectal Cancer Screening	Frequency	Percentage	Cumulative Percent
Within last year	22	23.7%	23.7%
1 year ago	5	5.4%	29.1%
2 years ago	8	8.6%	37.7%
3-5 years ago	17	18.3%	56.0%
Over 5 years ago	6	6.5%	62.5%
Never	35	37.5%	100.0%

As Table 8 shows, 44% of respondents indicated that they had not complied with national guidelines for obtaining a colon cancer screening test within the previous 5 years (based upon average age of respondents). Interestingly, all 93 (100%) respondents reported a fecal occult blood test within the previous 5 years, suggesting that perhaps the less invasive test is considered equivalent, and thus other tests (?) are avoided. Similarly, only 42 (47.2%) of the subjects indicated they had been screened for Diabetes within the prior 24 months, in spite of the fact that over 45% reported a history of diabetes within the immediate family. Tables 9 through 12 provide frequency, percentage and cumulative percent regarding adherence to additional screening guidelines specific to older men and women, including last mammogram, cervical exams, prostate cancer screening, and self exams for which nationally recommended guidelines currently exist. The mammogram and self-exam screening procedures reflect greater compliance rates of the more unpleasant screening exams such as pap smears and prostate exams.

Table 9 Health Risk Assessment (HRA)
Preventive Mammogram, Frequency Distributions, and Cumulative Percentages

Last Mammogram	Frequency	Percentage	Cumulative Percent
Within last year	42	56.8	56.8
1 year ago	9	12.2	69.0
2 years ago	10	13.4	82.4
Over 3 years ago	9	12.2	94.6
Never	4	5.4	100.0

Table 10 Health Risk Assessment (HRA)
Preventive Pap Exam, Frequency Distributions, and Cumulative Percentages

Last Pap Smear	Frequency	Percentage	Cumulative Percent
Within last year	23	31.1	31.1
1 year ago	17	23.0	54.1
2 years ago	11	14.8	68.9
Over 3 years ago	20	27.0	96.0
Never	3	4.1	100.0

Table 11 Health Risk Assessment (HRA)
Preventive Prostate Cancer Screening, Frequency Distributions, and Cumulative Percentages

Last Prostate Exam	Frequency	Percentage	Cumulative Percent
Within last year	8	50.0	50.0
2 years ago	1	6.2	56.2
Over 3 years ago	5	31.3	87.5
Never	2	12.5	100.0

Table 12 Health Risk Assessment (HRA)
Preventive Self Exam (Breasts/Testicles), Frequency Distributions, and Cumulative Percentages

Last Self Exam	Frequency	Percentage	Cumulative Percent
Monthly	48	51.6	51.6
Every few months	18	19.4	71.0
Rarely/Never	20	21.5	92.5
Don't Know	7	7.5	100.0

As captured in the HRA data, 56 (60.2%) of the subjects reported that they engaged in some form of exercise at least 3 times each week. Of these, 44 (47.3%) indicated that they exercise for at least 20 minutes per exercise session. The exact nature or definition of exercise was not captured. A more specific exercise question on the HRA, such as strength training, was endorsed by 19 subjects (20.4%).

Overall, a total of 90 participants (97.8%) reported on the HRA that they always use their seatbelts. Of those who responded to a similar question of safety behavior on the HRA, 23.2% said they sometimes drive more than 10 miles over the speed limit.

With respect to sleep, 54 subjects (58.0%) reported on the HRA that they slept fewer than 8 hours per night. Alcohol consumption was minimally endorsed, with 86% of respondents to the HRA indicating no use of alcohol, and of those who did endorse consumption, 100% indicated at least 2 drinks per occasion.

Regarding anxiety, 40.5% of respondents to the HRA reported feeling anxious at least 2-3 times per week, but 76.3% endorsed "getting enough emotional support if stressed".

Factor Analysis of the HABIT

In order to perform a factor analysis of all 50 items on the HABIT questionnaire, the original study protocol planned to recruit 300 subjects into the study (a multiplier of 6). At the end of a 4 month recruiting period, a total of 93 subjects had completed participation in the study. Although this was fewer than desired, the cost of recruiting and testing 93 subjects exceeded $11,000. The original budget of $10,000 was based upon six weeks of estimated time and labor by the pharmacist and his staff. In consideration of the time, difficulty, and considerable cost of recruiting additional subjects, it was jointly decided to end the study with a total of 93 subjects. Such a limited number of subjects precluded establishing construct validity readily because of low

subject to item ratio. It was therefore determined that an initial inverse cluster analysis would be performed to determine Average Linkage between Groups.

