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**Original Research**

# Development and validation of the Adherence to Asthma Medication Questionnaire (AAMQ)

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**Abstract**

**Background:** Adherence to medication is the cornerstone to achieve the best treatment outcome. Pharmacists are healthcare professionals found in a pivotal position to assess asthmatic patients' adherence to medication. A brief, reliable, and valid measure of patients adherence to mediations is useful to enable the pharmacists to deliver that vital service. **Objective:** To develop a reliable and valid adherence assessment tool for asthmatic patients. **Methods:** The Adherence to Asthma Medication Questionnaire (AAMQ-13) was developed based on an extensive literature review, followed by applying the Delphi technique, and then it was pilot-tested by 55 patients. The final AAMQ-13 was completed by 213 patients. Psychometric evaluation was assessed including reliability, criterion validity, and construct validity. **Results:** The AAMQ-13 is a feasible 13-item questionnaire, as it can be completed within an average of two minutes. It has high reliability (Cronbach's alpha= 0.87). Criterion-concurrent validity was established by comparing the AAMQ-13 to the Test of the Adherence to Inhaler (TAI) and the pharmacy refill records. Criterion-convergent validity was established by comparing the AAMQ-13 to the Asthma Control Test (ACT) questionnaire and the Positive Health Behaviors Scale (PHBS). Construct validity was established through AAMQ-13 factor analysis which revealed two factors explaining 51.76% of the total variance. **Conclusion:** The AAMQ-13 is a reliable and valid questionnaire with several desirable characteristics as it has high reliability, good criterion validity, and strong construct validity. The AAMQ-13 is a suitable questionnaire that can identify non-adherent patients and reveal the reasons behind their non-adherence

**Keywords:** Asthma; Adherence to medication; Compliance; Questionnaire; Self-report; Scale; Survey

## INTRODUCTION

Asthma is a controllable, but not curable disease affecting patients' respiratory system. It is characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from patient to another.[1] Asthma affects over 300 million people worldwide.[2] The main treatments for asthma include inhalable formulations of anti-inflammatory medications that are needed long-term (preventers), and bronchodilator medications that are used only when required (relievers).[1]

Data from recent studies show that asthma is still a poorly controlled condition.[3] One reason for uncontrolled asthma is patients' non-adherence to their preventer medications. This has been demonstrated repeatedly in real-life observational studies published globally during the previous 15 years; such studies highlight low rates of adherence to asthma preventer medications ranging from 14% to 50%.[4]

Low adherence to inhalers results in poor asthma control, more hospitalizations, higher mortality rates, and higher expenses.[5] Adherence is commonly defined as the degree to which patients accurately follow medical advice and take their medications as prescribed by the healthcare team.[6,7]

Experts believe that non-adherence is underpinned by different reasons, and hence, categorize non-adherence into different types. The two main types include: 1) intentional non-adherence (deliberate non-adherence which is associated mainly with patient beliefs), and 2) unintentional non-adherence (unplanned behavior which is mainly associated with lack of resources).[8,9]

To date, no method has been nominated as a universal gold standard method for measuring adherence. As objective measures are often costly or inconvenient; subjective measures such as patient self-reports are used more frequently in clinical and research settings. Self-report measures offer several advantages, including low cost, ability to differentiate between intentional and unintentional non-adherence, non-invasiveness, flexible to accommodate various conditions, and ease of administration. If devised well, self-report questionnaires can also provide valuable information such as the reasons behind non-adherence, beliefs about medications, and patient understanding of medications regimens.[9-11]

A well-devised adherence questionnaire should be reasonably applicable to the patient as they attempt to respond; in the case of asthma, given inhaled medications are the mainstay of treatment, the questionnaire should refer to inhaled medications, hence, the word 'preventer' medications is

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important to specify. These nuances make generic adherence questionnaires less applicable or relevant to asthma patients.

Some published questionnaires are long, consisting of 30 items,[12,13] developed with a relatively small sample size (n= 43-66 participants),[14-17] published without reported sensitivity and specificity,[15,18-20] published without a reported reliability,[16] had a reliability below 0.7,[14,21] or were only published in English language. Therefore, there is a clear need for a reliable and valid instrument that can be used to assess asthma patients' adherence to preventer therapy and identify reasons behind non-adherence. Such instruments are especially important for primary healthcare professionals such as pharmacists who have the opportunity to provide adherence support at the point of supply.

This study aimed to develop and validate a novel self-administrable asthma adherence assessment questionnaire for adult patients. The purpose of the proposed tool, named as the Adherence to Asthma Medication Questionnaire (AAMQ-13), is to provide a brief, patient-friendly tool for assessing adult asthma patients' adherence to preventer medications in any healthcare setting.

