



## NIH PUBLIC ACCESS

## Author Manuscript

*Med Care*. Author manuscript; available in PMC 2013 December 01.

Published in final edited form as:

*Med Care*. 2012 December ; 50(12): 1013–1019. doi:10.1097/MLR.0b013e318269e121.

## Initial validation of a self-report measure of the extent of and reasons for medication nonadherence

Corrine I. Voils, PhD<sup>1,2</sup>, Matthew L. Maciejewski, PhD<sup>1,2</sup>, Rick H. Hoyle, PhD<sup>3</sup>, Bryce B. Reeve, PhD<sup>4</sup>, Patrick Gallagher, PhD<sup>1</sup>, Christopher L. Bryson, MD<sup>5,6</sup>, and William S. Yancy Jr., MD, MHS<sup>1,2</sup>

<sup>1</sup>Center for Health Services Research in Primary Care, Durham Veterans Affairs Medical Center

<sup>2</sup>Department of Medicine, Duke University Medical Center

<sup>3</sup>Department of Department of Psychology and Neuroscience, Duke University

<sup>4</sup>Department of Health Policy and Management and Lineberger Cancer Center, University of North Carolina at Chapel Hill

<sup>5</sup>Northwest Center for Outcomes Research in Older Adults, Seattle Veterans Affairs Medical Center

<sup>6</sup>Department of Medicine, University of Washington School of Medicine

### Abstract

**Background**—Self-report measures of medication nonadherence confound the extent of and reasons for medication nonadherence. Each construct is assessed with a different type of psychometric model, which dictates how to establish reliability and validity.

**Objectives**—To evaluate the psychometric properties of a self-report measure of medication nonadherence that assesses separately the extent of nonadherence and reasons for nonadherence.

**Research Design**—Cross sectional survey involving the new measure and comparison measures to establish convergent, discriminant, and concurrent validity. The new measure was re-administered 2 to 21 days later.

**Subjects**—202 veterans with treated hypertension were recruited from the Durham Veterans Affairs Medical Center.

**Measures**—A new self-report measure assessed the extent of nonadherence and reasons for nonadherence. Comparison measures included self-reported medication self-efficacy, beliefs about

---

Address correspondence and requests for reprints to: Corrine I. Voils, Ph.D., Veterans Affairs Medical Center (152), 508 Fulton St. Durham, NC 27705, voils001@mc.duke.edu, Voice: (919) 286-6936, Fax: (919) 416-5836.

Complete author information:

Corrine I. Voils, Ph.D., Veterans Affairs Medical Center (152), 508 Fulton St. Durham, NC 27705, voils001@mc.duke.edu, Voice: (919) 286-6936, Fax: (919) 416-5836

Matthew L. Maciejewski, PhD, Veterans Affairs Medical Center (152), 508 Fulton St. Durham, NC 27705, matthew.maciejewski@va.gov, Voice: (919) 286-6936, Fax: (919) 416-5836

Rick H. Hoyle, PhD, Department of Psychology and Neuroscience, 417 Chapel Drive, Duke University, Durham, NC 27708-0086, rhoyle@duke.edu, Voice: (919) 660-5791, Fax: (919) 660-5726

Bryce B. Reeve, PhD, University of North Carolina at Chapel Hill, 1101-D McGavran-Greenberg Building, 135 Dauer Drive, CB 7411, Chapel Hill, NC 27599-7411, bbreeve@email.UNC.edu, Voice: (919) 843-8793, Fax: (919) 843-6362

Patrick Gallagher, PhD, Veterans Affairs Medical Center (152), 508 Fulton St. Durham, NC 27705, matthew.gallagher2@va.gov, Voice: (919) 286-6936, Fax: (919) 416-5836

Chris L. Bryson, MD, MS, Seattle Health Services Research and Development Center of Excellence, Ste 1400, 1100 Olive Way, Seattle, WA 98101, Christopher.Bryson@va.gov, Voice: (206) 277-1770, Fax: (206) 764-2935

William S. Yancy Jr., MD, MHS, Veterans Affairs Medical Center (152), 508 Fulton St. Durham, NC 27705, yancy001@mc.duke.edu, Voice: (919) 286-6936, Fax: (919) 416-5836

\$watermark-text

\$watermark-text

\$watermark-text

medications, impression management, conscientiousness, habit strength, and an existing nonadherence measure.

**Results**—Three items assessing the *extent of nonadherence* produced reliable scores for this sample,  $\alpha=0.84$  (95% CI: 0.80, 0.87). Correlations with comparison measures provided evidence of convergent and discriminant validity. Correlations with systolic ( $r=0.27$ ,  $p<.0001$ ) and diastolic ( $r=0.27$ ,  $p<.0001$ ) blood pressure provided evidence of concurrent validity. *Reasons for nonadherence* was assessed with 21 independent items. Intraclass correlations (ICC) were 0.58 for the *extent* score and ranged from 0.07 to 0.64 for the reasons.