The hypothesis presumed that the HABIT questionnaire would produce 8 distinct domains related to non-adherence. Because of the problem with the subject to item ratio, cluster analysis was used as an alternative to Factor Analysis of the HABIT. Using the Average Linkage Between Groups Method, cluster analysis was restricted to 8 clusters. During the cluster analyses the investigators discovered that 2 interpretable clusters emerged (Cluster 1 with 36 items and Cluster 8 with 3 items). When the clusters were identified, scores were calculated for the clusters, which were treated as 2 domains. Cluster scores were determined for each subject. There were then 2 scores for each subject, resulting in an acceptable subject to item ratio. A principal components varimax rotated analysis according to Kaiser's criterion was performed. The two clusters merged into one higher order factor, leading the investigators to the conclusion that Cluster 1 and Cluster 8 loaded on a single "HABIT Factor". The HABIT cluster analysis is displayed in Table 13.

Table 13
HABIT Cluster Analysis

Case	8 Clusters
Avoid people who smoke	1
Try to sleep 8 hours	1
Avoid cigarette smoke	1
Watch calories carefully	1
Test smoke alarms regularly	1
Obtain tests ordered by my doctor	1
Take logical approach to problem solving	1
Examine skin for unusual markings	1
Wear seat belts in cars	1
Take all prescriptions as directed by doctor	1
Eat enough fruits and vegetables	1
Get enough emotional support if stressed	1
Limit amount of caffeine consumed	1
Usually eat 3 meals a day	1
Avoid excessive use of alcohol	1
Ask friends not to smoke in my presence	1
Limit sugar intake	1
Get prescriptions filled promptly from doctor	1
Drink low fat or skimmed milk	1
Examine breasts or testicles for lumps	1
Get routine physical exams	1
Successfully cope with most stresses	1
Keep doctor's appoints I make	1
Follow advice of my physician	1
Limit amount of fat in diet	1
Able to keep a realistic view of stresses	1
Am on time for doctor appointments	1
Take prescribed medication for recommended period	1
Sit in non-smoking public places	1
Try to eat low cholesterol foods	1
Follow doctor's advice on health matters	1
Limit salt intake	1
People tell me I am a couch potato	1
Do not take prescribed medicines as instructed	1
Go to bed at regular time each night	1
Get enough rest each night	1
Avoid napping in day	2
Weigh myself on a regular basis	2
Eat meals while doing other things	3
Lift weights	4
Take stairs over elevator or escalator	4
Don't chew tobacco	4
Jog or Run	4
Practice formal relaxation/medication exercises	5
Wear sun screen on sunny days	5
Avoid fast food restaurants	6
Avoid snacking between meals	7
Exercise on a regular basis	8
Prefer to walk rather than drive if possible	8

Am physically active	8

As displayed in Table 13, Cluster 1 included 36 items. The reliability coefficient of Cluster 1 was .6953 (Chronbach's Alpha). Items in this Cluster, referred to as the overall Prevention Cluster, included preventive health habits such as performing routine self exams, getting sufficient sleep, avoiding tobacco products, eating low fat diets and limiting intake of salt, alcohol, and caffeine. Items related to coping with stress and following instructions (particularly physician's orders) were also included.

Cluster 8 (the second interpretable Cluster), referred to as the Exercise Cluster, included 3 items that were focused on physical exercise, i.e. "I exercise on a regular basis", "I prefer to walk rather than drive if possible", and "I am physically active". The reliability coefficient of Cluster 8 was .6505 (Chronbach's Alpha).

Collectively, these 39 items represent a Higher Order Factor. Both Clusters and the Higher Order Factor revealed a significantly negative correlation with the Overall Health Risk score derived from the HRA. This leads to the conclusion that the higher the HABIT score, (or the more positive health behaviors that the subject endorses), the lower his/her overall health risk and the less likely he/she is to experience hospital stays or to have high blood pressure or other diseases. Specific correlations between the HABIT and overall health risk (HRA % Risk Score) are displayed in Table 14.

Table 14
Pearson Inter-correlations between the HABIT, Health Risk Score, Adherence Ratio, and Number of Medications

		HRA% Risk Score	CLUS 1	CLUS 8	ADHRATIO
HRA % Risk Score	Pearson Correlation	1	-.388**	-.400**	-.054
	Sig. (1-tailed)	.	.000	.000	.321
	N	77	77	77	77
CLUS 1	Pearson Correlation	-.388**	1	.398**	-.139
	Sig. (1-tailed)	.000	.	.000	.092
	N	77	93	93	93
CLUS 8	Pearson Correlation	-.400**	.398**	1	-.123
	Sig. (1-tailed)	.000	.000	.	.121
	N	77	93	93	93
ADHRATIO	Pearson Correlation	-.054	-.139	-.123	1
	Sig. (1-tailed)	.321	.092	.121	.
	N	77	93	93	93
NUMMEDS	Pearson Correlation	-.088	.048	-.047	.119
	Sig. (t-tailed)	.228	.328	.334	.136
	N	74	87	87	87
HIORDRNU	Pearson Correlation	-.437**	.970**	.610**	-.153
	Sig. (1-tailed)	.000	.000	.000	.072
	N	77	93	93	93