## METHODS

### Phase One: Questionnaire development

A structured questionnaire with predefined domains of interest was constructed based on an extensive review of the items included previously in published adherence questionnaires.[12,13,16,17,19-31] The most commonly used items published in adherence questionnaires were included in the first draft of the questionnaire. Other items that seem important to assess adherence were added after being agreed upon by the research team. The finalized items for the first draft (AAMQ-V1) were reviewed by the research team in order to combine concepts and remove duplicates or irrelevant items.[32]

### Phase Two: Applying the Delphi technique

The Delphi technique was used to reach a convergence of opinions regarding the most valuable items to include in the questionnaire, based on the answers of an expert panel.[33,34] This phase involved providing the AAMQ-V1 to the panel for review. The panel review was organized in two rounds. These rounds involved the panel members allocating scores on criteria related to each item. The experts were requested to assess the face, and the content validity, and determine whether the selected items covered the three predefined domains of interest (*Belief, Barrier, and Behavior*).

#### *The first round*

The expert panel included six categories (doctors, pharmacists, pulmonologists, academics, people with asthma, and last-year pharmacy students). Each item included in the AAMQ-V1 was evaluated by the expert panel in terms of readability, clarity of words, consistency of the style layout, relevance, and importance.[32] The experts were requested to rank the importance of each item included in the AMMQ-V1 using a 5-point Likert scale (strongly agree this item is important, agree this item is important, neutral, agree this item is not important, and strongly agree this item is not important). The mean score for the importance of each item was calculated. Items agreed upon as being important questions by a percentage of 70% or more of the panel (mean item importance score ≥4, i.e., strongly agree this item is important or agree this item is important) were included in the final version of the questionnaire. Items with no clear consensus such as those with an agreement score between 50% and 70% produced the second version of the questionnaire (AAMQ-V2) and were retained in the second round.[22,35,36] The expert panel was also questioned about the appropriate acceptable number of items that should be included in the adherence assessment questionnaire. In round one, adding, deleting, editing, and rephrasing the items were undertaken based on the panel feedback.[36]

#### *The second round*

After the second round, the mean score for the importance of each item was calculated again and a final version of the questionnaire was developed from the items that obtained a high score (more than 70%) in either round.[34]

### Phase Three: Pilot testing

The AAMQ was pilot tested by participants with asthma. The participants were patients with asthma who were recruited through a face-to-face approach while they were waiting to see their respiratory specialist in two public hospitals. A standardized introductory script was followed in approaching all potential participants; the script involved informing the patients about the main objectives of the study. Those consenting to participate were then asked to complete the AAMQ. Their comments and suggestions were considered by the research team and were reflected in the questionnaire. Certain information about the questionnaire was also collected, such as the time needed to complete the questionnaire and whether the participants needed any explanations to understand the items.

To assist in the interpretation and the analysis of AAMQ scores, the scores were arbitrarily divided by the research team into three categories based on the decision made by the Delphi expert panel indicating: poor, moderate, and excellent adherence.

### Phase Four: Psychometric analysis (reliability and validity)

The reliability, criterion (concurrent and convergent validity), construct validity, sensitivity, and specificity were assessed in this phase. The final version of the AAMQ was made available to another set of participants with asthma. To be eligible for this phase of the study, participants must have been diagnosed with asthma by a specialist, have been prescribed regular inhaled corticosteroid inhalers for at least six months, and over the age of 18. The participants were asked about these inclusion criteria and were noted to only complete the questionnaire if they met these inclusion criteria. During this phase, participants were targeted through emails and social media (mainly Facebook and WhatsApp).

Demographic information (gender, age, living place, marital

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status, education, employment, and smoking status) were collected from the participants.[32] Four questionnaires were used in phase four (AAMQ-13, Test of the Adherence to Inhaler (TAI), Asthma Control Test (ACT), and Positive Health Behaviors Scale (PHBS)). The questionnaires (AAMQ-13, TAI, ACT, and PHBS) were translated from English to Arabic by qualified experts with many years of experience in translation. These experts were native speakers of the target language; they had a comprehensive knowledge of the relevant terminology and used a professional-related website in translation to ensure the accuracy of the terminologies used.[37] Afterward, the translation was validated by colleagues (n= 2) who were experts in the clinical research field and in language translation. Their comments and feedback provided were considered by the research team and then incorporated where appropriate.

The reliability was assessed through cronbach's alpha coefficient. The construct validity was assessed through AAMQ-13 factor analysis. The criterion-concurrent validity was assessed through a subjective measure (comparing the AAMQ-13 to the TAI).[27] The TAI is a validated 10-item questionnaire used to assess the adherence to inhalers in patients with asthma or COPD. It has a score range from 10 to 50 (each item has a score from 1 to 5, where 1 represents the worst possible score and 5 represents the best possible score). The cut-offs for TAI were 50 for adherent patients, 46-49 for intermediate adherent patients, and ≤45 for non-adherent patients.[27] The criterion-convergent validity was assessed by comparing the AAMQ-13 to the ACT,[38] and the PHBS.[39] The hypothesis behind using the ACT and PHBS was that participants with higher AAMQ-13 scores were more likely than those with lower scores to have well-controlled asthma. In addition, participants with higher AAMQ-13 scores were more likely to score higher in the PHBS, indicating that adherent patients generally have a better lifestyle.

