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PREDICTIVE VALIDITY OF A MEDICATION ADHERENCE MEASURE IN AN  
OUTPATIENT SETTING

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**ABSTRACT**

This study examines the psychometric properties and tests the concurrent and predictive validity of a structured, self-reported medication adherence measure in patients with hypertension. We also assessed various psychosocial determinants of adherence, such as knowledge, social support, satisfaction with care and complexity of the medical regimen. A total of 1367 patients participated in the study; mean age was 52.5 years, 40.8% were male, 76.5% were black, 51% graduated from high school, 26% were married, and 54.1% had income <\$5,000. The eight-item medication adherence scale was reliable ( $\alpha= 0.83$ ) and significantly associated with blood pressure control ( $P<0.05$ ). Using a cutpoint of less than 6, the sensitivity of the measure for identifying low versus higher adherers was estimated to be 93%, and the specificity was 53%. The medication adherence measure proved to be reliable with good concurrent and predictive validity in primarily low income, minority patients with hypertension, and might function as a screening tool in outpatient settings with other patient groups.

Keywords: Adherence, Compliance, Reliability and Validity, Hypertension, Blood pressure control, Morisky Scale

Abstract Word Count: 157

**Background:**

Hypertension is one of the most important risk factors for coronary heart disease, stroke, heart failure and end stage renal disease and remains an important public health challenge<sup>1-3</sup>. Although there are effective medical therapies for hypertension management, only 37% of hypertensive patients in a 2003–2004 survey were reported to have their blood pressure controlled<sup>1</sup>. One factor contributing to less than ideal blood pressure control is patient non-adherence to prescribed therapies. A meta-analysis revealed that the odds of good blood pressure control among patients adherent to anti-hypertensive medications, compared to those who were non-adherent was 3.44 (95% confidence interval 1.6, 7.37)<sup>4</sup>. Multiple factors that influence patient adherence to prescribed therapies have been described, these include: quality of life, complexity and side effects of medications, health care system issues, demographic, behavioral, treatment and clinical variables, lack of knowledge regarding hypertension, to name only a few<sup>5</sup>. A recent Harris Poll survey suggested that there has been an improvement regarding knowledge of hypertension risks, percentages of patients receiving specific medications, and numbers of patients controlled<sup>6</sup>. Nevertheless, patient non-adherence to anti-hypertensive treatment recommendations remains a global problem, and promoting patient adherence is a major clinical hurdle that is necessary to decrease cardiovascular morbidity and mortality<sup>7,8</sup>.

A first step in understanding adherence, or lack thereof, is assessing or measuring adherence. In outpatient clinical settings, there is a need for a valid, reliable, cost-effective tool that is accepted by both health care providers and patients for measuring

medication adherence. Widespread use of such a tool, which could provide insight into modifiable factors regarding adherence in different patient populations, would lead to better understanding of non-adherence and lay the groundwork for interventions aimed at increasing adherence to therapies.

The primary objective of the current study is to examine the psychometric properties and test the concurrent and predictive validity of an 8-item structured, self-reported medication adherence measure in primarily low income, minority patients with hypertension. Predictive validity is assessed through associations with blood pressure control, knowledge, social support, stress, and patient satisfaction with clinic visits, each of which was previously described to be associated with medication adherence<sup>9</sup>.

**Methods:** As part of a randomized experimental pre- and post-test study design over a 12-month period to evaluate the effects of structural and educational interventions on blood pressure control<sup>10</sup>, we examined the psychometric properties of an eight-item medication adherence measure. The study was undertaken at a large teaching hospital. Institutional Review Board approval was obtained from the medical center. Participants were randomly recruited from a list of approximately 1400 patients attending the Hypertension Clinic during regularly scheduled appointments at the medical center<sup>10, 11</sup>. Project staff explained the program to each patient. Individuals who consented to participate completed the baseline interview with a community health worker at the end of that clinic visit. More than 98% of the patients approached agreed to participate. The baseline interview assessed demographic information, medical history, pertinent health behaviors, appointment keeping and medication adherence. Other psychosocial factors

that were known to be related to treatment adherence were also evaluated including satisfaction with medical care, social support, stress, knowledge and attitudes towards blood pressure control treatment and coping skills<sup>7, 12-14</sup>.