**Conclusions**—The dual conceptualization of medication nonadherence allowed a stronger evaluation of the reliability and validity than was previously possible with measures that confounded these two constructs. Measurement of self-reported nonadherence consistent with psychometric principles will enable reliable, valid evaluation of interventions to reduce nonadherence.

### Keywords

adherence; reliability; scale development; self-report

---

Medication nonadherence is a significant clinical problem in chronic disease management. (1, 2) Medication nonadherence is associated with increased healthcare spending, hospitalization rates, morbidity, and premature mortality.(3)

Obtaining accurate estimates of medication nonadherence is essential to determine where intervention resources should be directed. There is no ‘gold standard’ for assessing nonadherence.(4, 5) Pill refills, pill counts, and computerized bottle caps can approximate how much medication patients are consuming, but only patients can report reasons for not taking their medications. The self-report method is also appealing because it can be administered in any setting, is low-cost, and can provide immediate feedback at the point of care.

Considerable effort has been made to assess self-reported medication nonadherence, yielding several self-report instruments.(6–9) Although an expert committee recently identified medication nonadherence as one of the constructs that should be assessed routinely in electronic health records, it did not recommend an existing measure and suggested further work was needed.(10) Others have also concluded that existing measures lack reliability and validity.(11)

Recently, we examined existing self-report measures of medication nonadherence to determine how measurement could be improved.(12) A key limitation of existing measures is that they confound two related but distinct nonadherence constructs: the *extent* to which doses are missed and the *reasons* for missing doses. Each construct is assessed by a different type of psychometric model, which has important measurement implications (Table 1). Existing self-report measures were not developed with this distinction in mind, compromising reliability and validity.(12) We developed a self-report measure that assesses the *extent* of and *reasons* for medication nonadherence separately using appropriate psychometric models. We developed the measure within the context of hypertension (HTN) because its prevalence is high and nonadherence to antihypertensive medications is common.(13, 14) We provide initial validation results.

## Methods

### Item Generation

To inform items assessing the extent of nonadherence, cognitive interviews were conducted at Duke University with hypertensive patients: 15 with English-speaking Black and White patients and 15 with Spanish-speaking patients. Participants were asked to discuss how the following wording choices would affect their estimates of the extent of nonadherence: (1) percentage versus frequency of doses and (2) recall period of last week versus last month. Patients found it difficult to quantify behavior in terms of percentages. Patients had various interpretations of the phrases 'last week' and 'last month,' suggesting the need to ask about a specific number of days. Although some patients thought that the 'last 30 days' more accurately reflected long-term adherence, they felt that 'the last 7 days' were more easily and accurately recalled and more sensitive to nonadherence. These findings were used to generate our initial item pool comprising 5 items asking about medication use over the previous 7 days.

To generate reasons for nonadherence, we used the 23 situations queried in the Medication Adherence Self-Efficacy Scale (MASES).<sup>(15)</sup> Our review of the literature and focus groups conducted previously<sup>(16)</sup> did not reveal additional situations. The recall period for these items was also 7 days.

### Design of Validation Study

The study involved two in-person assessments. At Time 1, the newly developed nonadherence measure and several psychosocial measures were administered. At Time 2 (2 to 21 days later), the newly developed measure was re-administered to provide initial evidence of stability. Blood pressure (BP) was obtained at both visits to provide evidence of concurrent validity.

### Participants

Participants were recruited from the Durham Veterans Affairs Medical Center (VA), where Institutional Review Board approval was obtained. Veterans aged > 40 years with a diagnosis of hypertension were identified from electronic medical records. Inclusion criteria determined during a screening telephone call were: prescription of at least one antihypertensive medication, stability of antihypertensive regimen for at least 3 months prior, and receipt of antihypertensive medications from VA. Exclusion criteria were: cognitive impairment based on a six-item screener,<sup>(17)</sup> unable to complete questionnaires unaided, unable to communicate in English or by telephone, resident in a nursing home or receiving home health care, or health problem that precludes participation.

### Recruitment and Study Procedures

Patients meeting initial inclusion criteria received a recruitment letter and telephone call. Eligible patients were scheduled for an assessment, which coincided with a scheduled medical appointment when possible. Reminder letters were mailed prior to the visit and included instructions not to smoke or consume caffeine or alcohol for at least 60 minutes prior to the assessment.

At Time 1, the RA conducted the consent process, obtained two BP readings according to recommended standards,<sup>(18)</sup> and administered the self-report measures orally. At Time 2, the RA obtained two BP readings and administered the new nonadherence measure orally. Participants received \$20 for each assessment.

## Measures

At Time 1, we collected demographic data, medication names, and dosing instructions in addition to the measures listed below.

**Extent of Nonadherence**—Participants rated the extent to which they have missed doses of their medications over the past 7 days via 5 items with response options: *strongly disagree*, *strongly agree*, *neutral*, *agree*, and *strongly agree*. Higher scores indicate greater levels of nonadherence.

**Reasons for Nonadherence**—Participants rated 23 reasons for missed antihypertensive medications in the past 7 days on 5-point scales anchored by *not at all* and *very much* (see Data, Supplemental Digital Content 1, which includes the *extent* and *reasons* items). Higher scores indicate greater endorsement of each reason for missing dose(s).

