

Stages of Change for Adherence with Medication Regimens for Chronic Disease: Development and Validation of a Measure

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ABSTRACT

Background: The stages-of-change (SOC) model has been used to explain and predict how behavior change occurs, but it is new as an approach to understanding why patients fail to take their medications as prescribed.

Objective: This study validated a 2-item measure of SOC for adherence with medication regimens in 2 groups of patients prescribed pharmacologic therapy for chronic conditions.

Methods: Two cross-sectional studies of attitudes toward medication adherence included the same measure of SOC for medication adherence. One was a sample of 161 HIV-positive patients in the United States, and the other was an international sample of 731 patients with hypertension. The validity of the measure of SOC for medication adherence was examined in both convenience samples using previously validated self-reported measures of adherence (the Medication Adherence Scale and a measure of adherence from the Medical Outcomes Study), and in the HIV sample using electronic monitoring of adherence behavior in 85 patients.

Results: Construct validity was demonstrated in both samples by associations between SOC and the previously validated measures of adherence ($P < 0.001$), and predictive validity was supported by significant associations between SOC for medication adherence and electronically monitored medication-taking behavior during the next 30 days ($P < 0.03$).

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Conclusions: Behavior-change theory suggests that stage-tailored communication strategies are more effective than uniform health-promotion messages. Our results provide a foundation for the development of interventions for medication adherence that are tailored to patients' readiness for change. Our validated 2-item measure of SOC for medication adherence can be used to match communication strategies to individual motivation and readiness for adherence with chronic disease medication regimens.

Key words: medication adherence, compliance, HIV, hypertension, stages of change, Medication Event Monitoring System. (*Clin Ther.* 2000;22:858–871)

INTRODUCTION

Over 1.5 billion prescription drugs are dispensed each year, and it has been suggested that ~50% of patients fail to take their medications as prescribed.^{1–6} Non-adherence with medication regimens leads to suboptimal outcomes and higher health care costs, and can bias the results of clinical trials and outcomes research.^{7–9} The literature on noncompliance with medication is extensive, but 1 review found that fundamental knowledge about noncompliance and effective strategies for enhancing compliance had changed little since 1980.¹⁰

One issue that has not been explored extensively in the literature is the distinction between unintentional and intentional noncompliance.¹⁰ At one time or another, most patients make unintentional errors in taking medications, usually because of forgetfulness or misunderstanding of instructions. However, the literature suggests that intentional noncompliance is also a significant problem, particularly among patients

with chronic disorders requiring long-term therapy, such as asthma, hypertension, HIV infection, and diabetes.^{4–6,11} In a study of medications prescribed for chronic obstructive pulmonary disease, the most prevalent reason given for missing medications in the previous month was “felt good and decided not to dose.”¹² In a study of noncompliance with zidovudine therapy, reasons for refusal of treatment included “fear of side effects” and belief that the treatment “was not necessary.”¹³ The results of these and other studies suggest that the adoption of medication adherence requires intentional behavior change.

The Stages-of-Change Model of Behavior Change

The transtheoretical model of change, or stages-of-change (SOC) model, has been particularly effective in helping to understand how individuals change their behavior.¹⁴ Table I summarizes the stages through which individuals progress as they change their behavior and the stage-matched strategies that predict progress to each subsequent stage. Five stages of change have been identified: precontemplation (not considering changing behavior in the next 6 months), contemplation (considering changing behavior in the next 6 months), preparation (planning to change behavior during the next month), action (currently changing behavior), and maintenance (successful behavior change for ≥ 6 months).

The SOC model has been used to identify stages of change in the adoption of positive health behaviors and the cessation of negative health behaviors, including reduction of fat in the diet,¹⁵ smoking cessation,^{16–18} participation in mammography screening,¹⁹ and adoption of exercise,²⁰ sun

Table I. Stages of change.