CLUS 1 = Prevention Cluster
CLUS 8 = Exercise Cluster
ADHRATIO = Adherence Ratio
NUMMEDS = Number of Medications taken
HIORDRNU = Higher Order Factor
HRA % Risk Score = Overall Health Risk result from HRA

** Correlation is significant at the 0.01 level (1-tailed).
* Correlation is significant at the 0.05 level (1-tailed).

As seen in Table 14, Cluster 1 (representing 36 items identified as the Prevention Cluster) is significantly, negatively correlated (-.388**) to overall Health Risk (HRA % Risk Score). This strong negative correlation was anticipated on the intuitive hypothesis that a lower risk for disease and/or poor health would be associated with increasingly positive preventive health behaviors (higher score on the HABIT). This is consistent with the increasingly significant negative correlations between Cluster 8 (representing 3 items identified as the Exercise Cluster) and the HRA

Overall Health Risk Score (-.400**), and the derived Higher Order Factor (HIORDRNU) with the HRA Overall Health Risk Score (-.437**).

Examining the relationship between the Higher Order Factor of the HABIT and the HRA Overall Health Risk Score, it is possible to interpret the fact that approximately 19% of the variability in health risk assessed by the Lifestyle Direction's Health Risk Assessment (HRA) is attributable to differences in health behaviors as measured by the Health Adherence Behavior Inventory (HABIT).

Correlation between the HABIT, the Health Risk Assessment and Biometric Variables

It was predicted that a negative correlation would be reflected between the number of self-reported, positive health behaviors on the HABIT and blood pressure level recorded on the Health Risk Assessment. This hypothesis was partially supported by a significant negative correlation between Systolic Blood Pressure and the Higher Order Factor of (-.177*) at a 0.05 significance level (1-tailed), suggesting that the more positive health behaviors an individual endorses (as reflected on the HABIT), the lower his/her systolic blood pressure. Table 15 highlights significant correlations between the HABIT and other variables, including biometric measures and self-reported data offered by the Health Risk Assessment (HRA). Most notable in these statistics is a significant negative correlation (-.247**) between the HABIT Factor and self reported servings of fats, butter, oil, and sweets in a typical day. The subjects who endorsed more healthy behaviors on the HABIT were less likely to consume excessive calories in fatty foods. There was also a strong negative correlation between the HABIT Factor and feeling anxious, (-.304**). The more frequently the individual reported that he/she was anxious, the less likely he/she was to endorse positive health behaviors presented in the HABIT. A similar significant correlation (-.391**) was found between the HABIT Factor and the respondent's last reported colorectal screening exam. Additional similarities were

observed between numerous items on the HRA and the HABIT, with statistically significant correlations. These similarities are presented more fully in the Discussion of this study.

Table 15
Correlations of HABIT with Health Risk Assessment and Biometric Variables

		HABIT Cluster 1	HABIT Cluster 8	HABIT Higher Order
Current self rating of health	Pearson Correlation	-.158	-.252**	-.158
	Sig. (1-tailed)	.066	.008	.066
	N	93	92	92
Current weight self reported	Pearson Correlation	.071	-.220*	.071
	Sig. (1-tailed)	.255	.019	.255
	N	89	89	989
No. days hospitalized for injury in past 12 months	Pearson Correlation	-.158	.199*	-.158
	Sig. (1-tailed)	.079	.037	.079
	N	81	81	81
No. days went to ER due to injury in past 12 months	Pearson Correlation	-.216*	.177	-.216*
	Sig. (1-tailed)	.025	.056	.025
	N	82	82	82
Systolic Blood Pressure	Pearson Correlation	-.177*	.117	-.177*
	Sig. (1-tailed)	.049	.136	.049
	N	93	93	93
No. Servings fats, butter, oil, sweets in typical day	Pearson Correlation	-.289**	-.054	-.289**
	Sig. (1-tailed)	.003	.308	.003
	N	90	90	90
Consumption of fiber in diet	Pearson Correlation	-.248**	-.051	-.248**
	Sig. (1-tailed)	.008	.314	.008
	N	93	93	93
Last screening for colorectal cancer	Pearson Correlation	-.391**	-.228*	-.391**
	Sig. (1-tailed)	.000	.016	.000
	N	89	89	89
Avg times per week exercise	Pearson Correlation	.251*	.426**	.251*
	Sig. (1-tailed)	.012	.000	.012
	N	80	80	80
Avg times per week strength training	Pearson Correlation	.163	.256*	.163
	Sig. (1-tailed)	.140	.043	.140
	N	46	46	46
How often you feel anxious	Pearson Correlation	-.304**	-.328**	-.304**
	Sig. (1-tailed)	.004	.002	.004
	N	74	74	74
Avg No. cigarettes Per day	Pearson Correlation	-.346**	-.266**	-.346**
	Sig. (1-tailed)	.001	.009	.001
	N	80	80	80
Currently taking Rx for Diabetes	Pearson Correlation	-.178*	.002	-.178*
	Sig. (1-tailed)	.044	.492	.044
	N	93	93	93
Currently taking Rx for Thyroid	Pearson Correlation	-.190*	-.161*	-.190*
	Sig. (1-tailed)	.044	.061	.044
	N	93	93	93