**Phase Five: Psychometric analysis (criterion-concurrent validity)**

The criterion-concurrent validity was assessed again, however, this phase included using an objective measure (pharmacy refill records). A retrospective audit was conducted; once the participants completed the AAMQ-13, the researcher extracted their pharmacy refill records for the previous eight months. The Medication Possession Ratio (MPR) was used to express the patients' pharmacy refill records.[40] The MPR is the percentage of time a patient has access to the medications. It was calculated as the days' supply of a medication at a particular time divided by the number of days from the first dispensing time to the end of the defined period. The research team considered that the patient has consumed the medication if he/she dispensed it. The extraction of data was examined by referring physicians to be accurate.

The five study phases used to develop and validate the AAMQ are illustrated in Figure 1.

**Ethical approval**

Ethics approval for the study was obtained from the Ethical Research Board of the Faculty of Pharmacy at the Applied Science Private University (Approval Number: 2019-PHA-13).

**Statistical analysis**

Data were analyzed using Statistical Package for Social Science (SPSS), Version 22.0 (IBM Corp., Armonk, New York, USA). Descriptive results were presented as means and standard deviations for continuous variables and percentages for qualitative variables.

## RESULTS

**Phase One: Questionnaire development**

The first draft of the Adherence to Asthma Medication Questionnaire (AAMQ-V1) had 31 items. The 31 items are listed in Table 1 with their original source.

**Phase Two: Applying the Delphi technique**

Forty-eight participants were chosen for the expert panel (eight participants from each category). The mean age of the expert panel was 35 years (SD= 10.70) and 62.5% of them were females.

The entire expert panel (100%) agreed that the items were understandable, and that the questionnaire had a good layout and style. Most of the expert panel (85.42%) agreed that the items were written clearly. The expert panel was asked about the appropriate acceptable number of items in an adherence assessment questionnaire, their answers varied widely and ranged from 6 to 25 items, with an average answer of 15 items.

After conducting the first round in the Delphi technique, twelve items were agreed upon by a percentage of 70% or more, as being important items to assess adherence. Eight items were excluded because they had an agreement score of less than 50%. Eleven items scored between 50% and 70% and were reassessed in the second round. Table 2 highlights the agreement scores on the importance of each item after the first round.

After conducting the second round, with 11 items, only one item scored above 70%. To conclude, the final AAMQ consisted of 13 items.

**Phase Three: Pilot testing**

Fifty-five participants with asthma were recruited; they confirmed that the items were clear and comprehensible. The questionnaire needed from one to three minutes to be completed, within an average of two minutes.

Each item in the AAMQ-13 has five possible scores ((1) Always, (2) Often, (3) Sometimes, (4) Rarely, and (5) Never; where (1) represents the worst possible score and (5) represents the best possible score). These response options were based on the consensus reached by the expert panel. The AAMQ-13 has a score range from 13 to 65 (Table 3). The final scores were divided into three categories of adherence: poor adherence (score= 13-29), moderate adherence (score= 30-47), and excellent adherence (score= 48-65). It is worth mentioning that we took into consideration that some patients with asthma do

