JOURNAL OF DRUG ASSESSMENT
2019, VOL. 8, NO. 1, 36–42
https://doi.org/10.1080/21556660.2019.1579729
Article 0019.R1/1579729

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ORIGINAL ARTICLE



# Translation and validation of the English version of the general medication adherence scale (GMAS) in patients with chronic illnesses

Atta Abbas Naqvi[a], Mohamed Azmi Hassali[a], Amnah Jahangir[b], Muhammad Nehal Nadir[c] and Bharti Kachela[c]

[a]Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM), Penang, Malaysia; [b]Department of Pharmacy, Ziauddin University Hospital, Karachi, Pakistan; [c]Faculty of Pharmacy, Ziauddin University, Karachi, Pakistan

**ABSTRACT**

**Objective:** This study aimed to translate the General Medication Adherence Scale (GMAS) into English language and validate it in patients suffering from chronic illnesses.

**Methods:** A 1-month study (January 2018) was conducted in a random sample of patients suffering from chronic illnesses who visited the outpatient departments of four tertiary healthcare facilities in Karachi, Pakistan. Translation of the tool and its content, as well as face validity, was carried out. Factor structure was explored (i.e. exploratory and partial confirmatory factor analyses were carried out) and fit indices were calculated for model fitting. Test–re-test reliability and internal consistency were analyzed. Validity of GMAS-English was established by convergent, discriminant, and concurrent validity analysis. Sensitivity analysis was conducted. Data was analyzed through SPSS version 23. The study was ethically approved by concerned authorities (Letter# NOV:15).

**Results:** The GMAS was translated into English language by standard procedure. Factor analysis indicated a 3-factor model. Fit indices, namely normed fit index, Tucker Lewis index, comparative fit index, and root mean square of error approximation, were calculated with satisfactory results (i.e. NFI, TLI, and CFI $> 0.9$ and RMSEA $< 0.08$). Internal consistency ($\alpha$) was 0.82. A high response rate of 91.6% was reported. GMAS-English established convergent, discriminant, and concurrent validities. The tool was sensitive (>75%) in screening patients with partial-to-low adherence based on their education level.

**Conclusion:** The tool was translated in English language and demonstrated adequate internal consistency. The results indicate that GMAS-English is a valid and reliable tool to measure medication adherence in patients with chronic illness.

**ARTICLE HISTORY**
Received 26 September 2018
Accepted 2 February 2019

**KEYWORDS**
Chronic illness; medication adherence; medication persistence; Pakistan; patient compliance; patients

## Introduction

Medication adherence is of prime concern for healthcare professionals when it comes to management of non-communicable diseases (NCDs)[1]. According to the United Nations report, NCDs have emerged as a major health issue of developing countries, since they focus more on communicable diseases[2]. NCDs are often referred to as chronic illnesses that are managed by medications throughout a patient's life. Adherence to medications in chronic illness is important not only from the patients' perspective but adds to the healthcare burden in terms of costs, i.e. emergency visits, increased hospital admissions, and cost of recovering from an exacerbation. Evidence indicates that cost of care for non-adherent patients exceeds more than US$100 billion annually[3].

Developing countries are mostly located in the tropical regions and may face an unusual situation of tropical disease epidemic as well as an increasing prevalence of chronic diseases[2]. Since communicable disease spread requires active control, a major amount of finance is channeled towards its control. This results in inadequate funds available to curb chronic illness. Moreover, patients in developing countries may have out-of-pocket medical expenditures[4–7]. This results in dilemma for patients as chronic illnesses affects their productivity, quality-of-life, and employment opportunities thereby increasing direct economic burden. Henceforward, measuring adherence to medications for NCDs in such a population becomes ever important. This would also help in investigating the determinants of non-adherence[2].

Adherence may incorporate a wide range of domains, such as patient behaviors, i.e. intentional and unintentional non-adherence, complexity of the regimen, comorbidities and subsequent polypharmacy or pill burden, out-of-pocket expenditures, negative perception about medicines, etc. In addition, other medicine taking behaviors with respect to drugs, as well as long-term drug therapy, may act as determinants of adherence[8–11].

