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Testing the Psychometric Properties of the Medication Adherence Scale in Patients with Heart Failure

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Abstract

Background—Many factors may contribute to medication nonadherence in heart failure (HF), but no standard measure exists to evaluate factors associated with nonadherence. In order to fill this gap, we developed the Medication Adherence Scale (MAS).

Objectives—To test the reliability and validity of the MAS in patients with HF.

Method—Questionnaire data were collected from 100 patients with HF at baseline using the MAS and objective adherence data were collected for three consecutive months using the Medication Event Monitoring System (MEMS).

Results—Principal component analysis yielded three factors that explained 63% of the variance in medication adherence: knowledge, attitudes, and barriers to medication adherence. Cronbach's alphas for these subscales ranged from .75–.94 which supported their internal consistency. The Spearman rho correlation coefficients between the MEMS and *Knowledge*, *Attitudes*, and *Barriers* scores were .25–.31 ($p < .05$), demonstrating support for construct validity.

Conclusion—These results support the reliability and validity of the MAS as a measure of knowledge, attitudes, and barriers of medication adherence.

Keywords

medication adherence; heart failure; psychometric testing

BACKGROUND AND SIGNIFICANCE

The treatment goals for heart failure (HF) include symptom control, maintenance or improvement in quality of life, reduction of morbidity and mortality, and attenuation of the progressive nature of the condition.¹ Lack of adherence to prescribed medications is a major cause of unnecessary hospitalizations, mortality, excessive medical costs,^{2–4} and poor quality of life^{5, 6} in patients with HF. Estimates of medication nonadherence rates range from 40%-60%.^{7–11} Enhancing patient adherence to prescribed medications is essential to achieve better outcomes. Despite the importance of medication adherence to the care of patients with HF, few instruments are available for the measurement of knowledge, attitudes, and barriers to medication adherence. The availability of such an instrument could benefit clinicians and researchers seeking to assess reasons for patient medication adherence or risk for nonadherence in a given patient.

There is no single theory that adequately encompasses the concepts identified in a comprehensive review of the literature as influencing adherence, thus the conceptual framework that guided the development of this instrument was based on a review of literature, the Theory of Planned Behavior (TPB), and the Health Belief Model (HBM). Based on our review of the literature, clinical experience and the above mentioned theories, we propose that knowledge, attitudes and barriers are the major constructs affecting medication adherence.

Knowledge is a fundamental prerequisite to adherence, although it is not sufficient alone to ensure adherence. Knowledge is defined according to the Cambridge dictionary as a basic understanding of or information held by people as a result of experience or study. A number of investigators^{12–15} have demonstrated a relationship between knowledge and medication adherence.

Attitudes are another essential component of adherence and the TPB has been useful in explaining behavior change based on attitudes, one of the core constructs of the TPB.¹⁶ An attitude is an opinion about something or someone, or a way of behaving that is caused by this opinion. In many studies,^{14, 17–24} investigators found that attitudes toward medications were highly correlated to medication adherence.

A third crucial element affecting medication adherence is patient perceptions of barriers to medication taking.^{25, 26} A barrier is an obstacle or impediment to achieving a goal or outcome. A barrier can be anything that obstructs or restrains. Perceived barriers are an important aspect of the HBM and one of the components of the HBM that has the most support.²⁷ In one study, barriers accounted for 50% of cases of nonadherence with antihypertensive medications.²⁵ Thus, although knowledge, attitudes, and barriers related to medication adherence are of interest to clinicians and researchers, there are no known reliable and valid instruments available to measure these constructs in patient with HF.^{7, 15, 18, 28} All existing measures focus only on one of the constructs of interest—there is no existing instrument that considers the multiple components that affect medication adherence.^{7, 15, 21, 24, 29}

The purpose of this study was to evaluate the psychometric properties of a new instrument, the *Medication Adherence Scale* (MAS), in patients with HF. This instrument was developed for use in clinical practice to guide education and counseling and for research to assess the factors that affect medication adherence. It is not a measure of adherence, but is a measure of the factors that potentially affect adherence. The specific aims of the study were to:

1. evaluate the construct validity by examining the factor structure of the MAS and by testing two hypotheses in patients with HF; and
2. assess the internal consistency reliability of the MAS.