Stage	Characteristics	Stage-Specific Intervention Strategies
Precontemplation	The individual has no intention of changing behavior in the next 6 months; people in this stage tend to be unaware of the benefits of changing their behavior and are resistant to efforts to modify it	Provide information about the benefits of changing, personalize consequences of the problem behavior, appeal to emotions
Contemplation	The individual has begun to think about changing behavior but not seriously, and has not made a commitment to taking action in the next 6 months.	Discuss the negative aspects of behavior change with the patient, address those the patient feels are most important, discuss misconceptions, continue to provide information about the benefits of change
Preparation	This is the stage of decision-making; a commitment to changing behavior during the next month has been made, and individuals may already be making changes in their behavior	Use strategies to enhance commitment, such as contracts, practice exercises, plans for a typical day that includes the new behavior
Action	Overt efforts to change occur; individuals are considered to be in this stage if they have recently modified their behavior but the behavior change is not yet stabilized	Support new changes in behavior with reminders, rewards, and social support; frequent monitoring of efforts to change is needed
Maintenance	Individuals are working to stabilize their behavior change and avoid relapse; in general, maintenance occurs after action has been sustained for ≥6 months	Continued but less frequent monitoring and support are necessary to prevent relapse to unhealthy behavior patterns

protection,²¹ and condom use.²² This model has also been applied to change in complex health behaviors such as the diet, exercise, and glucose monitoring changes required for diabetes self-management.^{23,24} One considerable advantage of the SOC model is that behavior-change interventions tailored to current readiness to change have been shown to be more effective than interventions using a single health-education message.²⁵⁻³⁰

The SOC model has not yet been tested as an approach to enhancing adherence with medication. The purpose of the present study was to develop a method for measuring SOC for adherence with medication regimens prescribed for chronic conditions. We examined the construct validity of SOC for medication adherence using previously validated self-reported measures of adherence in 2 groups of patients prescribed medication for chronic conditions (HIV and hypertension). We studied predictive validity using electronic monitoring of medication-taking behavior in a subset of HIV-positive patients.

PATIENTS AND METHODS

Sample 1

The primary purpose of study 1 was to develop measures of SOC for medication adherence and measures of related trans-theoretical model constructs, such as decisional balance and processes of change. The sample consisted of patients currently prescribed medication for HIV. Eligibility criteria included age between 18 and 74 years, a current prescription for approved protease inhibitors (saquinavir, ritonavir, nelfinavir, or indinavir), ability to read English, and positive HIV status. Subjects were recruited in 1994 during non-acute care

visits to 3 sites that provide primary HIV medical care and support services to >75% of the HIV-infected persons in Rhode Island. Approximately 18% of patients at the target sites had a CD4+ count of <200 cells/mm³, 56% had a CD4+ count between 200 and 500 cells/mm³, and 28% had a CD4+ count of >500 cells/mm³. Approximately 44% of the patients had peripheral viral loads below detectable limits (<500 copies/mL). Protease inhibitors were new to the market at the time of data collection, and all patients were new users of these drugs.

Procedure

Physicians informed eligible patients of the opportunity to participate in a study of attitudes about medications. They were offered a \$20 gift certificate for participation, and ~95% of patients attending the participating clinics agreed to take part. Research assistants were licensed pharmacists or senior-level pharmacy students. The research assistants explained the purpose of the study, emphasized its confidentiality, and obtained written consent using forms approved by the University of Rhode Island institutional review board (IRB) and the IRBs of all the clinical study sites. Questionnaires were administered in a private setting and required ~1.5 hours to complete. Color-scanned images of all antiretroviral medications were used to assist patients in recalling the names of medications while filling out the questionnaire.

After completion of the questionnaire, a subset of patients were randomly selected to receive a 30-day supply of their prescribed protease inhibitor in a vial with a Medication Event Monitoring System (MEMS) TrackCap™ (APREX Corporation, Union City, California). A second appointment was scheduled for 1 month

later, and data from the MEMS TrackCap were read using a MEMS-4 Communicator. Selected patients were offered a \$50 gift certificate for their participation, and ~90% agreed to take part.

Sample 2

Patients with a diagnosis of hypertension were recruited from 5 countries (United States, Canada, France, Germany, and Italy) for a survey on attitudes toward medication compliance conducted by Bristol-Myers Squibb Company, Princeton, New Jersey, and Sanofi Pharma, Paris, France. Questions designed to measure behavior-change constructs were added to the questionnaire to support a University of Rhode Island sabbatical project on SOC for medication adherence.