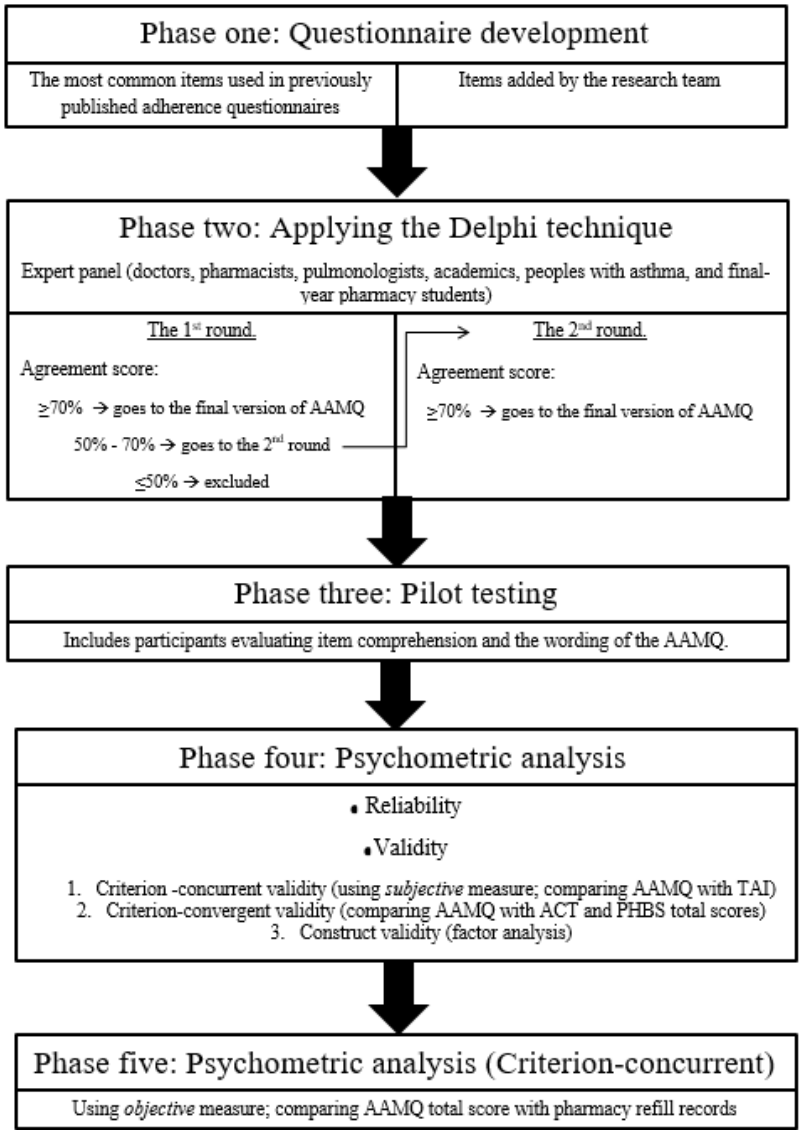


Figure 1. The five study phases used to develop and validate the Adherence to Asthma Medication Questionnaire (AAMQ).

Table 1. The AAMQ-V1 items with their original source

| **Items from previously published adherence questionnaires** | **Items added by the research team** |
|---|---|
| I decide not to take my medication.[19,21,26] | I think I do not need my medication. |
| I am careless at times about taking my medication.[15,23] | I think my medication is not effective. |
| I alter the dose (use less or more than the prescribed dose).[15,27] | I take natural products because they are better than medication in treating my asthma. |
| I stop taking my medication for a while.[21] | I do not take my medication because I dislike using corticosteroids. |
| I stop taking my medication when I am feeling well.[15,19,26,27] | I stop taking my medication when I am around people because I feel embarrassed. |
| I miss doses if taking the medication interferes with my work routine.[27] | I stop taking my medication because they disturb my sleep. |
| I stop taking my medication because they interfere with my daily routine.[27] | I stop taking my inhaler out of fear that it might cause addiction. |
| I stop taking my medication when I leave home or travel or during holidays and weekends.[23,27] | I do not take my medication because of insurance problems. |
| I stop taking my medication because I feel worse after taking them.[23] | I stop taking my medication because I have multiple medications to take. |

| | |
|---|---|
| I stop taking my medication when I am sad or nervous.[27] | I stop taking my medication because my doctor does not understand my asthma. |
| I stop taking my medication when I am sick (having a cold or a flu).[51] | I stop taking my inhaler because I did not understand my doctor/pharmacist instructions on how to use it. |
| I stop taking my medication out of fear of potential side effects.[27] | I do not take my inhaler as I find it difficult to use it. |
| I take my medication only when I feel breathless.[21] | I do not use my inhaler correctly although I know how. |
| I forget taking my medication.[13,15,19,26,27] | |
| I need someone to remind me to take my medication.[51] | |
| I do not take my medication as I run out of them.[19,26] | |
| I cannot afford my medication.[27] | |
| I stop taking my medication because it is hard for me to stick to my treatment plan.[23] | |

Table 2. The agreement score for each item included in the first draft of the AAMQ after conducting the first round of the Delphi technique

| **The items included in the first round of the Delphi technique (n= 31)** | **The overall agreement score** |
|---|---|
| I decide not to take my medication.* | 66.7% |
| I think I do not need my medication. | **75%** |
| I think my medication is not effective. | **77.2%** |
| I take natural products because they are better than medication in treating my asthma.* | 66.7% |
| I do not take my medication because I dislike using corticosteroids. | **81.3%** |
| I am careless at times about taking my medication.* | 56.3% |
| I alter the dose (use less or more than the prescribed dose).* | 64.6% |
| I stop taking my medication for a while.* | 64.6% |
| I stop taking my medication when I am feeling well. | **93.8%** |
| I miss doses if taking the medication interferes with my work routine.* | 68.7% |
| I stop taking my medication because they interfere with my daily routine. | 41.7% |
| I stop taking my medication when I leave home or travel or during holidays and weekends.* | 60.4% |
| I stop taking my medication because I feel worse after taking them. | 43.7% |
| I stop taking my medication when I am sad or nervous. | 37.5% |
| I stop taking my medication when I am sick (e.g., having a cold or a flu). | 39.7% |
| I stop taking my medication when I am around people because I feel embarrassed.* | 60.4% |
| I stop taking my medication because they disturb my sleep. | 41.7% |
| I stop taking my medication out of fear of potential side effects. | **85.4%** |
| I stop taking my inhaler because I am afraid of becoming addicted to it | **72.9%** |
| I take my medication only when I feel breathless. | **81.3%** |
| I forget taking my medication. | **83.4%** |
| I need someone to remind me to take my medication. | 33.4% |
| I do not take my medication as I run out of them.* | 54.2% |
| I cannot afford my medication. | **79.2%** |
| I do not take my medication because of insurance problems.* | 66.7% |
| I stop taking my medication because it is hard for me to stick to my treatment plan.* | 50% |
| I stop taking my medication because I have multiple medications to take. | **73%** |
| I stop taking my medication because my doctor does not understand my asthma. | 20.9% |
| I stop taking my inhaler because I did not understand my doctor/pharmacist instructions on how to use it. | **75%** |
| I do not take my inhaler as I find it difficult to use it. | **77.1%** |
| I do not use my inhaler correctly although I know how. | 29.2% |

* Items included in the second round of the Delphi technique.

