Derivation and Validation of the ASK-12 Adherence Barrier Survey

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BACKGROUND: The ASK-20 survey is a previously validated patient-report measure of barriers to medication adherence and adherence-related behavior.

OBJECTIVE: To derive and validate a shorter version of the ASK-20 scale.

METHODS: Patients with asthma, diabetes, and congestive heart failure were recruited from a university medical center. Participants completed the ASK-20 survey and other questionnaires. Approximately one-third of participants were randomized to a 2-week retest administration. Item performance and results of an exploratory factor analysis were examined for item reduction and subscale identification. Subsequent analyses examined reliability and validity of the shorter version of the ASK.

RESULTS: A total of 112 patients participated (75.9% female; mean age 46.7 y; 53.6% African American). Eight items were dropped from the ASK-20 based on factor loadings, floor effects, Cronbach's α, and the ability of each item to discriminate between groups of patients differing in self-reported adherence. The new total score (ASK-12) had good internal consistency reliability (Cronbach's α 0.75) and test-retest reliability (intraclass correlation 0.79). Convergent validity was demonstrated through correlations with the Morisky Medication Adherence Scale (r –0.74; $p < 0.001$), condition-specific measures, the SF-12 Mental Component Score (r –0.32; $p < 0.01$), and proportion of days covered by filled medication prescriptions in the past 6 months as indicated by pharmacy claims data (r –0.20; $p = 0.059$). The ASK-12 total score also discriminated among groups of patients who differed in self-reported adherence indicators, including whether a dose was missed in the past week, the number of days medication was not taken as directed, and treatment satisfaction. Three subscales were identified (adherence behavior, health beliefs, inconvenience/forgetfulness), and results provided initial support for their validity.

CONCLUSIONS: The ASK-12 demonstrated adequate reliability and validity, and it may be a useful brief measure of adherence behavior and barriers to treatment adherence.

KEY WORDS: adherence, ASK, chronic diseases, health-related quality of life, reliability, validity.

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Pharmacotherapy can have a range of benefits, including symptom reduction, preservation of physical function, reduced risk of death, and improved quality of life. However, the effectiveness of any medication depends on the patient's adherence to the treatment regimen. Poor adherence can limit the benefits of treatment, leading to decreased efficacy, greater adverse effect potential, disease relapse, increased medical expenditures, and decreased quality of life.[1-13] In contrast, better adherence is associated with improved health outcomes and reduced healthcare utilization. Yet, nonadherence remains a common problem across the full spectrum of medical and psychiatric conditions, including life-threatening and less serious conditions.[2,4,6,8,13-18] Poor adherence behavior may include discontinuing treatment early, taking a medication irregularly, or taking less or more than the prescribed dose.

Because adherence to prescribed medication regimens is essential for maximizing treatment effectiveness and improving patient outcomes, it is important to have useful, valid, and practical tools for assessing adherence and related factors in research and clinical settings.[19] Consequently, the ASK-20 survey (ie, Adherence Starts with Knowledge) has recently been developed to assess behavior and barriers related to treatment adherence.[20] This 20-item questionnaire is distinct from previous patient-report measures of adherence. Whereas previous measures, such as the Morisky Medication Adherence Scale, tend to be brief and focus primarily on the degree of medication adherence,[21] the ASK-20 was designed to provide a practical, yet detailed, assessment of adherence behavior as well as potential barriers to adherence. The ASK-20 is also distinct from condition-specific adherence mea-

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sures[22] because it was designed to be a generic instrument, applicable to patients regardless of their medical condition. The ASK-20 has been used in studies focusing on a range of treatments and settings, including an asthma medication adherence program,[23] a community pharmacy setting,[24] and health coaching programs.[25,26]

The ASK-20 total score has been found to have acceptable reliability and good construct validity.[27] The purpose of the current project was to refine this instrument. The first phase of the analyses focused on item reduction and subscale identification. Although the 20-item version is already a relatively brief questionnaire, item reduction was performed to make the questionnaire more practical for use in busy clinical settings, while enhancing the psychometric performance of the instrument. In the second phase, psychometric analyses were conducted to examine the reliability and validity of the shorter version of the instrument. Both internal consistency reliability and test-retest reliability were assessed, and validity of the refined ASK measure was examined by comparing the instrument with other subjective self-report measures as well as an objective index of adherence, proportion of days covered (PDC) based on pharmacy refill records.

Methods

STUDY DESIGN

This study was conducted with a sample of patients recruited from a university medical center during clinic visits as well as via flyers, media advertisements, and targeted mailings. Participants were required to have a self-reported diagnosis of asthma, type 2 diabetes, or congestive heart failure (CHF) for at least 1 year; be taking one or more prescription medications for these conditions; have continuous medical and pharmacy coverage from the university system for at least 1 year prior to study enrollment; be 18 years of age or older; and be able to read and write English. All participants attended a visit in which they completed consent procedures and study instruments. Approximately one-third of the sample was randomized to attend a second visit approximately 14 days (±4) after the first visit so that test-retest reliability of the ASK survey could be assessed. Pharmacy claims were obtained to calculate PDC. Descriptions of the sample and study design have previously been reported, along with results of analyses examining the 20-item version of the ASK survey.[27] This study was approved by the Duke University School of Medicine Institutional Review Board.