All patients were volunteers who responded to recruitment efforts. The sample was essentially a convenience sample, although distribution of the sample across countries was designed to be roughly proportional to population size. Two-stage cluster sampling was employed within each country to provide geographic representation (25 sites in the United States, ~15 in other countries). Quota sampling, based on self-reported compliance, was used to ensure an adequate distribution of those who were noncompliant with prescribed therapy. Individuals who were prescribed medication but had never taken it (17%), those who had discontinued their medication (22%), and those who were partially compliant (27%) were oversampled to ensure an adequate distribution. Only 34% of the sample reported taking their medication exactly as prescribed.

Patients were identified primarily through physicians, pharmacists, patient networks, and newspaper advertisements.

Professional recruiters contacted each patient to determine eligibility. Eligible patients were required to have been prescribed an antihypertensive agent from 3 to 18 months before the interview and to have been diagnosed with hypertension in 1992 or later. They must never have been diagnosed with or treated for angina, ischemic heart disease, arrhythmia, arteriosclerosis, myocardial infarction, or stroke, and must never have undergone cardiac bypass surgery or angioplasty.

The most commonly prescribed antihypertensive medications taken by study participants were angiotensin-converting enzyme inhibitors (28%), beta-blockers (21%), calcium channel inhibitors (18%), and diuretics (16%). The majority of patients (89%) were reimbursed for their medication costs.

Procedure

Trained interviewers explained that the study's purpose was to understand attitudes about high blood pressure and that all answers would be confidential. All patients gave written informed consent, and all data-collection procedures followed the Code of Standards and Ethics for Survey Research developed by the Council of American Survey Research Organizations.³¹ The questionnaire was administered in a 1-on-1 interview session at a research facility, the interviewer's home, or the patient's home. The interviewer reviewed instructions for each section of the questionnaire and was available to answer questions as the patient completed the form.

Measures

Stage of Change

Questions that have been used to measure SOC in previous applications of the

Table II. Questions used to assess stage of change for medication adherence.

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 my (high blood pressure/protease inhibitor) medication as directed. (Precontemplation)
 - B. No, I do not take but 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 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 of change is maintenance.

model^{18,32} were modified to describe medication adherence (Table II). Patients in sample 1 (HIV) were asked about their SOC for adherence with protease inhibitors, and patients in sample 2 (hypertension) were asked about their SOC for adherence with antihypertensive medication.

Self-Reported Adherence

The Medication Adherence Scale (MAS),³³ a previously validated measure of compliance, was included in the survey given to HIV-positive patients. The MAS contains 4 questions that are answered "yes" or "no" (Table III). A positive response to any question indicates a problem with adherence. The total score ranges from 1 to 4, with a higher score indicating poorer

adherence. A 1-item Likert-scaled measure of medication adherence from the Medical Outcomes Study (MOS)³⁴ was used in the survey given to antihypertensive patients. This item was part of a 4-item scale used to measure disease-specific adherence for hypertension. The other 3 items measured other adherence behaviors, such as following a low-salt diet, following a low-fat diet, and exercising regularly. The wording of the question was "How often have you taken your prescribed medication in the past 4 weeks?" and the 6 possible responses were 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. Categories 5 and 6 were combined, since patients who reported adherence most or all

Table III. The Medication Adherence Scale.³³

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?

of the time were considered adherent with medication.

Electronically Monitored Medication Compliance

The MEMS TrackCap records the time and date of every opening of the MEMS vial. The benefits of electronic monitoring are extensive: these devices provide data on the interval between doses and thus can reveal patterns of nonadherence or “drug holidays.”³⁵ However, because the TrackCap records only the time and date of opening, it has the disadvantage that multiple doses can be removed at 1 time. Patients were given a calendar page and asked to record occasions when >1 dose was removed from the vial and the additional doses were taken later in the day. The calendar page and electronic monitoring data were combined to calculate the proportion of total prescribed doses of protease inhibitors taken during 30 days of adherence monitoring.

Statistical Analyses

Descriptive statistics were used to characterize demographic variables and SOC for medication adherence. Construct validity of the SOC measure was examined by

comparing SOC with scores on the MAS and the MOS measure of adherence. A 1-way analysis of variance was performed to determine whether mean scores on the MAS differed by SOC for adherence.³⁶ The Bonferroni multiple-comparison procedure was used to identify which pairs of means were significantly different.³⁶ The chi-square statistic was used to examine the association between SOC for adherence and the MOS measure of adherence.