**Self-Efficacy to Take Antihypertensive Medication**—Self-efficacy to take medication as prescribed was assessed with the 13-item Medication Adherence Self-Efficacy Scale-Revised (MASES-R),(15) in which participants rated how sure they are that they can take their medication in certain situations. The internal consistency (estimated using Cronbach's coefficient alpha, hereafter referred to as alpha) in our sample was 0.94.

**Beliefs about Medicines**—The 18-item Beliefs about Medicines Questionnaire (BMQ) (19) comprises 4 factors: beliefs about the necessity of prescribed medication (*Specific-Necessity*; alpha=0.84); beliefs about the danger of dependence and long-term toxicity and the disruptive effects of medication (*Specific-Concerns*; alpha=0.78); beliefs that medicines are harmful, addictive poisons that should not be taken continuously (*General-Harm*; alpha=0.74; and beliefs that medicines are overused by doctors (*General-Overuse*; alpha=0.80). Higher scores indicate more positive beliefs about medications for the Necessity factor, and lower scores indicate more positive beliefs about medications on the others.

**Impression Management**—Participants completed the 20-item Impression Management (IM) subscale of the Balanced Inventory of Desirable Responding(20) to assess the tendency to portray a positive perception to others (alpha=0.72).

**Conscientiousness**—Participants indicated how well 25 adjectives described them from 1 *very inaccurate* to 5 *very accurate*. This scale was designed to assess facets of conscientiousness. Items were presented in a different random order for each participant to minimize order effects. Fifteen of the items yielded three facets: orderliness (alpha=0.84), impulse control (alpha=0.63), and reliability (alpha=0.80). The remaining 10 items not contributing to a facet in an exploratory factor analysis were not analyzed.

**Habit Strength**—The habit strength measure was adapted from previous measures (21, 22) to assess the frequency of medication-taking behavior with one item and situational consistency with five additional items (physical location, time of day, people present, mood, and event). Habit strength was calculated as the product of frequency and the mean of the five situational consistency items.

**Blood Pressure**—All BP measurements were performed using a digital sphygmomanometer. Participants sat quietly for 5 minutes. Arm circumference was measured for the appropriate size cuff, and BP was measured while participants were sitting in a chair with back rested, both feet on the floor, and arm supported at heart level. A second

reading was obtained one minute later. The average of the two BP readings was used in analyses.

**Existing Measure of Self-Reported Nonadherence**—Participants completed the 8-item version of the Morisky scale.<sup>(7)</sup> Two items (2 and 5) assess the extent of nonadherence over 2 weeks and yesterday, and six items assess reasons for nonadherence: forgetting (items 1, 4, and 8), feeling worse (item 3), BP in control (item 6), and feeling hassled (item 7). A summary score was calculated.<sup>(7)</sup> This scale was administered to provide evidence of convergent validity of the extent measure and to gain initial evidence as to whether separating *extent* from *reasons* improves the relationship with the criterion (BP).

## Analysis

The *extent of nonadherence* is represented by an effect indicator model, in which a person's level of medication nonadherence determines their item responses (indicators).<sup>(23)</sup> Descriptive statistics were examined for all *extent* items. Excessive skewness is indicated by values  $> 2$  and excessive kurtosis by values  $> 7$ .<sup>(24)</sup> Internal consistency and confirmatory factor analysis (CFA) were conducted to examine the extent to which a single latent variable contributed to indicators of *extent of nonadherence*. CFA is an inferential test of the hypothesis that a single factor accounts for the data. Due to the small item set, a two-factor model was not tested. To set the metric for the CFA model, all factor loadings were freely estimated, and the latent factor's variance was set to 1. Due to the non-normal item distributions, the response scales were treated as ordinal by specifying categorical variable type. Incremental model fit was assessed by the Comparative Fit Index (CFI)<sup>(25)</sup> and Tucker-Lewis Index (TLI);<sup>(26)</sup> values  $> 0.95$  are generally accepted as good model fit.<sup>(27)</sup> Absolute model fit was assessed by Weighted Root Mean Square Residual (WRMR), for which values  $< 0.90$  are generally accepted as good fit.<sup>(28)</sup> *Extent* items were considered for elimination due to excessive missingness, skewness, or kurtosis; insufficient inter-item and item-total correlations or factor loadings ( $< 0.40$ );<sup>(29)</sup> improvement in alpha once an item was deleted; or redundancy with other items, as indicated by inter-item correlations and factor loadings much higher than those for other item pairs. The mean of all retained items was calculated and used in all analyses (see Data, Supplemental Digital Content 2, which includes the item response theory analyses).

Pearson correlations were computed between *extent* and comparison measures to provide information about convergent and discriminant validity. As an a priori guideline, any correlation  $> 0.50$  was considered as evidence of convergent validity and any correlation  $< 0.30$  as evidence of discriminant validity. Because self-efficacy is a proximal determinant of behavior, we expected a large correlation between *extent* and medication self-efficacy. We also expected a large correlation between *extent* and the Morisky scale to provide evidence of convergent validity because some Morisky items assess missed doses. We expected small correlations between *extent* and the four BMQ subscales, impression management, conscientiousness, and habit strength to provide evidence of discriminant validity. Because factors other than nonadherence contribute to elevated BP,<sup>(30)</sup> we expected a small to moderate correlation between BP and *extent* to provide evidence of predictive validity.

