VALIDATION OF THE TRANSTHEORETICAL MODEL IN MEDICATION COMPLIANCE BEHAVIOR

by

CHRISTOPHER LAWRENCE COOK

(Under the direction of MATTHEW PERRI, III)

ABSTRACT

Practical and theoretically derived interventions are needed to improve medication compliance with prescribed therapies. The Transtheoretical Model of Behavioral Change (TTM) has been applied to various health related behaviors. This research examined whether the TTM is applicable to medication compliance behavior. A medication compliance measure using the TTM constructs of stages of change, decisional balance, and self-efficacy was developed. The scale development process consisted of two pilot trial phases and a patient testing phase.

Two pilot surveys were administered to community pharmacy populations of 159 and 70 subjects. Initial testing provided valuable information in item selection and reduction for the final survey. The pilot surveys demonstrated the stage of change construct to exist as a three-factor structure consisting of precontemplation, contemplation, and maintenance for medication compliance behavior. Analysis of these surveys also revealed complexities in the multiple-item stage of change measure providing support to the use of a single-item stage of change measure.

The final survey form was tested using patients from 5 primary care physicians' offices. Patients diagnosed with diabetes, hypothyroidism, hypercholesterolemia, hypertension, or being treated with hormone replacement therapy were asked to complete a survey consisting of demographic questions, the TTM construct measures, and three compliance measures. Pharmacy refill records were collected for participating subjects as a fourth measure of compliance. Moderate correlations ranging from 0.18 to 0.79 were found between the TTM-model constructs and the four compliance measures. Regression models demonstrated that a range 9.61% to 41.07% of the variance in medication compliance could be explained through the TTM-constructs. The study results support additional investigation of the TTM in medication compliance behavior.

INDEX WORDS: Medication compliance, Medication adherence, Chronic disease, Compliance measures, Transtheoretical model, Stage of Change, Decisional Balance, Self-efficacy

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DEDICATION

To my girls, Kimberly, Rachel, and Sarah Anne:

You bring joy to everything in my life.

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CHAPTER 1

INTRODUCTION

Non-compliance with medical therapy is estimated to cost the United States society more than 125,000 lives, thousands of hospitalizations (Department of Health and Human Services [DHHS], 1990), and greater than $100 Billion per year (Berg, Dischler, Wagner, Raia, Palmer-Shevlin, 1993). Numerous studies have investigated reasons patients fail to comply and many attempts have been made to improve the rate of patient compliance with prescribed therapy; however, compliance remains a problem and the costs to the system are staggering. The effects of noncompliance can be seen in premature loss of life, lost workdays, increased hospital and nursing home costs, and the cost to treat adverse drug reactions.

The ability to identify which patients will not comply and then provide intervention has the potential to save thousands of lives and billions of health care dollars each year. The literature has documented over 250 social, economic, medical, and behavioral factors that affect compliance (Fincham & Wertheimer, 1985). This multitude of demographic, sociographic, and psychographic variables all have value in alerting the health care practitioner of the potential for compliance problems, but it hardly points to any plans for action. Strand, Morley, Cipolle, Ramsey, and Lamsam (1990) list the causes of less-than-optimal outcomes as inappropriate prescribing, inappropriate delivery, inappropriate patient behavior, patient idiosyncrasy, and inappropriate monitoring. Of these five factors, only patient idiosyncrasies are not foreseeable and thus, the only unavoidable factor. Also, of these five factors, three relate to patient compliance.

A noticeable weakness of many compliance research articles to date is a lack of a scientific basis. As the National Pharmaceutical Council (1992) has stated, “Diagnosis and treatment of noncompliance must be based on sound basic research delineating the

characteristics and causes of this condition, and on demonstrations of effective interventions." The scientific merit of compliance studies range from primitive to exceptionally high. Practitioners are often cited in the literature empirically testing potential factors that might improve low compliance without regard to a theoretical basis (Haynes, 1982). Research of low methodological rigor does not further the foundation of knowledge to solve the compliance problem. Flaws in design and execution affect the certainty of the conclusions of these projects. For this reason this research will seek to establish a theoretical model that relates to patient medication compliance behavior.

Specifically, the Transtheoretical Model of Behavior Change (TTM), a relatively recent addition to the field of psychotherapy, will be explored in this study. First introduced in 1982, TTM attempts to integrate the best of previous psychotherapy research into a comprehensive approach to changing behavior. The transtheoretical approach assumes that a truly comprehensive model of change must be able to account for how people overcome problems on their own in the natural environment as well as how they change with the help of therapy. The question at hand is whether the transtheoretical model can serve as the framework for a compliance intervention program.

This research study will answer whether the TTM can be used to explain and predict compliance behavior. In order to discover the answer to this question, the development of adequate measures was completed first. The survey instruments developed were constructed and tested for three of the four key constructs in the TTM; the stages of change, decisional balance, and self-efficacy. The creation of these three measures allows health care practitioners to assess patient attitudes towards their medication therapy. The elements of the fourth key construct of the TTM, the processes of change, can then be integrated into intervention strategies to assist patients in changing their medication compliance behavior.

CHAPTER 2

MEDICATION COMPLIANCE LITERATURE REVIEW

Reports estimate that approximately one-half of the nearly 2 billion prescriptions prescribed annually are taken incorrectly (Cramer, 1992; Sackett 1979). While noncompliance varies widely depending on disease state, estimates of major chronic disease states indicate high rates of non-compliance. The Task Force for Compliance found noncompliance rates of 30-50% for epilepsy, 55-71% for arthritis, 40% for hypertension, 40-50% for diabetes, 20% for asthma, and 57% for estrogen replacement therapy (The Task Force for Compliance, 1994). A study by Jackson, Worthen, and McCampbell (1996) found that hypertensive patients were an average of 6.7 days late in obtaining their refills and, thus, out of medication 21% of the time. Talley and Laventurier (1974) found that an estimated 140,000 patients died and 1 million were hospitalized in 1971 due to adverse drug reactions. These shocking findings from previous research demonstrate the need to change the patient's drug-taking behavior.

Although prescription drugs only account for approximately 7% of the total $1.1 trillion health care budget (Oliver, 1999), non-compliance costs exceed an estimated $100 billion in health care and productivity costs. When patients do not take their medication or fail to take a needed medication correctly, one of three outcomes develops. A patient may fail to improve, worsen, or relapse. Each of these outcomes carries an economic cost associated to treat and correct the results. One would assume that a problem this costly could not be ignored, and it has not. However, no solution has been found.

The literature is replete with articles concerning the issue of medication compliance or medication adherence. The following section highlights what is known about medication compliance. The section examines what medication compliance is, who is affected by

noncompliance, what is known to affect compliance, how the non-compliant behavior can be identified, and what has been tried to improve compliance.

Definitions of Medication Compliance

Theoretical and operational definitions of compliance are still being debated. There is no "standard" definition of compliance. Definitions used vary significantly throughout the literature, often reflecting the views of the authors and different viewpoints of their work. With no consistent theoretical or operational definitions of compliance, comparing results in the literature is difficult. Each study must be analyzed according to the definition of compliance employed by the authors as well as to the methodologies used within the study.

One of the fundamental points of controversy is the distinction between compliance and adherence behavior. Historically, compliance has been viewed as the extent patients follow instructions provided by their physician. However, some in the medical community construe that compliance is a passive and non-participatory form of obedience. These behaviors can be seen as negative and unrealistic when dealing with the patients' involvement in their health treatment. Meichenbaum and Turk (1987) indicate that the term "adherence" implies a more active, voluntary, collaborative involvement in health care on the part of the patient. While adherence may be the desired outcome achieved with the patient, compliance remains the most popular term used in the literature to describe patient medication consumption behavior.

Another term used by some researchers that needs to be addressed is "intelligent non-compliance," which acknowledges that the patient is routinely making risk-benefit assessments of the prescribed therapy according to what is important to them (Becker, 1985). One must accept that the therapy the physician orders is optimal and that the patient-physician relationship is one of patriarchal control before one can find intelligent non-compliance as a problem. In adherence the patient is involved and collaborates with the physician about therapy. Not only has society moved away from the patriarchal patient-physician relationship of the 1950's, but patients are now expected to participate and assume a level of responsibility for their own health outcomes. Therefore, when a problem arises, the

patient is expected to alter the therapy as an educated consumer. Noncompliance may actually result in a better health outcome in instances when the patient experiences a misdiagnosis, severe adverse reactions, or abrupt changes in his/her condition. The patient-professional cooperation implied in the term "adherence" would actually preclude the need for "intelligent non-compliance." Within this manuscript and research, the terms compliance and adherence will be used interchangeably assuming the patient is involved in his/her health care decisions.

The problem of operationally defining compliance raises further issues. One issue is whether compliance is to be measured as a continuous or a dichotomous variable. Some researchers operationalize compliance by dividing their sample into compliers and non-compliers based on statistical measures such as median or mean level of medicine taken (Becker & Rosenstock, 1985). Others have used assigned values when a patient changes from being compliant to noncompliant. Hamilton and Briceland (1992) evaluated compliance as being within 0.2 times the day supply after the refill due date, whereas, others have created their own terms to estimate a patient's medication use. Powell and Edgren (1995) constructed the term "medication possession ratio" to represent the calculated total number of days' supply of a medication that was obtained divided by the number of days within the refill period. Other authors have tied the definition of compliance to the outcome of a particular therapy. Sackett et al. (1975) found that diastolic blood pressures were lower when a patient was at least 80% compliant with the therapy. Luscher, H. Vetter, Swigenthaler, and W. Vetter (1985) also utilized the 80% level of compliance for an antihypertensive regimen in order to achieve desired clinical outcomes. These objective definitions for compliance appear to be arbitrarily assigned and are inconsistent across studies (Katz, 1991).

The absence of a unified conceptual foundation to define compliance creates several problems. One is that a strategy for compliance intervention can only be evaluated within the context of the specific definition. Another difficulty is whether compliance is considered for each prescription interval or whether the entire regimen period should be considered. Lastly,

because of the variability in the definitions, one cannot compare and assess the available compliance literature.

Forms of Noncompliance

While noncompliance can occur for many reasons and in many ways, the compliance literature can be grouped into three basic noncompliance categories: “initial drug defaulting”, “persistence”, and “improper medication use”(Farmer, 1999; Perri, 1997). Each of these types of noncompliance can threaten patient health and lead to adverse effects. The first of these types, initial drug defaulting, occurs when prescriptions are written by the physician but fail to make it to the pharmacy to be filled or are never picked up from the pharmacy. Initial drug defaulting has been reported in the literature to range from 0.28% to 20% of all prescriptions written. Despite this wide range, the majority of published studies tend towards the lower end of this range with the majority finding the incidence of unclaimed prescriptions to be between 0.28% and 3% (Craghead & Wartski, 1989; Fincham & Wertheimer, 1986; Katz & Segal, 1971; McCaffrey, Smith, & Banahan, 1993). Of these unclaimed prescriptions, antibiotics, anti-inflammatories, cough/cold, and prenatal care were reported to represent the majority of the prescriptions. The literature indicates that chronic disease state therapies are not greatly affected by this type of noncompliance.

The second area of noncompliance is known as persistence or refill noncompliance. Patients who discontinue their medication earlier than prescribed place themselves at high risk of unfavorable health outcomes and increased health care costs in the long run. A study by Hammel (1981) found that refill compliance declined each month in antihypertensive therapy and that only 44% of prescriptions for medications were refilled after 6 months. This area of compliance varies across disease states and can have severe consequences. It is in this group of noncompliance problems that this study is hypothesized to have the greatest impact. Levy (1991) reports that over 72% of patients stated they did not get their refills because either they felt they did not need the medication or did not want to take the medication. One of the constructs within the TTM focuses on the patients’ balance of positives verses the negatives in complying with the prescribed therapy.

The third category of noncompliance consists of improper medication usage. This category consists of the traditional problems of either under- or over-utilization of a prescribed therapy. Included in this category is the sporadic noncompliant patient. The patient misses doses, overdoses, takes the wrong medication, does not complete a therapy (i.e. antibiotic), takes the dose at the wrong time, or does not follow special precautions. The patient understands he/she needs the medication, but does not use the medication properly. Many of these problems may result from lack of education and understanding. However, like the other noncompliance categories, the endpoint is still that the patient does not get the maximum benefits from his/her medication.

Factors in Compliance

The results of numerous research articles examining compliance have concluded that it is difficult to identify the factors that place an individual patient at high risk of noncompliance (HHS, 1990; Morris & Schultz, 1992; National Council on Patient Information and Education, 1995; National Pharmaceutical Council, 1992). Fincham and Wertheimer (1985) have reported that more than 250 social, economic, medical, and behavioral factors have been found to affect compliance. While demographic factors including age, sex, socioeconomic status, and education would seem to be important determinants of compliance, it has been found that these variables are poorly correlated with compliance (Morris & Schultz, 1992; The Task Force for Compliance, 1994). In a summary examination of the compliance literature, Haynes (1979) identified 12 factors that the literature supported as contributors to patient compliance. Of these, only three positively influence patient compliance. Table A on the following page summarizes Haynes' findings.

The National Council on Patient Information and Education (NCPIE) divides the factors that have been found significant into six groups that can serve as a basis for compliance solutions. They are inadequate patient/health professional communication about medicines and medication compliance, unresolved patient concerns, health care professional issues, special population issues, regimen-related issues, and environmental barriers. Some

of these factors are patient and disease specific while others are modifiable by the health care practitioner.

Table A: Summary of Important Factors in Patient Compliance

	Effect on Compliance
The Disease	
Mental illness, especially schizophrenia, paranoia, and personality disorders	Negative
Symptoms	Negative
Disability	Positive
The Referral Process	
Time from referral to appointment	Negative
The Clinic	
Waiting time	Negative
Individual appointment times	Positive
The Treatment	
Parenteral drug administration	Positive
Duration of treatment	Negative
Number of medications/treatment prescribed	Negative
Cost	Negative
Safety containers	Negative
Erring and errant pharmacists	Negative

Chart by R B Haynes p.61

Nagasawa, Smith, Barnes, and Fincham (1991) performed a meta-analysis of 26 compliance studies in diabetic patients. They found the 180 factors identified by the 26 individual studies could be reduced to some general findings. The factors related to good compliance include emotional stability, internal and external motivations, perceived benefits of therapy, and supportive social and family structure. The factors related to poor compliance included perceived barriers to therapy and a negative social environment.

Perri (1997) created a summary table of the disease, patient, and drug factors that are known to influence patient compliance. A reproduction of this compliance factor table is found on the following page as Table B. Within each of these factors, disease, drug, or patient specific areas may exist in the literature. While thousands of articles have been written on these factors, one is still unable to accurately predict who will be the non-compliant patient. The sum of years of research on compliance provide little consistent information other than the fact that many people do not take their medicine as prescribed.

Compliance as a Behavioral Disease

Dr. Richard Levy of the National Pharmaceutical Council first proposed the idea of associating medication compliance to a behavioral disease state. Medication noncompliance has several characteristics that resemble a disease. Many risk factors have been found in research to affect the rate of noncompliance. Noncompliance has been associated with important variations of severity, morbidity, and mortality. Triage is necessary to identify which patients are in the greatest need for treatment intervention. Many cases of noncompliance are curable while some are probably not. Lastly, noncompliance is a public health problem and thus, prevention is a major goal.

Table B: Summary of Factors Placing Patients at Higher Risk of Noncompliance

Factor	Category	Description	Example
Asymptomatic conditions	Disease	May be problematic since patients are not reminded that the medication is needed, or that there is any link between taking the medication and alleviating the disease	Hypertension
Chronic conditions	Disease	Chronic medications demonstrate lower compliance rates that those on short term therapy	Hypertension Arthritis Diabetes
Cognitive impairments	Patient or Disease	Diseases or conditions that interfere with a patient's ability to follow instructions, process information, recall direction, etc. lower compliance rates	Alzheimers disease
Complex regimens	Drug, Patient or Disease	Multiple drugs and increasing complexity of therapy lower compliance rates	Elderly with multiple disease states
Multiple doses	Drug	Increasing doses per day decreases compliance rates	TID and QID verses QD
Patient concerns	Patient	Patient fears about side effects, cost, etc. increase noncompliance with therapy	Hypertension medicine that causes sexual dysfunction
Poor communication	Patient	Poor communication between practitioners and patients results in decreased compliance	Rapport with pharmacist
Psychiatric illness	Disease or Patient	Patients with psychiatric conditions are less likely to comply with therapy	Schizophrenia

Adapted from Perri M.

Viewing medication compliance as a disease allows one to approach the problem from a different viewpoint. All patients should be examined for their compliance behavior, much as if for a physical disease. Public health has demonstrated the need to screen for hypertension, diabetes, and many other diseases. Screening for compliance can be performed by any number of methods that will be covered in the next section of this chapter. Logic

dictates the factors that increase risk of noncompliance should be examined and then identification of patients to target for intervention be performed. Interventions should then be customized to the needs of the patient, including the type of illness, the personality of the patient, and social circumstances of the patient.

Measuring Compliance

The topic of measuring patient medication compliance appears on the outset to be a simple and straightforward subject. Despite advanced technical development and the wealth of published material, it is still impossible to monitor patient compliance in an objective, unobtrusive and practical manner. Rudd (1979) identified these three characteristics as necessity for a compliance measure to achieve a "Gold Standard" status.

The ideal compliance measure is easy to envision. The instrument would indicate when and where the patient took his/her medicine. The device would have perfect sensitivity meaning that the health care practitioner would be able to assess when and how often the patient missed doses. The device would also possess perfect specificity, or the ability to measure the portion of patients who complied perfectly by the measure. Unfortunately, actual and ideal measures are far apart. The only way to achieve the ideal objectivity involves having someone follow the patient around at all times to verify when and if the patient takes the medicine. It is obvious, however, that this is neither unobtrusive nor practical.

Direct Measures of Compliance

The methods for detecting patient non-compliance fall under two main classifications. The measure is either a direct or an indirect measure of compliance. Direct measures include assays of a patient's bodily fluids and similar techniques. The advantage to this type of assessment is that it is objective and reasonably accurate. The most accurate of these measures is the blood/serum assay. According to Sackett (1979), the blood level is considered the "hardest" evidence of compliance to medication. Non-invasive direct measures such as urine or other bodily fluid assay also exist. The disadvantages to direct measures of compliance are numerous. Many medications do not have assay measurements

established. One way around this is to include a tracer compound such as phenobarbital or digoxin to the medication to be assayed in the blood levels. The application of this type of measure fails to even be considered on a regular or widespread basis due to it being unethical, cost prohibitive, and too time consuming. Direct measures are impractical except in certain limited applications.

Indirect Measures of Compliance

Patient Self-Reports and Interviews

The second type of compliance measure is an indirect measure. There are many different types of indirect measures, all with varying combinations of strengths and weaknesses. Patient self-reports are the easiest and most common compliance reports to obtain. The practitioner simply asks the patients about whether they are taking their medications as directed. The problem with patient self-reports is they have been found to overestimate compliance (Bergman & Werner, 1963; Hayes et al., 1980; Kass, Meltzer, Gordon, Cooper, & Goldberg, 1986). Even Hippocrates stated, "Patients often lie when they state they have taken certain medicines." This may be due to the patient feeling guilty about his/her lack of compliance, a need for approval, or the patient doesn't realize the extent of non-compliance. Interestingly, if a patient admits to being non-compliant, the truth is probably being told (Park & Lipman, 1964; Hayes et al., 1980).

Unfortunately, health care practitioners have also been repeatedly shown to overestimate the compliance of their patients. Even the best interviewers tend to be biased towards compliance. Physician, medical student, and nurse assessments are not reliable of the patient's compliance record (Charney et al., 1967; Moulding, Onstad, & Sbarbaro, 1970; Mushlin & Appel, 1977; Roth & Caron, 1978). Pharmacists have an advantage in they are found to be more accurate regarding the timeliness of refills, but there is little proof the patient is taking the medication correctly. So overall, the assessment from a health care professional does not constitute a valid measure.

Other alternatives that have been investigated include diaries and other forms of charts and records to track compliance. The validity of these measures is highly

questionable. The device may remind the patient to take his/her medication but now the patient must remember to take the medication and remember to complete the diary or log. Family interviews may be reliable if the family member is directly involved in the administration of the care, but only a small percentage of the population is cared for by a family caregiver.

Table C: Methods for Assessing Compliance to a Medication Regimen

Method	Type of Data	Advantages	Disadvantages
Drug level in biological fluid	Qualitative	- Recent use verified	- Data limited to recent use - Patient-specific kinetic variations - Expensive - May be invasive
Biological markers	Qualitative	- Recent use verified	- Same as above
Direct patient observation	Quantitative	- Verified use	- Impractical in outpatient setting
Patient interview	Qualitative	- Easy to use, inexpensive	- Influenced by question construction and interviewer skill
Patient kept diary	Quantitative	- Only self-report method with regimen data	- Potential for overestimation - Patient must return diary
Compliance questionnaire	Qualitative	- Easy to administer (on site, mail, phone) - Validated - May explain patient behavior	- Lack of continuous data - Accuracy is instrument specific
Pill Count	Quantitative	- Easy to use - Inexpensive	- No data on regimen compliance - Patient may forget or alter unused portion
Prescription record review, manual	Quantitative	- Noninvasive	- Limited to specific location
Prescription record review, electronic	Quantitative	- Noninvasive - Long-term data - Large populations	- Knowledge of database required - Validity of variables
Electronic monitoring	Quantitative	- Precise data on regimen compliance	- Expensive - Inconvenient

Adapted from Farmer KC (1999)

Pill Counts

Pill counts are a common method used to assess compliance. In a pill count, the number of dosage units remaining should equal the number of dosage units dispensed minus the number of doses that should have been taken. Several factors plague the reliability and validity of the results obtained in this method. The "parking lot" effect has been reported in clinical trials where patients simply discard the remaining pills in the bottles before they report. The opposite effect of "pill hoarding" is more likely to be seen when patients pay for

their own medications, although it has the same effect on monitoring. Despite the convenience and low expense of these measures, the accuracy of this method is questionable.

Electronic Monitoring

Many of the early studies used pill counts as the reference standard, but electronic monitoring devices have now replaced it as the reference standard. There are a number of mechanical devices currently available. The Medication Event Monitoring System (MEMS) is one such device that was created in the late 1980's. It utilizes a micro-electronic device that is embedded within the childproof cap of the prescription vial. The device records the time and date each time the bottle is opened. Opening the bottle assumes a dose taken. With the time pattern of openings, daily compliance information is obtained. Unfortunately, several problems still remain with these devices. First, one is still not assured the medication was taken. It is less likely that someone would open the vial just to confuse the data; however, forgetful patients may open the bottle several times extra throughout the day to try and remember if they had taken their medication. Secondly, the increased expense for the device is impractical and prohibitive to many studies.

Compliance Questionnaire

Several investigators have tried to compensate for the shortcomings of patient interviews and self-reporting methods by developing standardized questionnaires to measure medication compliance. Recently, Svarstad, Chewning, Sleath, and Claesson (1999) have developed a self-administered compliance specific instrument called the Brief Medication Questionnaire (BMQ). This measure consists of three constructs and a total of nine items: five regimen screen items, two belief screen items, and two recall screen items (see Appendix A). The measure inquires into the medication taken during the past week, perceived efficacy and bothersome features, and potential difficulties in patients remembering doses for each medication.

The regimen screen begins with a neutral open-ended question that asks the patient to list all medications taken in the past week. For each medication listed, four questions are asked regarding each medication: "How many days did you take it?"; "How many times per

day did you take it?"; "How many pills do you take each time?"; and "How many times did you miss taking a pill?" Each initial or spontaneous report indicating potential noncompliance with the current medication regimen is assigned one point (see Appendix B). A score of zero reflects no incidence of non-compliance from the patient. Indicators of potential non-compliance behavior include failure to mention the target medication (without prompting or interviewer assistance), stating that one cannot answer or remember, reporting any missed doses, or reporting extra doses. The score is summed for the section.

The second construct is the "belief screen," measuring two beliefs that have been linked to non-adherence in past studies (Meichenbaum & Turk, 1987; Svarstad, 1986). The first item examines the patient's belief in the effectiveness of each medication by asking, "How well does (did) this medication work for you?" The second item addresses the patient concerns about unwanted side effects, short-term or long term risks, or other bothersome features of a given medication by asking: "Do any of your medications bother you in any way?" Patients receive a score of "1" if they respond, "not well" or "I don't know" on the first item and a score of "1" if a medication was identified as troublesome. Items scores are summed to obtain a total belief score with positive scores indicating one or more belief barriers.

The final construct is called the "Recall screen" and includes two items that measure potential problems remembering all doses. The first item examines the dosing regimen of the patient. A single daily dosing regimen received a score of "0", whereas, more complicated regimens receive a score of "1". The second item asks the patient: "How hard is it for you to remember to take all the pills?" Response options are "very', "somewhat," or "not at all." Patients receive a score of "1" for a response of "very" or "somewhat." The total of the construct is derived from the summation of the two item total scores.