The healthcare system of Pakistan has traditionally focused on eliminating communicable diseases. Curbing

CONTACT Atta Abbas Naqvi naqviattaabbas@gmail.com, atta.abbas.naqvi@student.usm.my School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM), Penang 11800, Malaysia

Table 1. Scale construct and items.

| Constructs | Items |
|---|---|
| 1. Non-adherence due to patient's behavior, i.e. un-intentional and intentional non-adherence | 1. Do you have difficulty in remembering to take your medications?<br>2. Do you forget to take your medication due to your busy schedule, traveling, meeting, events at home, party, marriage, religious celebrations, etc.?<br>3. Do you discontinue your medication when you feel well?<br>4. Do you stop taking medications when you feel adverse effects such as gastric discomfort, etc.?<br>5. Do you stop taking medications without informing the doctor? |
| 2. Non-adherence due to additional disease and pill burden | 6. Do you discontinue your medicines due to other medicines that you have to take for your additional disease?<br>7. Do you find it is a hassle to remember your medications due to medication regime complexity?<br>8. During the last month, had there been any occasion when you missed your medicines due to progression of disease and addition of new medicines?<br>9. Do you alter medication regimen, dose, and frequency by yourself? |
| 3. Cost-related non-adherence | 10. Do you discontinue these medications because they are not worth the money you spent on them?<br>11. Do you find it difficult to buy your medicines because they are expensive? |

communicable diseases spread such as poliomyelitis, malaria, tuberculosis, primary amoebic meningoencephalitis (PAM) infections by naegleria fowleri, dengue viral haemorrhagic fever, and chikungunya viral spread has been priority for healthcare authorities[12–15]. This may have neglected the plight of patients who suffer from chronic diseases. Patients in Pakistan have limited options for health insurance and mostly pay out-of-pocket for their treatment. This is viewed as a potential barrier to treatment by health professionals, as patients belonging to a low socio-economic status find it difficult to afford treatment[4–6,16]. The World Health Organization (WHO) estimates that almost half of the deaths in Pakistan are because of chronic diseases, and reports the probability of dying from NCDs as high as 21%[17]. Therefore, it is imperative to evaluate if the patients of NCDs achieved their treatment outcomes. This could be evaluated by documenting their adherence to medication therapy[1,8].

There is a dearth of literature pertaining to documenting medication adherence among Pakistani patients. No other tool except the Morisky's Medication Adherence Scale (MMAS) was validated in the Pakistani population[18]. However, MMAS does not measure cost related non-adherence, which is one important determinant of adherence in this population. Recently, a novel tool known as the General Medication Adherence Scale (GMAS) was developed and validated by Naqvi *et al.*[8] that incorporates the determinant of cost. The GMAS was originally developed in Urdu.

This study was conducted to translate GMAS into English, as well as validate it in patients suffering from chronic illnesses. This ensured the availability of an English version of GMAS that was suitable for use by health professionals and researchers from other countries.

## Methods

### Study venues

A study was conducted in four tertiary care hospitals, namely the Clifton Central Hospital and Dr Ziauddin Hospitals (Clifton, KDLB, and North Nazimabad campuses), located in Karachi, Pakistan.

### Study duration and data collection timings

This month-long study i.e. January 2018, was conducted in the out-patient department (OPD) and involved survey-based data collection. The data was collected on Sunday, Tuesday, and Thursday, every week for 4 weeks. The time of data collection was from 6 pm to 9 pm in the evening. The selection of days and timings were based on OPD activity and peak patient visiting hours, respectively.

### Randomization and patient recruitment process

We carried out randomization by inviting patients based on their appointment number. This was done by inviting patients with an appointment slip ending with an odd number. A computer-generated list of odd numbered appointees was used to invite the patients.

### Participants and eligibility criteria

Male and female out-patients with a chronic illness and with a maximum of three comorbidities were invited. Patients who gave their consent were enrolled in the study. Participants who had four or more comorbidities and/or acute illnesses were not included. In-patients and those who did not consent to participate were left out.