Table 3. The Adherence to Asthma Medication Questionnaire (AAMQ-13)

**This questionnaire will assess your adherence to your <u>preventer</u> medication. Please answer based on what you actually do, not based on what should be done regarding your use of your daily preventer**

| | **Always (1)** | **Often (2)** | **Sometimes (3)** | **Rarely (4)** | **Never (5)** | **Score** |
|---|---|---|---|---|---|---|
| 1. I think I do not need my medication. | | | | | | |
| 2. I think my medication is not effective. | | | | | | |
| 3. I alter the dose (use less or more than the prescribed dose). | | | | | | |
| 4. I stop taking my medication out of fear of potential side effects. | | | | | | |
| 5. I do not take my medication because I dislike using corticosteroids. | | | | | | |
| 6. I stop taking my medication when I am feeling well. | | | | | | |
| 7. I take my medication only when I feel breathless. | | | | | | |
| 8. I stop taking my medication because I have multiple medications to take. | | | | | | |
| 9. I forget taking my medication. | | | | | | |
| 10. I cannot afford my medication. | | | | | | |
| 11. I stop taking my inhaler because I did not understand my doctor/pharmacist instructions on how to use it. | | | | | | |
| 12. I do not take my inhaler as I find it difficult to use it. | | | | | | |
| 13. I stop taking my inhaler because I am afraid of becoming addicted to it. | | | | | | |
| **Total Adherence Score (out of 65)=** | | | | | | |

**Cut-off points to determine the adherence level:**
Total score = 13-29 → poor adherence to medication
Total score = 30-47 → moderate adherence to medication
Total score = 48-65 → excellent adherence to medication

not use inhalers, and consequently, we decided to reduce the 13 items AAMQ to 10 items for these patients (AAMQ-10). Thus, to assess adherence, in the case of non-inhaler using patients with asthma, the first 10 items need to be answered (found in the Supplemental Material). In this scenario, the 10-items AAMQ will have a total possible score of 50. To assist in the interpretation, scores were arbitrarily divided into three categories indicating poor adherence (score= 10-22), moderate adherence (score= 23-36), and excellent adherence (score= 37-50).

**Phase Four: Psychometric analysis (reliability and validity)**

In phase four, 213 participants with asthma completed the four questionnaires (AAMQ-13, TAI, ACT®, and PHBS).[27,38,39] Their age ranged from 18 to 84 years with a mean of 36.9 years (SD= 13.62). The majority were females (n= 149, 70%), living in Amman (n= 174, 81.7%), married (n= 128, 60.1%), had a bachelor's degree (n= 158, 74.2%), employed (n= 97, 45.5%), and were non-smokers (n= 147, 69.0%) as shown in Table 4.

No correlation was found between the participants' age and the total score of the AAMQ-13. No significant difference was found based on participant's gender, living place, marital status, education, employment, smoking, and their adherence level.

**Reliability**

The cronbach's alpha coefficient for the final AAMQ-13 was found to be 0.87 suggesting that the questionnaire has a very high internal consistency. The questionnaire also has good split-half reliability (Spearman-Brown coefficient= 0.743). Item 4 *'I*

Table 4. Demographic characteristics of the study sample in phase four (n= 213)

| | |
|---|---|
| Age (years) , mean (SD) | 36.9 (13.62) |
| Gender, n (%)<br>• Male<br>• Female | <br>64 (30)<br>149 (70) |
| Living place, n (%)<br>• Amman<br>• Outside Amman | <br>174 (81.7)<br>39 (18.3) |
| Marital status, n (%)<br>• Married<br>• Single<br>• Divorced<br>• Widowed | <br>128 (60.1)<br>79 (37.1)<br>2 (0.9)<br>4 (1.9) |
| Education, n (%)<br>• Primary school<br>• Secondary school<br>• Collage<br>• Bachelor's degree | <br>4 (1.9)<br>22 (10.3)<br>29 (13.6)<br>158 (74.2) |
| Employment, n (%)<br>• Employed<br>• Unemployed<br>• Student<br>• Retired | <br>97 (45.5)<br>63 (29.6)<br>37 (17.4)<br>16 (7.5) |
| Smoking, n (%)<br>• Yes<br>• No | <br>66 (31)<br>147 (69) |

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*stop taking my medication out of fear of potential side effects'* had the highest item-total correlation (Table 5). The highest item-item correlation (0.755) was observed between item 11 *'I stop taking my inhaler because I did not understand my doctor/ pharmacist instructions on how to use it'* and item 12 *'I do not take my inhaler as I find it difficult to use it'*.