The accuracy of the measure was tested using the MEMS device as a reference standard. Compliance was labeled into three categories: >20% over or under compliance as "repeat noncompliance", 1-19% over or under compliance as "sporadic noncompliance", and "no noncompliance" when the compliance was 100%. The sensitivity was 80% for repeat

noncompliance for the regimen screen, 100% for the belief screen, and 40% for the recall screen. The specificity for the repeat noncompliance was 100% for the regimen, 80% for the belief, and 40% for the recall screen. The reported accuracy for the repeat noncompliance was 95% for the regimen, 85% for the belief, and 40% for the recall screen.

Prescription Record Review

Prescription record review has been used in numerous compliance studies because it is non-invasive, inexpensive, and generally readily available. Steiner and Prochazka (1997) identified 41 studies using prescription record review during the period of 1969 to 1994. Many of these studies were limited to individual pharmacy records; however, some more recent analyses have used centralized databases across multiple sites. While both methods have strengths and weaknesses, this study will utilize the individual pharmacy patient records to assess compliance.

Much of the evidence for the validity of prescription refill records has been established through correlation data. Several studies have found refill records correlate significantly with other compliance behaviors such as appointment keeping and medication consumption (Deyo, Inui, & Sullivan, 1981; Peterson, McLean, & Milligen, 1982; Steiner, Fihn, Blair, & Inui, 1991; Wandless, Mucklow, Smith, & Prudham, 1979). Also, moderate correlations between $0.2 - 0.7$ have been shown to exist between refill compliance measures and serum drug levels and drug effects such as blood pressure control (Bond & Manson, 1984; Inui, Carter, Recoraro, Perlman, & Dohan, 1980; Steiner et al., 1991; Steiner, Koepsell, Fihn, & Inui, 1988; Roth, Caron, & Hsi, 1971). Factors such as pharmacokinetics and patient specific factors are hypothesized to contribute to the modest correlations. Refill compliance measures have also shown partial compliance associated with adverse health outcomes (Maronde et al., 1989; Psaty, Koepsell, Wagner, LoGerfo, & Inui, 1990; Steiner et al., 1991). Correlation evidence indicates that refill records may be useful in compliance assessment.

Evidence supports the use of prescription refill records as compliance measures, although the method does contain several limitations. Refill records do not guarantee the patient has taken the medication. The refill compliance data simply identifies an "upper-

bound" for medication compliance. We are able to identify patients requiring more than is directed and those who are non-compliant because they have not received enough medication to be compliant. Secondly, refill measures can only assess compliance of medications intended for long-term, non-discretionary use. Short-term therapies such as antibiotics and "as needed" therapies cannot be assessed with this method. Lastly, refill measures cannot assess when the patient took each dose. The timing of dosing is critical to the effectiveness of many therapies.

Each of the different types of compliance measures available has a distinct combination of strengths and weaknesses. The only definite in measuring compliance is that multiple measures must be used to create the most effective measurement (Spilker, 1991). The choice of methods should be based on the usefulness and reliability of methods in light of the researcher's goals.

CHAPTER 3

BEHAVIORAL MODELS IN COMPLIANCE

Health Belief Model

Several behavioral models have been examined for explanation of compliance behavior. By far the most extensively studied model used in compliance research has been the Health Belief Model (HBM). The HBM was developed in the early 1950's by a group of social psychologists at the United States Public Health Service in an attempt to understand "the widespread failure of people to accept disease preventives or screening tests for the early detection of asymptomatic disease" (Rosenstock, 1974). Later, the model was applied to patients' responses to symptoms (Kirscht, 1974) and to following prescribed medical regimens (Becker, 1974).

Components of the Health Belief Model are derived from various psychological and behavioral models which hypothesize that behavior depends upon two main variables: 1) the value placed by an individual on a particular goal and 2) the individual's estimate of the likelihood that a given action will achieve that goal (Maiman & Becker, 1974). When these variables are conceptualized in context with health behavior, they become: 1) the desire to avoid illness or get well from illness, and 2) the belief that a specific health action will prevent or cure illness. The HBM integrates four specific variables dealing with the individual's perception as well as other non-specific variables that may modify the individual's decision towards the health action in question (See Appendix B).

The HBM measures an individual's desire to avoid or recover from an illness through the variables "perceived susceptibility" and "perceived severity". The perceived susceptibility dimension refers to one's subjective belief of the risk of contracting a condition. The perceived severity variable measures the feelings concerning the seriousness of contracting an illness (or leaving an illness untreated). This dimension includes both the evaluations of medical/clinical consequences as well as possible social consequences.

The HBM examines the individual's belief of the consequences of a specific health action. Perceived benefits examine the beliefs regarding the feasibility and effectiveness of the various actions available in reducing the threat of disease. The perceived barriers examine the potentially negative aspects of a particular health action that may act to impede the undertaking of a recommended behavior. A type of cost-benefit analysis is performed by the individual through the weighing of the benefits verses the costs of the health action.

In a review of the use of the HBM to predict medication compliance, Becker (1976) states, "Most studies have produced internally consistent findings in the predicted direction; taken together they yield relatively strong support for the conceptual model of the compliance behavior." Fincham and Wertheimer (1975) utilized components of the health belief model to investigate the attitudes of initial drug-defaulters verses those of initial compliers. This study found that HBM questionnaire discriminated the groups correctly at a level of 68.7%. The two groups in the study accounted for a total of 20% of the variance in the discriminant function.

Theory of Reasoned Action

The Theory of Reasoned Action (TRA) was the development from Fishbein and Ajzen's (1980) beliefs that intention to perform a behavior can be accounted for by a combination of attitudes about an action and the perceptions of likely normative reactions to that action. More specifically, the TRA focuses on the individual's attitude toward the behavior and his/her evaluations of the outcomes and on the subjective norms (see Appendix C). The subjective norms are the person's beliefs that individuals or groups think he/she should or should not perform the behavior and the motivation to comply with the specific referents. The addition of subjective norms adds a strong cultural component to the prediction of behavior. The TRA is similar to the HBM in that the sociodemographic factors operate only to influence the determinants of the behavioral intention.

The model has been successfully applied in the areas of smoking and intentions to engage in family planning. One study by Reid and Christensen (1988) examined the applicability of the HBM and the Theory of Reasoned Action (TRA) models in predicting

drug-taking compliance behavior among female patients with uncomplicated urinary tract infections. They found the HBM variables explained 10% of the variance while the TRA contributed an additional 19% of the variance.

Theory of Planning Behavior

An extension of the TRA has also been developed by Ajzen called the Theory of Planning Behavior (TPB). The theory goes beyond the intention towards a behavior to the prediction of the performance of the behavior. The theory states that the performance of a behavior is a function of the strength of a person's attempt to perform a behavior and the degree of control the person has over that behavior (See Appendix D). Control over the behavior may include both personal and external factors such as having a workable plan, skills, knowledge, time, money, willpower, opportunity, etc. Thus, the greater the effort of the individual towards completion of the behavior and the greater his/her control over the personal and external factors that may interfere with the behavior, the greater the likelihood that the behavior will be performed (Ajzen, 1985).

The TPB is the more appropriate of Ajzen's two models when the probability of success and actual control over performance of a behavior is less than perfect. Schifter and Ajzen (1985) tested a simplified model of the TPB using 83 college females who stated an intention to lose weight over a 6-week period. The study used the three variables of attitude towards losing weight, subjective norm regarding pressure to lose weight, and perceived control over body weight to assess the female's intention to lose weight. Non-motivational factors such as time, money, willpower, and skills were also included as influencing the performance of behavior. The authors concluded, "to the extent that a person has the required opportunities and resources, and intends to lose weight, he or she should succeed in doing so."

Health Decision Model

The Health Decision Model (HDM) developed by Eraker, Kirscht, and Becker (1984) was proposed as a "third generation model of patient behavior that focuses more specifically on health decisions." The model integrates the HBM with patient preference, decisional

analysis, and behavioral decision theory. This model was based on the strengths of the other models and includes bi-directional arrows and feedback loops (See Appendix E). The HDM also recognizes the importance of other factors affecting health decisions and behavior such as knowledge, experience, and sociodemographic variables. The bi-directional arrows and feedback loops reflect the notion that compliance behavior can affect health beliefs. Unfortunately, the authors did not statistically test the model for validity and predictability.

The relationships among health beliefs, decision analysis, and behavioral decision theory have been supported by a demonstration by McNeil, Weichselbaum, and Pauker (1978). The authors found that patient preference can change depending on how information is presented to them. Lung cancer patient's preference for alternative therapies shifted when the outcomes were framed in terms of probability of living or the probability of dying. The authors also found that people relied more on preexisting beliefs than on statistical data presented to them.

Social Learning Theory

Schlenk and Hart (1984) examined the use of Rotter's Social Learning Theory in patient medication compliance. They incorporated the constructs of health locus of control, health value, and social support in their model. The authors found social support and powerful others health locus of control accounted for 50% of the variance in compliance. Unfortunately, the result of this non-experimental design with a small number of subjects has not been repeated and the study limitations may have produced inflated results. The authors cite several factors that may have contributed to the unusually high compliance rates of their subjects. Compliance was measured using self-report and interview techniques which may have produced inflated or reactive results. The instrument used to measure compliance did not have established over time reliability. Participants included had to respond to a mailer sent from the investigators, so differences in compliance may have been seen between responders and non-responders. Also, most of the patients included in the study had been participants in an inpatient diabetes-teaching unit started two months before this study.

While the results are promising, the ability to generalize the results of the study is limited by the homogeneity of the sample population.

Transtheoretical Model

The Transtheoretical Model of Behavioral Change (TTM) is a relatively recent addition to the field of psychotherapy. First introduced in 1982, the TTM attempts to integrate the best of previous psychotherapy research in a comprehensive approach to changing behavior. The TTM assumes a model of behavioral change must be able to account for how people overcome problems on their own as well as how they change with the help of others. Prochaska and DiClemente (1981) explain the development of the transtheoretical approach, constructs of the model, and some of their early clinical results using the model within their book, The Transtheoretical Approach: Crossing Traditional Boundaries of Therapy. The model was developed by observing behavioral patterns of self-changers exhibited throughout their course of therapy.

Since the conceptualization of the model, TTM has been tested and found to be generalizable across a broad range of behaviors and a wide variety of populations. The model was originally tested in the patients who were quitting the smoking habit (Velicer, DiClemente, Prochaska, & Brandenburg, 1985). Other behaviors that have been studied and involve cessation of a negative habit include quitting cocaine usage, weight control, high-fat diets, and adolescent delinquent behaviors. Behavioral changes requiring the acquisition of a positive behavior have also been studied. Examples include adopting safe sex behaviors, condom usage, sunscreen usage, radon gas exposure, exercise acquisition, mammography screening, and physicians' preventive practices with smokers. According to Prochaska et al. (1994), the stages of change, the pros and cons, and the integration between them ". . . hold for behaviors differing on such dimension as acquisition and cessation, addictive and non-addictive, frequent and infrequent, legal and illegal, public and private, and socially acceptable and less socially acceptable." Given the support of the literature in other health related behaviors, the transtheoretical model appears to provide a framework for developing a compliance intervention program.

The TTM has evolved into the four main constructs that will be covered in detail within this section: stages of change; processes of change; self-efficacy; and decisional balance. The most extensively studied of these four constructs has been the stages of change. The stage of change construct consists of several domains that describe where the patient is in his/her awareness and willingness to alter behavior towards the desired goal. The constructs of self-efficacy and decisional balance have been shown to correlate with a patient's current stage of change. Patients who believe the positives of the behavior change outweigh the negatives of the change are said to have a positive decisional balance. Those who believe they can be successful at changing their behaviors demonstrate high self-efficacy and are more likely to succeed. Positive decisional balance and positive self-efficacy results in the patient progressing towards the desired behavioral change. The processes of change construct consist of ten processes individuals use to justify and alter their behavior. The model suggests patients throughout the behavioral change process utilize various processes at different times. Certain behavioral techniques are more effective for patients who are early in the stages of change while other techniques are more effective for those in later stages of change. Due to the complexities of the processes of change construct, it will not be utilized in the prediction stage of this research, but rather, will be integrated later into the intervention stages of this research.

For this current research proposal, the stages of change, decisional balance, and self-efficacy will be utilized in the compliance assessment. The construct assessment will be measured and correlated to the patient's compliance behavior. Providing this research finds the TTM applicable to medication compliance behavior and future research will integrate the "processes of change" construct into a compliance intervention program. The program will suggest patient specific intervention strategies depending on the patient assessment scores involving the three constructs tested within this research.

Stage of Change Construct

Precontemplation

The first stage in the transtheoretical model is known as the precontemplation stage. Patients in this stage are unaware that they have a problem or for some reason they have no consideration about changing their behavior. Others may see action by the individual as a health problem, while the individual is either ignorant of the consequences or refuses to believe the consequences could affect him/her.

Many patients have been diagnosed with diabetes or hypertension for years yet still do not understand the consequences of their disease state. These patients are ignorant of how the medications prescribed by their physician can control the conditions, lead to better quality of life, reduced morbidity, or prolong life expectancy. In these types of circumstances it would be hoped that proper patient education would advance these patients into the contemplation and action stages towards changing his/her non-compliant behavior.

Some noncompliant patients know they should be more compliant in taking their medications but choose not to seek or accept help. They seem to believe the less they know about the need to change their behavior, the less they have to acknowledge their compliance problem. As Prochaska and DiClemente (1984) describe,

> "For people to admit that in some significant ways they are not OK is disruptive to their self-esteem. They must also admit that some part of their life is out of control, since part of the very definition of psychological problems is that our behavior is to some extent out of personal control. If our behavior were not out of internal control, we would simply change it with little struggle. To contemplate going to therapy for help with problems is to admit that some significant aspect of life is out of control."

While this may sound a bit extreme in reference to medication compliance, it does resonate the failure of many patients to comply with their therapy. People who do not believe they have a problem are not likely to freely enter therapy. When these individuals are placed in some type of program either by force or urging of a loved one, they often enter hoping their actions will change others, not change their own behavior. They enter treatment hoping to pacify the "nagging" family member, the concerned neighbor, or their boss. They

may even change their behavior long enough to reduce the pressure exerted by the outside influence.

Prochaska and DiClemente (1984) state the types of problems most compatible with the precontemplation stage have serious but delayed negative consequences. The authors describe early troubled drinking, heavy smoking prior to physical changes, physical inactivity and poor diets as examples of frequently defended habits requiring change. Medication non-compliance can easily be added to this list. Whether it is an antibiotic therapy stopped early because the patient no longer felt sick or an anti-hypertensive medication regimen taken irregularly due to expense, the consequences are not immediate and the actions may be defended. The patient who only took four days of a ten-day therapy may or may not have a relapse of a more virulent bacterium in a week or two. Hypertensive patients have an even greater ability to defend their position. Many patients are asymptotic and have a problem taking medicine when they feel perfectly fine and/or the medication prescribed actually makes them feel worse. The results of their disease state may not be seen for years. The patient could know all there is to know and refuse to accept that a debilitating stroke or the massive myocardial infarction could happen to them. They refuse to accept the information and refuse to consider adopting the new behavior.

Overall, precontemplators tend to be defensive and distant about their own problems. They may enter into therapy or a treatment program not to change their own behavior but to appease a concerned loved one. Precontemplators are generally a higher risk of withdrawing from a therapy and are likely to have feelings they are being coerced by the efforts of a health care practitioner. The goal, once a patient in the precontemplation stage is identified, is to assist them to progress into the contemplation stage. Depending on the resistance of the patient, the precontemplation stage may last from minutes to a lifetime.

Contemplation

The contemplation stage is defined by the patient's awareness that a personal problem exists. The patient has admitted at least to himself/herself a part of his/her life is not as it should be. This realization causes distress in the individual. The patient begins trying to

understand the problem and its consequences. They actively seek more accurate and adequate information to allow them to solve their problems. During this stage, the patient has determined a problem exists, but has yet to make a commitment towards resolving it by a change of behavior.

The duration of this stage depends on the level of the problem, the amount of introspection of the patient, as well as the amount of understanding the patient gains before seeking treatment. Obsessive patients tend to believe that thinking about the problem and gathering more information will either resolve it or lead them to a simple solution. Smokers classified as self-changers have been found to spend between 12 and 24 months before seriously thinking about quitting (Prochaska & DiClemente, 1984).

The patient in the contemplation stage tends to want to talk about the problem. They often seek reassurance that the problem can be understood and resolved. While the patient appears anxious to learn about the problem, he or she is slow to take action until full understanding is achieved. As the patient moves further along in the contemplation stage, the less depressed he/she appears over the loss of self-esteem. Since they have already admitted to themselves that the problem exists, distress seen later in this stage tends to be more about what has to be given up in taking action as well as whether they will be able to succeed in solving the problem.

Preparation

Preparation was not included in the original development of the Transtheoretical Model but has been added as a modification to the model. Previous research indicates the preparation stage exists in many of the addictive behaviors where it appears the lifestyle modification is significant. Johnson, Grimley, and Prochaska (1998) however, report that several attempts at continuous staging measures found that preparation and action items did not separate into two independent sub-scales. The debate of the existence of the preparation stage has not yet been resolved in the literature.

The preparation stage is defined as when a patient is planning on changing behavior in the near future and has made at least one 24-hour attempt at changing behavior within the

last year. Often the patient has established goals and made a commitment to change the behavior in question. The near future is a relative term depending on the characteristics of the behavior in question. In smoking cessation, it has been defined as within 30 days. The near future could be defined for patient compliance as within the next refill period.

Action

Action represents a stage where a patient makes a conscious choice to change his or her behaviors to resolve the problem. In the action stage, the patient tends to display high self-esteem because one is acting on his or her own beliefs in self-efficacy. It is the most visible of the stages because the overt changes in behavior are recognizable to outsiders. While action is usually the shortest of the stages in duration of time, it is where the most progress is made. The action stage generally can last anywhere from one to three months but it can last as long as six months. Many patients believe they only need will power to change their behavior and often expend the most energy during this stage. However, enthusiasm for the behavioral change can only last so long. Because of this inability to maintain will power, many patients revert to the undesirable behavior before they achieve the maintenance stage.

Maintenance

Maintenance is the stage where the patient works to continue the successes of the action stage and to prevent a relapse to the prior problem behavior. Maintenance is not a stage absent of change, but a stage of continuing the change. Many patients experience success of the new behavior only to relapse several weeks or months into the process.

Fear of relapse is a characteristic in the maintenance stage. Patients may become rigid and structured in their everyday lives as if any change will result in a relapse. This type of behavior can be seen especially in the recovering patients of addictive substances like alcohol or cocaine. Fear of relapse controls their actions throughout the day from meal planning, exercise regimen, to avoiding a variety of situations. The fear of relapse often creates a long duration in the maintenance stage of model. The maintenance stage usually lasts at least six months, but it can last years or even a lifetime before the patient no longer

fears relapsing. Prochaska and DiClemente (1984) have found that self-changer smokers average three years of maintenance before they experience a minimal temptation to smoke.

Relapse

When maintenance does fail, relapse is the result. The patient reverts to the problematic behavior. Most individuals slide back to the contemplation stage, but some will regress all the way back to precontemplation. In longitudinal smoking cessation data, Prochaska and DiClemente (1984) found that 85% of patients who relapsed were seriously considering making another attempt to quit. Only 15% of the smokers were found to relapse to the precontemplation stage with no serious consideration to attempt quitting again.

One reason relapse can be so difficult to overcome is the psychological damage caused to the patient's self-esteem. Feelings of frustration, helplessness and guilt often accompany the relapse. The patient's sense of self-efficacy is shaken. These feelings can have serious repercussions on the efforts of the patient to try to change his/her behavior again.

Termination

Termination of a problem behavior does not occur until the person no longer has any temptations to return to the troubled behavior and no longer has to make efforts to keep from relapsing into that behavior. Some patients will never experience this stage where the problem is no longer a factor in their lives. The termination step is the exit to the revolving door of an unhealthy behavior.

Decisional Balance

The construct decisional balance is the weight the individual places towards the perceived benefits (pro's) against the perceived costs (con's) involved in adopting a new behavior. Research has demonstrated that decisional balance is a good predictor of successful change with a broad range of health related behaviors (Prochaska et al., 1994). The basis of the two-dimensional decisional balance construct has evolved from earlier work by Janus and Mann (1977). Janus and Mann described the motivation towards a behavior

was a balance between 8 constructs: the gains and losses expected for oneself; the gains and losses expected for significant others; the self-approval or self-disapproval due to the behavior; and the approval or disapproval by others due to the behavior. Velicer, DiClemente, Prochaska, and Brandenburg (1985) found that the original eight central constructs described by Janus and Mann could be reduced to the two-factor structure of pro's and con's.

Prochaska and colleagues maintain that the pro's and con's are excellent indicators of an individual's progress through the stages of change from precontemplation to contemplation to preparation (DiClemente, et al., 1991; Velicer, et al., 1985; Prochaska, DiClemente, Velicer, Ginpil, Norcross, 1985). Prochaska has directed multiple longitudinal studies across various behaviors and has determined that the con's outweigh the pro's during the precontemplation stage and that the pro's outweigh the con's at the action and maintenance stages (Prochaska, Velicer, Guadagnoli, Rossi, and DiClemente, 1991; Prochaska et al., 1994). Depending on the behavior in question, the crossover appears to occur during the contemplation to preparation stages. Previous findings indicate the decisional balance measure is relevant and useful during the early stages in understanding and predicting transitions between precontemplation, contemplation, and preparation. During the later stages of action and maintenance, decisional balance appears less important as a predictor of progress.

Self-Efficacy

Self-efficacy construct is defined as the conviction that one can successfully perform the behavior required to produce the desired outcome. The perceived efficacy of the individual has been demonstrated to affect the consideration of performing the behavior, the degree of effort the individual invests in changing, and the long-term maintenance of behavioral change (Bandura, 1982; O'Leary, 1985; Velicer, DiClemente, Rossi, & Prochaska, 1990). Research has documented that an individual's perception of his or her capabilities is predictive of a healthy behavior change in such diverse areas of health as cigarette smoking, weight control, contraception, alcohol abuse, pain management, recovery

from myocardial infarction and compliance to exercise programs (Strecher, DeVellis, Becker, & Rosenstock, 1986).

Assessment of this construct often involves asking subjects to rate how tempted they would be to engage in a behavior given a variety of situations or how confident they are that they could avoid the behavior in a variety of situations. The self-efficacy construct has been found to increase almost linearly across the stages from precontemplation to maintenance (Grimley, et al., 1996). In the precontemplation stage it is found to be at its lowest while it continues to increase to its peak in the action or maintenance stage. The self-efficacy construct is an important predictor of progress, especially during the later stages of action and maintenance.

Transtheoretical Model in Compliance Literature

To date, only two research articles have been published involving the application of the TTM in medication compliance. The first is a 1998 study by Johnson, Grimley, and Prochaska in which the predictive ability of the constructs of the Transtheoretical Model was compared against several static predictors in the area of medication compliance to oral contraceptives. The TTM constructs of stage of change, processes of change, decisional balance, and self-efficacy were compared against demographic variables and sexual history characteristics. The dependent variable for compliance used in the study was a measure that included four items regarding missed and off-scheduled doses over the three previous months. The population consisted of 306 contraceptive pill users in two clinic sites: the Women's Clinic at Health Services in a United States northeastern university and an affiliate of Planned Parenthood.

The analysis consisted of a stepwise multiple regression technique used to determine the model of compliance. The authors' conclusions confirmed previous research that demographic variables are poor predictors of medication compliance accounting for only 2-4% of the variability. The TTM variables accounted for 42% and 44% of the variability in the two samples examined. The authors state this evidence indicates the constructs of the TTM are strong predictors of compliance. Even when data were analyzed without the stage

of change as a predictor, the remaining TTM variables demonstrated value in predicting compliance. From the correlations found in the data, the strongest to weakest of the TTM variables for predicting noncompliance appeared to be stages of change, decisional balance, self-efficacy, and processes of change.

The second study article by Willey, et al. (2000) examined a method for measuring the stage of change construct in medication compliance. The patients were told that the study was to understand attitudes about their disease state. The stage of change measure being tested consisted of two questions (see appendix G). Two chronic disease populations were examined in conjunction with other ongoing studies: hypertensives and HIV-infected persons.

The methodology for the HIV-infected population consisted of measuring the stage of change construct against the MEMS TrackCap and a self-reported measure of compliance: the Medication Adherence Scale (MAS) (see appendix H). A one-way ANOVA was performed to determine whether the mean number of doses recorded electronically varied by stage of change for compliance. A second one-way ANOVA was performed to examine if the score on the MAS differed by stage of change for compliance. The hypertensive population tested a self-reported measure, the Medical Outcomes Study (MOS) measure of adherence (see appendix I), against the stage of change construct measure. The chi-squared statistic was then used to examine the association between the MOS and the stage of change construct.