CHAPTER 4

DISCUSSION

Considerable time and effort has been dedicated to the study of non-adherence and to the implications of this issue for all stakeholders in the healthcare delivery system. The vast majority of research studies have focused on attempting to understand and to define the key influencers of this phenomenon. This knowledge has demonstrated utility in the development of specific interventions which appear to improve adherence, under certain circumstances for various subsets of the population. Translating this knowledge into a comprehensive set of questions that represent discrete domains of non-adherence has proven to be more challenging. Given the complexity of the issue of non-adherence and the number of factors that may influence a particular patient at any given point in time, it is not surprising that no reliable instrument has yet been developed to predict, with any accuracy, a given individual's likelihood of adhering to his or her prescribed treatment by a healthcare provider. As such, the HABIT represents a new approach to addressing this challenging issue and the first of its kind to attempt to predict non-adherence based upon a universe of behaviors not previously observed to be related statistically. The principal research question for this study was the viability of developing a brief questionnaire which could be used to predict the relative degree of adherence by a patient with his/her physician's treatment orders. This was the first study to examine the validity of the Health Adherence Behavior Inventory as a reliable instrument for this purpose. The investigators of this study hypothesized that similar patients who are not compliant with prescribed treatment regimens, specifically adherence to medication, would be identifiable by a profile of behavioral characteristics captured through a systematic approach of questioning with self-reported responses to a dichotomous questionnaire.

The findings of this study are interesting because they offer support for the hypothesis that a finite number of items may ultimately be isolated to offer a practical and efficient approach to prospectively identifying patients whose health outcomes may be compromised by suboptimal treatment adherence. The Health Adherence Behavior Inventory offers additional insight about the specific types of behaviors that appear to be related consistently to overall health. The results presented in this study suggest that healthier patients do, indeed, engage in or refrain from certain behaviors which collectively reveal a pattern of habits that correlate significantly with their individual degrees of health risk. The individuals who endorse greater the number of positive health behaviors have lower individual overall health risks. Based upon this finding, it would be logical to expect that the relative risk of poor health would also be correlated significantly with the patient's adherence to medication, as measured by an adherence rate or possession ratio. Simply stated, medication adherence would be viewed as a positive health habit. Thus the less compliant patients are with treatment (taking their medications), the greater their risk of serious illness and the less likely they are to endorse other positive health habits. Interestingly, data from this study did not reveal a statistically significant relationship between the Health Risk Score as calculated by the Health Risk Assessment and the overall medication adherence ratio. No significant correlation between the HABIT and overall medication adherence ratio was observed. However, results of this study did reveal that the HABIT was significantly negatively correlated with a measure of systolic blood pressure at the 0.05 significance level (-.177*) and significantly negatively correlated at the 0.01 significance level with an overall health risk score as measured by the Health Risk Assessment (-.437**). The higher the individual scored on the HABIT, the lower their recorded systolic blood pressure and the relative risk of disease. Investigators concluded that approximately 19% of the variability of health risk was attributable to differences in health behaviors as measured by the HABIT.

Content Validity of the HABIT

The Health Adherence Behavior Inventory was designed to possess content validity. Prior to implementing the study, a panel of Physician Experts and Psychologists examined these items for relevance, clarity, and ease of understanding. The Expert Panel members agreed to review the items and were given the opportunity to revise items. All recommendations from the Expert Panel were integrated into the final list of items and resubmitted to the Panel for final review. 100% of the Panel agreed that these items adequately represented the domain of content related to adherence and health risk behaviors. The Expert Panel included Robert DiTomasso, Ph.D, ABPP, Interim Chair, Department of Psychology, Director of Clinical Research, Philadelphia College of Osteopathic Medicine with 25 years of practice as a Psychologist in Primary Care; Harry Morris, D.O., MPH, with 4 years as Chair Family Medicine and Director of Family Medicine Residency at Philadelphia College of Osteopathic Medicine with over 20 years practice in Primary Care; James Gamble, M.D.; and Barbara Golden, Psy.D., Faculty with Department of Psychology, Philadelphia College of Osteopathic Medicine.