### Sample size calculation

The sample size was calculated from a statistical aspect using the item response theory. Dowrick *et al.*[19] and Osborne and Costello[20] have suggested an item-to-respondent ratio of 1:5 up to 1:10. Therefore, the required sample size was 55 or 110, as per item-to-respondent ratios of 1:5 and 1:10, respectively, as GMAS consisted of 11 items. However, we gathered data from 196 patients, thereby improving the ratio to 1:17.

**Table 2.** Patients' demographic information.

| Demographic information | Sample (n) | Percentage |
|---|---|---|
| Gender | | |
| Male | 93 | 47.4 |
| Female | 103 | 52.6 |
| Marital status | | |
| Married | 133 | 67.9 |
| Single | 63 | 32.1 |
| Educational status | | |
| Primary (up to 6 years of education) | 4 | 2 |
| Secondary (up to 10 years) | 10 | 5.1 |
| Higher secondary (up to 12 years) | 33 | 16.8 |
| Graduate (up to 16 years of education) | 130 | 66.3 |
| Post-graduate (>16 years of education) | 19 | 9.7 |
| Occupation | | |
| Employed | 58 | 29.6 |
| Un-employed | 35 | 17.9 |
| Retired | 32 | 16.3 |
| Household | 51 | 26 |
| Self employed | 20 | 10.2 |
| Residence | | |
| Urban | 183 | 93.4 |
| Rural | 13 | 6.6 |
| Health insurance coverage | | |
| Insurance coverage | 66 | 33.7 |
| No insurance coverage | 130 | 66.3 |
| Comorbidity | | |
| Yes | 122 | 62.2 |
| No | 74 | 37.8 |
| Type of illness | | |
| Hypertension | 41 | 20.9 |
| Diabetes mellitus type I and II | 24 | 12.2 |
| Chronic kidney disease | 9 | 4.6 |
| Chronic obstructive pulmonary disorder | 18 | 9.2 |
| Rheumatoid arthritis | 9 | 4.6 |
| Osteoarthritis | 7 | 3.6 |
| Ischemic heart disease | 12 | 6.1 |
| Dyslipidemia | 2 | 1 |
| Depression | 8 | 4.1 |
| Asthma | 5 | 2.6 |
| Thyroid disorders (hyperthyroidism, hypothyroidism, etc.) | 5 | 2.6 |
| Liver diseases (jaundice, hepatitis A, B and C, cholithiasis, etc.) | 16 | 8.2 |
| Inflammatory bowel disease (Crohn's disease, ulcerative colitis, etc.) | 5 | 2.6 |
| Psychiatric disorders (Parkinsonism, Alzheimer's disease, epilepsy, etc.) | 21 | 10.7 |
| Gout | 3 | 1.5 |
| Metabolic disorders (Obesity, malnutrition, etc.) | 11 | 5.6 |

### *Translation process and expert panel*

The tool was originally formulated in Urdu, and translation into English was carried out according to standard guidelines[21–23]. It was conducted by a panel of experts, comprising two university professors with teaching experience in international universities, a pharmacist, and a general practitioner whose first language was Urdu and second language was English. A draft of the English version of GMAS was prepared by a university professor, pharmacist, and general practitioner. All three researchers were not aware (blinded) of each other during this process. The three versions were analyzed and compared by the expert panel, and a final version was prepared. This was handed separately to two independent translators belonging to a health and social sciences background, for back-translation. Special attention was paid to translate the linguistic, conceptual, and medical terminologies and technical equivalence. Inconsistencies and disagreements in the two sets of back-translated versions were resolved during an expert panel meeting. A final back-translated draft was then prepared by the expert panel, which was subjected to peer review by an English linguist. After review, it was considered fit to use. The constructs and their items are presented in Table 1.