MEASURES

ASK-20 Survey

The ASK-20 Survey is a 20-item, self-administered questionnaire designed to assess behavior and barriers associated with medication adherence. Items were generated through comprehensive literature review, expert panel input, and patient focus groups (all items are listed in Table 1).[20] Items 1–15, which assess barriers to treatment adherence, are rated with the following 5 response options: strongly agree, agree, neutral, disagree, and strongly disagree. Items 16–20, which assess adherence behavior, are rated with 5 different response options: in the last week, in the last month, in the last 3 months, more than 3 months ago, and never. For all items, except items 7–12, higher scores suggest greater problems with adherence. Items 7–12 are reverse scored so that their final recoded scores are in the same direction as the other 14 items, with higher scores representing stronger barriers to adherence. The ASK-20 total score is computed by summing responses to all 20 items after applying the reverse coding, yielding a score with a possible range of 20–100, with higher scores representing greater barriers to adherence. Reliability and validity of the ASK-20 have previously been demonstrated in the same sample used for the current analyses.[27]

Morisky Medication Adherence Scale

The Morisky Scale is a 4-item, self-reported adherence questionnaire that assesses 4 reasons for lack of adherence to medication treatment regimens: forgetting, carelessness, stopping the drug when feeling better, and stopping the drug when feeling worse.[21] The composite score of the questionnaire ranges from 0 to 4, with higher scores indicating better adherence. The questionnaire has demonstrated good concurrent and predictive validity.

Adherence Questions

A series of additional questions was administered to assess self-reported medication adherence and related constructs. The following 3 questions were included: Have you missed a dose of any of your medicines in the past week? Overall, in the past 2 weeks, how many days have you not taken your medicine exactly as directed? Overall, how satisfied are you with your current medicines?

Mini Asthma Quality of Life Questionnaire

The Mini Asthma Quality of Life Questionnaire (Mini-AQLQ) contains 15 items and was derived from the 32-item Asthma Quality of Life Questionnaire, which was designed to assess quality of life among adults with asthma.[28] The 15 items yield 4 subscales (symptoms, environment, emotions, activities) and an overall score. Higher scores reflect better quality of life.

Appraisal of Diabetes Scale

Appraisal of Diabetes Scale (ADS) is a brief 7-item, patient-reported scale that assesses the impact of diabetes on a patient's life.[29] Higher scores reflect greater impact of diabetes.

Medical Outcome Study 12-Item Short Form Health Survey

Patients completed the Medical Outcome Study 12-Item Short Form Health Survey (SF-12), a health status questionnaire that is a shorter version of the commonly used 36-item measure.[30] Like the SF-36, the SF-12 yields a Physical Component Summary score and a Mental Component Summary score (MCS). Higher scores reflect better quality of life.

Proportion of Days Covered Based on Pharmacy Claims Data

PDC, as indicated by 6 months of electronic pharmacy refill records, was computed to be used in analysis of validity of the ASK-20. To compute PDC, each of the 183 days prior to the ASK-20 completion date was given a yes/no flag. Days were counted as a *yes* if the patient possessed one or more disease-specific medications on that particular day, based on prescription fill dates and days' supply. Otherwise, days were counted as a *no*. PDC was computed as the number of days counted *yes* divided by 183 days. Each day could be counted only once, and therefore, an early refill or refills for multiple medications did not result in overadherence. This approach to estimating medication adherence has been used in previously published research.[31]

Examples of disease-specific medications used to compute PDC for participants with diabetes included metformin, insulin glargine, pioglitazone, and exenatide. Drugs used to compute PDC for asthma patients included albuterol, montelukast, and fluticasone.

STATISTICAL ANALYSIS PROCEDURES

SAS statistical software version 8.2 (SAS Institute, Cary, NC) was used for all psychometric analyses. Descriptive statistics were performed on sociodemographic and clinical variables. Continuous variables were summarized in terms of mean, standard deviation, range, median, percent at floor, and percent at ceiling. Categorical variables were summarized in terms of frequency and percentage.