METHODS

Design

Data were collected prospectively in patients with HF. At baseline, when patients were enrolled in the study, patients completed the MAS and detailed instructions on use of the MEMS bottle were given. Patients started medication adherence monitoring at baseline using the MEMS and continued for three months.

Samples and Setting

We recruited 107 patients, but only include the data on those 100 for whom we have full data from the MEMS. Data were missing in these 7 patients because of malfunction of the MEMS cap ($n = 1$), patient lost or never returned MEMS cap ($n = 4$), or problems with the software interface ($n = 2$). Patients were recruited from a HF clinic affiliated with an academic medical center. Those who agreed to participate and met the following selection criteria were included in the study: (1) diagnosis of chronic HF with preserved or non-preserved ejection fraction, (2) had undergone evaluation of HF and optimization of medical therapy and were on stable medication doses for at least one month, (3) able to read and speak English, (4) free of obvious cognitive impairment, (5) no co-morbid life threatening illness such as cancer, or chronic renal failure, (6) no history of myocardial infarction within the past three months, and (7) no history of cerebral vascular accident within the past 3 months or with major sequelae.

Measures

Medication Adherence Scale (MAS)—The 32-item MAS was designed to measure factors influencing adherence to the prescribed medication regimen. The initial version of the instrument was based on extensive review of the literature, clinical and research experience, and constructs of the TPB and the HBM. Derived from these sources, we developed the instrument to measure the three major factors—knowledge, attitudes and barriers—that appeared to affect adherence. The instrument was developed by a group of researchers and clinicians with expertise in the care of patients with HF. The number of items included in the instrument was based on the need to completely address the range of knowledge, attitudes and barriers relevant to medication taking behavior without burdening the respondent with an overly long instrument. Content validity was achieved by having the instrument reviewed by 4 experts in the field of heart failure adherence who commented on the appropriateness, completeness and wording of the items. Items on which there was not 100% agreement on these 3 issues were deleted, or in the case that wording only was of concern, the wording was changed.

The instrument was pilot tested with a group of 10 patients with HF from the target population who commented on the understandability, readability and appropriateness of items. Modifications were made to wording and format based on suggestions from the patients. The MAS takes 10–15 minutes to complete. Eighteen of the items constitute three subscales: knowledge, attitude, and barriers. The remaining 14 items measure general information about medication taking behaviors. The instrument subscales are scored by adding the response to items.

Knowledge: This subscale was designed to measure patients' knowledge about the medications they take daily. There are three items in the *Knowledge subscale*. Patients are instructed to rate how much they agree or disagree with each item on a scale from 0 (strongly disagree) to 10 (strongly agree). The scores on this subscale range from 0 to 30; higher scores indicate more knowledge of prescribed medication.

Attitude: This subscale was designed to measure patients' attitudes about medication taking. The *Attitude subscale* has four items. Patients are instructed to rate how much they agree or disagree with each item on a scale from 0 (strongly disagree) to 10 (strongly agree). One negatively worded item is reverse scored. The scores on this subscale range from 0 to 40; higher scores indicate more positive attitude toward medication adherence.

Barriers: This subscale was designed to measure the potential financial, cognitive, social and practical barriers to medication taking. Eleven items compose the *Barriers subscale*. Patients are instructed to rate how important each potential barrier of not taking pills is on a scale from 0 (not importance barrier) to 10 (very important barrier). The subscale scores range from 0 to 110; higher scores indicate more barriers in taking prescribed medication.

General Information on Medication Taking Behaviors: There are 14 open-ended items to which the respondents provide general information about how prescriptions for pills they have, how many pills they take per day, how many times they need to take pills on different time schedules, how they keep track of the pill times, whether or not they have anybody who helps make their medication schedule, whether or not they used pills for their heart that healthcare providers did not prescribe, whether or not they ever skip taking some of their pills, how they take their pills when they go out, and whether they have anybody to remind them to take their medication. These individual items are for descriptive purposes and were not included in the psychometric testing.