Validity of the SOC measure was tested by comparing patients’ self-reported SOC at baseline with the percentage of total prescribed doses taken during the subsequent 30 days of electronic monitoring. One-way analysis of variance was used to determine whether the mean number of doses recorded electronically varied by SOC for adherence at baseline, and the Bonferroni multiple-comparison procedure was used to identify which pairs of means were significantly different.³⁶

RESULTS

Demographic and baseline characteristics of the 2 samples are given in Table IV. The HIV-positive sample (N = 161) was predominantly male, with a mean age of 39.6 years, and the sample of hyperten-

Table IV. Characteristics of the 2 samples.

Characteristic	HIV-Positive Sample (N = 161)	Hypertensive Sample (N = 731)
Age (y), mean \pm SD	39.6 \pm 7.4	56.6 \pm 12.5
Sex (%)		
Male	83.0	45.0
Female	17.0	55.0
Race (%)		
White	78.9	94.9
African American	7.2	3.2
Hispanic	3.9	1.3
Other	10.0	0.6
High school education or more (%)	84.1	67.6
Health perceived as poor/fair (%)	13.1	23.4
Stage of change for adherence with medication (%)		
Precontemplation	1.3	28.8
Contemplation	5.7	19.8
Preparation	8.2	11.9
Action	44.0	6.8
Maintenance	40.9	31.1

sive patients (N = 731) was international (United States 200, Canada 97, France 133, Germany 151, Italy 150), predominantly female, and had a higher mean age.

The HIV-positive sample was skewed toward the action and maintenance stages—7.0% were in the precontemplation or contemplation stages, and 44.0% were in the action stage, perhaps because protease inhibitors were new to the market. Because the data were collected in clinical settings, they may have included patients more inclined to be adherent than would be found in a reference population. Because of the small proportion of individuals in the precontemplation and contemplation stages, these categories were combined in subsequent analyses.

The distribution of SOC in the sample of patients taking antihypertensive medication was bimodal, with the largest proportion of individuals in the precontemplation (28.8%) and maintenance (31.5%) stages. Those in the action stage were the smallest group in this sample (6.8%), and only 11.9% were in the preparation stage.

The validity of SOC for medication adherence was examined using 2 different self-reported measures and electronic monitoring of adherence behavior (Table V). A 1-way analysis of variance of the MAS by SOC for adherence with protease inhibitors showed significant differences by stage ($F = 7.46$, $P < 0.001$). The MOS adherence measure was strongly associated with SOC for adherence with antihy-

Table V. Associations between stage of change for adherence and other measures of 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)
	<i>F</i> = 7.46, <i>P</i> < 0.001	<i>F</i> = 2.95, <i>P</i> = 0.03	χ^2 = 441.3, <i>P</i> < 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.

*Analyses included only those patients with no missing data.

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

[‡]The Medical Outcomes Study measure of adherence.³⁴

pertensive medication (*P* = 0.001). Only 7.0% of those in precontemplation for adherence with antihypertensive medication responded that they were adherent with their medication regimen “most or all of the time,” compared with 96.9% of those in the maintenance stage.

Table V also demonstrates that SOC predicts adherence with medication as measured by an objective indicator of doses taken (MEMS, n = 85). One-way analysis of variance showed a statistically significant association between baseline SOC for adherence and adherence with protease inhibitor therapy during the next

30 days (*P* = 0.03), as measured by electronic monitoring of doses (MEMS).

DISCUSSION

A patient who receives a prescription for a medication to be taken on a long-term basis is essentially instructed to adopt a new lifestyle. Behavior-change theory suggests that patients vary in their readiness to adopt a new behavior and that strategies for encouraging behavior change should be tailored to “readiness for change.” The premise of basing interventions on an individual’s stage of

change is that behavior change is best encouraged in small steps. The objective of each contact is to move to the next stage of change rather than encouraging immediate action. The SOC theory suggests that rewards, monitoring devices, and reminder techniques are most useful for individuals who are in the action and maintenance stages, but individuals in earlier stages need consciousness-raising interventions that focus on awareness of the benefits of therapy.^{37,38}

Several authors have suggested that the efficacy of medication-adherence interventions might be improved by applying the SOC theory of behavior change.³⁹⁻⁴¹ Development of valid measures for assessing SOC for medication adherence is the first step toward designing stage-matched interventions targeted at adherence. The construct validity of the measure of SOC for adherence with medication in this study was supported by significant linear associations with previously validated measures, the MAS and the MOS adherence measure. We also demonstrated predictive validity using electronic monitoring of medication adherence in addition to self-reporting. The literature consistently indicates that most self-reported measures overestimate medication adherence by as much as 100%,^{35,42,43} but electronic monitoring provides an unobtrusive and objective measure compared with pill counts or serum levels.³⁵ Our results showed that SOC for adherence prospectively predicted the results of electronic monitoring of doses of protease-inhibitor therapy in a validation subsample of 85 HIV-positive patients.