The first phase of the analyses included item reduction and subscale identification of the ASK, beginning with the 20-item version. Four factors were considered when dropping items and identifying subscales. First, a substantial floor or ceiling effect (ie, >50% of the sample) was one potential reason for excluding an item. Second, *t*-tests were conducted to examine the ability of each item to discriminate between groups of patients who differed in medication adherence as indicated by their responses to the Morisky Medication Adherence Scale and 2 additional questions (Have you missed a dose of any of your medicines in the past week? Overall, in

Table 1. Exploratory Factor Analysis of the ASK-20: Factor Loadings

Rotated Factor Pattern (standardized regression coefficients)	Factor 1	Factor 2
Barrier items		
10. I understand my doctor's/nurse's instructions about the medicines I take.	0.73682	–0.16312
7. I feel confident that each one of my medicines will help me.	0.59293	0.02781
11. My doctor/nurse and I work together to make decisions.	0.58946	0.07557
12. I am able to read and understand pill bottle labels.	0.48425	–0.07073
8. I know if I am reaching my health goals.	0.45608	0.26772
9. I have someone whom I can call with questions about my medicines.	0.44712	0.18801
3. My use of alcohol gets in the way of taking my medicines.	0.32480	–0.10280
14. I have to take too many medicines a day.	0.29884	0.06154
6. I have felt sad, down, or blue during the past month.	0.28486	0.26951
4. I worry about how medicine will affect my sexual health.	0.19667	0.06232
1. I just forget to take my medicines some of the time.	–0.02355	0.68959
2. I run out of my medicine because I don't get refills on time.	0.03990	0.57991
13. Taking medicines more than once a day is inconvenient.	0.20867	0.49208
5. I sometimes forget things that are important to me.	0.21549	0.36000
15. It is hard for me to swallow the pills I have to take.	0.04432	0.15281
Behavior items[a]		
17. Have you skipped or stopped taking a medicine because you didn't think it was working?	0.59633	
18. Have you skipped or stopped taking a medicine because it made you feel bad?	0.55938	
16. Have you taken a medicine more or less often than prescribed?	0.50068	
19. Have you skipped, stopped, not refilled, or taken less medicine because of the cost?	0.46529	
20. Have you not had medicine with you when it was time to take it?	0.40098	

[a]Based on the eigenvalues, the exploratory factor analyses of these 5 behavior items strongly suggested a one-factor solution.

the past 2 weeks, how many days have you not taken your medicine exactly as directed?). Failure of an item to discriminate between groups of patients was a potential reason for excluding the item. Third, exploratory factor analysis (EFA) was conducted to identify items that could be grouped into subscales. Fourth, Cronbach's α was computed for each resulting subscale with each of the items deleted. If the α value increased substantially (ie, >10%) when deleting any item, this was a potential reason for excluding the item.

After dropping items and identifying subscales for the new version of the ASK (ie, ASK-12), reliability and validity of the shorter instrument were examined. Internal consistency was assessed for the ASK-12 total score and subscales using Cronbach's coefficient α, with a value of 0.70 or more generally considered acceptable.[32] To evaluate test-retest reliability, intraclass correlations (ICC) were conducted to assess the degree of association between scores at visit 1 and visit 2. Calculation of the ICC assumed a fixed effects analysis of variance model.[33] Paired *t*-tests were performed to evaluate whether there was a statistically significant change in scores from visit 1 to visit 2.

Construct validity is the degree to which an instrument reflects the underlying construct that it is designed to measure.[32] One type of construct validity is convergent validity, which is the degree to which an instrument is related to measures of similar constructs. To examine convergent validity of the ASK-12, Spearman's correlations with previously validated measures (eg, Morisky Scale) were performed. It was hypothesized that greater barriers to adherence and problems in adherence behavior as measured by the ASK-12 would be associated with less treatment adherence as assessed by the Morisky Scale, worse quality of life as assessed by the SF-12, greater symptom impact reflected by the MiniAQLQ and the ADS, and lower PDC. Correlation coefficients were interpreted as small (0.10), moderate (0.30), or large (0.50), following the guidelines proposed by Cohen.[34] Known-groups validity (eg, an instrument's ability to distinguish between groups known to differ on a relevant construct) was assessed using general linear models with Scheffe's post hoc pairwise comparisons, in which ASK-12 scores were compared among groups known to differ in their responses to the self-reported adherence questions.

Results

SAMPLE

A total of 112 patients participated in this study. This sample has previously been described in detail,[27] and demographic characteristics are reproduced in Table 2. For psychometric analyses of the ASK-12 that did not involve PDC, data from all 112 participants were used. Analyses involving PDC were conducted with the subset of 93 participants who had available pharmacy claims data and were categorized as either solely diabetes patients or solely asthma patients. Because of difficulties recruiting patients with CHF early in the data collection period, these patients were not recruited after the initial months of the study. Thus, only 3 participants had CHF. These patients were included in the baseline psychometric analyses but excluded from the analyses involving PDC.