Medication Adherence

Medication adherence was defined as the extent to which the patient's medication-taking behavior corresponded with the medication regimen prescribed by their healthcare provider.^{5, 30, 31} In order to increase accuracy of assessment of medication adherence, both objective and self-report measures were used.³² Medication adherence was measured objectively using the Medication Event Monitoring System (MEMS) and subjectively by one question from the Medical Outcomes Study (MOS) Specific Adherence Scale.^{33, 34}

MEMS—The MEMS is a microelectronic monitoring device in the caps of medication containers that records each time that the cap is removed from the medication bottle.^{35, 36} Real-time data are collected on the device and later transferred to a computer. The MEMS data were collected on one HF medication (i.e., ACE inhibitor, diuretic, β -blocker, or digoxin) for each patient. The MEMS is a valid instrument that has been used to measure medication adherence with high sensitivity in cardiovascular patients^{35–38} and patients with HF.^{9, 37, 39} Only one medication was used as prior research has demonstrated that monitoring one medication with the MEMS provides a valid indicator that patients took all of their medications.^{35, 37} We have also demonstrated that medication adherence of only one medication in the HF regimen measured using the MEMS predicts rehospitalization and mortality, providing further evidence for the validity of monitoring only one medication.⁴⁰ Two indicators of medication adherence were assessed (1) dose-count, defined as the percentage of prescribed doses taken during the 3-month monitoring period and (2) dose-time, defined as the percentage of doses taken within 6 hours of prescribed time for a drug taken once-a day or within 3 hours of the prescribed time for a drug taken twice-a-day.^{35, 36}

Self-report adherence—Self-reported medication adherence was measured using one item from the Medical Outcomes Study (MOS) Specific Adherence Scale.^{33, 34} The MOS Specific Adherence Scale was developed for patients with diabetes, hypertension, and heart disease. The scale has adequate reliability and validity,^{33, 34} and has been used successfully to measure adherence in patients with HF.⁴¹ In this study, only the one question from the MOS Specific Adherence Scale that is related to medication adherence was used. Patients were asked to rate

“how often did you take medication as prescribed (on time without skipping doses) in the past four weeks?” on a scale from 0 (none of the time) to 5 (all of the time). Higher scores indicated higher reported medication adherence. The construct validity of this one item from the MOS Specific Adherence Scale was also supported by significantly correlating with physicians’ attributes and practice style.³³

Procedure

Permission for the conduct of this study was obtained from the University of Kentucky Medical Institutional Review Board. Patient eligibility was confirmed by a research associate. The research associate explained study requirements to eligible patients, obtained informed, written consent, and arranged an appointment for baseline assessment. At baseline, the MAS was completed by patients. A research associate was present to answer questions and to confirm that no items were inadvertently skipped. After completing the MAS, detailed written and verbal instructions on use of the MEMS bottle were given to patients. Patients were instructed to take that medicine from the MEMS bottle for the next three months and close the lid after each use. Patients were given a medication diary to record unscheduled cap opening (i.e., refill the bottle, check on supply, or open by accident without taking any pill). If patients opened the bottle for any other reason, the time and date were recorded in the diary, so that that event could be excluded when data were downloaded. Patients who used a pill box were asked to keep the MEMS bottle beside their pill box and take the medicine from the MEMS bottle. Three months after baseline, patients returned the MEMS bottle. The data from the MEMS system were downloaded using a manufacturer-supplied communicator and software on a personal computer. MEMS data were then printed, compiled, and entered to SPSS file for further analyses.

Data Management and Analysis

Data were analyzed using SPSS software version 14. Data examination showed no problems with multicollinearity or violation of any of the following assumptions: linearity, independence, and homoscedasticity. Because the medication adherence rates measured by the MEMS and self-reported adherence were skewed toward low scores, the nonparametric Spearman’s rho test was used to examine the association between the medication adherence and the knowledge, attitude, and barrier scores of medication adherence. An alpha of .05 was set a priori.

Reliability—Internal consistency, item-total correlations, and inter-item correlations were used to examine the reliability of the subscales. A Cronbach’s alpha coefficient greater than .70 was considered acceptable support for the internal consistency of the MAS subscales.⁴² Item-total correlations and inter-item correlations were conducted to examine the homogeneity of the MAS. Coefficients greater than .30 were considered acceptable for item-total correlations. Inter-item correlation coefficients between .30 and .70 were considered acceptable. A coefficient less than .30 means that the item does not contribute to the instrument, while coefficients greater than .70 indicate redundancy.⁴³

Construct Validity—Exploratory factor analysis and hypotheses testing were used to evaluate the validity of the subscales. Factor analysis of the MAS was performed using principal component analysis extraction method, with Varimax rotation. Eigenvalues greater than one, scree plot, and total variance explained were the criteria for factor extraction, along with conceptual considerations. Loadings greater than .40 were used as a cutoff point for defining variables associated with a given factor.⁴⁴

The following hypotheses, based on previous findings in the literature demonstrating that patients with more knowledge related to medication adherence, fewer barriers, and better

attitudes were more adherent,^{12–15, 17–26} were tested to further investigate the construct validity of the MAS.