**Medication Adherence Measure:** The self-reported measure of medication taking was developed from a previously validated four-item scale and supplemented with additional items addressing the circumstances surrounding adherence behavior<sup>15</sup>. The theory underlying this measure was that failure to adhere to a medication regimen could occur due to several factors such as “do you sometimes have problems remembering to take your medication”, “do you sometimes forget to take your medication,” and problems with the complexity of the medical regimen such as, “do you ever feel hassled about sticking to your treatment plan”. The questions are phrased to avoid the “yes-saying” bias by reversing the wording of the questions about the way patients might experience failure in following their medication regimen since there is a tendency for patients to give their physicians or other health care provider’s positive answers. Each item is measuring a specific medication-taking behavior and not a determinant of adherence behavior. Response categories are yes/no for each item with a dichotomous response and a 5-point Likert response for the last item.

**Other Measures:** Using a standardized protocol, a calibrated mercury sphygmomanometer and stethoscope were used by an American Heart Association certified nurse to measure blood pressure. At least 5 minutes after the patient arrived for his/her medical examination, two blood pressure measurements were taken five minutes apart on the right arm with the patient sitting. Measures were collected for all outpatient visits during a six-month period following the baseline survey. The average of the

measurements was calculated and used in the analyses. Blood pressure was considered to be uncontrolled if either the mean of the systolic pressure was greater than or equal to 140mm Hg or the mean of the diastolic pressure was greater than or equal to 90 mm Hg, respectively.

Knowledge concerning high blood pressure was measured using a six-item index from a previous study regarding patient knowledge of hypertension<sup>16</sup>. The knowledge index ranged from 0 to 6, with higher scores indicating greater knowledge. Attitudes towards hypertension<sup>13</sup> were measured with a 13-item instrument using a 4-point Likert-type scale (alpha-reliability = 0.86). Patient satisfaction was measured by a six-item scale (alpha-reliability = 0.87) that measured the degree to which patients were satisfied with their clinic visit, including appointment waiting times, availability of doctor, amount of information received from doctor, and concerns the doctor had for the patients<sup>17, 18</sup>. A social support scale (alpha reliability = 0.76) measured the extent to which respondents were receiving social support from their family and friends to take their medications. A seven-item coping scale<sup>14</sup>, (alpha-reliability = 0.84) was used to measure social coping behaviors. A four-item scale (alpha-reliability = 0.79) was used to measure psychological stress<sup>19</sup>. A two-item index that incorporates the number of anti-hypertensive drugs taken and the number of times the medication should be taken each day was used to measure medication complexity.

### **Statistical Analyses**

Using standard statistical procedures described by Cronbach<sup>20</sup>, the reliability of the 8-item scale was derived. Concurrent validity of the scale with a previously validated 4-item measure of adherence<sup>15</sup> was assessed using Pearson's correlation coefficient.

Predictive validity of the scale was assessed through associations with blood pressure levels, knowledge, attitude, social support, stress, coping and patient satisfaction with clinic visits. Standard procedures, including confirmatory factor analysis, for assessing the dimensionality of the scale was used to confirm a single-factor scale<sup>21</sup>.

Multivariate logistic regression analysis was conducted to evaluate the odds ratios of various risk factors associated with medication adherence. To determine how well the 8-item scale would serve as a screening tool for identifying patients with poor blood pressure control, sensitivity, specificity and correct classification rates were estimated<sup>22</sup>.

## **Results**

The sociodemographic characteristics of the 1367 participants in the study are presented in Table I. The mean age of respondents was 52.5 years (SD=12.2 years), with 61.5% older than 50 years, % male, 76.5% black, 50.8% having graduated from high school, 26% married, and 54.1% having an income <\$5,000. The mean score for the medication adherence scale was 6.6 (standard deviation = 1.6). The item-total correlations were greater than 0.30 for each of the 8 items comprising the medication adherence scale (Table II).

The current 8-item scale was significantly correlated with the previously validated 4-item self-reported Medication-taking Scale<sup>15</sup> (Pearson correlation of 0.64;  $p < 0.05$ ). Confirmatory factor analysis (Table III) indicated that the eight-item scale was uni-dimensional and the items loaded well on the single factor.