DERIVATION OF THE ASK-12: ITEM REDUCTION AND SUBSCALE IDENTIFICATION

Two EFAs were performed on the ASK-20 items, 1 for the 5 behavior items and another for the 15 barrier items (see Table 1 for the wording of each item). The 2 types of items were separated for this analysis because they are conceptually different and they have different sets of re-

Table 2. Demographic Characteristics

Characteristics	Diagnosis Group[a]			Total Sample (N = 112)
	Asthma (n = 41)	Diabetes (n = 67)	CHF (n = 1)	
Sex, n (%)				
male	11 (26.8)	15 (22.4)		27 (24.1)
female	30 (73.2)	52 (77.6)	1 (100)	85 (75.9)
Age, y (mean ± SD)	42.0 ± 12.8	49.5 ± 8.2	46.0	46.7 ± 10.6
Race, n (%)				
white	18 (43.9)	26 (38.8)		44 (39.3)
African American	19 (46.3)	37 (55.2)	1 (100)	60 (53.6)
Hispanic		1 (1.5)		1 (0.9)
Asian	1 (2.4)	1 (1.5)		2 (1.8)
Native American	1 (2.4)			1 (0.9)
mixed	2 (4.9)	2 (3.0)		4 (3.6)
Marital status, n (%)				
single/never married	11 (26.8)	12 (17.9)		24 (21.4)
living with partner	3 (7.3)	5 (7.5)		8 (7.1)
married	17 (41.5)	28 (41.8)	1 (100)	47 (42.0)
divorced/separated/widowed	10 (24.4)	22 (32.8)		33 (29.5)
Education level, n (%)				
less than/some high school	2 (4.9)	2 (3.0)		4 (3.6)
high school or equivalent	3 (7.3)	14 (20.9)		17 (15.2)
technical/associate degree	4 (9.8)	7 (10.4)	1 (100)	13 (11.6)
some/all college	17 (41.5)	29 (43.3)		47 (42.0)
some/all graduate school	15 (36.6)	14 (20.9)		29 (25.9)
other		1 (1.5)		2 (1.8)

CHF = congestive heart failure.
[a]Three patients within the total sample of 112 are not included in the diagnosis groups: 2 patients with diabetes and CHF and 1 patient with diabetes and asthma.

sponse options. Each EFA was conducted without specifying a specific number of factors for the solution.

Behavior Items

Based on the eigenvalues, the EFA of the 5 behavior items strongly suggested a one-factor solution. All 5 items had factor loadings above 0.40 (Table 1). In addition, the scale and each item significantly discriminated between groups of patients differing in self-reported adherence, particularly when adherence was measured with the Morisky Scale (for the scale and each item, all $p < 0.01$). Three of the items did have notable floor effects (item 17, 56.3%; item 18, 55.4%; item 19, 50.9%). However, none of these 3 items was dropped from the scale; all were retained because of their strong factor loadings, discriminatory ability, and the decrease in Cronbach's α that resulted from dropping any of the 5 items. In sum, these 5 items were considered to contribute to a single subscale called *behavior*.

Barrier Items

For the 15 barrier items, an EFA was first run without specifying the number of factors. Based on the eigenvalues, there appeared to be 2 factors (eigenvalues in order: 2.54, 1.26, 0.57, and so on). Consequently, as the next step, 2 additional EFAs were run on this group of items, specifying 2 factors and 3 factors. The 3-factor EFA was run as a sensitivity analysis to ensure that a greater number of factors did not yield a better solution. As expected, the EFA with 2 factors yielded a more logical solution. Factor loadings are presented in Table 1.

Five items that did not load above 0.35 on either of the 2 factors were deleted (items 3, 4, 6, 14, and 15). None of these 5 items discriminated with respect to any of the 3 self-reported adherence anchors, and item 15 had a floor effect for 77.7% of respondents. The 10 remaining items sorted into 2 factors. The first factor had 6 items with factor loadings ranging from 0.45 to 0.74 (items 7–12). Despite their acceptable factor loadings, items 10 and 12 had floor effects over 50% and neither discriminated with respect to the self-reported adherence variables. Furthermore, discrimination of this subscale improved when these 2 items were dropped. Therefore, they were dropped, resulting in a 4-item subscale called *health beliefs*.

Four items loaded on the second factor. Items 1, 2, and 13 had factor loadings of 0.69, 0.58, and 0.49, respectively. These 3 items also had no substantial floor effects, and they all discriminated with respect to the self-reported adherence anchors. Item 5 (I sometimes forget things that are important to me) had a lower factor loading compared with the other 3 items (0.36), and it discriminated with respect to only 1 of the 3 adherence anchors. In addition, when this item was deleted, Cronbach's α for the scale increased from 0.61 to 0.64. Furthermore, item 5 appears to be conceptually different from the other 3 items, with no overt reference to treatment adherence. Consequently, this item was dropped for empirical and conceptual reasons, resulting in a 3-item subscale that was labeled *inconvenience/forgetfulness*.

DESCRIPTION OF THE ASK-12

In sum, a total of 8 items were dropped from the ASK-20, resulting in a 12-item scale called the ASK-12, with 3 adherence-related subscales called *behavior* (5 items: 16–20; all reverse-scored), *health beliefs* (4 items: 7, 8, 9, 11), and *inconvenience/forgetfulness* (3 items: 1, 2, 13; all reverse-scored). To score the ASK-12, each subscale score is computed as the sum of all items within that scale, and the total score is the sum of all 12 items. If a participant did not complete 1 item within a subscale, the subscale score can be computed by substituting the mean of the available responses for the missing response. If more than 1 item within a subscale is missing, that subscale score should not be computed. If responses are not available for up to 3 items, the total score can be computed using the same imputation strategy. If more than 3 items are unavailable, then the total score should not be computed. The total score has a possible range of 12–60. Higher ASK-12 scores indicate more barriers to adherence or greater problems with adherence behavior.