The authors found positive results in all three analyses (see Appendix J). The one-way ANOVA of the MAS by the stage of change construct showed significant differences across stages ($F = 7.46$, $P<0.001$). The MOS compliance measure was also strongly associated with the stage of change construct in antihypertensive medication ($\chi^2= 441.3$, $P=0.001$). In addition, a statistically significant association was demonstrated between the baseline stage of change for compliance and compliance with protease inhibitor therapy during the next 30 days ($P=0.03$) as measured by the MEMS device. The authors concluded the evidence gives validation to the two-item stage of change construct measure for

medication compliance. An analysis of interest not addressed by the authors involved the correlation between the two dependent measures of compliance, the MAS and the MEMS device, within the HIV population.

CHAPTER 4

RATIONALE, OPERATIONAL DEFINITIONS, AND HYPOTHESES

Rationale

A review of the compliance literature demonstrates the extent and impact of the medication noncompliance problem in terms of both patient care outcomes and societal economics. Many action interventions have been tried with varying degrees of success; however, no solution has been found to change the patient's medication taking behavior. The Transtheoretical Model (TTM) literature offers a different perspective in addressing the medication compliance problem. The TTM suggests that no single, simple solution exists in changing an individual's behavior. Practitioners should use the entire arsenal of what has been learned to influence how a patient views his/her behavior. Practitioners should provide patients with several tools specific to their needs to progress through the stages of change. The TTM was developed by observing how people change their behavior and discovered that people go through many of the same processes, but individuals use various sets and combinations of these processes to achieve their goals. This research will examine whether the transtheoretical model can be used as a theoretical base for intervention into medication compliance behavior.

Operational Definitions

Medication Compliance

Medication compliance in this study refers to the extent to which the patient's behavior coincides with the physician's prescribed directions for medication use. By default, this definition requires that the patient has been previously diagnosed with a condition to be treated in accordance with physician supervision. Compliance behavior was assessed by using four dependent measures: pharmacy refill rates (RR); the Brief Medication

Questionnaire (BMQ); the Medication Adherence Survey (MAS); and the Medical Outcomes Study measure of compliance (MOS). RR was considered the reference dependent measure in this study to be confirmed by the three subjective patient-reported measures.

Pharmacy Refill Records

All subjects participating in the study were required to sign a release of pharmacy patient records forms (see Appendix K). The investigator collected the previous six refill periods of data from the patient's pharmacy. For patients who were diagnosed and/or treated for less than six refill periods, the pharmacy records were collected from the date of first treatment to collection date. Refill dates were recorded by the pharmacy computer and represent the date the pharmacist filled the prescription. In addition to the refill dates, the name of the medication, dosage strength, directions, and quantity dispensed were collected.

Compliant patients in this study were defined as patients who received medications from the pharmacy, and presumably took, plus or minus 10% of the maintenance medication doses prescribed during the observation period. Noncompliant patients were defined as those whose computer refill records demonstrate greater than a 10% deviation from the prescribed days' supply. McKenney, Slining, Henderson, Devins, and Barr used this ±10% level during their 1973 study involving pharmacist intervention in hypertensive drug therapy and compliance. While multiple studies have used various definitions revolving around the ±20% deviation for adequate compliance, this author believes the ±20% deviation level is unacceptable. A 20% deviation indicates the patient has missed 6 days worth of medication in a 30-day month's supply. At this level, one could question whether the intended benefit of the prescribed therapy is capable of being achieved and argue that it cannot.

Refill records at the pharmacy were analyzed using the percent compliance method. The method was calculated by dividing the days' supply of medication by the days between medication refills and then multiplying by 100 percent. The percent compliance method utilizes parsimony in its calculations and allows straightforward understanding of the analysis.

Table D: Calculation of Prescription Refill Record Compliance (RR)

Percent Compliance = $\frac{\text{Days Supply Dispensed}}{\text{Days Between Refills}}$ X 100% Percent noncompliance = 100% – percent compliance

The quantitative evaluation of the data collected was referenced from the prescription directions or the 'sig'. When differences arose between the way the patient believed he/she had been instructed to take the medicine and the prescription directions, the physician's opinion served as the therapy directions.

Brief Medication Questionnaire (BMQ)

The second method of assessing patient compliance was through a short patient interview using the Brief Medication Questionnaire (BMQ). The BMQ has been shown to be a good predictor of medication compliance. As previously described in the literature review, pages 22-24, the measure consists of three mini-scales containing a regimen, a recall, and a belief scale (See Appendix A).

The BMQ scale scoring provides a continuous dependent variable of potential for noncompliant behavior. The scoring guidelines for the BMQ are outlined in Appendix B. The BMQ scoring guidelines assign points for each condition met in the guidelines. Lower scores, with zero representing the lowest possible score, indicate less potential for noncompliant behavior from the individual patient. As the BMQ score increases, the potential for medication noncompliance also increases. The scale score does not contain a ceiling due to the dependence of the maximum point allocation to the number of medications the patient is currently prescribed.

Medication Adherence Scale (MAS)

The Medication Adherence Scale (MAS) is a short four item "yes or no" questionnaire. Each item answered with a 'yes' receives a score of one point. The scale

scores range from zero to four with higher scores indicating a greater noncompliance problem. Table E contains the MAS.

Table E: The Medication Adherence Scale (MAS)

The response options are "yes" or "no" and the maximum score is 4.
1. During the last 3 months, have you ever stopped taking this medication because you felt better or worse?
2. During the last 3 months, have you forgotten to take this medication?
3. During the last 3 months, have you been careless about taking this medication?
4. During the last 3 months, have you ever taken less of this medication than your doctor prescribed because you felt better or worse?

Medical Outcome Study (MOS) measure of compliance

The Medical Outcomes Study compliance measure is a single-item likert-scaled measure, which asks the patient: "How often have you taken your prescribed medication in the past four weeks?" The six possible responses include none of the time, a little of the time, some of the time, a good bit of the time, most of the time, and all of the time. The patient is asked to select only one response.

Maintenance Medication

Defining the term "maintenance medication" is needed to properly select the subject population in question. According to the Merriam-Webster's collegiate dictionary, the verb "maintain" is to keep in an existing state. This study will define a "maintenance medication" as any medication used on a consistent prescribed regimen by the patient in order to keep a diagnosed disease in the existing state from progressing. Medications prescribed on an "as needed" or "prn" basis are not considered as maintenance.

Transtheoretical Model – Medication Compliance Behavior

In accordance with the previously defined medication compliance, a Transtheoretical Model (TTM) approach to studying medication compliance behavior requires a patient to have been diagnosed with an ailment by a physician and given a treatment regimen with which to comply. In this research, the behavior in question involves whether the patient is compliant with the physician's instructions regarding a scheduled medication therapy for a

chronic disease state. From this base understanding, the definition for each of the transtheoretical variables fits into place.

Stage of Change

Table F: Stages of Change Construct Operational Definitions

Stage	Definitions
Precontemplation	The patient is not concerned about missed or off scheduled doses of his/her medication and has no intention of changing his/her medication taking behavior in the foreseeable future.
Contemplation	The patient is considering changing his/her medication taking behavior in the next few months and is somewhat concerned about missed or off scheduled doses.
Preparation	The patient is more concerned about missed or off scheduled doses and is intending to change his/her behavior in the near future (within the next 30 days).
Action	The patient has successfully started taking his/her medication as directed and has been doing so for less than six months.
Maintenance	The patient has continued to successfully take his/her medication for more than six months.

The stage of change construct was examined using two different measures. The primary measure consisted of a multiple-item likert-type scale developed and pre-tested as part of the study protocol. The second measure was a single-item multiple-choice question. The validity and reliability of the short measure was compared to that of the multiple-item measure. Examples of scales using the Stages of Change construct in other behaviors can be found in Appendices M and P.

Decisional Balance

In terms of medication compliance behavior, decisional balance is the weighing of the positive attributes, or pro's, of taking one's medication as directed by the physician verses the negative attributes, or con's, of taking one's medication. Negative decisional balance occurs when the con's to complying with the physician's directions outweigh the benefits of complying. The opposite or a positive decisional balance occurs when the benefits of compliance outweigh the con's of a patient complying with his/her prescribed therapy. The crossover point and its relationship on patient compliance were examined in this study. Examples of decisional balance scales used in other behaviors studied can be found in Appendices K, L, N, O, P, and Q.

Self-Efficacy

Self-efficacy in this study consists of the patient's conviction that he/she can comply with the medication therapy as prescribed by the physician. Assessment of this construct involves asking the patients to rate how tempted they would be to not comply with the prescribed medication therapy given a variety of situations and/or how confident they are that they can avoid becoming noncompliant in a variety of situations. Examples of self-efficacy scales used in assessing other behaviors can be found in Appendices K and L.

Hypotheses

The primary research question was to test whether the TTM is an appropriate and applicable behavioral model to predict patient medication compliance behavior. Previous literature available using the TTM indicates that the TTM is applicable across a wide variety of behaviors. Applicability of the TTM in medication compliance behavior, however, has yet to be fully established. Johnson, Grimley, and Prochaska (1998) used correlation data in their study to examine the TTM constructs in medication compliance involving taking birth control pills and found positive results. The question that remained was whether the results demonstrated in a single disease prevention behavior are the same as medication compliance behavior across multiple chronic disease states. Willey et al. (2000) examined the compliance rates of patients across the spectrum of the stages of change construct in two chronic disease states. Their findings also lend evidence towards the use of the TTM in medication compliance. By examining only one of the model's constructs, questions remain regarding the use of the whole model in medication compliance behavior.

Findings presented above led to the first set of hypotheses tested in this study. Hypotheses 1 and 2 compare the results found in this study to that of previous TTM research. Hypothesis 1 examined the strength and direction of the correlation between each of the TTM constructs and level of medication compliance.

H1 = Stage of change, decisional balance, and self-efficacy constructs are positively significantly correlated with levels of medication compliance.

$H1_0$ = Stage of change, decisional balance, and self-efficacy constructs are not correlated with levels of medication compliance.

Hypothesis 2 examined the same stage of change relationship, but the focus is on quantifying the theoretical differences within the TTM measures and expressing these differences in real world figures. The compliance rates for patients in each of the stage of change dimension were examined.

H2 = Compliance rates are different across the stage of change construct of the TTM.

$H2_0$ = Compliance rates are equal across the stage of change construct of the TTM.

Understanding the relationship of the TTM constructs to medication compliance is necessary for the application of the model to the behavior. Also of essential importance is the relationship of the TTM constructs with each other. The TTM states that progression of a patient through the stages of change will correlate with an increase in both the patient's decisional balance as well as the patient's self-efficacy. Studies by Prochaska and others have demonstrated patterns exist between the three constructs. As discussed in the TTM literature review, both self-efficacy and decisional balance are lowest in the precontemplation stage and increase through the stages until they peak in either the action or maintenance stage. The next two hypotheses examined if this pattern holds true in medication compliance behavior.

H3 = Decisional balance and self-efficacy scores are different across the stages of change.

$H3_0$ = Decisional balance and self-efficacy scores are equal across the stages of change.

The next hypothesis examined the relationship between the four instruments measuring compliance. The primary dependent measure of compliance in this study is the pharmacy computer refill record. The literature demonstrates the refill record to be a reliable

and valid marker of patient compliance behavior. The testing and results of the Brief Medication Questionnaire (BMQ) indicate this new instrument may also prove useful in the evaluation of patient medication compliance. Other literature in this field has also cited the Medication Adherence Scale (MAS) as well as the single-item Medical Outcome Study (MOS) medication compliance question as useful measures.

In this study, the three self-reported measures were tested against the refill records in order to add further validation to the study results. Moderate correlations were predicted to exist between the differing methods of medication compliance measurement. The variations in the form and specifics of the measures result in the correlations being less than perfect. The BMQ utilizes a patient interview technique that focuses on compliance within the past week, whereas the prescription refill record determines the compliance indirectly through the purchase of the medication over a longer time frame. Previous literature has demonstrated correlations between subjective and objective compliance measures ranging from 0.43 to 0.74 (Craig, 1985; Haynes et al., 1980; Morisky, Green, Levine, 1986;). It was predicted the measures of compliance in this study would also fall within this moderate correlation range.

H4 = Pharmacy computer refill records, medical outcomes study compliance measure, medication adherence scale, and brief medication questionnaire are positively significantly correlated.

$H4_0$ = Pharmacy computer refill records, medical outcomes study compliance measure, medication adherence scale, and brief medication questionnaire are not positively significantly correlated.

The next study question examined the contribution to variance explanation of the TTM construct variables to compliance. The majority of the literature published concerning the TTM has focused on the "stages of change" with considerably less work published on the "decisional balance" and "self-efficacy" measures. Logic would lead one to believe that the "stages of change" would account for the majority of the TTM explanation of behavioral change. A multiple regression model was used to examine the level of contribution that each of the independent variables contributes to the prediction of the dependent variable compliance.

As mentioned earlier in the literature review, the R^2 found for other behavioral models ranged from 0.10-0.29 for compliance behavior. Using the TTM, the Johnson et al. study, found R^2 of 0.42 and 0.44 in two separate sample populations. In recognition that this survey is a general compliance measure and not a disease specific measure, the R^2 is likely to be lower than the previous Johnson research results. Given the evidence of the previous research, it was anticipated the models in this study would achieve $R^2 = 0.3$.

The following model will be tested:

$$Compliance = b_0 + b_1(stage\ of\ change) + b_2(decisional\ balance) + b_3(self\text{-}efficacy) + e$$

The following hypothesis tests the contribution significance of each of the TTM constructs:

H5 = The stages of change, decisional balance, and self-efficacy constructs contribute significantly to the explanation of variance in compliance behavior.

$H5_0$ = The stages of change, decisional balance, and self-efficacy constructs do not contribute significantly to the explanation of variance in compliance behavior.

The majority of previous studies in the compliance literature have demonstrated that demographic variables are not significantly correlated to levels of compliance. Johnson et al. (1998) examined the demographic variables of age, marital status, religious affiliation, ethnicity, educational achievement, employment status, and household income and found one significant finding. Non-Caucasian women were determined to be less adherent to the birth control pill regimen. The demographic variables collected within this study were included and analyzed in order to verify previous research findings. Demographic variables were tested for significant contribution to the explanation of variance against pharmacy refill record compliance measured within the study. The following multiple regression equation tests hypothesis six:

$$Compliance = b_0 + b_1(ttm\text{-}composite\ score) + b_2(age) + b_3(gender) + b_4(race) + b_5(marital\ status) + b_6(educational\ achievement) + b_7(household\ income) + b_8(out\ of\ pocket\ expense\ for\ Rx) + b9_0(medication\ duration) + b_{10}(number\ of\ medications) + e$$

H6 = Demographic variables contribute significantly to the explanation of the variance in the dependent variable compliance.

$H6_0$ = Demographic variables do not contribute significantly to the explanation of the variance in the dependent variable compliance.

While demographic variables have generally not been reported to relate to compliance behavior, it has not been examined extensively within the TTM. The next hypothesis explored whether the changes in the TTM constructs could be explained by demographic variables. The TTM constructs and the model itself should not be significantly explained by demographic variables. A finding of no significant difference will add to support the validity of the TTM.

$$\textit{Stage of Change Score} = b_0 + b_1(\textit{age}) + b_2(\textit{gender}) + b_3(\textit{race}) + b_4(\textit{marital status}) + b_5(\textit{education}) + b_6(\textit{income}) + b_7(\textit{out of pocket expense}) + b_8(\textit{medication duration}) + b_9(\textit{number of medications}) + e$$

H7 = Demographic variables contribute significantly to the explanation of the variance in the stages of change construct.

$H7_0$ = Demographic variables do not contribute significantly to the explanation of the variance in the stages of change construct.

The next two research inquiries are also related to testing the TTM itself. As mentioned earlier in the literature review of the Transtheoretical Model, the presence of the preparation stage is debated as a fifth stage in the stages of change construct. The literature describes the presence of the preparation stage in behaviors such as substance addiction. The literature also reports the preparation stage could not be separated from the action stage in several attempts at continuous staging measures. The stage of change construct in medication compliance behavior was proposed to be a four-factor measure. The factor structure of the stages of change construct was examined through factor analysis as described in detail in Chapter 5.

The next research question also dealt with examining the stages of change construct. One of the concerns of administering any type of questionnaire to patients involves the length of the questionnaire. If the same information can be gained from a single item measure, then

what reason could one give to ask ten items? This hypothesis tested a single item multiple-choice measure of the stages of change construct. The reliability and validity of the single-item measure was compared to that of the multiple-item measure. The single item scale was adapted from the Willey et al. (2000) study measuring individual disease states. A goal correlation of 0.7 between the measures was used to evaluate the efficacy of the shorter measure to the longer measure.

CHAPTER 5

STUDY DESIGN AND METHODS

The focus of this research project was to develop measures for the stages of change, decisional balance and the self-efficacy constructs for medication compliance behavior. This chapter establishes the methods used in the process of the scale development and testing. The University of Georgia Institutional Review Board Human Subjects approval was obtained for this project prior to any patient subject contact. This chapter is divided into two major sections. The first section describes the pilot testing of the survey items. From this pilot testing, the final form of the TTM-medication compliance survey was produced. The second section describes the testing of this instrument in a patient based population.

Development of a TTM-Compliance Survey Instrument

A review of the literature, as well as a panel of clinicians and patients was used for the item-generation stage. A total of 35 items were created representing the stages of precontemplation, contemplation, preparation, action, and maintenance. A total of nineteen items were generated representing the dimensions of pros and cons within the decisional balance construct. Last, a total of twenty items were generated for the self-efficacy construct representing temptations or situations when a patient may not comply with the prescribed medication therapy. Studies by Johnson, Grimley, and Prochaska (1988) and Willey et al. (2000) composed the main sources of TTM-item examples used in medication compliance (see Appendices G and K). Item examples from the behaviors of condom use adoption (see Appendix L), heavy drinking (see Appendix M), immoderate drinking (see Appendix N), mammography screening (see Appendix O), exercise (see Appendix P), and weight loss (see Appendix Q) were also considered. Items generated via this process were pilot tested in a community pharmacy population.

Pilot testing

The pilot survey form consisted of four scales; a 35-item stage of change measure, a 19-item decisional balance measure, a 20-item self-efficacy measure, and a single-item stage of change measure. The survey form directed subjects to indicate how important each statement was in respect to their decision to comply or not to comply with medication therapy. A five-item Likert scale, ranging from strongly disagrees (1) to strongly agree (5), was used. The pilot survey form along with the single-item stages of change measure was pre-tested in a community pharmacy population (Refer to Appendix R for the pilot study protocol, Appendix S for the subject consent form, and Appendix T for the pilot survey).

Pre-testing was completed by a convenience sample at a single community pharmacy location in rural Northeast Georgia. Patrons were asked to complete the TTM-compliance pilot survey and the single-item stages of change measure and to give their comments on the items and the measures in general. No incentives were offered in exchange for their time to participate. The number of patrons completing the survey was targeted to number between 2.5 – 5 times the number of survey items. The items for each measure were examined for strength of factor loading, reliability, and validity. Comments by the patrons were also taken into account when selecting the best items.

Item Analysis and Reduction

During the creation and validation process of the TTM-compliance scales, the MAP-R program was utilized to examine the pre-testing data. A multi-trait/multi-item correlation matrix was used to examine the relationship of each item to its hypothesized scale. Item internal consistency was considered substantial if an item correlates 0.40 or more with its hypothesized scale. Contingency plans were made to include, if necessary, items with as low as 0.30 correlations to its scale. The results should have each of the items correlated highest (>0.40) with its own scale, a moderate (0.20==0.40) correlation with the other constructs of the transtheoretical model, and a low (<0.20) correlation to any variables where little similarities should exist (see Table G).

The scale level analysis consists of an internal consistency reliability estimate of the each scale. Cronbach's alpha coefficient was used to measure reliability as it is based on both the number of items in the scale and the item homogeneity. The standard suggested by Nunnally (1978) of 0.7 was used as the minimum acceptable correlation. Item-total correlations were also examined in an effort to strengthen the reliability of the scale measure.

Table G: Prediction of Multi-trait/Multi-item TTM Scale Correlations

Item	Mean	S.D.	S.O.C.	D.B.	S.E.	# of Meds^	Time Since Diagnosis^
Stage of Change Scale							
SOC 1	x.xx	0.xx	***	**	**	*	*
SOC 2	x.xx	0.xx	***	**	**	*	*
SOC I	x.xx	0.xx	***	**	**	*	*
Decisional Balance Scale							
DB 1	x.xx	0.xx	**	***	**	*	*
DB 2	x.xx	0.xx	**	***	**	*	*
DB I	x.xx	0.xx	**	***	**	*	*
Self-Efficacy Scale							
SE 1	x.xx	0.xx	**	**	***	*	*
SE 2	x.xx	0.xx	**	**	***	*	*
SE I	x.xx	0.xx	**	**	***	*	*

*** = highest correlation (>0.40) **=medium correlation (0.20>=<0.40) *= weak correlation (<0.20)
x = any number ^ = example of discriminant variables

Correlations between scales were also examined for the scale level analysis. Each scale was expected to correlate highest with itself, moderately strong with similar scales, and lowest with unrelated scales. In this study, the three TTM constructs were expected to relate moderately with each other. Demographic variables are also used to examine discriminate validity of the scales. Table H describes the expected correlation table results.

Table H: Prediction of Scale Level Correlation Analysis

Scale	S.O.C.	D.B.	S.E.	# Meds	Time Since Diagnosis
Stages of Change	(1.0)				
Decisional Balance	**	(1.0)			
Self-Efficacy	**	**	(1.0)		
Number of medications	*	*	*	(1.0)	
Time Since Diagnosis	*	*	*	*	(1.0)

*** = strong (>=0.80)** = moderate (0.40><0.80)* = weak (<=0.40)

A component factor analysis was performed for each scale measure. The factor matrix will be analyzed using the orthogonal Varimax rotation in an effort to give a clearer

separation of the factors. The Varimax rotation was also selected because it is more reliable across differing subsets of data (Hair, Anderson, Tatham, 1987).

Several factor structure possibilities were examined for each of the scales. Because each of the constructs within the TTM had been previously established, an *a priori* criterion was set for each scale. The stages of change measure examined both the four-factor structure as well as the five-factor structure, the decisional balance measure examined the two-factor structure, and the self-efficacy scale examined a single factor structure. An additional test will be run for each of the measures utilizing the latent root criterion. A minimum eigenvalue of 1 was set for significant factors. All factors with latent roots less than one will be disregarded as insignificant.

The item selection criterion of each scale considered several factors. Factor loadings greater than ±0.40 were necessary to be considered significant loadings in accordance to MAP-R program default setting. The reliability for each scale was measured using the Coefficient Alpha. The Pearson Correlation Coefficient, r, was examined for each item according to its proper domain total score. Items with low correlation to total score or items that produce a substantial drop in item-to-total score were deleted from the scale.

Confirmatory factor analysis and the multi-trait/ multi-item method used in the MAP-R program were employed to examine the question of how many dimensions exist in the stage of change construct.

Testing

Testing of the final version of the TTM-compliance survey was administered to patients at five primary care physicians' offices. Subjects were asked to complete a demographic section, the three self-reported compliance measures, the single-item stage of change measure, the decisional balance measure and self-efficacy measure (See Appendix Y). Completion of each subject's data collection was estimated to have taken 10-15 minutes. Refer to Appendices V, W, and X for the study protocol, the subject consent form, and the release of patient pharmacy records, respectively.

Once a patient signed-in with the receptionist, the patient's chart was examined for potential entry into the study. Patients who met the inclusion criteria were approached and invited to participate in the study. Eligible patients were required to meet the following conditions:

1. Minimum age of 18
2. Must be currently being treated by the primary care physician for at least one of the following conditions:
    - Hypertension
    - Diabetes Mellitus
    - Hypercholesterolemia
    - Hypothyroidism
    - Hormone Replacement Therapy
3. The patient must be in control of his/her medication taking behavior (i.e. the patient is not a resident of a nursing home, does not have a personal caretaker or other individual controlling when and how often the patient receives his/her medication).
4. The patient must not use mail order to receive any of the medications in question.

The request for participation included an overview of what would be asked of them if they participated, the reading and completion of the informed consent form, the reading and completion of the release of pharmacy records form and time to answer questions and concerns the patient may have. A person completing the consent form and the patient's release of his/her pharmacy refill records for the past six refill periods was enrolled into the study.