*Reasons for nonadherence* are represented by a causal indicator model, in which each *reason for nonadherence* stands alone as a descriptive indicator for the construct because they would not necessarily be correlated. (12) Participants indicating any nonadherence (score  $\geq 2$  on any *extent* item) were considered nonadherent,<sup>(31)</sup> and descriptive statistics for their *reasons* items were examined (see Figure, Supplemental Digital Content 3, which includes the histograms). *Reasons* items were expected to be skewed and/or kurtotic and not highly

inter-correlated. We determined a priori that *reasons* items highly correlated ( $r > 0.60$ ) with one another would be examined for possible redundancy. Alpha was not calculated because it is inappropriate for causal indicators.(23)

To examine the test-retest reliability of the nonadherence measures, intraclass correlations (ICC) were calculated for the *extent* summary score and each *reason* using a two-way mixed model with time as a fixed variable and participants as a random variable.(32) Test-retest reliability assumes the nonadherence constructs are stable over the two assessment periods (which ranged from 2 to 21 days). For participants whose reference periods for the assessment points do not align, there is concern about the stability of the nonadherence constructs, especially for the *reasons* scale as reasons for missing a medication may change over time. Thus, we are not confident that test-retest reliability alone is an accurate indicator of reliability, nor should it be used alone as the only indicator to retain or remove an item from the scale.

The target sample size was 200, which provides  $> 99.5\%$  power to detect the significance of a correlation of  $0.30$  at  $p = 0.05$ . The CFA was performed using Mplus (version 6). The remaining analyses were performed using SAS (version 9; SAS Institute, Cary, NC).

## Results

Seven hundred forty recruitment letters were mailed, for which 566 patients were contacted by telephone. Of those, 100 were ineligible, 210 refused, 6 died before contact, and 250 were scheduled for a Time 1 visit. Forty-eight participants did not show, leaving a Time 1  $n$  of 202 (36%). Of those, 186 (92%) returned for the Time 2 visit.

Participants were 64 years on average, of mixed racial composition, and primarily male (Table 2). Nearly three-quarters of participants reported some education beyond high school, and only 10% reported insufficient income to pay bills.

### Extent of Nonadherence

Although the means of all *extent* items except item 4 were below the scale midpoint, the distributions were not highly skewed or kurtotic (Table 3). All items except item 4 had adequate item-total and inter-item correlations. A single factor accounted for the shared variance among the five *extent* items,  $\chi^2(5)=25.61$ ,  $p=.0001$ , CFI=0.99, TLI=0.99, WRMR=0.60. Although all items had sufficient factor loadings, the item 4 loading was lower than for the other items. Items 1 and 2 were substantially correlated ( $r = 0.84$ ), suggesting redundancy between them. Item 2 was retained in favor of item 1 because its wording is more specific, and item 4 was eliminated because it measures a related but different construct (i.e., being late for a dose). Items 2, 3, and 5 were averaged (unweighted) to create a final summary score,  $M=1.78$  ( $SD=0.96$ ). These items produced reliable scores,  $\alpha=0.84$  (95% CI: 0.80, 0.87).

As expected, *extent* was highly correlated with medication self-efficacy (Table 4). Although correlations between *extent* and the *harm* subscale of the BMQ and habit strength were larger than 0.30, they were not so high as to indicate measurement of a similar construct. Correlations between *extent* and the *necessity*, *concerns*, and *overuse* subscales of the BMQ, impression management, and the three facets of conscientiousness were small in magnitude, demonstrating discriminant validity. Finally, predictive validity was evidenced by correlations between *extent* and BP: for systolic,  $r(202)=0.27$ ,  $p < .0001$  and for diastolic,  $r(202)=0.27$ ,  $p < .0001$ .

## Reasons for Nonadherence

Means of the *reasons* items were well below the scale mid-point, and several distributions were positively skewed and kurtotic (Table 5). Sixty percent ( $N=122$ ) of participants were considered nonadherent (2 on any *extent* item). The reason endorsed (score 2) most was *I forgot*. (27%). The least commonly endorsed reasons were *feeling too ill to take them* (7%) and *going on a long car/plane/bus ride* (7%).

As expected, inter-item correlations were, with few exceptions, sufficiently small to suggest that these items are capturing independent reasons for nonadherence (range  $-0.01$  to  $0.81$ , average  $r=0.28$ ). Item 17 (*I felt well*) was eliminated because it was highly correlated with and subsumed by item 13 (*I felt I did not need them*). Item 23 (*I was going on a long car/bus/plane ride*) was eliminated because it was highly correlated with and subsumed by item 14 (*I was traveling*). The result was a list of 21 relatively independent reasons for nonadherence (range  $-0.01$  to  $0.64$ , average  $r=0.28$ ).