**Sensitivity and Specificity**

The sensitivity of the AAMQ-13 was 84.8% while the specificity was 95.2%. The positive predictive value was 88.9% while the negative predictive was 93.3%.

**Construct validity**

The AAMQ-13 had 13 items; hence, it was posed that at least 130 patients were needed to complete the questionnaire.[41] The AAMQ-13 was completed by 220 patients (7 cases were excluded as they were clear outliers).

The principal component analysis revealed the presence of two components having an eigenvalue of more than one (5.081 and 1.648). The two components explained a total of 51.76% of the variance, with component one contributing to 39.08% and component two contributing to 12.68% of the variance.

Varimax rotation showed that both components had a number of good loading and most of the variables were loaded substantially on one component. Items demonstrating a loading of 0.3 or greater were considered to measure a factor, and items which loaded 0.4 or more onto both factors were grouped according to the highest loading (n= 3).

**Criterion-concurrent validity (using subjective measure)**

A statistically significant correlation was found between AAMQ-13 and TAI total scores (r= 0.800, P-value< 0.001). The mean score for the AAMQ-13 was 46.21 (out of 65) while the mean score for the TAI was 36.20 (out of 50).

**Criterion-convergent validity**

A statistically significant correlation was found between AAMQ-13 and the ACT total scores (P-value< 0.005). The mean score for the AAMQ-13 was 46.21 (out of 65) while the mean score for the ACT® was 18.46 (out of 25).

A statistically significant correlation was found between AAMQ-13 and the PHBS total scores (P-value< 0.005). The mean score for the AAMQ-13 was 46.21 (out of 65) while the mean score for the PHBS was 43.06 (out of 81 for males, and 87 for females).

**Phase Five: Psychometric analysis (Criterion-concurrent validity (using objective measure))**

The pharmacy records were extracted for 50 participants. A statistically significant correlation was found between AAMQ-13 total score and the MPR (r= 0.716, P-value< 0.001).

## DISCUSSION

Among the several methods that can be used to assess patients' adherence to medications, self-reported questionnaires remain to be the most convenient method. The outcomes of this study successfully reached the aim of developing a feasible, reliable, valid, and patient-friendly method of assessing adult asthma patients' adherence to preventer medications in healthcare settings. This current work encompasses the development of and commendable psychometric properties (reliability, validity, sensitivity, and specificity) of a newly developed adherence questionnaire, 'The Adherence to Asthma Medication Questionnaire' (AAMQ-13). Noteworthy, the AAMQ-13 validity was established with a battery of validity tests including face, content, construct, and criterion (concurrent and convergent) validity. Moreover, some asthma adherence questionnaires available to date can only identify non-adherent patients,

Table 5. Item analysis of the AAMQ-13 generated via the reliability analysis

| AAMQ items | Mean (Standard deviation) | Item-Total Correlation | Cronbach's Alpha if Item Deleted |
|---|---|---|---|
| 1. I think I do not need my medication | 3.13 (1.091) | 0.388 | 0.863 |
| 2. I think my medication is not effective | 3.71 (1.027) | 0.474 | 0.858 |
| 3. I alter the dose (use less or more than the prescribed dose) | 3.45 (1.215) | 0.496 | 0.857 |
| 4. I stop taking my medication out of fear of potential side effects | 3.49 (1.254) | 0.646 | 0.848 |
| 5. I do not take my medication because I dislike using corticosteroids | 3.42 (1.387) | 0.605 | 0.851 |
| 6. I stop taking my medication when I am feeling well | 2.63 (1.383) | 0.595 | 0.851 |
| 7. I take my medication only when I feel breathless | 2.54 (1.503) | 0.529 | 0.856 |
| 8. I stop taking my medication because I have multiple medications to take | 3.83 (1.173) | 0.564 | 0.853 |
| 9. I forget taking my medication | 3.54 (1.192) | 0.531 | 0.855 |
| 10. I cannot afford my medication | 3.92 (1.239) | 0.415 | 0.862 |
| 11. I stop taking my inhaler because I did not understand my doctor/ pharmacist instructions on how to use it | 4.32 (0.901) | 0.564 | 0.855 |
| 12. I do not take my inhaler as I find it difficult to use it | 4.32 (0.908) | 0.545 | 0.856 |
| 13. I stop taking my inhaler because I am afraid of becoming addicted to it | 3.90 (1.301) | 0.615 | 0.850 |

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while results of this study indicate the utility of the AAMQ-13 in gauging reasons underlying poor adherence. Therefore, the AAMQ-13 is an instrument that can be used frequently in the clinical and research settings. When used by patients, the AAMQ-13 can improve patients with asthma adherence to medications because it identifies reasons behind non-adherence, assisting the healthcare team and the patients in deciding the appropriate intervention that should be taken afterward.