Construct Validity of the HABIT

In order to establish construct validity, the HABIT questionnaire was administered concurrently with a well documented and validated Health Risk Assessment. A strong correlation between these two instruments would suggest not only that the construct of the HABIT is sound insofar as the instruments are purported to have similar utility, but also that the HABIT measures what it is intended to measure. The Health Risk Assessment algorithm produces a single overall health risk score. This study found a significant correlation at the 0.01 significance level between

the health risk score and the HABIT. Additionally, the study of the HABIT has yielded 2 interesting findings. First, the HABIT questionnaire appears to capture one overall factor or dimension of health risk. That is, the HABIT represents a single domain of health behaviors that are significantly correlated with risks for poor health. Although this finding in itself does not offer a comprehensive set of the domains that influence non-adherence, the emergence of a single domain that correlates with health risk is important because non-adherence has been found consistently to be a significant contributor to poor health outcomes and elevated risks. The link between blood pressure control, health risk, and medication compliance in a hypertensive population is well established. Second, the absence of a statistically significant correlation between the HABIT and the recorded medication adherence ratio for these subjects raises worthwhile questions concerning methodological limitations of this study and introduces opportunities for refinement of the items in future research.

Additional Findings Related to the Health Risk Assessment

As previously discussed, the Lifestyle Directions instrument is a widely used health risk assessment that has been extensively studied. Thus other significant correlations were evident during this analysis on an item by item basis. For example, individuals who reported their self ratings of current health status as good or excellent were significantly more likely to endorse positive health behaviors and experiences. A positive correlation was noted between self report health status and satisfactory weight (.253**). Positive health status also correlated with fewer days missed from work for illness (.226*), and less time spent in the Emergency Room due to illness (.316**). Subjects who viewed their current health status as positive responded that they watched their caloric intake (.208*) and exercised more frequently (.374*) than those who reported a poorer health status. A positive attitude about health also correlated with self reported preventive exams, such as colonoscopy (.463*).

Overweight subjects were more likely to endorse poorer health habits, and indicated lower overall self ratings of their current health. Being overweight was negatively correlated with each of the following behaviors: exercise (-.303**), consumption of fruits and vegetables (-.185*), taking medication for hyperlipidemia (-.277**), and HDL, or good cholesterol (-.332**). Being overweight was also positively correlated with alcohol consumption (.482*), diastolic blood pressure (.215*), and consumption of fats and sweets (.392*).

Waist circumference was positively correlated to several poorer indications of health, including higher number of visits to a physician (.427*), days hospitalized (.444*), Emergency Room visits (.593**), Systolic Blood Pressure (.518*), Total Cholesterol (.590*), and LDL (.608*).

The number of medications that an individual was taking correlated significantly with the frequency of physician visits (.647**), reflecting a greater need to see a doctor when on chronic medications. Frequency of physician visits also correlated positively with the frequency of prescription refills (.217*), suggesting, perhaps, that the more an individual goes to the doctor the greater the likelihood that he or she will fill prescriptions.

Hospitalizations were significantly correlated with several biometric measures of acute health issues, including high triglycerides levels (.315**), fasting glucose levels, (.981**), and fat intake (.194*). Negative correlations between frequency of hospitalizations and self-reported medication compliance were observed in the following disease conditions: asthma (-.325**), heart conditions (-.201*), digestive disorders (-.208*), lung disease (-.385**), osteoporosis (-.222*), and smoking-.410*).

Systolic blood pressure was positively correlated with diastolic blood pressure (.306**), and random glucose (.248*). A negative correlation between systolic blood pressure and health behavior was also observed, including a negative correlation with self reported compliance with diabetes medication (-.245*) and cholesterol prescriptions (-.203*). Many participants who reported

currently taking medication to control blood pressure also reported higher servings of fats and sweets (.209*).

Diastolic Blood Pressure (DBP) was positively correlated to LDL, or bad cholesterol, at (.342**). A higher DBP was also correlated with increased frequency of prescription (days prescribed) at (.219*). Stated another way, those individuals with higher diastolic blood pressure readings were more likely to receive prescriptions.

HDL, or good cholesterol was negatively correlated to the following metrics: weight, (-.332*), waist circumference (-.494*), triglycerides (-.315*), and blood pressure ratio (-.961**). Triglycerides were positively correlated to fat intake (.213*), blood pressure ratio (.893*), cholesterol (.471**).

Fasting glucose was significantly correlated to daily servings of cheese and dairy products (.874*). Servings of fruit consumed daily was negatively correlated to weight (-.185*), waist circumference (-.511**), caloric intake (-.183*), fat intake (-.263**), and consumption of fiber (-.302**). Fruit consumption was positively correlated to vegetable intake (.617**), dairy foods (.346**), and poultry and rice (.341**).

Fat intake was positively correlated with total caloric intake (.680**), as well as with the number of days prescribed medication (.319**). Fat intake was also associated with frequently driving over the speed limit (.243*). Fats and sweets intake was positively correlated with level of anxiety (.283**). Total caloric intake was negatively associated with self reported compliance with cholesterol medication (-.278*) but positively correlated with the number of days prescribed medication (.197*). Drinking alcohol was similarly associated with higher average weight (.575**). Those with higher reported fat intake endorsed higher caloric intake (.197*), and reported that they more frequently drove over the speed limit (.273*).