Multiple Disease States

The disease state examined for the study was determined by a random drawing for any patient known to have more than one disease state being examined by this study. A cloth bag with different colored poker chips was used for the random drawing. Each colored poker chip represented one of the disease states of the patient. The bag was filled with the appropriate colored poker chips and shaken. A single chip was then taken from the bag indicating which disease state to be investigated for that patient during the study. This step was completed before approaching the patient for entry into the study.

Multiple Medications

It is common for a chronic disease state to be treated through utilization of more than one medication. Subjects who were taking multiple medications for a disease state being studied had compliance measured as a percentage for the whole therapy rather than by individual medications.

Sampling Methodology

According to the literature, an effect size of 0.3 is a conservative and realistic goal for compliance interventions (Perri, Martin, & Pritchard, 1995; Roter et al., 1998). Effect size is a dimensionless number that indicates the size of the change between the measured groups. The larger the difference between the groups, the smaller the size of the sample population needed to find a statistical difference between the groups. A power analysis suggested that a population of 37 to 153 would be required to observe a medium-large, 0.4, to a medium-small 0.2, correlation effect size respectively. This analysis included a power level of 0.8 and a single-sided confidence level of 95% (Cohen, 1977).

The subject recruitment goal was to enroll a minimum of 30 patients willing to participate in the study from each of five primary care physician's office. Within the sample collected, a minimum goal of 15 patients was to be surveyed from each of the dimensions within the stages of change construct. This enrollment goal was to ensure data collected from patients represents the full range of the TTM. The data collection was envisioned to take several days at each facility to achieve the proper subject enrollment numbers. The data collection days at each facility were governed by the willingness and coordination of each primary care physician. The investigator was present for the entire office hours during a data collection day.

Data Collection

The data collected consisted of several main areas. Demographic information was collected and included. The demographic variables collected were age, gender, race, marital status, education, income status, length of diagnosis for disease, length of medication treatment for disease, number of medications taken, and out-of-pocket costs for prescriptions.

Compliance rates were measured by four methods: pharmacy computer refill records; the Brief Medication Questionnaire; the Medical Outcomes Survey compliance question; and the Medication Adherence Scale.

The independent measures of the single-item stages of change, decisional balance, and self-efficacy were also collected. The study examined the patient medication compliance rates as percent compliance for up to 6 refill periods or 6 months prior to study entry. The compliance rates were examined as an aggregate compliance rate for the entire study period.

Analysis of Hypotheses

The analysis of the main study data was performed using the Statistical Analysis Software (SAS) versions 6.2 and 8. All measures utilized the $\alpha = 0.05$ level for statistical significance.

Hypothesis I

Hypotheses 1 examined the correlation between the Transtheoretical model and the established measures of medication compliance. Pearson's product moment correlation, r, was used to examine the relationship between variables within the study. The procedure utilized the nomiss option and subsequently may decrease the number of subjects included in the analysis.

Hypothesis II

Hypotheses 2 examined the mean medication compliance scores across the various stages of change were examined using ANOVA. It was predicted that significant differences exist among the stages of change; therefore, the Tukey's standardized range test for multiple comparisons was utilized to examine the pairwise differences between stages.

Hypothesis III

Hypothesis III examined the relationship between the three constructs of the transtheoretical model. Specifically, this hypothesis examined how decisional balance and self-efficacy change over the stage of change construct in medication compliance. The

hypothesis was tested using ANOVA. It was predicted that significant differences would exist among the stages of change; therefore, the Tukey's standardized range test for multiple comparisons was utilized to examine the pairwise differences between stages.

Hypothesis IV

Hypothesis 4 examined the relationship between the pharmacy computer refill records and the brief medication questionnaire, the medication adherence survey, and the Medical outcomes study medication adherence question. A large correlation table was used to examine these issues. It was predicted that all four independent measures of medication compliance would have significant, positive correlations to one another.

Hypothesis V

Hypotheses 5 examined the amount of variance in medication compliance explained by the transtheoretical model constructs of stage of change, decisional balance, and self-efficacy. The multiple regression equation to be tested was discussed earlier in the hypotheses section. The forward selection procedure was used in order to examine the explanation of variance in each of the models performed.

Hypothesis VI

Hypothesis VI examines the extent to which demographic variables contribute to the explanation of medication compliance. The multiple regression equation used to test this hypothesis was described earlier in the hypothesis section. Modifications to the multiple regression model were required and described below.

Several of the demographic variables displayed multi-collinearity with another demographic variable, so only one variable of each highly correlated pair was retained for inclusion into the model. The variables 'education' and 'household income' were correlated at 0.6256 (<0.0001). Education was retained in the model as it correlated stronger than household income to two of the three transtheoretical model constructs and three of the four independent measures of compliance. The variables 'number of prescription medications'

and ‘out of pocket medication expense’ were also highly correlated at 0.5017 (<0.0001). The variable ‘number of prescription medications’ was retained because it produced stronger correlations to two of the three transtheoretical model constructs and all four of the independent measures of compliance. ‘Race’ was removed as a variable from the regression model because all subjects except two were self-described as Caucasian. The final multiple regression equation tested was:

$$Compliance = b_0 + b_1(stage\ of\ change) + b_2(age) + b_3(gender) + b_4(marital\ status) + b_5(educational\ achievement) + b_6(length\ of\ treatment) + b_7(number\ of\ medications) + e$$

Hypothesis VII

Hypothesis 7 examined the amount of variance within the stage of change construct that can be explained through the demographic variables. The multiple regression equation used to test this hypothesis was described earlier in the hypothesis section. Modifications from the original proposed model were necessary as described above in Hypothesis VI. Thus, the multiple regression model tested in the study was:

$$Stage\ of\ Change = b_0 + b_1(age) + b_2(gender) + b_3(marital\ status) + b_4(educational\ achievement) + b_5(length\ of\ treatment) + b_6(number\ of\ medications) + e$$

CHAPTER 6

RESULTS

Three different trials of patient data were collected during the study period. A pilot trial of 159 subjects was completed testing all items created for the stage of change, decisional balance, and self-efficacy measures. The decisional balance and self-efficacy measures produced results consistent with the previous literature. The stage of change construct, however, produced a result different from what was expected. Therefore, a second pilot trial of 70 subjects was performed on the stage of change construct scale to confirm the finding from the first pilot trial. From these two pilot trial surveys, the final TTM-compliance questionnaire was developed and tested using 171 patients in five primary care physician offices. This chapter will detail the findings in each of the three data collection phases.

Pilot Trial – General Population Item Testing

The pilot trial tested all items created during the item generation phase. The five-page pilot survey questionnaire (see appendix T) contained 35 stage of change items, 19 decisional balance items, 20 self-efficacy items, and the single-item stage of change measure. A total of 159 community pharmacy patrons completed the survey.

Stage of Change Construct

The multiple-item stage of change measure failed to demonstrate a four or five factor structure as had been found in the majority of the transtheoretical model literature. Multiple item-reduction attempts were performed in an effort to find an acceptable four or five factor measure. Table I below contains the closest four and five factor results that could be achieved from the data. The minimum acceptable level of item internal consistency was set at 90% of scale items were required to achieve item-scale correlations of 0.40 or greater. The five-factor model was found to have only 86% of the items having a 0.40 or greater item-

scale correlation. The five-factor model also failed to achieve sufficient reliability. Cronbach's Alpha coefficient for the Preparation and Action dimensions was found to be only 0.64 and 0.61 respectively. The minimum acceptable level for scale reliability was set at 0.70. The four-factor model also was unacceptable in that only 77% of items were found to have an internal consistency greater than 0.40 with its designated scale dimension. The failure of the stage of change construct to reach sufficient internal consistency and reliability in the five or four factor structures led to an exploratory factor analysis of the data.

Table I: Pilot Trial 1 - Stage of Change Scale Statistics

Scale Statistics	5-Factor	4-Factor	3-Factor
Number of Usable Subjects (N)	138 (87%)	147 (92%)	131 (82%)
Item Internal Consistency			
- Percentage of Item-Scale Correlations ≥ 0.40	86%*	77%*	96%
Range of Item-Scale Correlations			
- Precontemplation	0.35 – 0.69	0.39 – 0.72	0.57 – 0.70
- Contemplation	0.20 – 0.66	0.19 – 0.63	0.50 – 0.75
- Preparation	0.16 – 0.59		
- Action	0.33 – 0.50	0.17 – 0.63	
- Maintenance	0.43 – 0.82	0.40 – 0.75	0.37 – 0.76
Item Discriminant Validity			
- Percentage of item-scale correlations at least 2 standard errors greater than the correlations of the item to other scales	83%	80%	94%
- Percentage of item-scale correlations greater than the correlations of the item to other scales	95%	89%	100%
Scale Reliability using Cronbach's Alpha			
- Precontemplation	0.86	0.87	0.88
- Contemplation	0.78	0.77	0.89
- Preparation	0.64*		
- Action	0.61*	0.75	
- Maintenance	0.88	0.87	0.87

* Failed to meet minimum requirements for acceptable scale measures

The exploratory analysis yielded a 3-factor structure to the stage of change construct. The proposed dimensions of precontemplation and maintenance were found to be distinguishable. The remaining proposed dimensions of contemplation, preparation, and action were found to load on to a single factor. Items that loaded on multiple constructs or provided item-scale correlations less than 0.30 were removed from the scale as poor items. With the removal of 8 poor items, an acceptable three-factor scale structure was identified. The amended scale consisted of eight precontemplation items, eleven contemplation items, and 8 maintenance items. The item internal consistency requirements were met in that 96% of item-scale correlations were found to be greater than 0.40. Only 1 item failed to meet this

standard and that one correlated to its intended scale at 0.37. The requirements for item discriminant validity were also successfully attained with 100% of items correlating higher to its intended scales than it correlated to a competing scale. Ninety-six percent of these items correlated significantly by correlating at least two standard errors higher to its intended scale than to a competing scale. Lastly, Cronbach's Alpha values were calculated on all scale dimensions and all demonstrated strong reliability numbers scoring 0.87, 0.88, and 0.89.

Decisional Balance Construct

The decisional balance construct was found as hypothesized to be a two-dimension construct reflecting the positives or pros and the negatives or cons to performing the desired behavior. Items were reduced from the pros and the cons dimension to create an 8-item single construct scale. The internal consistency correlations ranged from 0.50 to 0.63 for the scale. This provided a 100% satisfactory results for internal consistency >0.40. The discriminant validity demonstrated 84% of the items to be significantly greater correlations to the hypothesized scale than to competing scales. No items were found to have higher correlations with a competing scale than to the Decisional balance scale. Lastly, the Cronbach's alpha for the decisional balance scale was 0.84 (see Table J).

Table J: Pilot Trial 1 - Decisional Balance and Self-Efficacy Scale Statistics

Scale Statistics	Decisional Balance	Self-Efficacy
Number of Usable Subjects (N)	147	147
Item Internal Consistency		
- Percentage of Item-Scale Correlations ≥ 0.40	100%	100%
Range of Item-Scale Correlations	0.50 – 0.63	0.55 – 0.74
Item Discriminant Validity		
- Percentage of item-scale correlations at least 2 standard errors greater than the correlations of the item to other scales	84%	93%
- Percentage of item-scale correlations greater than the correlations of the item to other scales	100%	100%
Scale Reliability using Cronbach's Alpha	0.84	0.87

Self-Efficacy Construct

The self-efficacy construct was the cleanest of any of the scales developed. All the items achieved greater than 0.40 item to scale correlation. The range of the item to scale

correlations was 0.40 to 0.81. The discriminant validity tests also proved to be successful. All item-scale correlations were greater than the correlations of the item to other scales, and 86% of item-scale correlations were at least 2 standard errors greater than the correlations of the item to other scales. The scale reliability as measured by Cronbach's Alpha was 0.95 (see Table J).

The 20-question length of the self-efficacy measure was a concern. The six areas of potential temptations for medication non-compliance covered by the 20-questions could be described as concerns about side effects, feeling better, feeling worse, depressed or lazy, getting out of one's routine, inability to tell a difference from the medicine, lack of time, and financial difficulties. It was decided that the strongest item in each of the six areas would be used to form a reduced item measure. The strongest item was determined through evaluation of high item-scale correlation, clear item-level discriminant validity tests, and a subjective evaluation of the face validity of the item.

The reduced measure also performed well. The item to scale correlations ranged from 0.55 to 0.74. All item to scale correlations were greater than the correlations of the item to competing scales, and 93% of the item-scale correlations were at least 2 standard errors greater than the correlations of the item to other scales. The scale reliability was only slightly reduced, as the Cronbach's Alpha was 0.87.

Pilot Trial 2 – Refined Stage of Change Scale Testing

Due to the unexpected results for the stage of change construct scale in the first pilot trial, a second pilot trial was needed to confirm the factor structure. In an effort to reduce the burden on subjects and due to the clean results of the decisional balance and self-efficacy scales in the first pilot trial, only the stage of change construct was tested in the second pilot trial. The protocol and consent forms used in the original pilot trial were also utilized for the second pilot trial. Fifteen of the best items based on high item-scale correlations, strong item-level discriminant validity, and a subjective measure of face validity were selected from the original 35 stage of change construct items to be included in the second survey (See Appendix U). Three items from each of the five stage of change dimensions described by

Prochaska were included in the survey. The analysis for this trial included a principle components analysis to confirm the best structure was achieved.

The second pilot trial resulted in 70 community pharmacy patrons completing the survey. After dropping two relatively poor items, a clean three dimensional stage of change construct scale was produced. Once again the precontemplation and maintenance dimensions were distinct, while the items designed for the contemplation, preparation, and action dimensions converged into a single dimension. The item internal consistency demonstrated 92% of the items correlating ≥ 0.40 to its designed scale. The only item not to achieve the item-scale consistency mark was correlated to its scale at 0.37. The discriminant validity of the items was also successful in that 100% of the items correlated higher to its hypothesized scale than to a competing scale. Ninety percent of the item-scale correlations were significantly higher by at least two standard errors greater than the correlations of the item to other scales. Reliability of the scale dimensions was also acceptable with the Cronbach's Alpha coefficient being 0.80 for precontemplation, 0.87 for contemplation, and 0.79 for maintenance. The Stage of Change construct scale statistics are shown below in Table K.

Table K: Pilot Trial 2 – Stage of Change Scale Statistics

Scale Statistic	3-Factor
Number of Usable Subjects (N)	70
Item Internal Consistency	
- Percentage of Item-Scale Correlations ≥ 0.40	92%
Range of Item-Scale Correlations	
- Precontemplation	0.63 – 0.67
- Contemplation	0.37 – 0.83
- Maintenance	0.48 – 0.75
Item Discriminant Validity	
- Percentage of item-scale correlations at least 2 standard errors greater than the correlations of the item to other scales	90%
- Percentage of item-scale correlations greater than the correlations of the item to other scales	100%
Scale Reliability using Cronbach's Alpha	
- Precontemplation	0.80
- Contemplation	0.87
- Maintenance	0.79

Multiple-Item verses Single-Item Stage of Change Measures

Criticism of the Transtheoretical Model has argued that the process of adapting or altering a behavior is a continuum process rather than a true stage model. According to

Bandura (1997), "In a genuine stage theory the personal attributes at one stage are transformed into qualitatively different ones at the next stage of a fixed sequence." By the definition of a stage theory, an individual can only be in one stage at a moment in time. During analysis of the data, multiple subjects recorded higher than average scores for more than one construct. The surveys resulted 56 out of 159 (35.2%) and 8 out of 70 (11.4%) respondents scored on higher than average on more than one stage. The majority of these multi-stage respondents (43 of 56; 5 of 8) selected the maintenance option in the single-item scale and then scored higher than average on the contemplation as well as the maintenance scales.

A moderate strength of correlation was demonstrated between the multiple-item measure and the single-item measure. In the first edition of the survey, 103 of the 137 (75.2%) of the subjects were classified into the same stage. A total of twelve subjects (8.8%) were classified into different stages by the two measures. The second edition multiple-item survey also produced moderate correlation results to the single-item measure. 41 of 63 (65.1%) subjects were classified into the same stage, while seven of 63 (11.1%) subjects were classified into different stages. The remaining subjects in the two survey samples either did not score above average on any of the stages to designate their classification or the subject failed to complete the single-item measure in order to correlate the results.

The results from this pilot testing addressed two primary study goals. First, the factor structure was determined to be neither a four or five-factor model, but a three factor model. The second study goal addressed concerned whether a single-item measure could be used and garnish the same information as a multiple-item scale. Due to the complexities of subjects scoring higher than average on more than one stage with the multiple-item measure and the simplicity of the single-item measure with moderately strong correlations, it was decided to use only the single-item measure in the main study.

Main Study

One hundred and seventy one subjects across five primary care physician offices located in a rural community in Northeast Georgia agreed to participate in the

Transtheoretical Model Medication Compliance Study. The following sections describe in detail the population characteristics of this sample, a review of the individual scale responses, and results to the study hypotheses described earlier in the text.

Study Population Demographics

The study population contained a large number of Caucasians and females. The convenient sample consisted of 121 (70.8%) females and 50 (29.24%) males. The racial background of the study population reflected that of the general population of the rural mountain community in that 169 (98.83%) subjects were Caucasian. One African-American and one American Indian represented 0.58% of the population each.

The age of the subjects appeared to be a near normal distribution. The ages ranged from 20 years old to 94 years old. The average age was 61.4 years old with the median age at 64 years old. The standard deviation was 14.96 years and the interquartile range was 22 years.

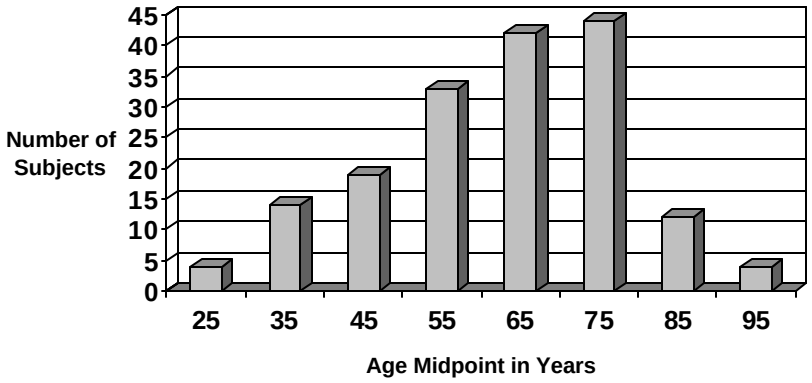

Figure 1: Age Distribution

Married subjects comprised 109 (63.74%) of the marital status of the population. Thirty-six (21.05%) widows or widowers made up the second largest group in the study population. Only 18 subjects (10.53%) in the population reported being divorced while only 8 (4.68%) individuals reported being single.

The educational status of the subjects ranged from completing less than high school to completion of a graduate school degree. Nearly one-third of the population had not completed high school. In this category, there were 50 subjects (29.24%). Fifty subjects (29.24%) also responded that completing high school highest level of education attained. Fifteen (8.77%) subjects reported completing trade school, while 44 (25.73%) subjects reported completing college. Twelve subjects (7.02%) in the sample reported completing a graduate degree.

Table L: Summary Table of Population Demographic

Variable	Classification	Frequency	Percent
Gender	Female	121	70.76%
	Male	50	29.24%
Race	African-American	1	0.58%
	American Indian	1	0.58%
	Caucasian	169	98.83%
Marital Status	Single	8	4.68%
	Married	109	63.74%
	Divorced	18	10.53%
	Widowed	36	21.05%
Education	Less than High School	50	29.24%
	High School	50	29.24%
	Trade School	15	8.77%
	College	44	25.73%
	Graduate School	12	7.02%
Household Income	Less than $15,000	47	27.65%
	$15,000 to $30,000	50	29.41%
	$30,001 to $50,000	32	18.82%
	$50,001 to $100,000	31	18.24%
	$100,001 to $250,000	9	5.29%
	Greater than $250,000	1	0.59%

The household income distribution of the population found that nearly 60% of the sample households made less than $30,000 annually. Forty-seven (27.65%) households reported earning less than $15,000 annually, while another 50 (29.41%) households earned less than $30,000 annually. Thirty-two (18.82%) families stated household incomes in the $30,001 to $50,000 range. Another thirty-one (18.24%) households were classified in the $50,001 to $100,000 range, while 9 (5.29%) households reported incomes between $100,000 - $250,000 per year. One subject (0.59%) reported a household income in excess of $250,000 per year.

Medical Demographics of the Sample Population

The patient interviews were conducted at five primary care physician locations in a rural Northeast Georgia county. Of the five facilities, the first contained one physician, one physician's assistant, and one nurse practitioner. Forty patients were interviewed at this office. The second facility contained a single physician in a solo practice where twenty-six patients were interviewed. The third and fifth facilities contained two physicians in a practice group where thirty-three and thirty-six patients respectively were interviewed. The fourth practice contained 2 physicians and 2 physician assistants. Thirty-six patients were interviewed at this facility.

Of the 171 patients completing the survey, sixty-six patients (38.60%) were interviewed about hypertension. Diabetes was the next most prevalent disease state with 30 (17.54%) patients. Twenty-nine (16.96%) female patients were interviewed about hormone replacement therapy. Hypercholesterolemia and hypothyroidism patients were the least interviewed at 24 (14.04%) and 22 (12.87%) respectively.

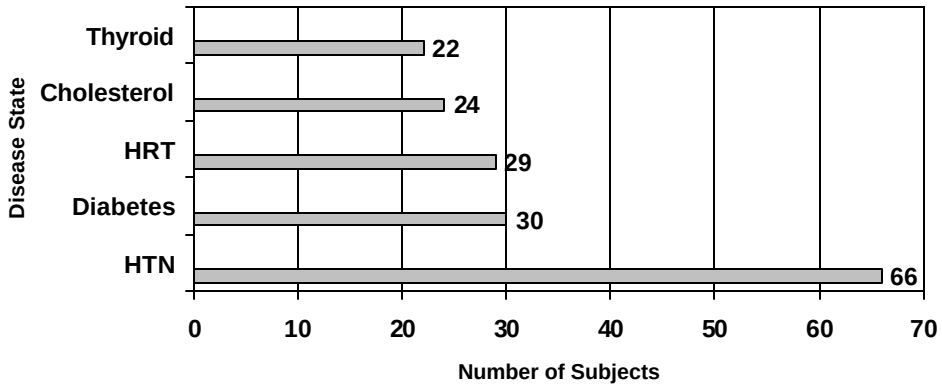

Figure 2: Disease State Participants

Each subject was asked how many prescription medications he or she took on a regular basis. The average number of prescription medications taken regularly is four per patient. The median number was 4.182353 and the mode being 3.00. Ten percent of the sample population was currently taking more than 7 prescriptions regularly. Six patients

interviewed were found to be regularly taking ten or more prescriptions with one patient taking as many as 15 prescriptions.

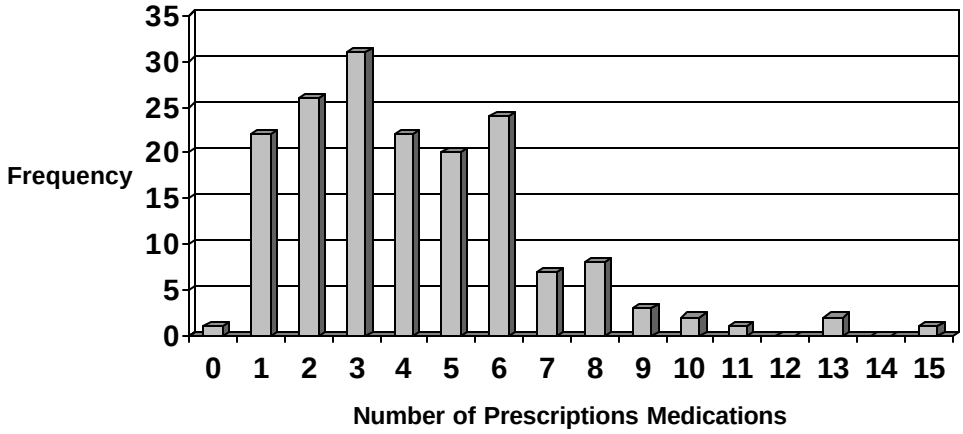

Figure 3: Number of Prescription Medications Taken Regularly

Patients were also asked to estimate how much money they spent each month out of their own pockets. The responses ranged from 2 patients reporting having to spend no money for their monthly prescriptions to a patient estimating the she spent approximately $2000.00 per month. Twenty-three (13.94%) patients stated they spent $10.00 or less per month, while 28 (16.36%) reported spending greater than $200.00 per month on prescriptions. The average of all observations was $121.71 per month. This average dropped to $110.26 per month with the exclusion of the $2000.00 per month outlier. The median response was $65.00 per month and the mode being $20.00 per month. The out of pocket expense is summarized in Figure 4.