The development of the AAMQ-13 followed a stringent series of steps commencing with a literature review, drafting, three rounds of re-drafting, and user testing besides the psychometric evaluation. Our expert panel stated that the appropriate acceptable number of items in an adherence assessment questionnaire would be from 6 to 25 items. The AAMQ-13 is perfectly compatible with this present finding, as it has 13 items, making it a brief questionnaire. Moreover, the most important driver of the number of items in an instrument is a function of the number of the domain being measured by the instrument; the AAMQ-13 was conceptualized with three specific domains; thus, it has a fairly good balance of items. The number of items in the AAMQ-13 falls within the range of the published questionnaires, as some questionnaires consisted of four items, such as the Morisky Medication Adherence Scale (MMAS-4) and the Brief Adherence Rating Scale (BARS),[17,23] or five items such as the Adult Asthma Adherence Questionnaire (AAAQ),[42] while other questionnaires had up to 30 items such as the Drug Attitude Inventory (DAI) and the Personal Evaluation of Transitions in Treatment (PETiT).[12,13] Hence, the robust process in the development allowed for a good balance between discriminatory power and respondent/assessor fatigue. In addition, the 13-item solution is well centered as both long questionnaires and short ones have been reported to be problematic.[43,44]

The AAMQ-13 was developed with a good sample size, considered high enough to give comprehensive and representative results. In comparison to other published questionnaires, some of them were developed with a small sample size (n= 43) such as the Brief Medication Questionnaire (BMQ),[14] in contracts, others were developed with a relatively large sample size (n= 1009), such as the Test of the Adherence to Inhalers (TAI).[27]

The AAMQ-13 has high internal reliability (0.87) that falls within the range (0.61 in MMAS-4 - 0.93 in DAI) of the cronbach's alphas of some published questionnaires.[12,23] A high item-item correlation between item 11 and item 12, and to the overall item score, indicate the importance of inhaler use issues as a major factor in adherence.

The AAMQ-13 could be well utilized at the point of inhaler supply in pharmacies. It is well acknowledged that the key to solve the problem of non-adherence should encourage a "blame-free" environment.[45] All of the healthcare team should have a vital role in supporting medication adherence, however, pharmacists can have a unique one since they interact with almost every outpatient and are the last to see the patients after they purchase their medication.[46] The high item-total correlation observed in item 4 highlights the importance of correcting patient's misbeliefs as many patients stop taking their medication out of fear of potential side effects. However, chronic diseases such as asthma are controllable but not curable, and can only be controlled with patient's commitment to medications, otherwise, the frequency and severity of the symptoms may increase. Thus, healthcare providers should be aware of patient's beliefs about their medication, as it has been previously documented that having strong beliefs in the benefits of asthma medications can contribute to better adherence.[47]

The interpretation of the two components was different, however, very close to the predefined domains of interest (*Belief*, *Barrier,* and *Behavior*) identified by the research team. In designing the AAMQ-13, all potential items were stemmed from these three domains. The factor analysis suggested the presence of two factors, interestingly, all of the *'Barrier'* domain items loaded strongly on component one, and all of the *'Behavior'* domain items loaded strongly on component two, while the *'Belief'* domain items (n= 3) were found to be distributed between the two components (Table 6). A person's behavior is determined by his/her intention to perform a behavior as stated in the theory of reasoned action. The person's intention to perform a behavior is influenced by the person's attitude toward that behavior and the environmental surroundings.[48] This would highly explain why the last domain (*Belief*) did not show as a separate component in the factor analysis. As beliefs cause barriers and lead to behaviors; as a consequence, the AAMQ-13 picks the endpoints. Therefore, it was decided to extrapolate the factor analysis results and conclude that the AAMQ-13 is not only able to identify non-adherence patients and classify their adherence level (poor, moderate, and excellent adherence), but it can also give adequate information about the patterns of non-adherence (intentional or unintentional non-adherence). This can be achieved by comparing the total score of the five behavior items (items number 3, 4, 5, 6, and 7) which represent intentional non-adherence, and the total score of the five barrier items (items number 8, 9, 10, 11, and 12) which represent unintentional non-adherence.

The AAMQ-13 has a high sensitivity (0.85) and specificity (0.95) values, which make it a good candidate to assess asthmatic patient adherence to their medications. The sensitivity of the most used published questionnaires ranged from 0.63 in the PIAQ to 0.848 in the TAI (when the cut-off of the TAI score was 45).[16,49] As for the specificity ranged from 0.226 in the TAI to 1.0 in the BMQ (for the regimen screen part in the questionnaire), and 0.91 in the PIAQ.[16,28,49]

Methods used to assess the criterion validity of each questionnaire varied widely from one questionnaire to the other; some questionnaires used subjective method (e.g., therapist report) such as in the DAI questionnaire, while the other questionnaires chose an objective method (e.g., the medication event monitoring system (MEMS)), such as the BMQ and the BARS questionnaires.[17,28,50] The AAMQ-13 was validated using both methods.