Smoking was negatively correlated with resting pulse rate (-.763**) as was alcohol consumption (-.800**). A negative correlation was found between the number of cigarettes per day and Cluster 1 of the HABIT (-.346**); significant correlation was also found between cigarettes and Cluster 8 of the HABIT (-.266*). Cigarette smoking was negatively correlated with self reported medication compliance (-.234*), as well as with weight (-.575**).

There was a strong correlation between last mammogram and last pap smear (.356**) as well as the last pap smear and colonoscopy (.347*). There was a negative correlation between anxiety and exercise (-.325*). Preventive self exam of testicles was associated with higher prescription refill rates (.631**). Self reported attitudes about exercise, stress, nutrition, weight, and drinking were all significantly correlated. A positive attitude about stress and strong coping strategies were associated with healthier attitudes towards weight management (.413**), nutrition (.752**), exercise (.680**), smoking (.708**), and alcohol (.613**). A positive attitude about exercise was associated with a positive attitude about smoking (.688**) and alcohol (.696**). Likewise, a positive attitude about nutrition and diet management was associated with a positive attitude towards exercise (.667**), stress (.752**), smoking (.706**), and alcohol (.649**). Certainty about maintaining health, or self efficacy, was negatively correlated with random glucose (-.276*), and fat intake (-.256*). It was also positively correlated with preventive exams such as colonoscopy (.463**) and cancer screenings (.279*).

Those who reported currently taking medication to control cholesterol reported higher servings of fats and sweets (.184*). These individuals also reported a greater number of medications for associated heart disease (.304**) and thyroid disease (.244**).

There were several correlations between individuals' self reported compliance with asthma medications and other variables. Specifically, individuals who reported that they that complied with asthma medication made fewer visits to the doctor (-.289**), made fewer visits to a hospital (-

.325**), spent fewer days in the hospital (0.247**), experienced fewer days missed from work or other activities (-.262**), and made fewer trips to the Emergency Room (-.261*). The more compliant the subjects were with asthma medications the more compliant they reported themselves with other medications, such as those for osteoporosis (.290**), lung disease (.655**), allergies (.537**), and weight control (.520**).

A positive attitude about nutrition correlated to higher refills of prescriptions (.379**). Less anxious individuals endorsed more positive health behaviors on the HABIT (-.304**), and less tobacco use (-.346**). Total blood cholesterol was correlated to triglyceride levels (.893*), but negatively to HDL (-.315**), and positively correlated to fat intake (.213*). HDL was negatively correlated to alcohol (-.654*), and certainty amount maintaining(???) health was correlated to random glucose (-.276*).

These findings suggest the need for future research on related variables of interest.

Internal Consistency of the HABIT

In order to assess the internal consistency of the HABIT scores, Chronbach's coefficient alpha reliability was calculated. The coefficient alpha of the entire scale was .705.

The Dimensions of Non-Adherence

The findings from this study of the HABIT appear to uncover two basic types of behaviors that are related to health risk. The first set of behaviors is somewhat passive in nature; however, the second set of behaviors may be described as more proactive in nature. For discussion purposes, the first cluster of statements is referred to as the "prevention cluster" and the second cluster of statements is referred to as the "exercise cluster". Behavior statements that were endorsed in the

prevention cluster included phrases like “avoid people who smoke”, “avoid excessive use of alcohol”, “avoid napping in the day”, “avoid fast food restaurants”, “ “avoid snacking”, “limit caffeine”, “limit sugar”, “limit fat”, “limit cholesterol foods”, and so forth. Behaviors statements that were endorsed in the exercise cluster, though limited, included the phrases “I exercise on a regular basis”, “I prefer to walk rather than drive if possible”, and “I am physically active”. Initial consideration was given to the value of interpreting these clusters as representing different “themes”. For example, could exercise be considered a more proactive behavior, requiring more motivation on behalf of the subject and therefore be more predictive, whereas avoidance behaviors require less effort? With such small numbers, a reliable answer to this question could not be determined; however, the subtle difference suggests that further research to assess these behaviors as independent domains may be fruitful.

Collectively, based upon this sample size, both clusters were determined to represent a single factor or dimension of non-adherence, which was jointly referred to as the “HABIT Factor”; this factor was determined to account for 19% of the variability in health risk as calculated by the HRA. In an effort to understand how the behaviors reported on the HABIT were related to the Adherence Ratio, further investigation of the raw data revealed interesting findings with respect to certain responses. Specifically, when the frequency distribution of the Days Fill Ratio (numerator and denominator) was examined, it was apparent that 83 of the 93 subjects (89.2%) had an antihypertensive prescription written for a full calendar year (365 days). The remaining 10 subjects had a prescription written for at least 6 months. Yet the corresponding prescription fill rate (number of days for which the patient actually had medication), was far less in most cases. In fact, none of the subjects had sufficient medication for the entire prescribed period, and 34 patients (36.6%) had fill rates of less than 50%. This information was reliable, based upon the pharmacy records and patients’ self-reported use of a single pharmacy for filling all prescriptions. This is consistent with

the literature on medication adherence rates, but not generally considered acceptable for therapeutic efficacy. Another 8 patients (8.6%) had filled their prescriptions 65.7% of the time, and 13 patients (13.9%) had a minimum supply of 270 days (73.9% Days Fill Ratio). Roughly expressed, a handful of patients had missed only 2 days of medication each week, or 8 days per month, yet another 42 (45.1%) patients failed to take the prescribed medication between 34.2% and 100% of the time. Less than 28% of the subjects missed fewer than 6 days per month medication.