Hypothesis #1: Patients who have higher knowledge and attitude scores and lower barrier score will have a higher medication adherence assessed by the MEMS.

Hypothesis #2: Patients who self-report greater adherence to their prescribed medication will have higher knowledge and attitude scores and lower barrier scores.

RESULTS

Sample Characteristics

A total of 100 patients who met the inclusion criteria were included in the analysis (Table 1). This sample size was chosen based on the needs for performing factor analysis, and a power analysis that demonstrated the sample needed given a small effect size for the correlations of knowledge, attitudes and barriers with actual medication adherence. This sample was largely patients with advanced heart failure as reflected by the majority (66%) whose NYHA functional class was III/IV. Patients with both preserved and non-preserved systolic function were enrolled (mean left ventricular ejection fraction $33 \pm 13\%$). General information on patients' medication taking behaviors as well as descriptive statistics for the MAS is presented in Table 2. Adherence as measured by the MEMS and the self-report instrument are presented in Table 3.

Reliability

Cronbach's alpha for the MAS was .85, which supported the internal consistency reliability of the MAS. Internal consistency reliability was calculated for the three subscales corresponding to the three factors extracted from factor analysis. Cronbach's alpha for the *Knowledge* subscale was .75, indicating acceptable internal consistency. All item-total correlations were between .52 and .67). The inter-item correlations were adequate (.39 to .57) for all items.

Cronbach's alpha for the *Attitude* subscale was .50, indicating poor internal consistency. In the inter-item correlations, the correlation coefficient between item #3, *believed that it is OK to skip my pills when I am feeling better*, and all other items were less than .30, indicating no contribution to this scale. The corrected item-total correlation coefficient of this item was .12, also indicating no contribution to this scale. All other item-total correlations were > .30. The inter-item correlations were adequate for all other items (> .30). After deleting item #3, the Cronbach's alpha for the 3-item *Attitude* subscale was .75, indicating acceptable internal consistency. Corrected item-total correlation coefficients for all three items were between .48 and .71, indicating adequate homogeneity of the items. The inter-item correlations were adequate (.41–.67) for all items.

Cronbach's alpha for the *Barriers* subscale was .94, indicating acceptable internal consistency. All item-total correlations were > .30 (.57 to .83). The inter-item correlations were adequate (.30 to .87) for all items. The correlation coefficients between item #9, *amount of pills that I need to take a day*, and two items (i.e., item #10, *the frequency of my medication schedule*, and item # 6, *belief that my symptoms are better*) were greater than .80, indicating redundancy. However, based on the current literature, amount of pills taken per day,^{14, 22, 45} frequency of medication schedule,^{9, 37, 46} and beliefs about the necessity of medication^{26, 47} were significant predictors of medication adherence. Therefore, we did not delete any items from the Barriers subscale. The inter-item correlations were adequate for all other items (.30–.78).

Construct Validity

Factor Structure—The 18 items of the three subscales of the MAS were subjected to principal component analysis. Prior to performing principal component analysis, the suitability of data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of .30 and above. The Kaiser-Meyer-Olkin value was .81, exceeding the recommended value of .60 and the Bartlett's Test of Sphericity reached statistical significance, supporting the factorability of the correlation matrix.⁴⁴

Principal component analysis extraction method was used to examine the dimensionality of the MAS. Based on eigenvalues greater than one, the scree plot, total variance explained for factor extraction, and conceptual considerations, three factors were retained and rotated using Varimax rotation (Table 4). These three factors were named knowledge, attitudes and barriers as conceptualized during the development of the instrument. We originally developed the instrument with the assumption (based on theory and review of the literature) that it captured these three constructs. The three factors explain 63% of the total variance. All items except item #3 demonstrated moderate to strong loadings ($> .40$) on one of the three factors. Item #3, *believe that it is okay to skip my pills when I am feeling better*, failed to load on any factor. The items that loaded on Factor 1 were related to attitude about medication adherence. The items that loaded on Factor 2 were related to knowledge of prescribed medication. The items that loaded on Factor 3 were related to barriers to medication adherence.