ASK-12 DESCRIPTIVE STATISTICS

Descriptive statistics for the individual items have been previously presented in a study focusing on validation of the ASK-20 total score.[27] There were no missing data on the ASK-12. The mean subscale scores were 10.5 (behavior), 8.1 (health beliefs), and 8.9 (inconvenience/forgetfulness). The mean total ASK-12 score was 27.5, with a range of 16–49 (Table 3).

RELIABILITY

The ASK-12 total score demonstrated adequate internal consistency reliability, with a Cronbach's α of 0.75, and adequate test-retest reliability, with an ICC of 0.79 and no significant change in scores from visit 1 to visit 2 (Table 4). Reliability statistics of the subscales were somewhat lower. There were no statistically significant differences between visit 1 and 2 scores in any of the subscales.

CONVERGENT VALIDITY

Convergent validity of the ASK-12 was demonstrated through correlations with self-report measures, with coefficients in the moderate to strong range (Table 5). The correlation of the ASK-12 total score with the Morisky Scale had a coefficient in the strong range. The ASK-12 total score was also significantly correlated with other patient-reported mea-

sures, including the SF-12 MCS score, the ADS among patients with type 2 diabetes, and the MiniAQLQ among patients with asthma. The correlation of the ASK-12 total score with the PDC was in the expected direction and in the small range, approaching clinical significance.

The ASK-12 behavior subscale was strongly correlated with the Morisky Scale. This subscale was also significantly correlated with the ADS among diabetes patients. Correlations with the MiniAQLQ, SF-12, and PDC were not significant.

The ASK-12 health beliefs subscale was significantly correlated with all patient-reported measures.

The inconvenience/forgetfulness subscale was strongly correlated with the Morisky Scale. This subscale had small but statistically significant correlations with the ADS and the SF-12 MCS. It was also correlated with PDC.

Table 3. Descriptive Statistics for the ASK-12 Subscales and Total Score

ASK-12 Scales[a]	n	Mean ± SD	Median	Floor (%)	Ceiling (%)	Range
Behavior	112	10.5 ± 3.8	10.0	0.0	0.0	5–23
Health beliefs	112	8.1 ± 2.7	8.0	0.0	0.0	4–16
Inconvenience/ forgetfulness	112	8.9 ± 3.0	9.0	0.0	3.6	3–15
ASK-12 total score	112	27.5 ± 7.2	27.0	0.0	0.0	16–49

[a]Higher scores on individual items and the summary scores indicate greater barriers to adherence.

KNOWN-GROUPS VALIDITY

All ASK-12 scales discriminated between patients who reported missing a medication dose in the past week (total score 31.5) and those who said that they did not miss a dose (total score 24.0) ($t = 6.3$; $p < 0.0001$). Differences between these 2 groups followed the same pattern for the behavior, health beliefs, and inconvenience/forgetfulness subscales. These subscale scores were 12.3, 8.8, and 10.3 for patients who said they missed a dose, compared with 8.8, 7.6, and 7.6 for those who said they did not miss a

Table 4. Test-Retest and Internal Consistency Reliability of the ASK-12[a]

	Test-Retest Reliability				
ASK-12 Scales	Visit 1, mean ± SD	Visit 2, mean ± SD	p Value[b]	ICC	Cronbach's α[c]
Behavior	11.1 ± 4.1	11.0 ± 4.2	0.92	0.67	0.61
Health beliefs	8.3 ± 2.6	7.8 ± 2.5	0.06	0.79	0.66
Inconvenience/forgetfulness	8.5 ± 2.7	8.5 ± 2.9	0.94	0.74	0.64
ASK-12 total score	27.9 ± 6.7	27.3 ± 6.9	0.42	0.79	0.75

ICC = intraclass correlation coefficient.
[a]n = 38 for test-retest analyses, including visit 1 and visit 2 means; n = 112 for internal consistency.
[b]p value is for a *t*-test comparing the visit 1 and visit 2 scores.
[c]Measure of internal consistency reliability.