Each subject was asked how long he or she had been treated for the disease state in question. The responses ranged from diagnosed and beginning treatment that day to having been treated for the condition for about seventy years. The mean treatment reported was 9.65 years with the median at 5 years and the mode at 10 years. Fourteen (8.28%) subjects reported being treated for 6 months or less while 15 (8.88%) subjects had been treated greater than 6 months but not more than one year. Seventeen (10.65%) patients reported have been

treated greater than 1 year but not more than 2 years. Thirty-six patients (23.67%) stated being treated for greater than 2 years but not more than 5 years. Another 31 (18.35%) subjects reported being treated greater than 5 years but not more than 10 years, while the remaining 45 (26.63%) stated they had been treated for greater than 10 years.

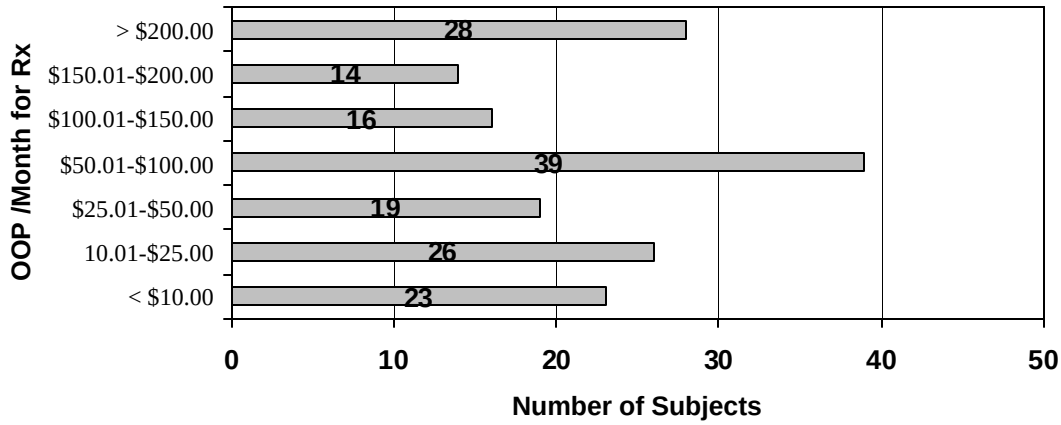

Figure 4: Monthly Out of Pocket Expenses for Prescription Medications

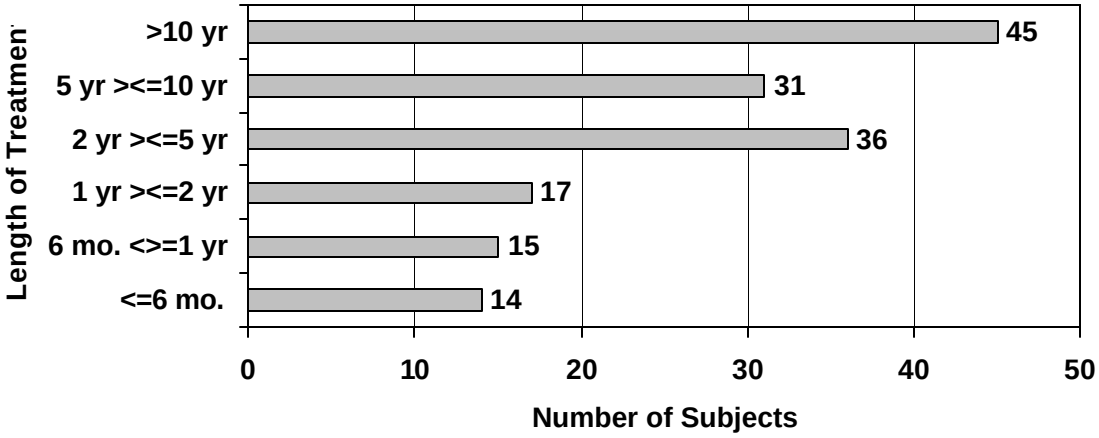

Figure 5: Length of Treatment Variable

Compliance Measure Results

Medical Outcome Study (MOS) measure of compliance

The MOS measure of compliance is a single-item simply asking the patient "how often have you taken your prescribed medication in the past four weeks?" The vast majority

of subjects, 154 or 90.06%, reported taking their medication "most or all of the time." Three patients (1.75%) stated they took the medicine "a good bit of the time," while four (2.34%) patients claimed to take their medicine "some of the time." Only one subject (0.58%) stated to take medicine "a little of the time." Eight patients (4.68%) said they had taken the medicine "none of the time."

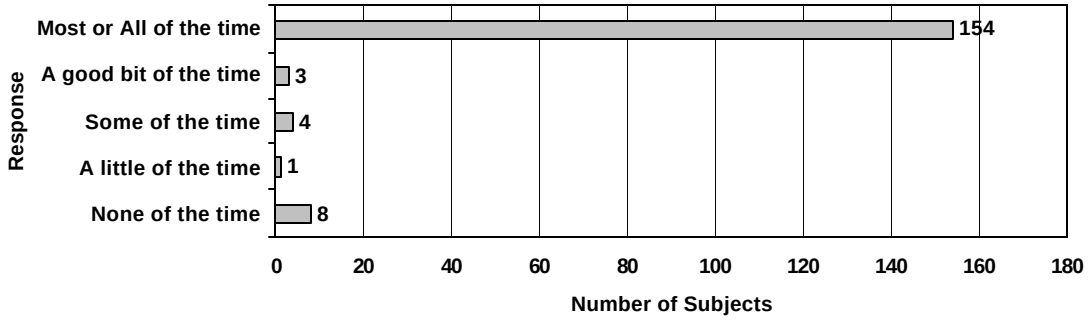

Figure 6: Results of the MOS Measure of Compliance

Medication Adherence Scale (MAS) compliance measure

The MAS consists of four-items in a "yes" or "no" question format. A point is assigned for each "yes" response for a possibly zero to four score. A higher score reflects greater non-compliance problems with the patient. The majority of patients, 103 (60.59%), received a score of zero. An additional 47 (27.65%) patients answered "yes" to only one question. Fifteen (8.82%) of subjects scored two "yes" questions, while only 4 (2.35%) subjects responded "yes" to 3 questions. Only a single subject (0.59%) responded "yes" to all four questions.

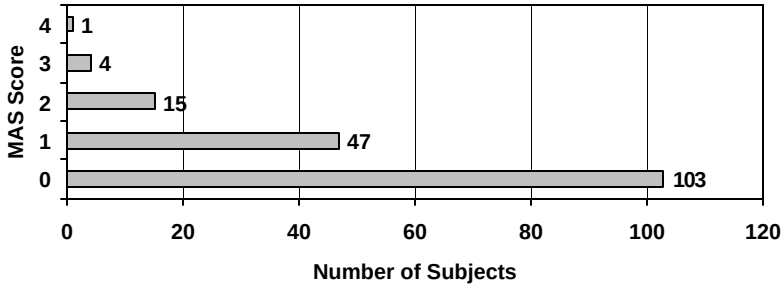

Figure 7: Results of the MAS Measure of Compliance

Brief Medication Questionnaire (BMQ) compliance measure

The Brief Medication Questionnaire consists of three sub-scales and a total overall score. The higher the score in each aspect indicates an increased potential for compliance problems. Because this study only examined only one disease state for each patient, lower scale score results are reflected compared to other previously cited literature using the entire patient medication regimen. As was often the case, a patient may be responding to how he or she takes only one or two of his or her regular medications.

The overall BMQ scores ranged from zero to five. Eighty-four (49.41%) of the patients demonstrated no difficulty in one's medication regimen with a score of zero, while fifty-one (30.00%) patients scored only one. Fourteen (8.24%) and eight (4.71%) patients respectively scored two and three. Twelve (7.06%) patients scored a four, while one (0.59%) individual scored a five on the scale.

The pattern of the majority of patients demonstrating no signs of compliance problems with their medications continued with the sub-scales. The individual sub-scale scores are displayed in Table M.

Table M: BMQ scores

Scale	Score	Frequency	Percent	Cumulative Frequency	Cumulative Percent
BMQ-total	0	84	49.41	84	49.41
	1	51	30.00	135	79.41
	2	14	8.24	149	87.65
	3	8	4.71	157	92.35
	4	12	7.06	169	99.41
	5	1	0.59	170	100.00
BMQ- regimen	0	111	65.29	111	65.29
	1	41	24.12	152	89.41
	2	13	7.65	165	97.06
	3	3	1.76	168	98.82
	4	2	1.18	170	100.00
BMQ-belief	0	151	88.82	151	88.82
	1	15	8.82	166	97.65
	2	4	2.35	170	100.00
BMQ-recall	0	131	77.06	131	77.06
	1	29	17.06	160	94.12
	2	10	5.88	170	100.00

Prescription Refill Records

One hundred and sixty patient profiles were collected from 15 different community pharmacies. The remaining 11 profiles were unable to be obtained due to various reasons. Each medication percent compliance rate was calculated based on six-monthly refills or up to six months worth of data. The majority of patients were prescribed one medication for treatment of the condition in question, however the range of medications prescribed ranged from one to four. The days supply examined ranged from zero to 660 with a mean (median) of 167 (180) days supply. The number of days between refills ranged from 14 days to 817 days examined. The mean (median) time span examined was 237 (202) days. The overall average percent compliance was 70%. The range was from 0% to 214% compliance with the median being 83% compliance rate.

The compliance rate varied across disease state. Hypertension, diabetes, and hypothyroidism reporting similar mean (median) compliance rates respectively at 75% (88%), 77% (90%), and 71% (89%). Hypercholesterolemia and hormone replacement therapy demonstrated lower mean (median) compliance rates respectively at 54% (63%) and 60% (70%).

Table N: Prescription Refill Record Summary

Variable	N	Range	Max	Min	Mean	Median	Std Dev
Days Supply	160	660	660	0	166.9	180	120.2
Days Between First and Last Refill	160	803	817	14	237.2	202	114.6
Compliance	160	214%	214%	0%	70%	83%	37%

Table O: Refill Record Across Disease State

Disease State	N Obs	N	N Miss	Range	Mean	Median	Std Dev	Lower 95% CI for Mean	Upper 95% CI for Mean
Hypertension	66	61	5	214%	76%	88%	38%	67%	86%
Hypercholesterolemia	24	22	2	123%	54%	63%	43%	35%	73%
Diabetes	30	30	0	120%	77%	90%	33%	65%	90%
Hormone Replacement	29	28	1	105%	60%	70%	34%	47%	73%
Hypothyroidism	22	19	3	110%	71%	89%	36%	53%	88%

Transtheoretical Model compliance measures

The single-item stage of change, the decisional balance, and the self-efficacy measures developed in the pilot trial were utilized in the main study. The stage of change measure found the majority of the subjects had been on their medication regimens for greater than 6 months with 144 (84.71%) of patients selecting the choice corresponding to maintenance phase. The remaining 26 (15.29%) subjects constituted the remaining stages of change. The precontemplation and contemplation stages recorded four (2.35%) subjects each, while the preparation stage had 3 (1.76%) responses. The action stage contained 15 (8.82%) subjects who had been taken their prescribed medication regimen for less than six months. These numbers reflect similar responses to the other patient reported measures.

Table P: Summary of Stage of Change Responses

Stage	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Precontemplation	4	2.35	4	2.35
Contemplation	4	2.35	8	4.71
Preparation	3	1.76	11	6.47
Action	15	8.82	26	15.29
Maintenance	144	84.71	170	100.00

The Decisional Balance measure consisted of eight items in a 5-point likert scale format. The possible range for scores are 8 to 40. The study group responses ranged from 23 to 40. Twenty-eight (16.67%) subjects scored the ceiling score of 40 while zero subjects even approached the floor score of 8. The mean score for decisional balance was 36 with the median also near the ceiling at 37. The lowest quartile of scores was 34. A summary of the decisional balance and self-efficacy scores are shown in Table Q below.

The self-efficacy measure displayed a similar pattern of scores to the decisional balance measure. With six 5-point likert scale items, the possible range for the self-efficacy scale was from a score of 6 to 30. The actual range scored by subjects was from 9 to 30. Ninety-four (55.29%) subjects recorded ceiling scores of 30 with the top 3 quartiles recording a score of 26 or higher. This distribution reflects other patient reports of the majority of patients not demonstrating any compliance difficulties.

Table Q: Summary of Decisional Balance and Self-Efficacy Scale Scores

Quantile	Decisional Balance	Self-Efficacy
100% Max	40	30
99%	40	30
95%	40	30
90%	40	30
75% Q3	39	30
50% Median	37	30
25% Q1	34	26
10%	31	23
5%	29	20
1%	25	12
0% Min	23	9

Results for Hypotheses

Hypothesis I

Hypothesis I examines the correlation between the Transtheoretical model and the established measures of compliance. This hypothesis implies that each of the transtheoretical model variables will increase as the level of medication compliance increases. Hypotheses I was tested using the Pearson correlation coefficient. The nomiss option included 157 observations in the analysis. The results are demonstrated in Table R below.

The first hypothesis to be tested was:

Hypothesis I: The stages of change, decisional balance, and self-efficacy constructs are positively significantly correlated with levels of medication compliance.

The null form of this hypothesis was stated:

Null: The stages of change, decisional balance, and self-efficacy constructs are not correlated with levels of medication compliance.

For each measure of stage of change, decisional balance, and self-efficacy scores there was a significant positive correlation ($p<0.05$) with measures of medication compliance. The correlations ranged from 0.17535 – 0.78986 with p-values ranging from <0.0001 to 0.0281. Therefore, we can reject the null hypothesis of no relationship between each of the variables. Power was calculated using the procedures described by Cohen (1977) and ranged from a

low of 65 to >99.5. Nine of the twelve pairwise power measures was found to be greater than 85.

The Stage of Change variable demonstrated positive significant correlations to all medication compliance measures. The correlation to the MOS compliance measure was found to be 0.78986 ($p<0.0001$), the MAS measure at 0.49246 ($p<0.0001$), pharmacy refill records 0.28153 ($p=0.0004$), and the BMQ measure at 0.23870 ($p=0.0026$).

Table R: Pearson Correlation Table for Hypotheses I and IV

	Stage of Change	Decisional Balance	Self-Efficacy	Pharmacy Refill Records	MOS measure	MAS Measure	BMQ measure
Stage of Change (p-value) (1-ß)	1.00000						
Decisional Balance (p-value) (1-ß)	0.45274 (<0.0001) (>0.995)	1.00000					
Self-Efficacy (p-value) (1-ß)	0.41116 (<0.0001) (>0.995)	0.49817 (<0.0001) (>0.995)	1.00000				
Refill Records (p-value) (1-ß)	0.28153 (0.0004) (0.9412)	0.18308 (0.0217) (0.6939)	0.17535 (0.0281) (0.6591)	1.00000			
MOS measure (p-value) (1-ß)	0.78986 (<0.0001) (>0.995)	0.34181 (<0.0001) (>0.9800)	0.37364 (<0.0001) (>0.9800)	0.20007 (0.0120) (0.7701)	1.00000		
MAS Measure (p-value) (1-ß)	0.49246 (<0.0001) (>0.995)	0.38810 (<0.0001) (>0.9800)	0.51938 (<0.0001) (>0.995)	0.26764 (0.0007) (0.9120)	0.42840 (<0.0001) (>0.995)	1.00000	
BMQ measure (p-value) (1-ß)	0.23870 (0.0026) (0.8513)	0.18145 (0.0229) (0.6865)	0.31951 (<0.0001) (>0.9800)	0.09024 *(0.2610) (0.2888)	0.25516 (0.0013) (0.8858)	0.22828 (0.0040) (0.8179)	1.00000

* fails to meet significance at alpha = 0.05

The Self-Efficacy measure was found to correlate significantly to all medication compliance measures. The correlation to the MAS measure was found to be 0.51938 ($p<0.0001$), the BMQ measure at 0.31951 ($p<0.0001$), the MOS measure at 0.37364 ($p<0.0001$), and the pharmacy refill records at 0.17535 ($p=0.0281$).

The Decisional Balance variable also correlated significantly with all four of the measures of compliance. The significant correlations were 0.38810 ($p<0.0001$) for the MAS measure, 0.34181 ($p<0.0001$) for the MOS measure, 0.18308 ($p=0.0217$) for the pharmacy refill records, and 0.18145 ($p=0.0229$) for the BMQ measure.

Hypothesis II

The second hypothesis examined whether a difference exists in the mean compliance rate between the different stages of change. The hypothesis implies that patients will demonstrate different levels of medication compliance at different stages of change. The study examines the stage of change construct in terms of the 3-stage model for medication compliance identified within the pilot trials described previously. The hypothesis was tested using ANOVA. Tukey's standardized range test for multiple comparisons was used to determine where the significant pairwise differences exist.

The second hypothesis tested was:

Hypothesis II: Medication compliance rates are different across the stage of change construct of the TTM.

The null form of this hypothesis was stated:

Null: Medication compliance rates are equal across the stage of change construct of the TTM.

The ANOVA for hypothesis II resulted in a significant F-value of 7.88 ($P=0.0006$) indicating that medication compliance rates are not equal across the Stage of Change measure. Tukey's standardized range test was performed to examine the mean compliance rate differences between each stage. In each pairwise comparison, all but one pair of compliance rate means were found to be significantly different. The difference of mean compliance rates between precontemplation and maintenance as well as between contemplation and maintenance were found to be statistically significant. The mean rate of medication compliance between precontemplation and contemplation was not found to

achieve statistical significant difference. The mean percent compliance for each stage demonstrated large differences with precontemplation= 23.80%, contemplation=47.92%, and maintenance=74.33%. Large standard deviations accompany the mean values. Table S below summarizes the findings for Hypothesis II.

Table S: Percent Compliance Across Stages of Change

Level of Stage of Change	N	t-tests	Prescription Refill Rates	
			Mean	Standard Deviation
Precontemplation	4	P/C P/M*	0.2380	0.4761
Contemplation	19	C/P C/M*	0.4792	0.5595
Maintenance	136	M/P* M/C*	0.7433	0.3201

*Represents significantly different means at alpha=0.05

Hypothesis III

Hypothesis III examines the relationship between the three constructs of the transtheoretical model. Specifically, this hypothesis examines how decisional balance and self-efficacy change over the stage of change construct in medication compliance. The hypothesis was tested using ANOVA. Tukey's standardized range test for multiple comparisons was used to determine where the significant pairwise differences exist.

The third hypothesis tested was:

Hypothesis III: Decisional balance and self-efficacy scores are different across the stage of change construct of the TTM.

The null form of this hypothesis was stated:

Null: Decisional balance and self-efficacy scores are equal across the stage of change construct of the TTM.

The ANOVA over the stage of change construct were significant for the decisional balance and the self-efficacy constructs. The F-values were 14.24 ($p<0.0001$) and 5.73 ($p<0.0039$) for the decisional balance and self-efficacy constructs respectively. Therefore, we reject the null hypothesis that the decisional balance and self-efficacy scores are equal across the stages of change.

The Tukey's standardized range test revealed that all the levels across the stage of change construct are significantly different in the decisional balance measure. The Tukey's pairwise comparisons revealed a different outcome for the self-efficacy measure. Only the precontemplation and maintenance pairwise comparison was found to be significantly different statistically. No mean self-efficacy stage score showed significant difference with a neighboring stage score. The pairwise comparison between the stages precontemplation and contemplation as well as between stages contemplation and maintenance were found not to be statistically significantly different (see Table T).

Table T: Decisional Balance and Self-efficacy Across Stage of Change

Stage of Change	Decisional Balance		Self-Efficacy	
	t-tests	Mean (std dev)	t-tests	Mean (std dev)
Precontemplation	P/C*, P/M*	29.25 (4.79)	P/C, P/M*	23.50 (7.90)
Contemplation	C/P*, C/M*	33.95 (3.85)	C/P, C/M	26.24 (5.98)
Maintenance	M/P*, M/C*	36.48 (3.11)	M/P*, M/C	28.12 (2.80)

* Indicates t-test between means that meet significant difference at alpha=0.05

Hypothesis IV

Hypothesis IV examines the correlations between the different medication compliance measures. This hypothesis implies that an increase in compliance measured by one scale will be shown as an increase in compliance in all the compliance measures in this study. Pearson's correlation table of these relationships can be seen above in Table R.

The fourth hypothesis tested was:

Hypothesis IV: Pharmacy computer refill records, medical outcomes study compliance measure, medication adherence scale, and brief medication questionnaire are positively significantly correlated.

The null was:

Null: Pharmacy computer refill records, medical outcomes study compliance measure, medication adherence scale, and brief medication questionnaire are not positively significantly correlated.

All correlations were significant at $p<0.05$ with the exception of one correlation. The five significant correlations ranged from a low between medical outcomes study compliance question and pharmacy computer refill records at 0.20007 ($p=0.0120$) and a high correlation between medical outcomes study compliance measure and medication adherence scale at 0.42840 ($p<0.0001$). The only non-significant test was found between pharmacy computer refill records and brief medication questionnaire with a correlation of 0.09024 ($p=0.2610$). From this evidence, we reject the null hypothesis of no relationship between the measures of compliance, with the exception of the pharmacy computer refill records and the brief medication questionnaire. Power analysis supports these results with the significant correlation tests ranging from a low of 77 to a high of >99.5.

Hypothesis V

Hypothesis V examines the amount of variance in medication compliance explained by each of the transtheoretical model constructs. The hypothesis implies that the constructs of stages of change, decisional balance, and self-efficacy all contribute significantly to the explanation of medication compliance behavior. All four of the compliance measures were tested each using the general regression equation:

$$\text{Compliance} = \beta_0 + \beta_1(\text{stage of change}) + \beta_2(\text{decisional balance}) + \beta_3(\text{self-efficacy}) + e$$

The fifth hypothesis to be tested was stated:

Hypothesis V: The stages of change, decisional balance, and self-efficacy constructs contribute significantly to the explanation of variance in compliance behavior.

The null form of this hypothesis was stated:

Null: The stages of change, decisional balance, and self-efficacy constructs do not contribute significantly to the explanation of variance in compliance behavior.

The results of the regression analysis are shown in Table U below. The transtheoretical model explanation of compliance variance was different depending on which medication compliance measure was examined. The transtheoretical model variables were

able to explain a large amount of variance in the medical outcomes study compliance measure and the medication adherence scale at 41.07% and 35.63% respectively. The results for the pharmacy refill records and the brief medication questionnaire measure were far weaker explaining 9.61% and 11.56% respectively.

The contribution from the transtheoretical model constructs to the explanation of variance was also diverse between the different measures of compliance. The stage of change construct accounted for the largest explanation of variance in two of the medication compliance measures. The stage of change construct explained 8.51% of pharmacy computer refill records and 36.01% of medical outcomes study compliance measure variance. The self-efficacy construct was the principal explanatory construct in the brief medication questionnaire and medication adherence scale measures accounting for 10.25% and 27.30% of the variance respectively.

Table U: Hypothesis V Regression Analysis for Explanation of Compliance Variance

	Stage of Change	Decisional Balance	Self-Efficacy	R^2	Adj. R^2
Pharmacy Refill Records	p=0.0031*	p=0.6894	p=0.3419	0.0961	0.0784
MOS measure	p<0.0001*	p=0.7708	p=0.0017*	0.4107	0.3998
MAS measure	p=0.0001*	p=0.2846	p<0.0001*	0.3563	0.3444
BMQ measure	p=0.1266	p=0.8340	p=0.0007*	0.1156	0.0993

* indicates parameter estimates significant at the p=0.05 level

Hypothesis VI

Hypothesis VI examines the extent to which demographic variables contribute to the explanation of medication compliance. This hypothesis uses regression analysis to examine whether demographic variables can be used to assess which patients will be better about complying with the prescribed medication therapy. The hypothesis implies that patients having significant demographic variables attributes should have higher rates of medication compliance. The regression model performed included the stage of change measure plus the demographic variables. The regression equation tested was:

$$Compliance = b_0 + b_1(stage\ of\ change) + b_2(age) + b_3(gender) + b_4(marital\ status) + b_5(educational\ achievement) + b_6(length\ of\ treatment) + b_7(number\ of\ medications) + e$$

The sixth hypothesis to be tested was stated:

Hypothesis VI: Demographic variables contribute significantly to the explanation of the variance in the dependent variable compliance.

The null to this hypothesis was stated:

Null: Demographic variables do not contribute significantly to the explanation of the variance in the dependent variable compliance.

Results of the regression model found that none of the demographic variables could account for any significant portion of the variance in medication compliance. The variables tested included age, gender, marital status, education, length of treatment, and number of prescriptions. The t-values (p-values) for the demographic variables ranged from 1.12 (0.2652) to 0.01 (0.9922) as shown in Table V below. The results of this regression model indicate that this study failed to reject the null hypothesis.