In assessing the sensitivity and specificity of the self-report measure to identify patients with poor blood pressure control, all possible cutpoints were examined. Final cutpoints were chosen based on the relationship with blood pressure control, so that the medication adherence scale could provide useful information in a clinical setting (Table IV). Highly adherent patients were identified with the score of 8 on the scale, medium adherers with a score of 6 to < 8, and low adherers with a score of <6. Using these cutpoints, this study population had 32.1% low adherers, 52.0% medium adherers, and 15.9% high adherers. Patients who scored high on the adherence scale were more likely to have their blood pressure under control compared with patients who scored medium or low. A significant relationship between the adherence scale and blood pressure control (chi-square, 6.6;  $P < .05$ ) was found (Table IV). Correct classification with blood pressure control was based on a dichotomous low versus high/medium measure of adherence, with a rate of 80.3%. Sensitivity and specificity of the 8-item scale were 93% and 53% respectively. In the multivariate model (adjusted for age, ethnicity, marital status, income, and education), attitude, knowledge, social support, patient satisfaction, coping and stress were evaluated with respect to medication adherence (Table 5). When all of these variables were included in the model, knowledge, patient satisfaction, coping, stress level and medication complexity were each found to be significantly associated with adherence at the 0.05 level. Patients who displayed high knowledge of the medical regimen, higher satisfaction with medical care, positive family member social support, and stronger coping behavior were significantly more likely to have high levels of adherence. On the other hand, patients who reported high levels of stress, greater complexity of the medical

regimen, and poor perceived health status were found to have significantly lower levels of medication adherence.

## **Discussion**

Hypertension is the most prevalent health problem among adult patients affecting approximately 65 million people in the United States and about one billion persons worldwide, but its recognition and treatment are still suboptimal<sup>1, 23, 24</sup>. It is one of the leading risk factors for cardiovascular disease, the leading cause of death in the United States. Adherence to appropriate medical therapy for hypertension can result in controlled blood pressure and reduction in adverse outcomes. With increasing need for long-term adherence to treatment, a reliable and valid measure of patient adherence, which can be easily administered, is needed. This study reports the development and evaluation of a medication adherence scale that is easy to administer. The scale can be used as an initial tool to screen patients for low adherence, and at risk for uncontrolled blood pressure, compared to patients with medium to high adherence. When appropriate, tailored interventions can be implemented, such as education of the patient regarding hypertension care, correcting misunderstandings and incorrect beliefs regarding hypertension treatment, reducing stress and improving coping skills among patients, or establishing a treatment regimen to foster medication adherence.

Adherence to treatment for high blood pressure is influenced by a number of factors, some of which are modifiable<sup>14-19</sup>. Adherence rates have been shown to be associated with age, gender and race. Several studies have noted demographic disparities regarding medication adherence with lower adherence reported among younger individuals<sup>25, 26</sup>, men<sup>26</sup>, and black persons<sup>27</sup>. Other factors reported to negatively impact adherence to

prescribed therapies include depression<sup>28</sup>, lack of knowledge regarding hypertension and its treatment<sup>29</sup>, complexity of medication regime<sup>30</sup>, health care system perceptions by the patient<sup>31</sup>, sexual dysfunction<sup>32</sup>, side effects of medication<sup>33</sup> and poor quality of life<sup>34</sup>. In our study, we identified several modifiable variables in the logistic regression model that predict medication adherence. Some of the interesting findings in the model indicated that knowledge of hypertension, patient satisfaction and coping skills were significantly associated with medication adherence. This implies the need for patient education to increase knowledge regarding hypertension treatment and for effective communication between the physician and patients to improve understanding regarding hypertension and its treatment.

A national US survey found 30% of the patients who reported a value of 140 mm Hg or higher for systolic blood pressure indicated that they did not have high blood pressure<sup>29</sup>. In addition, about 20% of patients acknowledging a diagnosis of high blood pressure were not taking medications as prescribed. Reasons for non-adherence were recorded as forgetfulness (46%), blood pressure under control (40%), did not like taking medications (33%), adverse effect (30%), blood pressure controlled other ways (28%), and cost (16%)<sup>29</sup>. In another study, a similar finding was reported: hypertensive patients had poorer awareness of normal blood pressure values than normotensive participants<sup>35</sup>. In a general study of over 600 adults taking prescribed medications for hypertension, 80% reported having reservations about their therapy with 66% indicating they preferred to lower their blood pressure without taking blood pressure pills<sup>36</sup>. Another study found that hypertensive African American patients with controlled blood pressure reported higher mean self-efficacy scores compared to patients with uncontrolled hypertension<sup>37</sup>.