Self-reported responses captured by the HABIT were not subject to verification; however, results indicated that 96.8% of the 93 subjects in the study reported that they got their prescribed medications filled promptly, and 94.6% of them indicated that they took prescribed medications for the recommended period. When asked about following their doctor's advice, 93.5% said they followed their doctors' advice on matters related to their health.

One possible explanation for the observed discrepancy is a desire to "fake good". All of the participants in this study were, by definition, diagnosed with hypertension. In addition, 85 of the 93 subjects reported experiencing a previous heart attack. One consideration is that this could represent a bias in the population which may be reflected in distorted perceptions of actual adherence. Given that 83 of the subjects had been diagnosed with hypertension for more than a year, it is not unreasonable to assume that many of the subjects have had their blood pressures monitored by their physicians for some time. In fact, they may well have had serious discussions with their physicians related to their conditions. To admit that they were not taking medication or were not following their physicians' advice might have resulted in cognitive dissonance and subsequent distorted perceptions of their own behaviors.

The Health Risk Assessment does not contain items specific to medication compliance. The respondent is simply asked to check from a list of conditions for which they are currently taking a medication. The presence of a condition is utilized in the health risk algorithm, but compliance is

not. Quantitative measures such as age, weight, and lab values weigh more heavily in the calculation than qualitative responses. As a result, there is little opportunity to "fake good" on the Health Risk Assessment.

As previously mentioned, numerous theories have been offered to explain why one person will adhere to his/her physician's advice and another person will not. Some of the factors proposed as influencing adherence include the nature of the condition or disease, the complexity of the treatment regimen, and individual psychological characteristics. These theories are useful to establish hypotheses about the rationale for behavior, but the majority of research in this area does not expand on the types of behaviors observed by compliant or non-compliant patients. The most common tool at the disposal of healthcare professionals and health insurance plans remains the retrospective claims analysis. This type of automated analysis utilizes claims databases to identify diagnosed patients who, based upon quantitative data, appear to be non-adherent with medication or other prescribed treatment guidelines. Interventions can then be targeted to these individuals, and often include case management, patient education or compliance reminder mailings, etc.

Additional reasons posited for non-adherence are external or situational factors, such as the relative cost and the patient's access to medical care. Studies examining these factors contribute to the literature by offering additional insight into the dimensions and behavior which correlate with poor patient adherence and by offering further evidence that these factors correlate with overall health risk. Further research with larger and more diverse study populations may support the development of a limited number of questions representing a comprehensive set of domains that correlate with non-adherence. This may ultimately allow for the development of patient profiles that could facilitate the identification of critical targets for treatment in non-adherent patients. In practice, if the instrument is refined, prudent use of the HABIT may enable the clinician to improve

therapeutic outcomes through earlier intervention in which patient behaviors may compromise overall treatment.

Methodological Limitations of the Study

There are several limitations to the current study, including those that are specific to this study and those that are more universal. In general, self-reports are influenced by the wording of the questions, content, and format. As a result, the subjects who participated in this study may have interpreted the questions differently. They may also have been more or less motivated to respond is ways that would be socially desirable. The questions on the HABIT deal with personal health behaviors that may be associated with an individual's perception of "character". The nature and structure of the questions and the relative transparency of the content make it possible to overstate a response, and thus increase (?) the overall degree of its importance. There are no right or wrong answers and no direct way to assess the patient's subjective state independently. Bias and inaccuracy can be additionally compromised by the rapport with the clinician and by the physical conditions (such as medication or food immediately prior to a biometric screening).

Another limitation of this study concerns the demographics of the population. The volunteers were, on average, older subjects and predominantly female. This resulted in a higher than anticipated number of seniors whose health, based upon age alone, would be expected to be at greater risk for serious illness. This was most evident in the percentage of individuals who reported a previous heart attack (91.4%). The co-morbidities, health insurance benefits, and seriousness of overall health conditions reflected in this population would not necessarily be representative of the general population; this results in findings that necessitate further investigation.

These deficiencies negate neither the overall value of the HABIT questionnaire nor the relative contributions of this study. The correlation between the HABIT and the Health Risk

Assessment suggest that the current version of the HABIT may provide a cost effective alternative to other assessments that are underutilized due to length, cost, and complexity.