## Relationship with Existing Measure of Nonadherence

To demonstrate the value of treating nonadherence as two related yet distinct constructs, we examined the structure of the Morisky scale (see Data, Supplemental Digital Content 4, which includes results of a confirmatory factor analysis). Items 2 and 5, assessing extent of nonadherence, were only correlated at  $r=0.13$ . Inter-item correlations for the remaining items, assessing reasons for nonadherence, ranged from  $-0.10$  to  $0.55$ , average  $r=0.22$ . Thus, the Morisky scale did not measure a single underlying construct in this sample. The correlation between the Morisky total score and *extent* was  $r(202)=-0.62$ ,  $p<0.0001$ , providing evidence of convergent validity of our *extent* measure. The Morisky score was not correlated with BP: systolic  $r(202)=-0.03$ ,  $p=0.68$  and diastolic  $r(202)=-0.02$ ,  $p=0.74$ .

## Stability of Nonadherence over Time

Time 1 and Time 2 were separated by 2 to 21 days ( $M=8.32$ ,  $SD=5.00$ ). ICCs of the individual *extent* items ranged from  $0.45$  to  $0.52$  (Table 3), and the 3-item total score was  $r=0.58$ , demonstrating moderate short-term stability in the extent of nonadherence. ICCs for the *reasons* items varied greatly, ranging from  $0.07$  to  $0.64$  (Table 5).

## Discussion

Our self-report measure reflects a dual conceptualization of nonadherence.<sup>(12)</sup> Although related, the two facets are distinct, requiring different measurement approaches and evaluation using different psychometric models. Consistent with our conceptualization, the extent of nonadherence was assessed with three positively correlated items, which produced reliable scores and correlated as expected with related constructs. Also consistent with our conceptualization, reasons for nonadherence were assessed with several independent items. In contrast to the *extent* items, which are averaged into an overall score, the reasons items are treated individually in a descriptive manner to inform treatment decisions or to tailor interventions to increase adherence.

Although short measures are always desirable for research and clinical settings, reliability and validity must be a priority. Multiple items (in this case, three), rather than a single item, are needed to assess the *extent of nonadherence* because the reliability, and therefore predictive validity, of effective indicators is increased by the use of multiple items. Some portion of the unreliability in individual items is not shared with other items that vary in wording and, as such, the composite score, which reflects the commonality across items, reduces the impact of unreliability on scores.

The need to assess *reasons for nonadherence* with many items to provide construct validity is underscored by the endorsement of individual items by only a small proportion of participants and by the lack of sizable inter-item correlations. Future research is needed to determine whether the improved content validity translates to better ability to detect intervention outcomes or improves clinical practice.

One practical advantage of measuring *extent* and *reasons* separately is that the measurement process can be streamlined: The three *extent* items can be used to help identify patients with suboptimal levels of adherence, followed by the *reasons* items to identify targets of intervention if necessary. This approach is similar to depression screening, where a positive 2-item Patient Health Questionnaire (PHQ) is followed by a more comprehensive depression measure or diagnostic interview.<sup>(33)</sup> Although the response scale for *extent* items is continuous, various cutoffs could classify nonadherent individuals, depending on a researcher's or clinician's goals.

Another advantage of measuring the two constructs separately is that longitudinal assessments may provide a more fine-grained picture of medication taking behavior. Previous studies have suggested that adherence is episodic.<sup>(34)</sup> Due to the content of existing self-report measures, it is difficult to determine whether the *extent* of nonadherence or the *reasons* for nonadherence vary over time. The separate measurement of *extent* and *reasons* in this self-report measure enables independent assessment of both constructs. The ICCs for *extent* individual items and total score were moderate to large over 2–21 days, suggesting that some individuals report a consistent level of nonadherence. In contrast, ICCs for many *reasons* items were more modest, indicating that some reasons for nonadherence are highly variable. More research is needed to elucidate longitudinal patterns of medication taking behavior, which could inform intervention development and clinical practice.

As scale development is an iterative and ongoing process, we will continue to refine the measure and build the body of evidence for its reliability and validity. For example, because the extent items and response scales were not subjected to cognitive interviews, cognitive interviews should be conducted to improve further the instructions and evaluate different response scales. More evidence of convergent validity of the *extent* measure could be obtained by comparing it to electronic medication monitoring, commonly characterized as a more objective method.<sup>(35)</sup>

More evidence of criterion-related validity is needed as well. Although the *extent* and Morisky measures were highly correlated, only the *extent* measure was significantly associated with BP. Thus, despite some shared variance between the *extent* and the Morisky scales, they account for different variance in BP. This pattern of correlations should be examined in other samples to provide more evidence on the predictive validity of the new measure. Criterion-related validity may be difficult to establish in hypertension because BP is highly variable and reflects the influence of other factors.<sup>(30, 36)</sup> In diseases in which the outcome is more stable over time, such as LDL treated by statins, a higher correlation might be expected between *extent* and the criterion.