More recent surveys suggest that patient knowledge and control rates are improving<sup>6</sup>. In addition to addressing patient non-adherence to therapy as a contributor to poor blood pressure control, there is an important issue of clinical or therapeutic inertia where physicians or other healthcare providers do not adhere to treatment guidelines to change or intensify antihypertensive therapy if blood pressure remains uncontrolled on pharmacotherapy<sup>38</sup>.

In order for physicians or other health care providers to adequately address in the provider-patient encounter poor adherence to therapy by the patient as a key factor leading to inadequate blood pressure control, they must first be able to reliably assess it. In the outpatient setting, there are four approaches, which are commonly reported for measuring medication adherence: self-report, electronic monitoring, pill count, and pharmacy fill rates<sup>5, 39, 40</sup>. Each of these approaches can lead to a quantifiable measure of adherence and, with the exception of self-report, these approaches are objective. Recent attention has been given to electronic monitoring with systems such as medication event monitoring systems (MEMS). Provided they are used correctly, these systems capture data on daily intake and dosing over time allowing analyses of long-term patterns and opportunities to identify white-coat adherers<sup>39</sup>. However, these devices are relatively expensive and somewhat cumbersome to carry, are subject to interference by the patient or other devices, can fail, and are able to capture large quantities of data points over time posing challenges for data analysis. Research involving MEMS caps as a measure of adherence identified several problems with this approach, including not using the electronic monitoring device (EMD) consistently (36%), taking out more than one dose at a time (41%), and reporting opening the EMD but not taking the medication (26%)<sup>41</sup>. In addition, each medication that is being

monitored for adherence requires its own device, and reasons for non-adherence are not captured by the electronic system.

In contrast, self-report measures, such as the one proposed in this study, are simple and economical to use, and can provide real-time feedback regarding adherence behavior and potential reasons for poor adherence including social, situational and behavioral factors affecting adherence. Although self-report measures may be subject to recall bias, overestimation of adherence, and elicitation of socially acceptable responses, efforts aimed at increasing validity and reliability of self-report measures in different populations will facilitate the adoption and use of these tools in clinical practice. In a racially diverse sample of elderly patients with hypertension in a managed care setting, the 8-item medication adherence scale and anti-hypertensive medicine pharmacy fill rates were significantly correlated ( $r= 0.46, P<.001$ )<sup>34</sup>. Other work has been conducted in research settings with self-reported medication adherence measures<sup>15, 42, 43</sup>, however, further refinement of these tools and consistent demonstration of validity and reliability in different populations is needed prior to widespread adoption. Several studies have highlighted the importance of assessing medication-taking behavior and the positive benefits of enhanced provider/patient communication<sup>44</sup>.

Given the validity and reliability reported with the 8-item instrument and its ease of use in the outpatient setting, this self-report measure could function as a screening tool in the clinic setting to identify patients who are poorly adherent and at risk for uncontrolled blood pressure. The eight-item scale had a higher sensitivity than the original 4-item scale. This sensitivity of 93% indicates that the scale is good at identifying patients who have low medication adherence and have uncontrolled blood

pressure relative to all patients who have uncontrolled blood pressure. The specificity of the eight-item scale of 53% indicates moderate performance of the scale in identifying patients who do not have problems with medication adherence and have their blood pressure under control relative to all those with controlled blood pressure. This self-reported adherence classification along with blood pressure control data could be useful in the clinical decision-making process. For example, a patient with high medication adherence and good blood pressure control could be complemented on his/her medication-taking behavior and reminded of the benefits of controlled blood pressure and importance of continued adherence to medications. A patient with inadequate blood pressure control but high medication adherence could be considered a patient with difficult to control or refractory hypertension or with inappropriate or inadequate pharmacologic treatment. In this case, intensification of therapy or change in therapy to achieve the appropriate blood pressure response should be considered<sup>45</sup>. Alternatively, for patients classified as having low adherence to medications and with poor blood pressure control, the physician may consider discussing potential side effects of medications with the patient, engaging family member support, using cueing behaviors or memory devices<sup>46</sup>.

***Limitations:*** The results of this study should be interpreted with the following limitations in mind. This study was conducted in very low income minority patients treated for hypertension seeking routine care in a clinic setting and may not be representative of patients from other socioeconomic backgrounds. Also, as noted previously, a recent survey suggests that patient knowledge and control rates are improving<sup>6</sup>, yet opportunities still exists to improve these rates if we are to achieve the

Healthy People 2010 Goals for the Nation. Although the scale was not validated with pharmacy refill rates in this study, it was correlated with another 4-item adherence scale<sup>15</sup>, which was previously found to have a moderate level of reliability and high levels of concurrent and predictive validity, and was validated with a chemical marker for actual medication taking behavior<sup>47</sup>. Further research is recommended with more objective measures in patients with hypertension.