Interventions based on SOC often include individualized information on the pros and cons of adopting a new behavior. This strategy is most useful in interactions targeting individuals in the early

stages of change, since scores on measures of pros and cons predict movement out of the precontemplation stage.⁴⁴ Although health care providers are acutely aware of the benefits of adopting adherent behavior (eg, reduction of symptoms, lower risk of complications), the prevalence of noncompliance with medication suggests that for many patients, the negative aspects of long-term medication adherence (eg, minor side effects, being reminded of their illness or condition) often outweigh the benefits. The pros and cons of adherence with specific medication regimens vary according to the relevant side-effect profile, complexity of the regimen, degree of symptomatic relief, and many other factors.⁴⁵ Therefore, applications of the SOC theory that employ a generic stage-tailored approach may not be as effective as intervention strategies that take into account the unique pros and cons of adherence with a specific regimen.

For example, providers of care for HIV-positive patients could encourage open discussion of fears about side effects with patients in the precontemplation and contemplation stages of change. Patients with hypertension who are in the precontemplation or contemplation stages may need information about the benefits of adherence, such as prevention of stroke or heart attack, and the feeling of being actively engaged in protecting their health. Health care providers may sometimes assume that patients are familiar with these benefits when, in fact, they are not. For many patients with hypertension, the cons associated with minor side effects may be more compelling than the pros of long-term therapy. The primary goal of interactions with early-stage patients is to shift their attention from focusing on the negative aspects of therapy to a more bal-

anced view of both the benefits and costs of therapy.

However, discussing pros and cons of adherence with patients who are ready for action or are in the maintenance stage may in fact be counterproductive.^{44,46} These patients are no longer focused on thinking about changing their behavior but are actively modifying it. Patients in the later stages of change still need assistance with adherence; we found an average adherence of 86% among HIV-positive patients in the maintenance stage of adherence, which may not be adequate for virologic success.⁴⁷ The SOC theory suggests that behavioral strategies for change, such as reminders, rewards, and support from others, are appropriate strategies for patients in the action or maintenance stages of change.⁴⁸⁻⁵¹

Study Limitations

Limitations of this study include the small numbers of individuals in the early stages of change for adherence with HIV medication. Although this reduced the study's power to detect differences, the results of statistical tests were significant, attesting to the strength of the effects observed. Also, because of the time and expense associated with the use of electronic monitoring devices, we examined the predictive validity of SOC for medication adherence by electronically monitoring only 1 type of medication for only 1 month. The samples studied were not representative population-based samples and should be viewed as convenience samples used for validation purposes. Although it is unlikely that selection bias could explain the concordance between SOC for medication adherence and other adherence measures in individual patients, attempts to replicate these findings should be carried

out in diverse patient groups with longer follow-up and other medication regimens in population-based samples.

These measures were self-administered in private settings, and their use by clinicians may be more subject to social desirability bias (ie, underreporting of such socially undesirable responses as non-compliance) than our results indicate. However, health care providers can assess SOC for adherence in less direct ways. For example, the provider might ask if a patient feels ready to begin the medication regimen and understands the benefits of therapy. If the patient is not sure, this is an indication that he or she may be in an earlier stage of readiness for medication adherence, calling for further exploration of attitudes about the pros and cons of adherence.

CONCLUSIONS

Behavior-change theory suggests that tailored intervention strategies are more effective than uniform health-promotion messages. Our results provide a valid 2-item measure of SOC for medication adherence that can serve as a foundation for medication-adherence interventions tailored to readiness for change. This measure can be used to identify many patients with potential adherence problems and to match communication strategies to individual motivation and readiness for adherence with chronic disease medication regimens.

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