### *Measurement purification of GMAS-English*

The English version of GMAS was sampled in chronic patients in Pakistan with an item-to-respondent ratio of 1:17 for exploration of factor structure followed by its confirmation in another sample[24]. Absolute fit indices, namely the root mean square error of approximation (RMSEA), as well as incremental fit indices such as the normed fit index (NFI), Tucker Lewis index (TLI), and comparative fit index (CFI), were also calculated. A value of NFI and TLI greater than 0.90 as well as CFI above 0.95 indicated a good model fit. A value of RMSEA less than 0.08 highlights a good model fit according to the literature[25–30]. These were considered in evaluating the tool's adherence property.

Table 3. Factor structure.

| | Components | | |
|---|---|---|---|
| Constructs | 1 | 2 | 3 |
| 1 | 0.503 | | |
| | 0.708 | | |
| | 0.727 | | |
| | 0.770 | | |
| | 0.738 | | |
| 2 | | 0.541 | |
| | | 0.773 | |
| | | 0.783 | |
| | | 0.836 | |
| 3 | | | 0.903 |
| | | | 0.618 |

### Convergent and discriminant validities

The convergent validity and discriminant validities were assessed. If the average factor loading of a construct was above 0.7, construct validity was established. Discriminant validity was established if the average variance between two constructs was greater than their squared correlation coefficients.

### Internal consistency and reliability

The internal consistency was measured by test–re-test method using Cronbach's alpha ($\alpha$) values and Pearson correlation coefficient ($\rho$). Literature indicates that an $\alpha$ value of 0.5 or higher is considered acceptable[31,32]. Pearson's correlation coefficient ($\rho$) was used to assess the test–re-test reliability between two time-points with a 2-week gap. A value of $\rho > 0.75$ and a $p$-value less than 0.05 was considered a significantly strong correlation[32,33]. Item-to-total correlation (ITC) with a value greater than 0.2 was considered acceptable as per literature[31,34,35]. Intra-class correlation (ICC) was also calculated[33,36].

### Concurrent validity

We established concurrent validity of the GMAS by measuring patient compliance to the prescribed regimen for a duration of 4 weeks. Compliance was determined as a percentage, and was measured by the following formula:

$$C = \frac{Nd}{Nt} \text{ x } 100\%$$

where $C$ denotes patient compliance, $Nd$ is the number of doses taken by patients for the stated duration, and $Nt$ is the number of doses prescribed to the patients for the stated duration. If there was more than a single medication, the compliance could be calculated using the following formula:

$$\Sigma C = \frac{\Sigma Nd}{\Sigma Nt} \text{ x } 100\%$$

where $\sum C$ denotes cumulative compliance to all medications in a regimen, $\sum Nd$ denotes the sum of all doses taken by patients for a stated duration, and $\sum Nt$ is the sum of all doses of all medications prescribed to the patient for the stated duration. This could be further clarified using the following equation:

$$\Sigma C = \frac{Nd1 + Nd2 + Nd3 \ldots}{Nt1 + Nt2 + Nt3 \ldots} \text{x } 100\%$$

where $\Sigma$,$C$ is the cumulative compliance to all medications in a regimen, $Nd1$, $Nd2$, $Nd3$ are the number of doses taken by patients for the stated duration for medications 1, 2, 3, and so on, and $Nt1$, $Nt2$, $Nt3$ are the number of doses of medications 1, 2, 3, and so on, that are prescribed for the stated duration. The final percentage obtained is categorized as high (90–100%), good (81–89%), partial (51–80%), low (31–49%), and poor (0–30%), i.e. as per the grading criterion of GMAS for cumulative adherence[8]. Pearson correlation coefficient ($\rho$) was used to assess the concurrent validity. A value of $\rho > 0.75$ and a $p$-value less than 0.05 was considered a significantly strong correlation[32,33].

### Sensitivity analysis

Sensitivity analysis of GMAS was conducted to screen patients with adherence levels based on their education level.

### Ethical approval and consent

This study is based on a research project approved by the Institutional Review Board of Allied Med Ethics (Ref: NOV:15). The data collection for validation purpose was conducted after obtaining permission from the concerned hospitals. Patients were briefed about the study objectives and asked to participate in the study. Data collection was started after obtaining patient consent.