Table 6. Outcomes showing factor analysis for the AAMQ 13 items

| | | Factor 1 rotated component loading | Factor 2 rotated component loading |
|---|---|---|---|
| Eigenvalue | | 5.081 | 1.648 |
| % varianve explained | | 39.08% | 12.68% |
| **AAMQ items, their predefinid domain of interest and their factor loading:** | | | |
| 1. I think I do not need my medication | Belief Domain | 0.055 | **0.584** |
| 2. I think my medication is not effective | Belief Domain | **0.428** | 0.359 |
| 3. I alter the dose (use less or more than the prescribed dose) | Behavior Domain | 0.371 | **0.451** |
| 4. I stop taking my medication out of fear of potential side effects | Behavior Domain | 0.409 | **0.620** |
| 5. I do not take my medication because I dislike using corticosteroids | Behavior Domain | 0.323 | **0.650** |
| 6. I stop taking my medication when I am feeling well | Behavior Domain | 0.080 | **0.842** |
| 7. I take my medication only when I feel breathless | Behavior Domain | 0.047 | **0.803** |
| 8. I stop taking my medication because I have multiple medications to take | Barrier Domain | **0.606** | 0.326 |
| 9. I forget taking my medication | Barrier Domain | **0.459** | 0.405 |
| 10. I cannot afford my medication | Barrier Domain | **0.692** | 0.036 |
| 11. I stop taking my inhaler because I did not understand my doctor/pharmacist instructions on how to use it | Barrier Domain | **0.832** | 0.115 |
| 12. I do not take my inhaler as I find it difficult to use it | Barrier Domain | **0.867** | 0.052 |
| 13. I stop taking my inhaler because I am afraid of becoming addicted to it | Belief Domain | **0.551** | 0.447 |

This study comes with few limitations; due to the coronavirus pandemic and public quarantine that happened in March 2020 in Jordan, interviewing patients was impossible in phase four (n= 213), and it was not possible to meet patients face-to-face. Thus, in order to complete the study, phase four was conducted using an online platform. Moreover, conducting the test-retest reliability was not applicable. Yet, the online procedure followed gave the needed results and answered the aim of the study. Finally, the AAMQ-13 was studied in an Arabic population, and hence, would need to be validated in an English-speaking population.

## CONCLUSION

Through the extensive work put into this study, an adherence assessment tool for asthmatic patients was developed. The AAMQ-13 has high reliability, good criterion validity, and strong construct validity. All these findings suggest that the AAMQ-13 is a promising tool for future use as an adherence assessment questionnaire in asthmatic patients. From a clinical perspective, uncontrolled asthma requires long-term adherence to the medications and prescribed treatment plan; thus, a short, brief, feasible, reliable, and valid measure of patient's adherence is needed. Most of the questionnaires available up to date can only identify non-adherent patients. The AAMQ-13 is the only questionnaire that was specifically designed and validated in the Middle East to assess asthmatic patients' adherence to their medications, predicting patients' pattern of non-adherence. It can also predict other important clinical outcomes, as a significant correlation was found between the AAMQ-13 and ACT, and PHBS questionnaires. Thus, it can give an indication of whether the patient's asthma symptoms are controlled, and it gives an insight into the patient's lifestyle and quality of life.

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## CONFLICTS OF INTEREST

The authors declare no relevant conflicts of interest or financial relationships.

## AUTHORS' CONTRIBUTIONS

Razan I. Nassar: Study conception and design, Methodology, Data curation, Analysis and interpretation of results, Investigation, Visualization, and Writing – original draft.

Bandana Saini: Study conception and design, Methodology, Analysis and interpretation of results supervision, Project administration, Supervision, Validation, and Writing – review and editing.

Nathir M. Obeidat: Methodology, Resources, Project administration, and Writing – review.

Iman A. Basheti: Study conception and design, Methodology, Analysis and interpretation of results supervision, Project administration, Validation, Supervision, and Writing – review and editing.

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**The Adherence to Asthma Medication Questionnaire (AAMQ-10)**

This questionnaire will assess adherence to preventer medication for non-inhaler using patients with asthma. Please answer based on what you actually do, not based on what should be done regarding your use of your daily preventer.

| | Always (1) | Often (2) | Sometimes (3) | Rarely (4) | Never (5) | Score |
|---|---|---|---|---|---|---|
| 1. I think I do not need my medication. | | | | | | |
| 2. I think my medication is not effective. | | | | | | |
| 3. I alter the dose (use less or more than the prescribed dose). | | | | | | |
| 4. I stop taking my medication out of fear of potential side effects. | | | | | | |
| 5. I do not take my medication because I dislike using corticosteroids. | | | | | | |
| 6. I stop taking my medication when I'm feeling well. | | | | | | |
| 7. I take my medication only when I feel breathless. | | | | | | |
| 8. I stop taking my medication because I have multiple medications to take. | | | | | | |
| 9. I forget taking my medication. | | | | | | |
| 10. I cannot afford my medication. | | | | | | |
| **Total Adherence Score (out of 50)=** | | | | | | |
| **Cut-off points to determine the adherence level:**<br>Total score = 10-22 → poor adherence to medication<br>Total score = 23-36 → moderate adherence to medication<br>Total score = 37-50 → excellent adherence to medication | | | | | | |