By removing those items that do not load on the single habit factor, and by refining the remaining items into a smaller subscale, it may be possible to construct a more comprehensive questionnaire that addresses additionally relevant domains of non-adherence. Specifically, several questions related to following physician's advice and obtaining medication are similar in wording and the data from this study revealed nearly identical responses. New research on application of the Transtheoretical Model and Health Belief Model is underway for the explicit purpose of developing interventions to improve adherence. These studies are more narrowly focused on the concept of self-efficacy and stages of change as they relate to distinct profiles of non-adherent individuals. The relative utility of segregating persons of similar beliefs into categories of non-adherence, i.e. non-adherers, partial adherers, and near-optimal adherers, may also provide additional insight as to the behavioral characteristics that make these groups unique. Additionally, restructuring the HABIT questions into a Likert scale may offer greater sensitivity to capture subtle differences less evident in a dichotomous format.

Implications for Research and Future Direction

It is clear that many factors operate to impact adherence and that these factors vary not only across demographics and individuals, but also across illnesses. The reliability of future research may be challenged by errors of measurement that may take place due to problems such as inconsistency of examinees (e.g., motivation, interest, and attention), flaws in research design, testing site differences, and distractions. Other challenges may necessitate modification of the items to lessen the transparency of questions. One possibility is to utilize another instrument such as an acceptable measure of social desirability to assess the impact of this issue.

Conclusions

The HABIT questionnaire shows promise in capturing reliable information that correlates with non-adherence. Specifically, a selection of self reported health behaviors appear to be linked to health risk in ways that offer partial explanations and predictions which account for variability in health outcomes. These behaviors represent one dimension of non-adherence that is relatively easy information to collect and assess. Numerous theories and research on non-adherence have proposed both internal and external factors as critically influential in determining treatment adherence. Further work is necessary to incorporate the learnings from this study into future research which applies theoretical concepts to expand the universe of predictable behaviors.

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Addendum: Combination Drugs for Hypertension

Combination Type	Fixed-Dose Combination, mg	Trade Name
ACEIs and CCBs	Amlodipine/benazepril hydrochloride (2.5/10, 5/10, 5/20, 10/20) Enalapril maleate/felodipine (5/2.5, 5/5) Trandolapril/verapamil (2/180, 1/240, 2/240, 4/240)	Lotrel Lexxel Tarka
ACEIs and diuretics	Benazepril/hydrochlorothiazide (5/6.25, 10/12.5, 20/12.5, 20/25) Captopril/hydrochlorothiazide (25/15, 25/25, 50/15, 50/25) Enalapril maleate/hydrochlorothiazide (5/12.5, 10/25) Lisinopril/hydrochlorothiazide (10/12.5, 20/12.5, 20/25) Moexipril HCI/hydrochlorothiazide (7.5/12.5, 15/12.5, 15/25) Quinapril HCI/hydrochlorothiazide (10/12.5, 20/12.5, 20/25)	Lotensin HCT Capozide Vaseretic Prinzide Uniretic Accuretic

ARBs and diuretics	Candesartan cilexetil/hydrochlorothiazide (16/12.5, 32/12.5) Eprosartan mesylate/hydrochlorothiazide (600/12.5, 600/25) Irbesartan/hydrochlorothiazide (150/12.5, 300/12.5) Losartan potassium/hydrochlorothiazide (50/12.5, 100/25) Olmesartan/hydrochlorothiazide (20/12.5, 40/12.5, 40/25) Telmisartan/hydrochlorothiazide (40/12.5, 80/12.5) Valsartan/hydrochlorothiazide (80/12.5, 160/12.5, 160/25)	Atacand HCT Teveten HCT Avalide Hyzaar Benicar HCT Micardis HCT Diovan HCT
BBs and diuretics	Atenolol/chlorthalidone (50/25, 100/25) Bisoprolol fumarate/hydrochlorothiazide (2.5/6.25, 5/6.25, 10/6.25) Propranolol/hydrochlorothiazide (40/25, 80/25) Propranolol LA/hydrochlorothiazide (80/50, 120/50. 160/50) Metoprolol tartrate/hydrochlorothiazide (50/25, 100/25, 100/50) Nadolol/bendrofluthiazide (40/5, 80/5) Timolol maleate/hydrochlorothiazide (10/25)	Tenoretic Ziac Inderide Inderide LA Lopressor HCT Corzide Timolide
Centrally acting drug and diuretic	Methyldopa/hydrochlorothiazide (250/15, 250/25, 500/30, 500/50) Reserpine/chlorothiazide (0.125/250, 0.25/500) Reserpine/hydrochlorothiazide (0.125/25, 0.125/50)	Aldoril Diupres Hydropres
Diuretic and diuretic	Amiloride HCl/hydrochlorothiazide (5/50) Spironolactone/hydrochlorothiazide (25/25, 50/50) Triamterene/hydrochlorothiazide (37.5/25, 75/50)	Moduretic Aldactazide Dyazide, Maxzide

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker; BB = beta-blocker; CCB = calcium channel blocker.
Source: http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf; 9-12-03 and current PIs.