Hypothesis Testing—To test Hypothesis #1, two indicators from the MEMS (percentage of prescribed number of doses taken and percentage of doses taken on schedule) had significant correlations with the *Attitude* score ($r = .30, .30$, respectively, $p < .05$), and with the *Barrier* score ($r = -.31, -.25$, respectively, $p < .05$). However, the relationships between the *Knowledge* score and MEMS variables were not significant. Hypothesis #2 was supported. Patients who self-reported greater adherence to their prescribed medications had significantly higher *Attitude* scores ($r = .30, p < .05$), *Knowledge* scores ($r = .25, p < .05$), and *Barrier* scores ($r = -.28, p < .05$). The degree correlation is acceptable because this scale is a measure of factors affecting medication adherence, not medication adherence itself. Many factors are related to medication adherence. Small correlation was expected as in previous studies.^{7, 15, 18, 21} Thus, the results of hypothesis testing supported the construct validity of the MAS subscales.

DISCUSSION

The results of this study demonstrated the reliability and validity of the MAS and support the use of the MAS to measure knowledge, attitudes, and barriers related to medication adherence in patients with HF, after elimination of one item. The results of reliability and validity (i.e., factor analysis and hypotheses testing) in this study provided support for three factors: (1) knowledge of prescribed medications; (2) attitude toward medication adherence; and (3) barriers to medication adherence. These three factors extracted were supported by the previous studies.^{23, 24, 48} There are many possible factors that contribute to poor medication adherence. In many studies, knowledge of medication was positively correlated with medication adherence.^{12–15} In a recent study, both knowledge and beliefs were related to medication adherence.²⁴ In addition, prior research demonstrated that patients' attitudes, beliefs, and perceptions about the necessity and importance of taking the prescribed medication were the significant predictors of medication nonadherence.^{24, 26, 48, 49} In one qualitative study, participants expressed their strong need to learn about their medications in order to adhere to prescribed medication regimens.²³ Finally, in many studies, barriers to taking prescribed medication have been shown to be highly correlated with medication nonadherence.^{25, 26, 47} Those barriers include forgetting, cost, too many pills taken per day, and a too frequent

medication schedule. Patients who had more barriers were less likely to adhere to medications. 14, 17, 19–23, 25, 26, 28, 50–53

IMPLICATIONS

This paper describes the first steps in developing a reliable and valid measure of patients' knowledge, attitudes, and barriers related to medication adherence. Such an instrument would be of value to clinicians and researchers as no standard instrument exists for use in patients with HF. We continue to use this instrument in our work and plan to report results of psychometric testing in larger, diverse samples. Medication adherence is extremely important in managing HF symptoms and reducing morbidity and mortality. Even though this issue had been studied for decades, medication nonadherence remains high. The role of patients' knowledge, attitudes, and barriers to adhering to the medication regimen has not been regularly assessed yet they likely play a large role in determining adherence. Development of the MAS provides a tool for beginning to advance our understanding in this area. The findings from this study support the reliability and validity of the MAS for measuring patients' knowledge, attitudes, and barriers related to medication adherence.

Information about knowledge, attitudes, and barriers related to adherence can be used by clinicians to provide education targeted at each patient's individual responses. The clinician can implement interventions to increase their knowledge of HF medications, enhance patients' attitudes, and to decrease their barriers in order to improve adherence. Large-scale studies are needed to explore the appropriate cutoff points for each subscale to help clinicians quickly identify high risk patients who might be more likely to be more nonadherent due to knowledge, attitudes, or barriers.

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Table 1Demographic and Clinical Characteristics of Patients with Heart Failure ($N = 100$).