## Results

### Patients' demographic information

A total of 214 patients were invited, and 199 consented to participate in the study, giving a response rate of 91.6%, three questionnaires were incomplete and were excluded. Data of 196 patients was analysed. Most respondents were females ($n = 103$, 52.6%) and the majority indicated that they were married ($n = 133$, 67.9%). More than half of the patients were graduates ($n = 130$, 66.3%) and a third ($n = 58$, 29.6%) were employed. The majority of patients ($n = 183$, 93.4%) lived in urban areas and had comorbidities ($n = 122$, 62.2%). The demographic information is tabulated in Table 2.

### Factor analyses

The instrument was subjected to factor analyses for measurement purification. The sample was divided into two equal random sub-samples, i.e. 98 each. An exploratory factor analysis (EFA) was conducted on the first sample to explore the structure using principle component analysis (PCA) with varimax rotation. The Kaiser-Mayer-Olkin (KMO) measure of sampling adequacy was 0.832, and Bartlett's test of sphericity was significant ($p < 0.0001$) with a $\chi^2$ value of 623.870. Factors were extracted based on Eigenvalues >1.0. A three-factor structure was obtained with a total variance of 59.15%. Factor loadings >0.3 on a single component and

non-salient loadings <0.3 on others were considered a single factor. As a result, five items were loaded onto factor one, four onto factor two, and two onto factor three. At least two item loadings are necessary for designating the component as an independent factor in principle component analysis (Table 3)[37,38].

This structure was then confirmed by conducting partial confirmatory factor analysis (PCFA) using Maximum likelihood method with varimax rotation, on the second sample. Non-salient factor loadings were normally distributed ($X = 0.14$, SD = 0.103). Goodness-of-fit test reported an implied $\chi^2$ value of 42.477 (df = 25). Fit indices were calculated using these values. The value for both NFI and TLI was 0.93, i.e. >0.90 and the value for CFI was 0.97, i.e. >0.95. The value for RMSEA was reported at 0.06, which was less than 0.08. All these values confirmed a good 3-factor model fit.

### Convergent and discriminant validity

The average factor loadings were reported at 0.70 for the first construct, 0.73 for the second, and 0.76 for the third. Hence, all constructs reported average factor loadings > 0.7 that established convergent validity[32]. The discriminant validity was observed by calculating average variance between constructs and their squared correlation coefficients. Discriminant validity was established if the average variance between two constructs was greater than their squared correlation coefficients[32]. The average variance between construct one and two was reported at 0.573, and squared correlation coefficient was 0.45. Similarly, average variance between constructs one and three was 0.56, and squared correlation coefficient was 0.093. Furthermore, the average variance between constructs two and three was 0.63 and squared correlation coefficient was 0.30. This established discriminant validity among all constructs.

### Internal consistency and reliability

The reliability ($\alpha$) for construct one was 0.78, 0.79 for the second construct, and 0.66 for the third. Overall reliability ($\alpha$) for all items was reported at 0.819. All were positively correlated with each other, except item 10, which was negatively correlated with item 1. All items in the first construct demonstrated the lowest item-total correlation (ITC) above 0.4, intra-class correlation coefficient (ICC) at 0.78 (95% CI = 0.727–0.825). The second construct reported its lowest ITC greater than 0.49, ICC at 0.785 (95% CI = 0.732–0.83), while the third construct reported its lowest ITC above 0.25, ICC at 0.263 (95% CI = 0.024–0.444). The test–re-test reliability was checked by correlating the adherence scores of participants at baseline and, at follow-up (week 4). The test–re-test Pearson's correlation was 0.861 ($p < 0.01$).

### Concurrent validity

Concurrent validity was checked by correlating the categories of adherence scores of participants obtained from GMAS and their compliance rates at follow-up (week 4). The test–re-test Pearson's correlation was 0.701 ($p < 0.01$). Hence, concurrent validity was established.

### Sensitivity analysis

The tool demonstrated high sensitivity (>75%) while screening patients with partial-to-poor adherence based on education[9].