Equally important is establishing the psychometric properties of this measure in other diseases and patient populations. As expected of effect indicator models, the *extent* measure should have stable psychometric properties across diseases and populations. The *reasons* measure will need to be tailored to characteristics of the disease, patient populations, and medications used.

In summary, the dual conceptualization of the extent of nonadherence and reasons for nonadherence provided a framework for the measurement of these constructs. Using this conceptualization, we developed a preliminary version of a measure to assess these facets



separately, thereby allowing a stronger evaluation of the reliability and validity than was possible with existing measures. By improving the measurement of self-reported nonadherence, we hope to enable better evaluation of interventions to improve patient-centered outcomes and clinical practice.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

This research was supported by a grant from the National Institute on Aging (R21 AG035233; funding July 1, 2010–June 30, 2012).

## References

1. Horne, R. Adherence to medication: A review of existing research. In: Myers, LB.; Midence, K., editors. *Adherence to Treatment in Medical Conditions*. London: Harwood Academic; 1998. p. 285–310.
2. Sherbourne CD, Hays RD, Ordway L, et al. Antecedents of adherence to medical recommendations: results from the Medical Outcomes Study. *J Behav Med*. 1992; 15:447–468. [PubMed: 1447757]
3. McDermott MM, Schmitt B, Wallner E. Impact of medication nonadherence on coronary heart disease outcomes: A critical review. *Arch Intern Med*. 1997; 157:1921–1929. [PubMed: 9308504]
4. DiMatteo MR. Enhancing patient adherence to medical recommendations. *JAMA*. 1994; 271:79–83. [PubMed: 8258895]
5. Osterberg L, Blaschke T. Adherence to medication. *N Engl J Med*. 2005; 353:487–497. [PubMed: 16079372]
6. Kim MT, Hill MN, Bone LR, et al. Development and testing of the Hill-Bone Compliance to High Blood Pressure Therapy Scale. *Prog Cardiovasc Nurs*. 2000; 15:90–96. [PubMed: 10951950]
7. Morisky DE, Ang A, Krousel-Wood M, et al. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens*. 2008; 10:348–354.
8. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care*. 1986; 24:67–74. [PubMed: 3945130]
9. Svarstad BL, Chewing BA, Sleath BL, et al. The Brief Medication Questionnaire: A tool for screening patient adherence and barriers to adherence. *Patient Educ Couns*. 1999; 37:113–124. [PubMed: 14528539]
10. Identifying core behavioral and psychosocial data elements for the electronic health record: Executive summary. National Institutes of Health and Society for Behavioral Medicine; 2011.
11. Koschack J, Marx G, Schnakenberg J, et al. Comparison of two self-rating instruments for medication adherence assessment in hypertension revealed insufficient psychometric properties. *J Clin Epidemiol*. 2010; 63:299–306. [PubMed: 19762213]
12. Voils CI, Hoyle RH, Thorpe CT, et al. Improving the measurement of self-reported medication nonadherence. *J Clin Epidemiol*. 2011; 64:250–254. [PubMed: 21194887]
13. Hajjar I, Kotchen TA. Trends in prevalence, awareness, treatment, and control of hypertension in the United States, 1988–2000. *JAMA*. 2003; 290:199–206. [PubMed: 12851274]
14. Rosamond W, Flegal K, Furie K, et al. Heart disease and stroke statistics--2008 update: A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation*. 2008; 117:e25–146. [PubMed: 18086926]
15. Fernandez S, Chaplin W, Schoenthaler AM, et al. Revision and validation of the medication adherence self-efficacy scale (MASES) in hypertensive African Americans. *J Behav Med*. 2008; 31:453–462. [PubMed: 18784996]
16. Voils C, Sandelowski M, Dahm P, et al. Selective adherence to antihypertensive medications as a patient-driven means to preserving sexual potency. *Patient Preference and Adherence*. 2008; 2:201–206. [PubMed: 19920964]