Table V: Regression Model of Refill Records with Demographic Variables

The REG Procedure
Model: MODEL1
Dependent Variable: Percent Compliance

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	7	2.65633	0.37948	2.93	0.0067
Error	148	19.18878	0.12965		
Corrected Total	155	21.84512			

Root MSE	0.36007	R-Square	0.1216
Dependent Mean	0.69819	Adj R-Sq	0.0801
Coeff Var	51.57285		

Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|	Standardized Estimate
Intercept	1	-0.12902	0.25749	-0.50	0.6171	0
Stage of Change	1	0.25218	0.06891	3.66	0.0004	0.29713
Age	1	0.00236	0.00211	1.12	0.2652	0.09582
Gender	1	0.00066	0.06713	0.01	0.9922	0.00080
Marital Status	1	0.01861	0.03695	0.50	0.6153	0.04343
Education	1	-0.02373	0.02271	-1.04	0.2979	-0.08385
Length of Treatment	1	-0.00306	0.00279	-1.10	0.2743	-0.09189
Number of Prescriptions	1	0.00321	0.01135	0.28	0.7773	0.02260

Hypothesis VII

Hypothesis VII examines the amount of variance within the stage of change construct that can be explained through the demographic variables. This hypothesis was to examine whether the stage of change could simply be explained by demographic variable attributes. A regression model was created and performed using the stage of change construct as the dependent variable and the demographic variables from the previous model.

$$\textit{Stage of Change Score} = b_0 + b_1(\textit{age}) + b_2(\textit{gender}) + b_3(\textit{marital status}) + b_4(\textit{educational achievement}) + b_5(\textit{length of treatment}) + b_6(\textit{number of medications}) + e$$

The seventh hypothesis tested was stated:

Hypothesis VII: Demographic variables contribute significantly to the explanation of the variance in the stages of change construct.

The null for this hypothesis was stated:

Null: Demographic variables do not contribute significantly to the explanation of the variance in the stages of change construct.

The results demonstrated that the variables age, gender, marital status, and length of treatment did not contribute to the variance in the stage of change measure. Two demographic variables did achieve statistical significance at the level of alpha= 0.05. Educational achievement was determined to be a negative factor for stage of change with a p-value=0.0418. The number of prescriptions was found to be a positive factor for stage of change with a p-value of 0.0081. The regression model was able to explain a total of 9.9% of the variance in the stage of change measure (see Table W). Results from this study indicate that we can reject the null hypothesis for the variables educational achievement and number of prescriptions. We fail to reject the hypothesis for the demographic variables of age, gender, marital status, and length of treatment.

Table W: Regression of Stage of Change with Demographic Variables

The REG Procedure
Model: MODEL1
Dependent Variable: Stage of Change

Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	6	3.22809	0.53801	2.93	0.0097
Error	160	29.38269	0.18364		
Corrected Total	166	32.61078			

Root MSE	0.42853	R-Square	0.0990
Dependent Mean	2.82036	Adj R-Sq	0.0652
Coeff Var	15.19432		

Variable	DF	Parameter Estimate	Standard Error	t Value	Pr > |t|	Standardized Estimate
Intercept	1	2.71017	0.20830	13.01	<0.0001	0
Age	1	-0.00076	0.00241	-0.31	0.7534	-0.02589
Gender	1	0.05796	0.07684	0.75	0.4517	0.06007
Marital Status	1	-0.00435	0.04185	-0.10	0.9173	-0.00861
Education	1	-0.05298	0.02582	-2.05	0.0418	-0.15886
Length of Treatment	1	0.00621	0.00319	1.95	0.0535	0.15599
Number of Prescriptions	1	0.03455	0.01289	2.68	0.0081	0.20326

CHAPTER 7

DISCUSSION AND CONCLUSIONS

Previous research has demonstrated the success of the Transtheoretical model in predicting behavioral changes within various health-related behaviors. The results of this study give support for the use of the Transtheoretical model in medication compliance behavior. Within each of the validation measures performed, the Transtheoretical model presented evidence strengthening the case for its viability within medication compliance research.

Hypothesis I

The elements of the Transtheoretical model including stage of change, decisional balance, and self-efficacy each demonstrated positive significant correlation with patient level of compliance. This positive correlation provides the evidence needed to associate higher-level scores on the transtheoretical model construct scales to higher levels of medication compliance by patients. Likewise, a lower score by a patient indicates the need for the practitioner to individually assess and intervene to improve the compliance to therapy by the patient. By assessing each of these variables, a healthcare practitioner is provided insight into possible causes of a patient's noncompliance.

Stage of Change

A positive relationship was found between a patient's stage of change in the transtheoretical model and the patient's level of medication compliance as measured in this study. This finding was supported by each of the compliance measures including pharmacy computer refill rate, the medical outcomes study compliance measure, the medication adherence scale, and the brief medication questionnaire. Patients in the earlier stages of the

stage of change construct were associated with lower levels of compliance. This should be a useful result for healthcare practitioners in that patients who are in the precontemplation and contemplation stages may need additional support, education, etc. to encourage or improve compliance to therapy.

The major implication of assessing patients with the single-item stage of change is that compliance measurement can be accomplished promptly and without difficulty. This simple tool can allow practitioners to instantly identify patients with the greatest need for intervention. Equally, if not more important for the hurried practitioner, is the ability to rapidly identify the patients for whom complying with therapy is not a problem. The patient's location within the stage of change construct provides healthcare professionals an indication of the patient's willingness to comply with therapy. Once the assessment is made, further evaluations and possible interventions can be specially tailored to the patient.

Decisional Balance

For all compliance measures, decisional balance was found to have a significant correlation with compliance. This implies that patients who have a positive decisional balance see more benefit of medication taking and are more likely to have higher levels of compliance. Patients who have a negative decisional balance are more likely to have lower levels of compliance.

The findings suggest to healthcare practitioners that education about the positive aspects of taking a medication may be helpful in forming more positive compliance behaviors. As practitioners, we should not assume our patients understand all the consequences of their prescribed therapy. Communicating to the patient the benefits of the therapy as well as the overall goals in treatment is essential to creating a patient who is involved in their own health. Identifying patients' negative beliefs about therapy also have to be addressed in order to improve compliance to any therapeutic regimen. Negative beliefs may present as a physical, emotional, or psychological barrier. Removal or reduction of

these barriers should result in a positive increase in decisional balance as well as improved compliance to therapy.

Self-Efficacy

Results produced a positive relationship between a patient's self-efficacy and each of the measures of compliance used in this study. Patients who believed they were capable of sustaining medication compliance demonstrated higher levels of medication compliance. Identification of when patients fail to comply with their medication regimen is fundamental to corrective action. Often, the practitioner can provide a simple answer to the compliance problem that the patient has never considered. Straightforward solutions such as a daily pillbox can provide forgetful patients evidence of whether they have taken their medicine today. Other barriers can provide a greater challenge for the practitioner to solve, but educating patients about how they can overcome compliance barriers can increase the self-efficacy of the patient and therefore should be considered useful for healthcare practitioners who want to improve medication compliance.

Hypothesis II

The ANOVA demonstrated compliance rates are not equal across the stage of change construct. Patients scoring lower on the stage of change scale demonstrated lower medication compliance while patients scoring higher on the stage of change demonstrated higher medication compliance rates. This finding lends validity to the usefulness of the stage of change construct in assessing medication compliance.

The Tukey's analysis of stage comparisons revealed that only some of the multiple comparisons were significantly different. Two factors appear to contribute to this outcome. First, the low number of patients who present in the precontemplation and contemplation stages relative to the maintenance stage creates a problem. A larger sample of precontemplators and contemplators would provide greater confidence in the mean compliance reported. However, this breakdown in stage assignment is consistent to that reported by Willey et al.(2000). Secondly, the wide individual differences among patients

represent the difficulties in medication compliance research. Large standard deviations reflect the wide range of responses by patients even within the same stage. These individual differences confound statistical inferences and increase the number of patients needed to accurately examine compliance behavior. The significant differences observed in this study despite the low numbers and large variations attest to the strength of the results.

The positive relationship between mean compliance rates across the stage of change construct validates the use of the stage of change measure as a method to assess a patient's need of compliance intervention. The difference this result provides is the evidence that progression through the stage of change dimension can be seen as a marked change in percentage of medication doses taken by the patient. Healthcare practitioners could design and adjust specific counseling strategies with individual patients utilizing the processes of change construct within the transtheoretical model to meet the needs of the patient.

Hypothesis III

ANOVA analysis revealed differences exist between the mean scores of the decisional balance and self-efficacy measures across the stage of change scale. The results of this hypothesis indicate that decisional balance scores and self-efficacy scores increase as a patient progresses through the stage of change construct. These findings support the previous research results found in other health behaviors concerning the relationship of the Transtheoretical model constructs (Prochaska et al., 1994). Patients in earlier stages of change demonstrated lower scores on both the decisional balance and the self-efficacy scales. Likewise, the highest scores were seen for both the decisional balance and self-efficacy scale score for the patients in the maintenance phase. Additional evidence of this relationship was provided through the Pearson correlation table. Correlations between the three-transtheoretical model constructs ranged from a low of 0.41116 for stage of change and self-efficacy to a high of 0.49817 for decisional balance and self-efficacy. All p-values were less than 0.0001 and power >99.5.

The Tukey's standardized range test revealed stronger results for the decisional balance measure across the stages of change than for the self-efficacy measure. The

decisional balance means were found to be significantly different across all stages of change. The self-efficacy scale was found to have significant score differences among the non-adjacent stages. Adjacent stage scores increased as predicted, however the differences did not achieve significant levels. The low number of respondents in both the precontemplation and contemplation stages as well as large standard deviations among the few respondents is hypothesized to be contributing factors for the failure to reach significant differences among adjacent stages. The significant differences found despite the low numbers and large variations again attest to the strength of the results.

Hypothesis IV

Hypothesis IV examined the relationships between the four measures of medication compliance used within the present study. A Pearson correlation table was used to examine this hypothesis. The results indicate a positive significant relationship exists between each of the medication compliance measure except between the pharmacy refill records and the brief medication questionnaire. While this relationship was positive in the predicted direction, the correlation was only 0.09024 and the p-value failed to reach significance at 0.2610. The remaining five out of six correlations ranged from 0.20007 to 0.42840. The p-values ranged from 0.0120 to <0.0001 with power ranging from 77 to >99.5.

The results of this hypothesis highlight one of the major difficulties in compliance research. While each of the four measures claim to be a valid and reliable source of predicting medication compliance behavior, no two measures were highly correlated to another. The two short (one single-item and one four-item measure) self-reported measures only correlated slightly above 0.40. Four of the measures correlations were between 0.2 and 0.3, indicating that for any individual patient widely varied results may be produced depending on which measure is used to assess the compliance. These results varied widely even though multiple self-reported measures were compared. The correlation results with the pharmacy refill records compared favorably with the MAS and MOS measure results. The difference being that the refill records reflect a patient's past medication compliance performance verses the other measures acting as self-reported instruments of performance.

The results of this hypothesis are positive from a statistical perspective; however, a clinician would be quick to point out the weaknesses in the strength of these findings in terms of clinical significance.

Hypothesis V

The fifth hypothesis examined the amount of variance in medication compliance explained by each of the transtheoretical model constructs. Independent regression models were performed using each of the four compliance measures as the dependent measure. The stages of change construct and the self-efficacy construct demonstrated their usefulness as predictive variables. However, the decisional balance construct failed to contribute significantly to any of the four models. Overall, the TTM model constructs demonstrated mixed success in the explanation of medication compliance behavior.

The transtheoretical model accounted for 41.07% and 35.63% of variance demonstrated for the MOS and MAS measures respectively. In both of these models, the stages of change and self-efficacy constructs contributed significantly to the explanation of variance. These findings support the previous results reported by Johnson et al. (1988) using a similar short self-reported measure. The findings exceed the stated goals expected for the study and provide encouraging support for use of the TTM in medication compliance behavior.

However, the testing performed on the remaining two compliance measures provided less encouraging results. The TTM model variables only contributed 9.61% and 11.56% explanation of the pharmacy refill records and BMQ measure respectively. In each of these models, only one TTM construct was found to contribute significantly. The stages of change provided the largest explanation of variance for the pharmacy refill records, while not contributing significantly to the BMQ explanation of variance. The self-efficacy provided the complete opposite to the stage of change in the explanation of variance. The self-efficacy construct provided nearly the complete contribution by the TTM constructs for the BMQ measure, while not significantly contributing to the explanation of the variance in pharmacy refill records.

The failure of the decisional balance measure to contribute significantly to any of the models was not expected as an outcome in this study. Multicollinearity between the Transtheoretical constructs of stage of change, self-efficacy, and decisional balance appears to be one contributing factor to the finding. Since the constructs measure related aspects of a behavior, the shared explanation of variance is accounted for by the other construct measures. Other possible explanation includes the decisional balance measure is weaker than expected as a compliance measure in the patient population.

The major implications of these findings are that once again measurement of medication compliance remains an elusive objective. Since, the transtheoretical model relies on the self-reported measures of patients, it correlates well with other self-reported measures of medication compliance performance. As is known in practice as well as throughout previous literature, patients often over-estimate their compliance to a therapy. This gap between the patients' intentions and the patients' performance in medication compliance indicates that barriers still exist for many of the well-intended patients. The Theory of Planning Behavior (Ajzen, 1985) recognizes that behavior is a function of both the strength of a person's attempt to perform a behavior and the degree of control the person has over that behavior. When a patient is psychologically ready to comply with therapy, all efforts need to be made to eliminate or minimize any physical or planning barriers that may be present. Healthcare providers have the opportunity to identify areas where the patient needs assistance and offer suggestions to overcoming barriers hindering medication compliance. The Transtheoretical model would appear to be an appropriate choice as the theory based cornerstone for integration in a comprehensive compliance program.

Hypothesis VI

The contribution of demographic variables was examined to support previous compliance literature. The regression analysis findings in this study demonstrated that demographic variables do not contribute to the explanation of medication compliance variance. The demographic variables tested included age, gender, marital status, educational achievement, length of treatment, and number of medications. The implication of this

hypothesis is to add validity to the overall study results. Supporting previous research findings indicates that the study population and conditions were similar to those in other settings. These findings lend credibility that the results produced in this study could be repeated in other similar populations and provide the same results.

Hypothesis VII

The final hypothesis examined the contribution of demographic variables to the stage of change construct. The purpose behind this hypothesis was to add discriminant validity to the stage of change construct in medication compliance behavior. The same demographic variables used in hypothesis VI were utilized. The total contribution to the explanation of stage of change by the demographic variables was 9.9%.

The variables of age, gender, and marital status were not significant variables in the explanation of the stage of change construct. The variable number of prescriptions did not achieve statistical significance at the $\alpha = 0.05$ level. However, the variable was close to achieving statistical significance with a $p=0.0535$. This finding is intuitive in that the longer an individual has been treated for a chronic disease the more likely they are to be taking their medication on a regular basis or in terms of the transtheoretical model to be further down the stage of change construct. The provision of more time allows a greater number of opportunities that a change in behavior may exist.

The variables educational achievement and number of prescriptions were found to be statistically significant. Educational achievement was found to be a negative factor towards progression in the stage of change. Individuals with higher levels of education are more likely not to be compliant with the therapy prescribed by their physician. One argument is that those with more education are more likely to evaluate the physician's directions as suggestions. The term "intelligent non-compliance" indicates the patients are knowledgeable about their condition and evaluates the prescribed therapy as to whether they will comply. One goal of a good education is to provide the individual with the ability to think for oneself. This finding could be a direct reflection of the educated patient constantly evaluating the benefits verses risk of any prescribed medication therapy.

The main implication of this hypothesis is that the stage of change construct cannot be explained by demographic characteristics of a patient. Discriminant validity is as important in the validation process of a new construct as convergent validity. The study results provide evidence that the stage of change construct is independent to age, gender, and marital status.

Limitations

Several limitations must be considered when evaluating the results of this study. First, the population studied may not be reflective to other patient populations or the population as a whole. Patient sampling was performed using patients in a single rural county in Northeast Georgia. As demonstrated by the demographics, the testing area is overwhelmingly Caucasian with very little ethnic or cultural diversity. Aside from the lack of multicultural input, one cannot be assured that the results of a rural population would reflect that of a suburban or urban population.

The difficulties of accurately measuring medication compliance have yet to be solved. This study demonstrated four validated measures of compliance having a wide range of correlations from a low, weak association of 0.09024 to a high, strong association of 0.78986. None of the measures utilized can be considered a perfect measure. All contain inherent strengths and weaknesses associated with the scale format. One must examine the available evidence and formulate whether the evidence in this or any other compliance study is sufficient to support the study results and claims. This study included four previously validated medication compliance measures in an attempt to provide the results in a fair, unbiased manner.

A limitation of the study was the ability to identify and include individuals in the early stages of the transtheoretical model stages of change construct. Patients who have previously been diagnosed and are being treated for their disease represent the majority of patients within a physician's practice. The true "precontemplators" are ignorant of their health condition, in denial, or choose to reject therapy. None of these options provide easy access or regular inclusion into the conventional medicine channels.

The difficulty in obtaining patients in the early stages of the stage of change construct impacted another aspect of the study. While not a specific hypothesis within the study, it was hoped that a comparison between disease states could be evaluated. However, due to the low numbers of precontemplators and contemplators, analysis could only be performed for the chronic conditions as a whole. Additional data collection could still be included at a later date to make this goal possible. Despite the fact that low numbers of precontemplators and contemplators were entered into the study, the majority of the tests in this study demonstrated statistical significance, thus verifying the strength of the effects.

Future Direction

Future research projects may include any one of several directions involving the Transtheoretical model in medication compliance behavior. From the beginning of this project, the long-term goal has been to integrate the transtheoretical model constructs into a practitioner-based program designed to identify, assess, and provide intervention strategies based on the patient's stage of change. These interventions could be individualized to the specific barriers and needs recognized for that patient. Such a comprehensive program should include the provisions to minimize or remove all physical, mental, and emotional barriers confronting the patient. Perri, Nichols-English, and Poirier (2000) have undertaken such a comprehensive algorithm. The integration of the Transtheoretical model into such an algorithm can provide a theory-based approach for handling the psychological issues with the patient's medication compliance evaluation.

A transtheoretical model based program could be presented in multiple formats depending on the practitioner and setting. Some practitioners may want to use an interview approach to design and implement interventions for the patient. However, others may elect to use a computer guided algorithm program that highlights the areas in which a patient may need assistance. Regardless of how such a program is presented, the advantage of a theory-based program that can be flexible to the individual needs of the patient is that the patient receives guidelines that are appropriate to his or her readiness to change, decisional balance, and self-efficacy.

Duplication of these research hypotheses is welcomed in an effort to better understand the relationship of the transtheoretical model constructs within medication compliance behavior. Suggestions include an effort to strengthen the items within each transtheoretical model construct scale, the inclusion of larger sample sizes to detect differences between disease state responses, the use of more sensitive methodology such as structural modeling, and the inclusion of other known chronic disease states.

Conclusions

The results of this study give support for the use of the Transtheoretical model in medication compliance behavior. Each of the validation measures performed provided an increasingly stronger case for the use of this behavioral model within medication compliance research. The successes of testing the transtheoretical model against four previously validated measures of medication compliance reinforce the reliability and validity of the findings in this study.

Three hypotheses provide convergent validity that the Transtheoretical model constructs demonstrated positive relationships to medication compliance. The correlations between the TTM and the other compliance measures resulted in significant findings at every point. This finding was supported and followed up by providing evidence that mean compliance rates increase as stage of change progresses. Lastly, the Transtheoretical model constructs were tested to explain the variance in medication compliance behavior. The Transtheoretical model ranged from 9.61% to 41.07% of the variance explained depending on the compliance measure being used. In lies the difficulty in evaluating medication compliance research. Some evidence indicates the Transtheoretical model provides the best explanation for medication compliance behavior to date. At worst, the Transtheoretical model is equal to some previously tested behavioral models. These results provide compelling evidence to further refine and study the application of the Transtheoretical model in medication compliance behavior.

Two hypotheses examine the internal structure of the Transtheoretical model in compliance behavior. The third study hypothesis found that both decisional balance and self-

efficacy constructs increase as progression occurs in the stage of change construct. This relationship reflects the same structure between the constructs of the model that exists in other health related behaviors. The seventh study hypothesis provides divergent validity to the stage of change construct. The demographic variables of age, gender, marital status, and number of prescriptions could not be used to explain the stage of change construct.

Two hypotheses were included in the study to assure that the study results were not spurious or an anomaly. The four previously validated measures of compliance were correlated to examine the strength of their relationship. This testing proved that all but one pair of correlations was significant. While each measure claims to be accurately measuring compliance, there was wide variation between the measures as expected. The sixth study hypothesis provided discriminant evidence that medication compliance could not be explained through demographic variables. These two hypotheses provide ample support that the medication compliance measures used within this study performed as expected.

The final conclusion to this research is that the Transtheoretical model holds promise as a tool to assist healthcare providers in improving medication compliance behavior in patients. Implementation of this model into a comprehensive compliance intervention program should be considered for future research initiatives.

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APPENDICES

Appendix A

Brief Medication Questionnaire

1. Please list all of the medicines you took in the PAST WEEK. For each medication you list, please answer each of the questions in the box below.

IN THE PAST WEEK						
a. Medication name and strength	b. How many days did you take it?	c. How many times per day do you take it?	d. How many pills did you take each time?	e. How many times did you miss taking a pill?	f. For what reason were you taking it?	g. How well does the medicine work for you? 1= well 2=okay 3=not well

2. Do any of your medications bother you in any way? YES _____ NO_____
   a. IF YES, please name the medication and check below how much it bothers you.

How much did it bother you?					
Medication Name	A Lot	Some	A Little	Never	In what way did it bother you?

3. Below is a list of problems that people sometimes have with their medicines. Please check how hard it is for you to do each of the following:

	Very hard	*Somewhat hard*	*Not hard at all*	*Comment (Which medicine)*
a. Open or close the medicine bottle				
b. Read the print on the bottle				
c. Remember to take all the pills				
d. Get your refills on time				
e. Take so many pills at the same time				

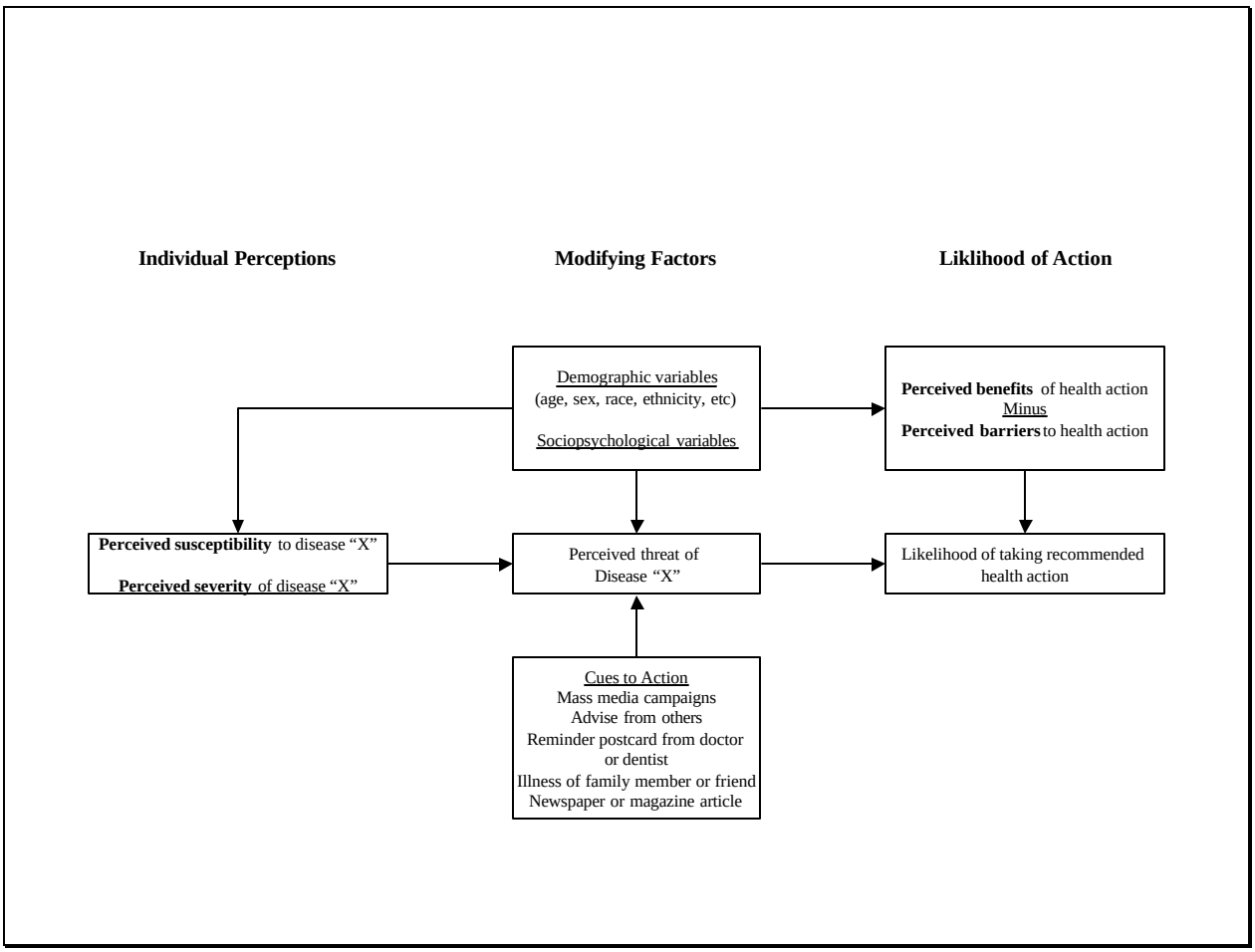
Appendix B

Scoring Procedures for BMQ Screens

Screen	Scoring
Regimen Screen (Question 1a-1e)	
Did Respondent fail to list the prescribed drug in the initial (spontaneous) report?	1=yes 0=no
Did Respondent stop or interrupt therapy due to a late refill or other reason?	1=yes 0=no
Did Respondent report any missed days or doses?	1=yes 0=no
Did Respondent reduce or cut down the prescribed amount per dose?	1=yes 0=no
Did Respondent take any extra doses or more medication than prescribed?	1=yes 0=no
Did Respondent report, "don't know" in response to any questions?	1=yes 0=no
Did Respondent refuse to answer any questions?	1=yes 0=no
Note: Score of >=1 indicates positive screen for potential nonadherence.	
Belief Screen (Questions 1g and 2-2a)	
Did Respondent report "not well" or "don't know" in response to Q 1g?	1=yes 0=no
Did Respondent name the prescribed drug as a drug that bothers him/her?	1=yes 0=no
Note: Score of >=1 indicates positive screen for belief barriers.	
Recall Screen (Questions 1c and 3c)	
Did Respondent receive a multiple dose regimen (2 or more times/day)?	1=yes 0=no
Did Respondent report "very hard" or "somewhat hard" in response to Q 3c?	1=yes 0=no
Note: Score of >=1 indicates positive screen for recall barriers.	