Characteristics	Range (Mean $\pm$ SD) or Number (%)
Age (Mean $\pm$ SD)	24–84 (61 $\pm$ 12)
Sex	
Male	62 (62%)
Female	38 (38%)
Marital status	
Married/cohabitate	59 (59%)
Single/divorced/widowed	41 (41%)
Living status	
Alone	29 (29%)
With others	71 (71%)
Education level	
Less than high school	28 (28%)
High school graduate	22 (22%)
Greater than high school	50 (50%)
Ethnicity	
African American	10 (10%)
Caucasian	90 (90%)
New York Heart Association functional class	
I/II	33 (34%)
III/IV	63 (66%)
Left ventricular ejection fraction	12–70 (33 $\pm$ 13%)

Table 2

Descriptive Statistics for The MAS (N = 99)

Characteristics	Range (Mean $\pm$ SD) or Number (%)
Knowledge score (Mean $\pm$ SD)	0–30 (21.0 $\pm$ 8.8)
Attitude score (Mean $\pm$ SD)	9–30 (28.6 $\pm$ 3.3)
Barrier score (Mean $\pm$ SD)	0–110 (20.3 $\pm$ 30.6)
Number of prescriptions (Mean $\pm$ SD)	3–23 (9.3 $\pm$ 4.0)
Number of pills (Mean $\pm$ SD)	3–40 (12.8 $\pm$ 7.3)
Frequency of medications	1–9 (2.5 $\pm$ 1.1)
Twice per day	52 (53%)
Three times per day	33 (34%)
Medication Aids	
No specific method	34 (34%)
Use a written schedule	1 (1%)
Use a pill box	53 (54%)
Other method(s)	11 (11%)
Received help with medication schedule?	
Yes	21 (21%)
No	78 (79%)
Use alternative medicine not prescribed by health care providers	
Yes	30 (31%)
No	68 (69%)
Anybody reminds you to take medication	
Yes	34 (34%)
No	65 (66%)
How to take pills when need to go out?	
Take my pills in my purse or pill box	71 (73%)
Skip pills	2 (2%)
Take pills earlier	10 (10%)
Take pills after I go home	14 (15%)

Table 3

Prevalence of Medication adherence (N = 100)

Indicator	Mean	SD	Median	Min	Max
Dose-count ^a	86.4	17.9	94.2	12.2	100
Dose-time ^b	61.1	30.7	70.1	0	100
Self-report medication adherence	4.49	.9	5	1	5

SD, standard deviation; Min, the lowest value in the sample and max, the highest value.
MEMS, Medication Event Monitoring System

^a MEMS data, dose-count: % of prescribed number of doses taken

^b MEMS data, dose-time: % of doses taken on schedule

Table 4Factor Analysis with Varimax Rotation of the Medication Adherence Scale ($N = 99$).

Item	Factor ^a		
	1	2	3
1. Believed that it is important to take all of the pills my doctor prescribed for my health	<u>.88</u>	.16	-.05
4. Understand why I need to take pills prescribed for me	<u>.81</u>	.21	.03
2. Believed that it is important to take my pills on time	<u>.67</u>	.03	-.14
3. Believed that it is okay to skip my pills when I am feeling better	-.10	.35	-.20
7. Know the side effects of the pills that I take everyday	.12	<u>.80</u>	-.01
5. Know all the names of pills that I take everyday	.23	<u>.78</u>	-.01
6. Know the dose of each pill that I take everyday	.17	<u>.73</u>	.08
16. Amount of pills that I need to take a day	-.03	-.05	<u>.88</u>
9. Confusing the medication times	.02	.01	<u>.86</u>
13. Belief that my symptoms are better	-.27	.02	<u>.84</u>
17. The frequency of my medication schedule	.02	.10	<u>.84</u>
12. Belief that I'll be fine even though I skip one dose of medication	-.28	-.05	<u>.83</u>
18. Having no support from my family or somebody for reminding me to take my medication	.01	.06	<u>.80</u>
10. Not trusting the efficacy of medications in my disease	-.22	.02	<u>.79</u>
14. Belief that my symptoms are the same even though I skip the medication	-.40	.03	<u>.77</u>
11. Cost of medication	.02	-.22	<u>.68</u>
15. Not carrying my medication when I am out	.10	-.24	<u>.67</u>
8. Forgetting the time of medication	.20	-.16	<u>.65</u>

^aFactor 1 = Attitude about medication adherence

Factor 2 = Knowledge of prescribed medications

Factor 3 = Barriers to medication adherence