Table 5. Convergent Validity: Spearman Correlations of the ASK-12 with Proportion of Days Covered and Self-Report Measures

		Correlation Coefficients			
PDC and Self-Report Measures	n	Behavior	Health Beliefs	Inconvenience/ Forgetfulness	ASK-12 Total Score
PDC	93	–0.17	–0.08	–0.20[a]	–0.20[b]
Morisky Medication Adherence Scale	112	–0.69[c]	–0.26[d]	–0.65[c]	–0.74[c]
ADS score	67	0.31[e]	0.44[c]	0.25[e]	0.44[c]
MiniAQLQ score	41	–0.17	–0.47[d]	–0.29	–0.33[e]
SF-12 physical component summary	106	–0.04	–0.36[c]	–0.03	–0.16
SF-12 mental component summary	106	–0.18	–0.29[d]	–0.25[e]	–0.32[d]

ADS = Appraisal of Diabetes Scale; MiniAQLQ = Mini Asthma Quality of Life Questionnaire; PDC = proportion of days covered; SF-12 = Medical Outcome Study 12-Item Short Form Health Survey.
[a]p = 0.05.
[b]p = 0.059.
[c]p < 0.05.
[d]p < 0.01.
[e]p < 0.001.

dose (group differences significant at $p < 0.05$ for health beliefs and $p < 0.0001$ for the other 2 subscales).

All ASK-12 scales also discriminated among patients who varied by the self-reported number of days that they did not take their medication exactly as directed in the past 2 weeks (Table 6). Pairwise comparisons found that all differences between these 3 group means on the total score were statistically significant (all $p < 0.01$), and results for the subscales followed similar patterns. The ASK-12 scores also discriminated among patients with different levels of treatment satisfaction (Table 7).

Discussion

As a result of the current analysis, 8 items were dropped from the ASK-20, resulting in the more streamlined ASK-12, which demonstrated comparable psychometric performance to the original 20-item version. Cronbach's α and the 2-week intraclass correlation coefficient indicated that the ASK-12 met generally accepted standards for internal consistency reliability and test-retest reliability.[32] The ASK-12 demonstrated convergent validity through correlations with other patient-report measures, including disease-specific measures, a generic health-related quality of life measure, and a previously validated brief measure of treatment adherence. Furthermore, the ASK-12 discriminated among groups of patients differing in their self-reported treatment adherence and satisfaction with drug therapy. These findings suggest that the ASK-12 is a reliable and valid questionnaire for assessing patients' perceptions of potential barriers to medication adherence and adherence-related behavior. Furthermore, the brief ASK-12 is somewhat more convenient to complete than the longer ASK-20, which suggests that it may be practical for use in more research and clinical situations.

The ASK-12 performed slightly better than the ASK-20 with regard to the correlation with PDC. This variable was derived from 6 months of insurance claims data, and it is considered to be an objective indicator of treatment adherence.[19] In a previous analysis using the current data set, the

Table 6. ASK-12 Subscales and Total Score by the Number of Days Not Taken Medication Exactly as Directed[a]

ASK-12 Scales	Number of Days Not Taken Medicine Exactly as Directed (mean ± SD)[b]			Overall F Value	Significant Pairwise Comparisons[c]
	0 days (n = 39)	1–2 days (n = 29)	3+ days (n = 43)		
Behavior	8.0 ± 2.8	10.0 ± 2.3	13.1 ± 3.8	27.0[d]	A,[e] B,[d] C[d]
Health beliefs	7.2 ± 2.4	8.5 ± 2.2	8.6 ± 2.8	3.8[e]	B[e]
Inconvenience/forgetfulness	7.3 ± 2.6	8.6 ± 2.3	10.7 ± 2.9	17.6[d]	B,[d] C[f]
ASK-12 total score	22.5 ± 4.9	27.1 ± 4.8	32.4 ± 7.2	29.1[d]	A,[f] B,[d] C[f]

[a]n = 111.
[b]This variable is the response to the question "Overall, in the past two weeks, how many days have you not taken your medicine exactly as directed?"
[c]Pairwise comparisons: A: 0 days vs 1–2 days; B: 0 days vs 3+ days; C: 1–2 days vs 3+ days.
[d]$p < 0.001$.
[e]$p < 0.05$.
[f]$p < 0.01$.

Table 7. ASK-12 Subscales and Total Score by Satisfaction with Current Medications[a]

ASK-12 Scales	Satisfaction with Medications (mean ± SD)[b]			Overall F Value	Significant Pairwise Comparisons[c]
	Very Satisfied (n = 32)	Satisfied (n = 70)	Dissatisfied or Very Dissatisfied (n = 10)		
Behavior	8.7 ± 2.6	10.7 ± 3.5	14.4 ± 5.6	10.7[d]	A,[e] B,[d] C[e]
Health beliefs	7.0 ± 2.2	8.4 ± 2.6	9.7 ± 3.3	5.4[f]	A,[e] B[e]
Inconvenience/forgetfulness	7.2 ± 3.1	9.6 ± 2.6	9.9 ± 3.4	8.8[d]	A,[d] B[e]
ASK-12 total score	22.8 ± 4.6	28.8 ± 6.4	34.0 ± 11.0	14.9[d]	A,[d] B[d]

[a]n = 112.
[b]This variable is the response to the question "Overall, how satisfied are you with your current medicines?"
[c]Pairwise comparisons: A: very satisfied vs satisfied; B: very satisfied vs dissatisfied or very dissatisfied; C: satisfied vs dissatisfied or very dissatisfied.
[d]$p < 0.001$.
[e]$p < 0.05$.
[f]$p < 0.01$.