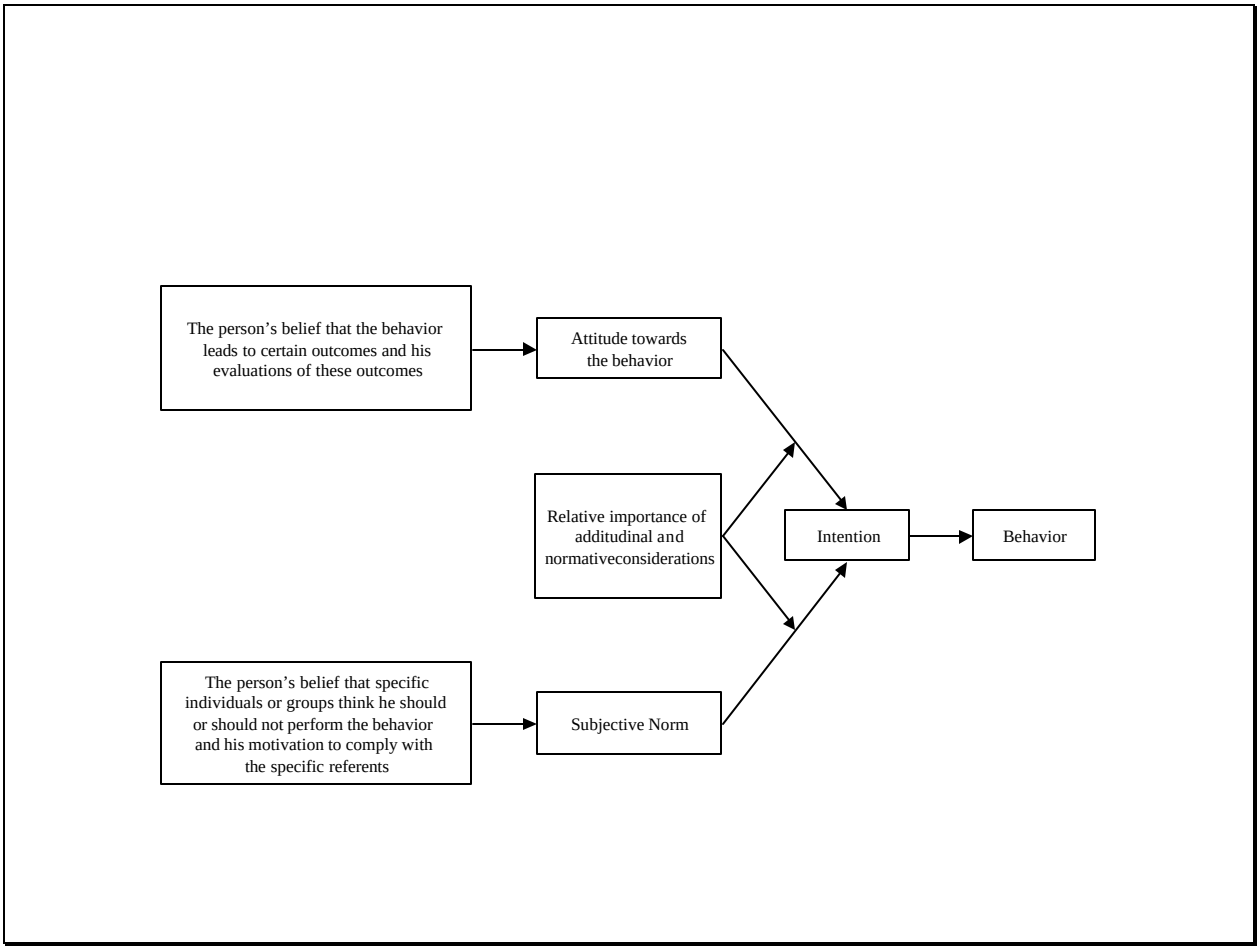
Appendix C

Health Belief Model



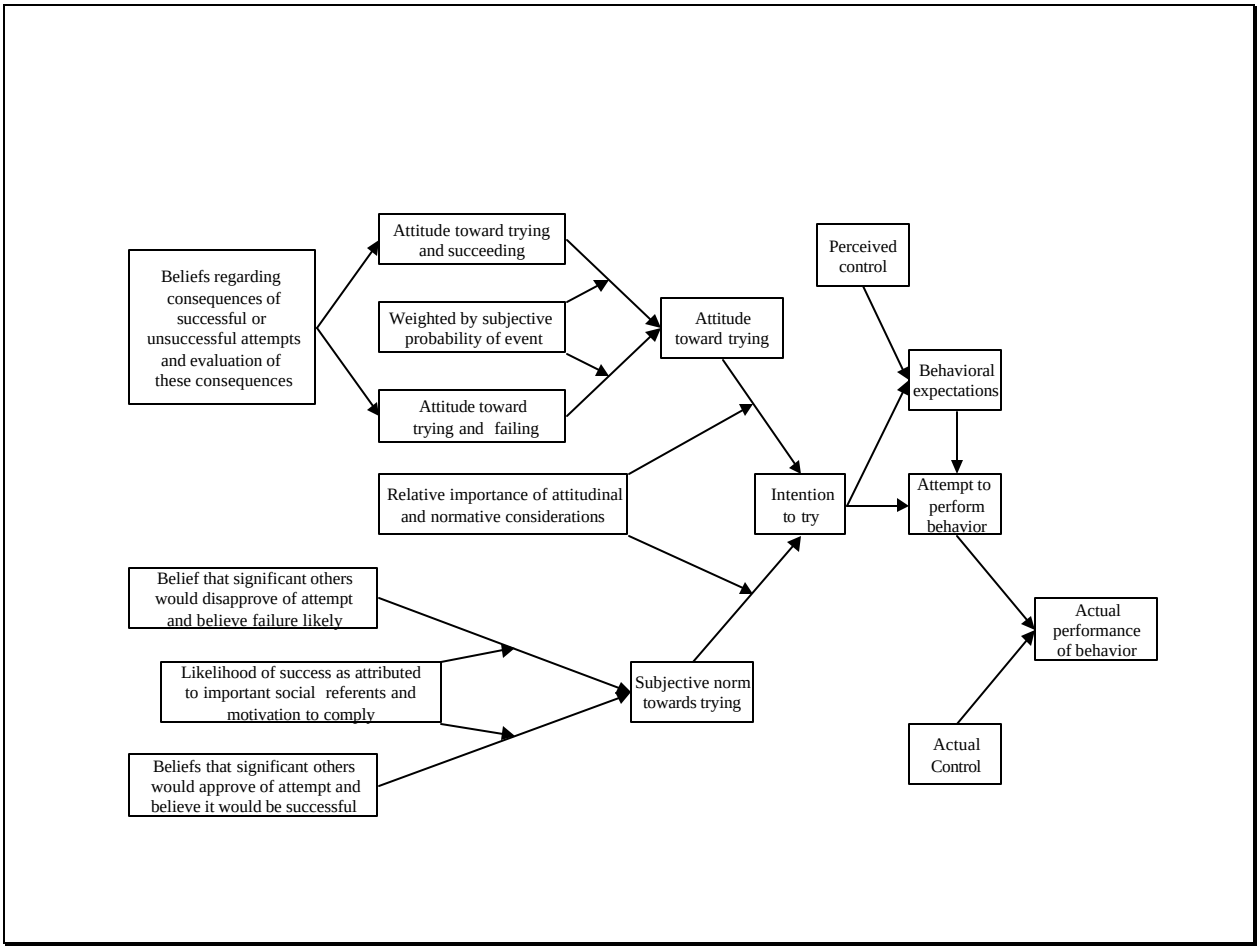
Appendix D

Theory of Reasoned Action



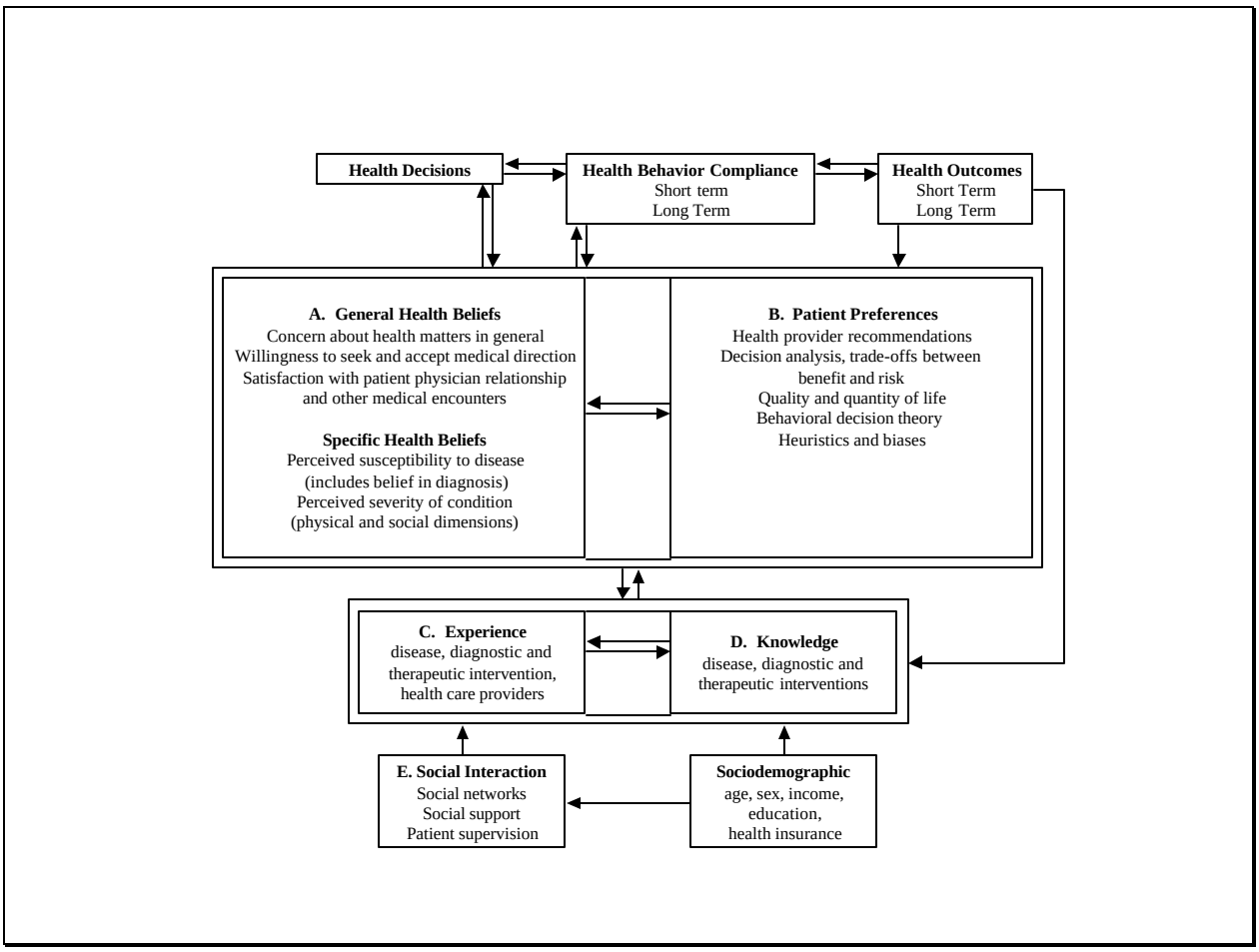
Appendix E

Theory of Planned Behavior



Appendix F

Health Decision Model



Appendix G

Questions Used to Assess Stage of Change for Medication Compliance

1. People sometimes find it difficult to take their medication as directed by their physician. *As directed* means consistently taking the amount of medication prescribed by your physician at the time(s) prescribed by your physician. Please find the statement that best describes the way you feel right now about taking your (high blood pressure/ protease inhibitor) medication as directed.
    A. No, I do not take and right now am not considering taking by (high blood pressure/ protease inhibitor) medication as directed. (Precontemplation)
    B. No, I do not take by right now am considering taking my (high blood pressure/ protease inhibitor) medication as directed. (Contemplation)
    C. No, I do not take but am planning to start taking my (high blood pressure/ protease inhibitor) medication as directed. (Preparation)
    D. Yes, right now I consistently take my (high blood pressure/ protease inhibitor) medication as directed.

If the answer to question 1 is D, then ask:

2. How long have you been taking your (high blood pressure/ protease inhibitor) medication as directed?
    A. ≤3 months
    B. >3 months to 6 months
    C. >6 months to 12 months
    D. >12 months

If the answer to the question 1 is D and the answer to question 2 is A or B, then the stage of change is action. If the answer to question 1 is D and the answer to question 2 is C or D, then the stage is maintenance.

Willey Cynthia, et al. Stages of change for adherence with medication regimens for chronic disease: development and validation of a measure. Clinical Therapeutics, vol. 22, no.7, 2000, p858-871.

Appendix H

The Medication Adherence Scale (MAS)

The response options are “yes” and “no,” and the maximum score is 4.

- During the last 3 months, have you ever stopped taking this medication because you felt better or worse?
- During the last 3 months, have you ever forgotten to take this medication?
- During the last 3 months, have you at times been careless about taking this medication?
- During the last 3 months, have you ever taken less of this medication than your doctor prescribed because you felt better or worse?

Appendix I

Medical Outcomes Study (MOS) Measure of Adherence

How often have you taken your prescribed medication in the past 4 weeks?

A. None of the time
B. A little of the time
C. Some of the time
D. A good bit of the time
E. Most of the time
F. All of the time

Appendix J

Associations Between Stage of Change Construct and Adherence

Stage of Change	Protease-Inhibitor Therapy*		Antihypertensive Medication*
	MAS Score, Mean ± SE (no.) (n=161)	% of Doses Taken, Mean ± SE (no.) † (N=85)	% Reporting Adherence Most or All of the Time, Mean ± SE (no.)‡ (n=718)
Precontemplation/ Contemplation (PC/C)	1.63 ± 0.11 (8)	69.8 ± 4.67 (4)	15.3 ± 0.00 (353)
Preparation (PREP)	1.73 ± 0.04 (11)	64.2 ± 2.65 (5)	52.3 ± 0.03 (86)
Action (A)	0.61 ± 0.06 (67)	86.5 ± 2.23 (31)	95.9 ± 0.01 (49)
Maintenance (M)	0.81 ± 0.08 (64)	86.9 ± 1.67 (41)	96.9 ± 0.00 (226)
	F = 7.46, P<0.001	F = 2.95, P=0.03	χ^2 = 441.3, P<0.001
Significant Mean Differences	PREP-M PC/C-PREP PC/C-M PC/C-A PREP-A	PC/C-M PC/C-A PREP-A PREP-M	

MAS = Medication Adherence Scale

* Analysis included only those patients with no missing data

† Measured using the Medication Event Monitoring System (APREX Corporation, Union City, California).

‡The Medical Outcome Study measure of adherence

Appendix K

Decisional Balance and Temptations for Oral Contraceptives Compliance

Items of the Decisional Balance for Compliance

1. Taking the pill as directed allows me to avoid using back-up methods.
2. Taking the pill as directed is easier than other available methods of birth control.
3. I don't have to use a back-up method if I keep on schedule with my pills.
4. Taking the pill as directed is more convenient than other methods.
5. Taking the pill as directed allows me to worry less about having sex.
6. The daily routine required when taking the pill is no big deal compared to other methods.
7. Taking the pill at the same time everyday is much less trouble than the other method(s) that I could use.
8. It's hard to take the pill as directed on weekends.
9. My lifestyle makes it hard to take the pill as directed.
10. I have trouble consistently taking my pills.
11. It is difficult for me to take the pill at the same time each day.
12. It takes some effort to keep on schedule with the pill.
13. When I'm not home for several days, taking the pill as directed is difficult.
14. Having to remember to take the pill at the same time every day seems like a bother.
15. Taking the pill at the same time each day is a hassle.

Temptations for Noncompliance Measure

1. When I break up with my partner.
2. When I don't expect to have sex for a while.
3. If my relationship ends.
4. If I think that there may be long term side effects.
5. If I hear or read about potential health risks.
6. If I start to worry that my health might be harmed.
7. If my period is late.
8. If I miss a period.
9. If I feel like I've gained weight.
10. If my skin breaks out.
11. If it changes my body shape.

Personal Correspondence with Sara S. Johnson, Ph.D. from her research in Oral Contraceptive Adherence using the Transtheoretical Model. June 2000.

Appendix L

Decisional Balance and Self-efficacy for Condom Use

Decisional Balance Item Condom Use, Primary Partner	Women at High Risk PCA loading M (SD)	College Students CFA Loading M (SD)
Pros	**Alpha = .82**	**Alpha = .75**
1. I would be safer from disease.	.91 4.37 (1.23)	.93 4.39 (1.06)
2. I would feel more responsible.	.86 4.08 (1.36)	.95 4.17 (1.12)
3. It protects my partner as well as myself.	.93 4.35 (1.27)	.98 4.50 (0.91)
4. I would be safer from pregnancy.	.88 4.16 (1.40)	.97 4.69 (0.79)
5. It is easily available.	.82 4.22 (1.27)	.82 4.27 (1.11)
Cons	**Alpha = .81**	**Alpha = .78**
1. It makes sex feel unnatural.	.75 2.63 (1.62)	.81 2.55 (1.38)
2. It would be too much trouble.	.77 2.14 (1.55)	.79 2.14 (1.31)
3. My partner would be angry.	.83 2.36 (1.60)	.77 2.00 (1.30)
4. I would have to rely on my partner's cooperation.	.78 2.74 (1.70)	.81 3.31 (1.46)
5. My partner would think that I donot trust him or her.	.74 2.59 (1.69)	.81 2.10 (1.22)

Table adapted from Grimley DM et al. 1996; 20(6):411.

Self-Efficacy Item "How confident are you that you would use a condom …"	Women at High Risk PCA loading M (SD)	College Students CFA loading M (SD)
Condom use, primary partner	**Alpha = .84**	**Alpha = .82**
1. When you have been using alcohol or other drugs?	.72 2.88 (1.71)	.89 3.23 (1.44)
2. When you are sexually aroused?	.97 3.04 (1.66)	.88 3.47 (1.45)
3. When you think your partner might get angry?	.81 2.83 (1.68)	.94 3.75 (1.36)
4. When you (or your partner) are already using another method of borth control?	.83 2.94 (1.66)	.59 2.51 (1.48)
5. When you want your partner to know you are committed to your relationship?	.84 3.24 (1.70)	.95 3.72 (1.46)
Condom use, nonprimary partner(s)	**Alpha = .88**	**Alpha = .89**
1. When you think the risk for disease is low?	.80 4.15 (1.30)	.97 3.91 (1.27)
2. When you have been using alcohol or other drugs?	.81 3.72 (1.51)	.94 3.91 (1.27)
3. When you are sexually aroused?	.87 3.67 (3.61)	.94 3.71 (1.30)
4. When you think your partner might get upset?	.80 3.61 (1.50)	.72 3.71 (1.27)
5. When you are already using another method of birth control?	.80 3.68 (1.52)	.88 3.24 (1.44)

Table adapted from Grimley DM et al. 1996; 20(6):413.

Appendix M

Stage of Change for Heavy Drinkers

Item	Factor		
	Precontemplation	Contemplation	Action
1. I don't think I drink too much (P)	.25	-.47	-
5. It's a waste of time thinking about my drinking (P)	.83	-	-
10. There is no need for me to think about my drinking (P)	.36	-.46	-
12. Drinking less alcohol would be pointless to me (P)	.85	-	-
3. I enjoy drinking but sometimes I drink to much (C)	-	.59	-
4. Sometimes I think I should cut down on my drinking(C)	-.25	.66	-
8. I am at the stage where I should think about drinking less (C)	-	.61	.37
9. My drinking is a problem sometimes (C)	-	.71	-
2. I am trying to drink less than I used to (A)	-	.29	.64
6. I have just recently changed my drinking habits (A)	-	-	.79
7. Anyone can talk about wanting to do something about drinking, but I am actually doing something about it (A)	-	-	.80
11. I am actually changing my drinking habits right now (A)	-	.20	.79

Table adapted from Budd RJ, Rollnick S. The structure of the readiness to change questionnaire: a test of Prochaska & DiClemente's transtheoretical model. *British Journal of Health Psychology* (1996), 1, 365-376.

Appendix N

Decisional Balance for Immoderate Drinking

Item	Component		
	I	II	III
1: Pros			
1. I can talk with someone I am attracted to better after a few drinks.	.87		
2. I am more self-confident when I drink.	.84		
3. Drinking helps me have fun with friends.	.82		
4. I feel happier when I drink.	.82		
5. Drinking makes me more relaxed and less tense.	.80		
6. Drinking gives me more courage.	.79		
7. Drinking helps keep my mind off problems.	.78		
8. Drinking gives me a thrilling high feeling.	.70		
9. Drinking makes me feel more independent.	.70		
10. When I drink my body feels better.	.63		
2: Cons – Potential			
1. Drinking could kill me.		.85	
2. Drinking could land me in trouble with the law.		.79	
3. I might end up hurting somebody.		.74	
4. Drinking is bad for my health.		.73	
5. Drinking could get me addicted to alcohol.		.72	
3: Cons – Actual			
1. I do not like myself as much when I drink.			.77
2. Drinking makes me feel out of control.			.73
3. After drinking I often wake up feeling down.			.67

Table adapted from Migneault JP, et al. Decisional balance for immoderate drinking in college students. *Substance Use & Abuse, 34 (10), 1325-1346, 1999.*

Appendix O

Decisional Balance for Women's Decisions about Mammography

Statement Wording	Component Loading
Cons Scale: 1. If I eat a healthy diet, I will lower my cancer risk enough that I probably do not need to have a mammogram.	.75
2. Mammograms have a high risk of leading to unnecessary surgery.	.74
3. I would probably not have a mammogram if the mammography facility were more than a few minutes drive away.	.77
4. I would probably not have a mammogram unless I had some breast symptoms or discomfort.	.69
5. If a mammogram finds something, then whatever is there will be too far along to do anything about anyway.	.77
6. Once you have a negative mammogram, you don't need to have any more.	.69
Pros Scale: 1. Mammograms are most helpful when you have one every year.	.43
2. I would probably not have a mammogram if my doctor expressed even a little doubt about whether I really needed one.	-.65
3. I would be more likely to obtain a mammogram if my doctor told me how important it was.	.66
4. Having a yearly mammogram will give me a feeling of control over my health.	.82
5. If my doctor gives me a breast exam at the office, I don't need to have a mammogram.	-.69
6. Mammograms are now a very routine medical test.	.68
7. My family will benefit if I have a mammogram.	.72

Table adapted from Rakowski W, et al. Assessing elements of women's decisions about mammography. *Health Psychology*, 1992, 11(2), 111-118.