## Discussion

There has been only a single medication adherence tool that was translated and validated in Pakistani patients by Saleem *et al.*[18], i.e. MMAS Urdu version. However, MMAS-Urdu does not incorporate cost-related non-adherence (CRNA). This was a limitation of MMAS-Urdu, as CRNA is one important determinant of overall medication adherence for Pakistani patients as well as for patients in other countries[39,40]. Moreover, MMAS-Urdu was validated through convenience sampling.

This scale was originally formulated in Urdu by Naqvi *et al.*[8], and was validated in Pakistani patients suffering from chronic illnesses. English translation of GMAS was a prerequisite to its international availability. This study translated GMAS in English language and validated it in this population. The translation process involved a team of experts and followed standard guidelines for translation followed by pilot testing for reading, clarity, and coherence. Following successful acceptability of the English version in patients, the tool was analyzed for its adherence measuring property. We sampled GMAS-E in a randomized patient population visiting OPDs of four tertiary care hospitals. Factor analyses were conducted to study factor structure, and a three-factor model was observed with factor loadings that were similar to GMAS-Urdu. Absolute and incremental fit indices were calculated that were in standard ranges, as mentioned in the literature[26,29,31,32]. This validated the findings reported by Naqvi *et al.*[8]. The sampling process, number of study venues, and usage of EFA and PCFA are major strengths of this study.

Furthermore, convergent and discriminant validity were also established for all three constructs. This implied that tool successfully measures adherence across all three domains, like its Urdu predecessor[8]. Only the Urdu version of MMAS had established convergent validity in Pakistani patients[18]. Since MMAS has no sub-domain, the discriminant validity has never been analyzed in this population before. Hence, this aspect could be considered as a major strength of the GMAS-E. The overall reliability of GMAS-E was reported at 0.819, with correlation coefficients ranging from 0.779–0.854 that indicated high internal consistency. Since tool validation studies in this population are lacking, the study that used MMAS-Urdu was used as a bench mark. It was found that the Cronbach alpha ($\alpha$) value of GMAS-E was higher than that reported for the Urdu version of MMAS in the Pakistani population, i.e. 0.701[18]. This higher internal consistency may be regarded as a strength of GMAS-E.

The English version of GMAS could not establish known group validity. This might be since all patients who opted to take the English version were educated and had better understanding of adherence issues, greater employment opportunities, and higher family income compared to uneducated patients. Hence, there were no associations with demographic characteristics of the patient, as was the case with the Urdu version of GMAS[8]. However, the sensitivity analysis revealed that the tool was able to screen patients with partial-to-low adherence based on their education profile. The sensitivity of GMAS was greater than 75%, which was better than that demonstrated by MMAS-Urdu in this population[18]. It was better than the values reported by the Shea Scale, and was equal to that reported by the Adherence to Refills and Medications Scale (ARMS)[42,43].

Forbes *et al.*[44] mentioned that adherence could only be adequately documented by utilizing a combination of adherence evaluating methods. We used a combination of two adherence reporting methods. This was done to check for the concurrent validity of GMAS-E, which was done by utilizing the data on patient compliance to prescribed medications over a course of 4 weeks. The findings were satisfactory, as there was a significantly strong correlation between the adherence score obtained from GMAS-E and patient compliance data. This not only established the convergent validity, but also highlighted the efficiency of the tool in adherence reporting. This is a major strength as GMAS-E is the first tool to establish concurrent validity in this population.

This translation and validation of the GMAS-E will ensure availability of this tool to the researchers and health professionals in other countries for its translation in native languages and to validate it in other patient populations. The authors recommend validating the tool in other patient populations as well as in patients with specific illnesses.

## Conclusion

The general medication adherence scale was successfully translated into English and was validated in patients with chronic illnesses. The validation results indicate that GMAS-English is a reliable and valid research instrument to measure medication adherence in patients with chronic illnesses.

## Transparency

### *Declaration of funding*

This manuscript received no funding

### *Declaration of financial/other relationships*

The authors and JDA peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

## ORCID

Atta Abbas Naqvi http://orcid.org/0000-0003-4848-6807

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