ASK-20 had a weak, nonsignificant correlation with PDC (r –0.13). The correlation between the ASK-12 and PDC was somewhat stronger at –0.20, which was in the expected direction (although the p value of 0.059 did not meet the significance threshold of $p < 0.05$), indicating that adherence barriers assessed by the ASK-12 tended to increase as PDC decreased. Objective and subjective measures of adherence have different strengths and are generally not expected to be strongly related to each other. Objective measures provide the most direct assessment of adherence, but they are often not practical in many research and clinical settings. Furthermore, analysis of prescription refill records (eg, PDC) may overestimate adherence because this approach can only document whether a patient possesses a medication, not whether the patient actually takes it as directed.[19,35] Subjective measures of adherence (eg, ASK-12) are also subject to potential inaccuracy because they depend on a patient's memory and willingness to report poor adherence.[19,35-37] Given the substantial differences between objective and subjective approaches and the potential for inaccuracy in both, the correlation with PDC in the expected direction may support the validity of the ASK-12, even though it is in the small range. Further research is needed to better understand the association between adherence barriers as assessed by the ASK-12 and objective measures of adherence. Ideally, this research could be conducted with larger samples and electronic methods of monitoring adherence behavior.

In the current analysis, subscales of the ASK-12 were identified, allowing for separate assessment of adherence-related behavior and barriers. All subscales had good factor structure and evidence of validity. Test-retest reliability of the behavior subscale and internal consistency reliability of all 3 subscales were slightly below generally accepted cutoffs for adequate reliability.[32] Therefore, more research is needed to examine the reliability of the ASK-12 subscales in a larger sample, particularly since reliability places an upper limit on a scale's validity.

The behavior subscale includes 5 items asking patients to report how recently they have been nonadherent. Two of these items focus on general adherence behavior, while the other 3 ask about nonadherence for specific reasons (eg, skipped or stopped taking medication because it made you feel bad). The first barrier subscale, health beliefs, includes 4 items assessing patients' beliefs about their medication, treating clinician, and health goals. The second barrier subscale, inconvenience/forgetfulness, uses 3 items to assess the degree to which patients forget to take medication, fail to obtain prescription refills on time, and consider taking medication to be inconvenient. If these subscales accumulate stronger evidence of reliability, they may provide a unique method for quickly assessing specific barriers to treatment adherence.

The most significant limitation of this study is the sample size. Thus far, the second empirical validation of the ASK-20[27] and the initial validation of ASK-12 have been conducted with this same small data set, consisting primarily of patients with asthma and type 2 diabetes. Instrument validation is an ongoing process, and confidence in any questionnaire develops based on gradually accumulating psychometric data.[38] Given the small sample, the current analysis should be considered the initial step in the validation of the ASK-12, and we hope that future research can further examine this questionnaire. For example, analysis of a larger sample of patients may be able to identify cutoffs that could aid in the interpretation of scores. With clinical or objective adherence measures, it may be possible to determine an ASK-12 score above which patients would be considered at risk for nonadherence. Furthermore, it would be helpful to examine whether the ASK-12 would be responsive to change in adherence behavior or barriers. For such an analysis, the ASK-12 could be administered before and after a structured patient education program aimed at improving treatment adherence. Another limitation is that demographic characteristics of the current sample could limit generalizability of results. In this sample, women and African American patients were overrepresented relative to the general population. In sum, additional research with larger, more diverse samples is needed to build confidence in the ASK-12.

In this initial validation, the ASK-12 appears to be a practical brief measure with promising preliminary evidence of reliability and validity. This instrument can be used in research evaluating individuals' treatment outcomes or patient education programs aimed at improving adherence. In addition, clinicians can conveniently use this brief measure with their patients in order to identify, address, and minimize barriers to adherence, potentially enhancing effectiveness of medication treatment. Patients' ASK-12 responses may alert clinicians to adherence barriers that could have otherwise gone unnoticed, thus facilitating targeted discussion between clinicians and patients. Because the ASK-12 requires slightly less time to complete, review, and discuss than the ASK-20, it may be more likely to be implemented in a busy clinician's office. However, it is difficult to quantify the impact of reducing a scale from 20 items to 12 items across all settings. The shorter instrument may be more practical for some clinicians, while others may prefer the added detail offered by the 20-item version. Thus, both questionnaires remain available for use. In sum, the ASK-12 may provide a unique source of information on adherence behavior and barriers in a range of clinical and research settings.

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Derivación y Validación del "ASK-12 Encuesta Sobre Barreras en la Adherencia"

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EXTRACTO

TRASFONDO: El estudio ASK-20 es una medida previamente validada para reportar barreras del paciente en cuanto a la adherencia a medicamentos y su manera de pensar sobre la misma.