Appendix P

Decisional Balance for Exercise Scale

Statement Wording	Component Loading
Pros:	
I would have more energy for my family and friends if I exercised regularly.	.77
Regular exercise would help me relieve tension.	.81
I would feel more confident if I exercised regularly.	.86
I would sleep more soundly if I exercised regularly.	.72
I would feel good about myself if I kept my commitment to exercise regularly.	.86
I would like my body better if I exercised regularly.	.81
It would be easier for me to perform routine physical tasks if I exercised regularly.	.84
I would feel less stressed if I exercised regularly.	.83
I would feel more comfortable with my body if I exercised regularly.	.85
Regular exercise would help me have a more positive outlook on life.	.85
Cons:	
I think I would be too tired to do my daily work after exercising.	.71
I would find it difficult to find and exercise activity that I enjoy that is not affected by bad weather.	.52
I feel uncomfortable when I exe rcise because I get out of breath and my heart beats very fast.	.62
Regular exercise would take too much of my time.	.79
I would have less time for my family and friends if I exercised regularly.	.70
At the end of the day, I am too exhausted to exercise.	.78

Stages of Change Scale – Exercise Scale Example

Stage	Statement Wording
Precontemplation	I currently do not exercise and do not intend to start exercising in the next 6 months.
Contemplation	I currently do not exercise, but I am thinking about starting to exercise in the next six months.
Preparation	I currently exercise some, but not regularly.
Action	I currently exercise regularly but I have only begun doing so within the last 6 months.
Maintenance	I currently exercise regularly and have done so for longer than 6 months.

Tables adapted from Marcis BH, Rakowski W, Rossi J S. Assessing motivational Readiness and decision making for exercise. *Health Psychology*,1992, 11(4), 257-261.

Appendix Q

Decisional Balance for Weight Loss

Item	Content Category	Item Scale Correlation	Component	
			I	II
Part I. Pro Scale				
1. I would feel more optimistic if I lost weight.	Self-app.	.65	.72	.04
2. I would feel sexier if I lost weight.	Self-app.	.68	.70	.20
3. My self-respect would be greater if I lost weight.	Self-app.	.77	.81	.13
4. My family would be proud of meif I lost weight.	Other app.	.68	.75	.06
5. I would be less self-conscious if I lost weight.	Self-app.	.74	.77	.22
6. Others would have more respect for me if I lost weight.	Other app.	.59	.64	.19
7. I could wear more attractive clothing if I lost weight.	Instr. Self	.72	.73	.30
8. My health would improve if I lost weight.	Instr. Self	.65	.75	.02
9. I would feel more energetic if I lost weight.	Instr. Self	.74	.79	.12
10. I would be able to accomplish more if I carried fewer pounds.	Instr. Self	.57	.66	.08
Part II. Con Scale				
11. The exercises needed for me to lose weight would be a drudgery.	Instr. Self	.47	.30	.51
12. Dieting would take the pleasure out of meals.	Instr. Self	.58	-.06	.72
13. I would be less productive in other areas if I was trying to lose weight.	Instr. Self	.40	.08	.47
14. I would have to cut down on some of my favorite activities if I try to lose weight.	Instr. Self	.51	.15	.59
15. In order to lose weight I would be forced to eat less appetizing foods.	Instr. Self	.65	.03	.77
16. I would have to avoid some of my favorite places if I were trying to lose weight.	Instr. Self	.61	.15	.71
17. My dieting could make meal planning more difficult for my family or housemates.	Instr. other	.49	.31	.51
18. Trying to lose weight could end up being very expensive when everything is taken into account.	Instr. Self	.38	.25	.40
19. I would not be able to eat some of my favorite foods if I were trying to lose weight.	Instr. Self	.65	.09	.77
20. I would have to cut down on my favorite snacks while I was dieting.	Instr. Self	.53	.05	.68

Table adapted from O'Connell D, Velicer WF. A decisional balance measure and the stages of change model for weight loss. *Intern. J. Addictions*, 23(7), 729-750, 1988.

Appendix R

TTM – Medication Compliance Pilot Study Protocol

Purpose and Overview

This research study is intended to examine the relationship between the variables of the Transtheoretical Model of behavioral change and patient medication compliance behavior. Pharmacy patrons will be asked to complete a questionnaire. The information from each of the survey question items will then be examined to create the final version of the TTM-medication compliance questionnaire.

Procedure

Step 1: Subject Identification

Pharmacy patrons will be approached by the primary researcher and asked if he/she would be willing to participate in a survey taking approximately 10 minutes of his/her time.

Step 2: Request for participation

If the patient indicates he/she may be willing to participate, the patient will be taken to a private or semi-private area for a complete briefing of the study requirements. The complete briefing will consist of:

An overview of what will be asked of them if they participate.
Reading the informed consent sheet to the patient.
Answer all questions and concerns the patient may have.
Complete the Informed Consent Form.

Step 3: Data Collection

The subject will be given the TTM survey to complete. The questionnaire will consist of four sections: demographic questions, stages of change, decisional balance, and self-efficacy.

Step 4: Patient Completion

The primary investigator will thank the subject for his/her time and participation in the survey.

Appendix S

Pilot Study Consent Form

I agree to take part in a study titled Validation of the Transtheoretical Model in Medication Compliance Behavior, which is being conducted by Christopher L. Cook, R.Ph., Pharm.D., Department of Clinical and Administrative Sciences, College of Pharmacy, The University of Georgia, (706) 542-0418, under the direction of Matthew Perri III, R.Ph., Ph.D., Department of Clinical and Administrative Sciences, College of Pharmacy, The University of Georgia, (706) 542-5365. I do not have to be in this study if I do not want to be; I can stop taking part at any time without giving any reason, and without penalty. I can ask to have information related to me returned to me, removed from the research records, or destroyed.

- ❑ The purpose of the study is to examine whether the Transtheoretical Model of behavioral change is an appropriate model to use in explaining patient medication compliance behavior.
- ❑ You should not expect to benefit directly from this research. However, your participation in this research may lead to information that could help your healthcare providers better understand patient needs and behaviors. This understanding, in turn, could help healthcare providers improve the treatment of their patients.
- ❑ If I volunteer to take part in this study, I will be asked to complete a survey on patient medication compliance expected to take 10-15 minutes.
- ❑ I understand no discomforts or stresses are expected.
- ❑ I understand no present or future risks are expected.
- ❑ The results of this participation will be anonymous.
- ❑ The researcher will answer any further questions about the research, now or during the course of the project, and can be reached by telephone at: (706) 542-0418.
- ❑ I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____

Signature of Researcher Date

_____

Signature of Participant Date

For questions or problems about your rights please call or write: Ms. Julia Alexander, Human Subjects Office, University of Georgia, 606A Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-6514; E-mail Address IRB@uga.edu.
A:\Consent Form – Pilot Test.doc

Appendix T

Pilot Trial 1 Survey

MEDICATION COMPLIANCE SURVEY

Directions: Please read each sentence carefully and select the number best representing your level of agreement about the statement in regards to how you take your medications.	1 = strongly disagree 2 = disagree 3 = neutral 4 = agree 5 = strongly agree
Example: It is easier to swallow a small pill than a large pill.	1 2 3 4 **(5)**

1. My condition is not serious enough to need medicine.	1	2	3	4	5
2. When I miss doses it concerns me.	1	2	3	4	5
3. It is hard to justify paying for medicine every month, but I know I need to take it.	1	2	3	4	5
4. I am not concerned if I do not have my prescription filled.	1	2	3	4	5
5. I have been trying to make taking my medicine a daily habit.	1	2	3	4	5
6. Taking my medicine daily has become an old habit.	1	2	3	4	5
7. I think about how I can take my medicine on a more regular basis.	1	2	3	4	5
8. Taking my prescription would be pointless for me.	1	2	3	4	5
9. I am going to get better about taking my medicine.	1	2	3	4	5
10. I have been taking my medicine as prescribed lately.	1	2	3	4	5
11. I know I should take my medicine more regularly.	1	2	3	4	5
12. I can control my condition without medication.	1	2	3	4	5
13. I am getting ready to follow my doctor's orders about my medicine.	1	2	3	4	5
14. It is a waste of time for me to get my prescription filled.	1	2	3	4	5
15. I am considering getting my prescription filled.	1	2	3	4	5
16. I am taking my medicine better than I used to.	1	2	3	4	5
17. I rarely miss a dose of my medicine.	1	2	3	4	5
18. Next month I will be better about taking my medicine.	1	2	3	4	5

Appendix T (page 2)

1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Disagree

19. I have not had my prescription filled.	1	2	3	4	5
20. If I took my medicine more regularly, I would be healthier.	1	2	3	4	5
21. I have ways to remind myself when I need to take my medicine.	1	2	3	4	5
22. I am going to have my prescription filled within the next month.	1	2	3	4	5
23. I always have my prescriptions filled before I run out of medicine.	1	2	3	4	5
24. I have recently begun taking my medicine as prescribed.	1	2	3	4	5
25. I do not plan to have my prescription filled.	1	2	3	4	5
26. I am considering taking my medicine more regularly.	1	2	3	4	5
27. I do not take the medicine my doctor prescribed for me.	1	2	3	4	5
28. I always take my medicine regularly.	1	2	3	4	5
29. It is a waste for me to spend my money on medicine.	1	2	3	4	5
30. I should find out about ways to help me remember to take my medicine more regularly.	1	2	3	4	5
31. I have taken my medicine exactly as prescribed for a long time.	1	2	3	4	5
32. I am going to start taking my prescribed medicine within the next month.	1	2	3	4	5
33. I would be concerned if I missed doses of my medicine.	1	2	3	4	5
34. I would not be concerned if I missed doses of my medicine.	1	2	3	4	5
35. I have ways to remind myself when I need to get my prescription refilled.	1	2	3	4	5

Appendix T (page 3)

1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Disagree

Section II

1. I feel worse when I take my medicine.	1	2	3	4	5
2. It is hard to remember when to take my medicine.	1	2	3	4	5
3. The medicine tastes funny.	1	2	3	4	5
4. The pills are too big to swallow.	1	2	3	4	5
5. Taking my medicine will keep my condition from getting worse.	1	2	3	4	5
6. I have problems when I take my medicine.	1	2	3	4	5
7. I do not take my medicine regularly because I am afraid of the side effects.	1	2	3	4	5
8. I may be able to get better without taking medicine.	1	2	3	4	5
9. I feel like I am getting old by taking this many pills.	1	2	3	4	5
10. Medicine costs too much money.	1	2	3	4	5
11. I feel better when I take my medicine.	1	2	3	4	5
12. It will make my family happy if I follow the doctor's orders.	1	2	3	4	5
13. Taking my medicine will help me stay healthy.	1	2	3	4	5
14. I will get better if I take my medicine.	1	2	3	4	5
15. I cannot tell that my medicine is helping me.	1	2	3	4	5
16. I take my medicine because my doctor says this is what I need to do.	1	2	3	4	5
17. It will make my doctor happy if I follow his/her orders.	1	2	3	4	5
18. Taking my medicine will help me to live longer.	1	2	3	4	5
19. I am happier when I take my medicine.	1	2	3	4	5

1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Disagree

Section III

1. I am tempted to skip doses when I read about potential health risks.	1	2	3	4	5
2. I am tempted to miss a dose when I think there may be long-term side effects.	1	2	3	4	5
3. I miss doses when I start to worry that my health might be harmed.	1	2	3	4	5
4. I am tempted to miss a dose when I think side effects will happen to me.	1	2	3	4	5
5. I am tempted to miss a dose when I believe my condition has improved.	1	2	3	4	5
6. I sometimes skip doses when I feel better.	1	2	3	4	5
7. I miss doses when I feel more energetic.	1	2	3	4	5
8. I am tempted to skip a dose when I feel lazy.	1	2	3	4	5
9. I sometimes miss doses when I feel worse.	1	2	3	4	5
10. I am tempted to miss doses when I feel depressed.	1	2	3	4	5
11. I miss doses when I get out of my daily routine.	1	2	3	4	5
12. I sometimes miss a dose when I go on vacation.	1	2	3	4	5
13. I miss doses when I go out of town.	1	2	3	4	5
14. I sometimes miss a dose during the holidays.	1	2	3	4	5
15. I am tempted to miss a dose when I cannot tell a difference of when I have and have not taken a dose.	1	2	3	4	5
16. I miss doses when I am in a hurry.	1	2	3	4	5
17. I sometimes miss a dose when I do not have the time to take it.	1	2	3	4	5
18. I am tempted to skip a dose when I think it is just too inconvenient.	1	2	3	4	5
19. I sometimes skip doses when I am short on money.	1	2	3	4	5
20. I am tempted to skip a dose when the price goes up.	1	2	3	4	5

Last Question:
People sometimes find it difficult to take their medication as directed by their physician. *As directed* means consistently taking the amount of medication prescribed by your physician at the time(s) prescribed by your physician. Please find the statement that best describes the way you feel right now about taking your medication as directed.

A. No, I do not take and right now I am not considering taking my medication as directed.

B. No, I do not take but right now I am considering taking my medication as directed.

C. No, I do not take but I am planning to start taking my medication as directed.

D. Yes, right now I consistently take my medication as directed, however I have been doing so for less than 6 months.

E. Yes, right now I consistently take my medication as directed and I have been doing so at least six months.

Thank you for your participation!!!

Appendix U

Pilot Trial 2 Survey

MEDICATION COMPLIANCE SURVEY

Directions: Please read each statement carefully and circle the number best representing your level of agreement about the statement in regards to how you take your medications.	1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree
Example: I take my medicine as prescribed by my doctor.	1 2 3 4 **(5)**

1. I do not take the medicine my doctor has prescribed for me.	1	2	3	4	5
2. Taking the medicine my doctor prescribed would be pointless to me.	1	2	3	4	5
3. I am currently not taking the medicine the doctor has prescribed, but I am considering it.	1	2	3	4	5
4. I have not had my prescription filled.	1	2	3	4	5
5. I am considering getting my prescription filled.	1	2	3	4	5
6. I am thinking about starting to take the medicine the doctor prescribed for me.	1	2	3	4	5
7. I will begin following the doctor's order within the next month.	1	2	3	4	5
8. Within the next 30 days, I am going to start taking my prescribed medicine.	1	2	3	4	5
9. I have recently started taking my prescribed medicine regularly.	1	2	3	4	5
10. I take my medicine daily as directed, but have only been doing so lately.	1	2	3	4	5
11. Next month, I will start taking my medicine regularly.	1	2	3	4	5
12. I always have my prescriptions filled before I run out of medicine.	1	2	3	4	5
13. I have started taking my medicine as my doctor prescribed within the last six months.	1	2	3	4	5
14. I have taken my medicine as prescribed for a long time.	1	2	3	4	5
15. Taking my medicine daily has become a habit.	1	2	3	4	5

People sometimes find it difficult to take their medication as directed by their physician. *As directed* means consistently taking the amount of medication prescribed by your physician at the time(s) prescribed by your physician. Please find the statement that best describes the way you feel right now about taking your medication as directed.

A. I do not have any medications prescribed for me by my physician.
B. I do not take and right now I am not considering taking my medication as directed.
C. I do not take but right now I am considering taking my medication as directed.
D. I do not take but I am planning to start taking my medication as directed.
E. Right now I consistently take my medication as directed, however I have been doing so for less than 6 months.
F. Right now I consistently take my medication as directed and I have been doing so at least six months.

Thank you for your participation!!!

Appendix V

TTM-Medication Compliance Study Protocol

Purpose and Overview

This research study is intended to examine the relationship between the variables of the Transtheoretical Model of behavioral change and patient medication compliance behavior. Patients will be asked to complete a questionnaire while waiting in their primary care physician's office. The information from these surveys will then be compared against two measures of patient medication compliance; the pharmacy refill record and the patient brief medication questionnaire.

Procedure

Step 1: Subject Identification

At the time a patient checks into the physician office for a visit, the patient chart will be pulled. The chart will be examined for inclusion into the study. If the answers to the following questions are all 'yes', the patient is eligible for inclusion in the study:

Is the patient 18 years old or older? _____
Is the patient currently being treated by his/her primary care physician for one of the following conditions:
Hypertension _____
Diabetes Mellitus _____
Hypercholesterolemia _____
Hypothyroidism _____
Hormone Replacement Therapy _____
Is the patient is full-control of his/her medication taking behavior? _____ (Yes indicates the patient is NOT a resident of a nursing home, does NOT have a personal caretaker, or other person controlling when and how often the patient receives his/her medication)
Does the patient receive his/her medication from a community retail pharmacy? (Yes indicates the patient does not receive his/her medications through a mail order facility?)

Step 2: Disease state treatment selection

a. If a patient has only one of the five conditions being studied, then that condition will be the study disease state.

OR

b. If the patient is being treated for more than one of the five conditions, a disease state selection process needs to occur. A colored chip representing each condition the patient has will be placed into a cloth bag. The bag will be shaken to mix up the chips. A single chip will then be randomly removed from the bag and it will represent the disease condition that will be studied for that patient.

Step 3: Request for participation

Either a member of the physician's office personnel or the primary investigator will approach each patient who meets all criteria for study inclusion into the study. If the patient indicates he/she may be willing to participate, the patient will be taken to a private area for a complete briefing of the study requirements. The complete briefing will consist of:

An overview of what will be asked of them if they participate.
Reading the informed consent sheet to the patient.
Explain the need to access his/her pharmacy records.
Answer all questions and concerns the patient may have.
Complete the Informed Consent Form and the Release of Pharmacy Records form.

Step 4: Data Collection

The primary investigator will administer the brief medication questionnaire with the patient. Upon completion of the questionnaire interview, the subject will be given the TTM-compliance survey to complete. The questionnaire will consist of a demographic section, the Medication Adherence Scale, the MOS compliance question, the single-item stage of change measure, and the three TTM construct measures.

Step 5: Patient Completion

The primary investigator will thank the subject for his/her time and participation in the survey.

Appendix W

TTM – Medication Compliance Study Consent Form

I agree to take part in a study titled Validation of the Transtheoretical Model in Medication Compliance Behavior, which is being conducted by Christopher L. Cook, R.Ph., Pharm.D., Department of Clinical and Administrative Sciences, College of Pharmacy, The University of Georgia, (706) 542-0418, under the direction of Matthew Perri III, R.Ph., Ph.D., Department of Clinical and Administrative Sciences, College of Pharmacy, The University of Georgia, (706) 542-5365. I do not have to be in this study if I do not want to be; I can stop taking part at any time without giving any reason, and without penalty. I can ask to have information related to me returned to me, removed from the research records, or destroyed.

- ❑ The purpose of the study is to examine whether the Transtheoretical Model of behavioral change is an appropriate model to use in explaining patient medication compliance behavior.

- ❑ You should not expect to benefit directly from this research. However, your participation in this research may lead to information that could help your healthcare providers better understand patient needs and behaviors. This understanding, in turn, could help healthcare providers improve the treatment of their patients.

- ❑ If I volunteer to take part in this study, I will be asked to complete a questionnaire lasting approximately 5-10 minutes that covers my medication taking behavior. I will also be asked to authorize my pharmacist to release my patient records for the past six refill periods.

- ❑ I understand no discomforts or stresses are expected.

- ❑ I understand no present or future risks are expected.

- ❑ Any information we obtain about you as a participant in this study, including your identity will be held confidential. Your responses to the survey and your pharmacy records will be coded without connection to your identity. All data will be kept in a secure, limited access location. Your identity will not be revealed in any publication of the results of this research.

- ❑ The researcher will answer any further questions about the research, now or during the course of the project, and can be reached by telephone at: (706) 542-0418.

- ❑ I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____

Signature of Researcher Date

_____

Signature of Participant Date

For questions or problems about your rights please call or write: Ms. Julia Alexander, Human Subjects Office, University of Georgia, 606A Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-6514; E-mail Address IRB@uga.edu.

A:\Consent Form – Main Study.doc

Appendix X

Release of Patient Pharmacy Records

I, _____, give my permission for the pharmacist at _____ to release my pharmacy records in order to participate in the research study, *The Validation of the Transtheoretical Model in Patient Compliance Behavior*. This written permission is good only for this one time release of my patient records to the investigator of the above-mentioned study.

_____

Patient SignatureDate

_____

WitnessDate

Appendix Y

TTM-Medication Compliance Study Survey

<table>
<tr><td>1) Date of Birth: _____</td><td>2) Gender: ___ Male ___ Female</td></tr>
<tr><td>3) Race: ___ African American
___ Asian
___ Caucasian
___ Hispanic
Other: _____</td><td>4) Marital Status: ___ Single
___ Married
___ Divorced
___ Widowed</td></tr>
<tr><td>6) What is the highest level of formal education you have completed?
A. Less than High School
B. High School
C. Trade School
D. College
E. Graduate School</td><td>7) What is your estimated yearly household income?
A. Less than $15,000
B. $15,000 to $30,000
C. $30,001 to $50,000
D. $50,001 to $100,000
E. Greater than $100,000</td></tr>
<tr><td colspan="2">8) How long have you been diagnosed with diabetes? _____</td></tr>
<tr><td colspan="2">9) How long have you been treated with medication for diabetes? _____</td></tr>
<tr><td colspan="2">10) How many prescription medications do you take on a regular basis? _____</td></tr>
<tr><td colspan="2">11) How much money do you estimate you spent out of your pocket for prescription medications in the last year? _____</td></tr>
<tr><td colspan="2">12) How often have you taken your prescribed medication in the past four weeks?
A. None of the time
B. A little of the time
C. Some of the time
D. A good bit of the time
E. Most of the time, and all of the time</td></tr>
</table>

Directions: Please read each statement below carefully and then select the number to the right best representing how you feel about the statement	1 = Strongly Disagree 2 = Disagree 3 = Neutral 4 = Agree 5 = Strongly Agree
1. Taking my medicine will keep my condition from getting worse.	1 2 3 4 5
2. It will make my family happy if I follow the doctor's orders.	1 2 3 4 5
3. Taking my medicine will help me to live longer.	1 2 3 4 5
4.I take my medicine because my doctor says this is what I need to do.	1 2 3 4 5
5. It is hard to remember to take my medicine.	1 2 3 4 5
6. The medicine tastes bad.	1 2 3 4 5
7. The pills are too big to swallow.	1 2 3 4 5
8. I cannot tell that the medicine is helping me.	1 2 3 4 5
9. I am tempted to miss a dose when I think there may be long-term side effects.	1 2 3 4 5
10. I sometimes skip doses when I feel better.	1 2 3 4 5
11. I miss doses when I get out of my daily routine.	1 2 3 4 5
12. I sometimes skip doses when I go out of town.	1 2 3 4 5
13. Sometimes I skip doses when I am short on money.	1 2 3 4 5
14. I am tempted to miss doses when I feel depressed.	1 2 3 4 5

Directions:

People sometimes find it difficult to take their medication as directed by their physician. *As directed* means consistently taking the amount of medication prescribed by your physician at the time(s) prescribed by your physician. Please select the statement that best describes the way you feel right now about taking your medication as directed.

E. I do not take and right now I am not considering taking by medication as directed.

F. I do not take but right now I am considering taking my medication as directed.

G. I do not take but I am planning to start taking my medication as directed.

H. Right now I consistently take my medication as directed, however I have been doing so for less than 6 months.

I. Right now I consistently take my medication as directed and I have been doing so for at least six months.

Directions:

Please respond either "yes" and "no" to each of the following questions about your medication behavior.

1. During the last 3 months, have you ever stopped taking this medication because you felt better or worse? _____

2. During the last 3 months, have you forgotten to take this medication? _____

3. During the last 3 months, have you been careless about taking this medication? _____

4. During the last 3 months, have you ever taken less of this medication than your doctor prescribed because you felt better or worse? _____

Appendix Y (page 4)

Brief Medication Questionnaire

1. Please list all of the medicines you took in the PAST WEEK. For each medication you list, please answer each of the questions in the box below.

IN THE PAST WEEK						
a. Medication name and strength	b. How many days did you take it?	c. How many times per day do you take it?	d. How many pills did you take each time?	e. How many times did you miss taking a pill?	f. For what reason are you taking it?	g. How well does the medicine work for you? 1= well 2=okay 3=not well

2. Do any of your medications bother you in any way? YES _____ NO_____
   a. IF YES, please name the medication and check below how much it bothers you.

How much does it bother you?				
Medication Name	A Lot	Some	A Little	In what way did it bother you?

3. Below is a list of problems that people sometimes have with their medicines. Please check how hard it is for you to do each of the following:

	Very hard	*Somewhat hard*	*Not hard at all*	*Comment (Which medicine)*
a. Open or close the medicine bottle				
b. Read the print on the bottle				
c. Remember to take all the pills				
d. Get your refills on time				
e. Take so many pills at the same time				