17. Callahan CM, Unverzagt FW, Hui SL, et al. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care*. 2002; 40:771–781. [PubMed: 12218768]
18. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003; 289:2560–2572. [PubMed: 12748199]
19. Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol Health*. 1999; 14:1–24.
20. Paulhus, D. *Paulhus Deception Scales*. Pearson; 1998.
21. Wood W, Quinn J, Kashy D. Habits in everyday life: Thought, emotion, and action. *J Pers Soc Psychol*. 2002; 83:1281–1297. [PubMed: 12500811]
22. Wood W, Tam L, Guerrero Witt M. Changing circumstances, disrupting habits. *J Pers Soc Psychol*. 2005; 88:918–933. [PubMed: 15982113]
23. Bollen K, Lennox R. Conventional wisdom on measurement: A structural equation perspective. *Psychol Bull*. 1991; 110:305–314.
24. Curran P, West S, Finch J. The robustness of test statistics to nonnormality and specification error in confirmatory factor analysis. *Psychol Methods*. 1996; 1:16–29.
25. Bentler P. Comparative fit indices in structural models. *Psychol Bull*. 1990; 107:238–246. [PubMed: 2320703]
26. Tucker L, Lewis C. A reliability coefficient for maximum likelihood factor analysis. *Psychometrika*. 1973; 38:1–10.
27. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. *Struct Equ Modeling*. 1999; 6:1–55.
28. Muthen, B. *Mplus Technical Appendices*. Los Angeles, CA: Muthen & Muthen; 1998–2004.
29. Pett, M.; Lackey, N.; Sullivan, J. *Making sense of factor analysis: The use of factor analysis for instrument development in health care research*. Thousand Oaks, CA: Sage Publications, Inc; 2003.
30. Hayen A, Bell K, Glasziou P, et al. Monitoring adherence to medication by measuring change in blood pressure. *Hypertension*. 2010; 56:612–616. [PubMed: 20696980]
31. Trivedi RB, Ayotte B, Edelman D, et al. The association of emotional well-being and marital status with treatment adherence among patients with hypertension. *J Behav Med*. 2008; 31:489–497. [PubMed: 18780175]
32. McGraw K, Wong S. Forming inferences about some intraclass correlation coefficients. *Psychol Methods*. 1996; 1:30–46.
33. Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: Validity of a two-item depression screener. *Med Care*. 2003; 41:1284–1292. [PubMed: 14583691]
34. Ryan G, Wagner G. Pill taking ‘routinization’: A critical factor to understanding episodic medication adherence. *AIDS Care*. 2003; 15:795–806. [PubMed: 14617501]
35. Shi L, Liu J, Fonseca V, et al. Correlation between adherence rates measured by MEMS and self-reported questionnaires: A meta-analysis. *Health Qual Life Outcomes*. 2010; 8:1–7. [PubMed: 20053296]
36. Powers BJ, Olsen MK, Smith VA, et al. Measuring blood pressure for decision making and quality reporting: Where and how many measures? *Ann Intern Med*. 2011; 154:781–788. [PubMed: 21690592]

**Table 1**

Using Effect vs. Causal Indicators for Measuring Extent of Nonadherence and Reasons for Nonadherence, Respectively

<b>Characteristic</b>	<b>Extent of nonadherence (effect indicators)</b>	<b>Reasons for nonadherence (causal indicators)</b>
Number of items	Few	Many
Inter-item correlations	High, positive	No requirement
Reliability	Internal consistency (Cronbach's coefficient alpha), test-retest (same reference period, stable population)	Test-retest
Validity	Content (focus groups, cognitive interviews); Construct (factor analysis); Convergent and discriminate validity (correlations with other measures)	Content (focus groups, cognitive interviews)
Scoring	Averaged to estimate level of nonadherence	Items stand alone as descriptors for reasons for nonadherence
Use in research	Covariate or stratifying variable for treatment efficacy; outcome in intervention to improve adherence	Provide qualitative information about reasons for nonadherence; help inform the design or tailoring of interventions
Generic vs. disease-specific	Generic-to be used in any disease population and for any medication	Both-some reasons are reported across populations, whereas others are more relevant for a particular disease population or medication

**Table 2**Demographic Characteristics of Participants ( $n=202$ )

<b>Demographic Characteristic</b>	
Age, M(SD)	64.1 (11.0)
Male N(%)	173 (86%)
Race	
White	92 (46%)
Black	99 (50%)
American Indian	2 (1%)
Hawaiian or Pacific Islander	1 (<1%)
Other	4 (2%)
Education	
Grade school/jr. high	4 (2%)
Some high school	8 (4%)
High school equivalent or graduate	41 (21%)
Trade/technical/vocational school	7 (4%)
Some college credit	48 (25%)
Associate's degree	29 (15%)
Bachelor's degree	30 (16%)
Post graduate work or graduate degree	24 (13%)
Financial status	
Difficulty paying bills no matter what	20 (11%)
Enough to pay bills because cut back on things	17 (9%)
Enough to pay bills but little spare for special things	49 (26%)
After paying bills, still have enough for special things	103 (54%)

*Note.* Within a characteristic, *ns* may not sum to 202 due to missing data.

**Table 3**

Characteristics of *Extent of Nonadherence* Items

<b>Descriptive Statistics</b>											
<b>Item</b>	<b>N</b>	<b>M (SD)</b>	<b>Skewness</b>	<b>Kurtosis</b>	<b>Item-Total Correlation</b>	<b>Standardized factor loading</b>	<b>ICC (95% CI)*</b>				
1. As prescribed	202	1.52 (0.90)	2.06	3.97	0.75	0.94	0.52 (0.41, 0.62)				
2. All doses	202	1.56 (0.94)	2.03	3.74	0.78	0.95	0.48 (0.37, 0.59)				
3. Missed or skipped	202	2.04 (1.27)	0.98	-0.40	0.66	0.83	0.45 (0.31, 0.57)				
4. Later than usual	202	2.53 (1.40)	0.28	-1.50	0.28	0.43	0.50 (0.38, 0.60)				
5. Not able to take	199	1.74 (1.07)	1.69	2.18	0.73	0.85	0.47 (0.34, 0.57)				
<b>Inter-Item Correlations (n=202)</b>											
<b>Item</b>	<b>1. As prescribed</b>	<b>2. All doses</b>	<b>3. Missed or skipped</b>	<b>4. Later than usual</b>	<b>5. Not able to take</b>						
2. All doses	0.84	1.00									
3. Missed or skipped	0.58	0.63	1.00								
4. Later than usual	0.21	0.23	0.25	1.00							
5. Not able to take	0.67	0.67	0.61	0.29	1.00						

Note.