**Conclusion:**

The medication adherence scale presented in this research is relatively simple and practical to use in clinical settings. The instrument can be used initially to identify patients with adherence problems, and can also be used to monitor adherence over the course of the treatment. One important feature of the scale is that treatment-related attitudinal and behavioral problems that the patient may be facing can be immediately identified and health care providers may provide reinforcement and advice such that the patient can take positive steps early on to address these issues. Further research is needed to validate this measurement scale in other settings and with other health problems.

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A patient education booklet, “High Blood Pressure. What You Should Know About It and How You Can Help Your Doctor Treat It.” is available from the Hypertension Education Foundation P.O. Box 631 Scarsdale, NY 10583.



Potential Conflicts of Interest: NONE

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**Table 1. Sociodemographic Characteristics of the Participants at Baseline**  
(N = 1367)

Sociodemographic Characteristic	Percentage
Gender	
Male	40.8 %
Female	59.2 %
Age, years	
18-39	12.2 %
40-49	26.3 %
50-59	32.9 %
60+	28.6 %
Ethnicity	
Black	76.5 %
Hispanic	20.6 %
Asian	1.1 %
White	0.9 %
Other	0.9 %
Income	
No income	31.4 %
< \$5,000	22.7 %
\$5,000 – 14,999	36.6 %
\$15,000 – 24,999	5.5 %
\$25,000 - 49,999	3.6 %
> \$50,000	0.2 %
Marital Status	
Married	26.0 %
Living w/ someone	4.3 %
Divorced/separated and alone	28.9%
Never married	27.0 %
Widowed, alone	13.8 %
Highest Educational Level	
Less than High School	48.5 %
High School Graduate	40.6%
Some College	9.9 %
Graduate School	0.3 %
Other	0.7 %

**Table 2: The Eight-Item Medication Adherence Scale**

Item	Corrected Item-to-total Correlation
1. Do you sometimes forget to take your high blood pressure pills?	.4639
2. Over the past two weeks, were there any days when you did not take your high blood pressure medicine?	.5108
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	.4277
4. When you travel or leave home, do you sometimes forget to bring along your medications?	.4095
5. Did you take your high blood pressure medicine yesterday?	.3038
6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	.5044
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your blood pressure treatment plan?	.4009
8. How often do you have difficulty remembering to take all your blood pressure medication?	.5896

Alpha Reliability = 0.83



Table 3. Factor Loadings of the Eight-item Medication Adherence Scale

Item	Factor Loadings *
1. Do you sometimes forget to take your high blood pressure pills?	0.566
2. Over the past two weeks, were there any days when you did not take your high blood pressure medicine?	0.617
3. Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?	0.519
4. When you travel or leave home, do you sometimes forget to bring along your medications?	0.493
5. Did you take your high blood pressure medicine yesterday?	0.425
6. When you feel like your blood pressure is under control, do you sometimes stop taking your medicine?	0.543
7. Do you ever feel hassled about sticking to your blood pressure treatment plan?	0.479
8. How often do you have difficulty remembering to take all your blood pressure medication?	0.668

\* RMSEA < .01

**Table 4: Relationship between Adherence Scale and Blood Pressure in Control**

	<b>Blood Pressure In Control*</b>	
	No	Yes
Low Adherence < 6	67.2%	32.8%
Medium Adherence 6 - <8	55.2%	44.8%
High Adherence 8	43.3%	56.7%

\*( $\chi^2 = 6.6$ ;  $p < 0.05$ )

Blood pressure in control: Systolic BP < 140 mm Hg, and Diastolic < 90 mm Hg

**Table 5: Odds Ratios of Determinants of High Medication Adherence**

	<b>Odds Ratio</b>	<b>95 % Confidence Interval</b>
Knowledge	1.15	1.03 – 1.29*
Attitude	0.99	0.96 – 1.03
Satisfaction	1.07	1.02 – 1.11*
Social Support	1.06	1.02 – 1.37*
Coping	1.94	1.19 – 3.15*
Stress	0.91	0.86 – 0.98*
Medication Complexity	0.55	0.38 – 0.81*

\* Significant at  $p < 0.05$ .