OBJETIVO: Crear y validar una versión corta de esta escala.

METODOLOGIA: Pacientes con asma, diabetes, y fallo cardíaco Congestivo fueron reclutados de un Centro Médico Universitario. Los participantes completaron el estudio ASK-20 y otros cuestionarios. Aproximadamente un tercio de los pacientes fueron escogidos al azar para la administración de una reexaminación por 2 semanas. La ejecución de las premisas y los resultados de un análisis exploratorio factorial (EFA) fueron examinados para una reducción de premisas y la identificación de una sub-escala. Análisis subsecuentes examinaron la confiabilidad y validez de la versión corta del ASK.

RESULTADOS: Un total de 112 pacientes participaron (75.9% mujeres; con edad promedio de 46.7 años; 53.6% Afro-americanos). Ocho premisas fueron eliminadas del ASK-20 basadas en diferentes factores y por la habilidad de cada premisa en discriminar entre grupos de pacientes diferenciando en auto-reportes de adherencias. La nueva puntuación (ASK-12), tiene una buena credibilidad y consistencia interna (Cronbach's $\alpha = 0.75$) y una credibilidad en la reexaminación de la prueba (ICC = 0.79). Validez convergente fue demostrada a través de correlaciones con la Escala de Adherencia a Medicamentos de Morisky ($r -0.74$; $p < 0.001$), medida de condición específica, el SF-12 Escala de Componente Mental ($r -0.32$; $p < 0.01$) y proporción de días cubiertos por medicamentos prescritos en los pasados 6 meses según indicado por información de las reclamaciones en farmacia ($r -0.20$; $p = 0.059$). La puntuación total del ASK-12 también discriminó entre grupos de pacientes que se diferencian en los indicadores de los auto reportes de adherencia incluyendo de todos modos aunque una dosis de medicamento se olvidara en la pasada semana, el número de días en medicación que no se haya tomado según ordenados y la satisfacción del tratamiento. Tres sub-escalas fueron identificadas (actitud sobre la adherencia, creencias en salud, inconveniencias/faltas en recordar) y los resultados proveyeron el soporte inicial para la validez.

CONCLUSIONES: El ASK-12 demostró adecuada credibilidad y validez; y puede ser una breve medida útil para analizar actitud hacia la adherencia y las barreras a la adherencia al tratamiento.

Traducido por Wilma M Guzmán-Santos

Adhésion: Dérivation et Validation de l'Échelle ASK-12

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RÉSUMÉ

OBJECTIF: L'objectif de cette étude est de modifier et de valider une version courte de l'échelle ASK-20, échelle qui mesure les barrières à l'adhésion du patient et les comportements associés à l'adhésion.

MÉTHODES: Les patients avec l'asthme, le diabète, et l'insuffisance cardiaque ont été recrutés dans un centre hospitalier universitaire. Les participants ont complété le questionnaire ASK-20 et d'autres questionnaires. Environ un tiers des participants a été randomisé pour effectuer un retest. La performance au niveau des différentes questions et les résultats de l'analyse factorielle exploratoire ont été analysés. Les analyses postérieures ont évalué la fiabilité et la validité de la version courte de l'échelle ASK.

RÉSULTATS: Un nombre de 112 patients ont participé à l'étude dont 75.9% étaient des femmes, moyenne d'âge de 46.7 ans, et 53.6% étaient de race afro-américaine. Huit questions ont été éliminées de l'échelle ASK-20 selon l'analyse factorielle, l'effet de plancher, l'analyse Cronbach's alpha, et la capacité de chacun des éléments de discriminer entre les groupes de patients selon une autoévaluation de l'adhésion. Le nouveau score total (ASK-12) avait une bonne fiabilité interne (Cronbach's $\alpha = 0.75$) et une bonne fiabilité au test retest (ICC = 0.79). La validité convergente a été démontrée par des corrélations entre l'échelle d'adhésion à la médication de Morisky ($r -0.74$; $p < 0.001$), la condition de mesures spécifiques, le score de l'échelle psychologique SF-12 ($r -0.32$; $p < 0.01$) et la proportion des jours durant laquelle les médicaments ont été délivrés durant les derniers 6 mois précédant l'étude tel qu'indiqué par les déclarations des pharmaciens ($r -0.20$; $p = 0.059$). Le résultat total de l'échelle ASK-12 a discriminé les groupes des patients qui présentaient des différences dans les indicateurs d'autoévaluation de l'adhésion en incluant si une dose de médicament avait été oubliée dans la semaine précédant l'étude, le nombre de jours durant lequel le médicament n'a pas été pris comme prescrit, et la satisfaction au traitement. Trois sous-échelles ont été identifiées et les résultats préliminaires supportent leur validité.

CONCLUSIONS: L'échelle ASK-12 a démontré une fiabilité et une validité et peut s'avérer une mesure intéressante pour mesurer les comportements associés à l'adhésion et les barrières pour l'adhésion au traitement.

Traduit par Louise Mallet