\* ICC=intraclass correlation, CI=confidence interval. Response scales ranged from 1 (*strongly disagree*) to 5 (*strongly agree*), with greater scores indicating greater levels of nonadherence.

**Table 4**Correlations between *Extent of Nonadherence* and Individual Difference Measures (n=202)

<b>Individual Difference Measure</b>	<b>Extent items</b>	
	<i>r</i>	<i>p</i>
Medication self-efficacy	-0.42	<.0001
Beliefs about medications-necessity	-0.13	.07
Beliefs about medications-concerns	0.25	<.0001
Beliefs about medications-harm	0.31	<.0001
Beliefs about medications-overuse	0.16	.02
Impression management	-0.11	.12
Conscientiousness: Orderliness	-0.11	.12
Conscientiousness: Impulse control	-0.11	.11
Conscientiousness: Reliability	-0.15	.04
Habit strength	-0.39	<.0001

**Table 5**

Characteristics of *Reasons for Nonadherence* Items

Reason for nonadherence	M (SD) <sup>d</sup>	Skewness <sup>d</sup>	Kurtosis <sup>d</sup>	N (%) endorsed <sup>b</sup>	ICC (95% CI) <sup>c</sup>
1. I was busy	1.37 (0.93)	2.8	7.2	22 (18.0)	0.27 (0.09, 0.43)
2. There was no one to remind me	1.59 (1.18)	2.0	2.8	33 (27.0)	0.47 (0.32, 0.60)
3. They caused some side effects	1.25 (0.84)	3.3	10.0	12 (9.8)	0.37 (0.20, 0.52)
4. I worried about taking them for the rest of my life	1.52 (1.23)	2.3	3.6	23 (18.9)	0.57 (0.43, 0.68)
5. They cost a lot of money	1.34 (0.98)	2.9	7.2	16 (13.1)	0.46 (0.31, 0.60)
6. I came home late	1.30 (0.75)	2.7	6.5	22 (18.0)	0.34 (0.16, 0.49)
7. I did not have any symptoms of high blood pressure	1.27 (0.77)	3.3	11.2	18 (14.8)	0.24 (0.06, 0.41)
8. I was with friends or family members	1.22 (0.67)	3.6	14.0	16 (13.1)	0.23 (0.04, 0.39)
9. I was in a public place	1.21 (0.67)	3.4	10.9	14 (11.5)	0.32 (0.14, 0.48)
10. I was afraid of becoming dependent on them	1.37 (1.08)	2.8	6.1	14 (11.5)	0.50 (0.35, 0.63)
11. I was afraid they may affect my sexual performance	1.54 (1.28)	2.1	2.9	21 (17.2)	0.58 (0.45, 0.69)
12. The time to take them was between my meals	1.28 (0.84)	3.2	10.6	16 (13.1)	0.29 (0.12, 0.45)
13. I felt I did not need them	1.22 (0.73)	4.0	16.6	14 (11.5)	0.64 (0.51, 0.74)
14. I was traveling	1.20 (0.70)	4.0	16.8	13 (10.7)	0.31 (0.14, 0.47)
15. I was supposed to take them more than once a day	1.20 (0.75)	4.2	17.2	10 (8.2)	0.07 (-0.11, 0.25)
16. I had other medications to take	1.30 (0.91)	3.3	10.2	15 (12.3)	0.63 (0.51, 0.73)
17. I felt well	1.36 (1.00)	2.9	7.3	18 (14.8)	0.16 (-0.03, 0.33)
18. They make me want to urinate while away from home	1.48 (1.17)	2.3	3.9	21 (17.2)	0.44 (0.28, 0.58)
19. I ran out of medication	1.34 (0.98)	3.0	8.1	16 (13.1)	0.14 (-0.03, 0.31)
20. I was afraid the medication would interact with other medication I take	1.34 (1.01)	3.1	8.1	15 (12.3)	0.54 (0.39, 0.66)
21. My blood pressure was too low	1.17 (0.64)	4.1	17.2	10 (8.2)	0.15 (-0.03, 0.33)
22. I was feeling too ill to take them	1.16 (0.67)	4.6	21.4	9 (7.4)	0.51 (0.36, 0.64)
23. I was going on a long car/bus/plane ride	1.16 (0.67)	4.6	21.4	9 (7.4)	0.58 (0.45, 0.69)

<sup>a</sup> Among 122 participants reporting any degree of nonadherence on at least one extent of nonadherence item.

<sup>b</sup> Defined as responding at least 2 on 1–5 scale where 1=not at all and 5=very much.

<sup>c</sup> ICC=Intraclass correlation, CI=confidence interval. n=113 due data missing for Time 2.