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Original Article

Validation of Persian 10-item patient satisfaction survey in Iranian patients receiving comprehensive medication management

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ABSTRACT

Comprehensive medication management (CMM) is a clinical service that aims to ensure that a patient's medications are individually assessed. This assessment determines whether the medications have an appropriate reason for use, are effective in treating the patient's medical condition or helping meet defined patient or clinical goals, are safe considering comorbidities and other medications being taken. This single-center cross-sectional study was performed in the oncology clinic of our institution. Inclusion criteria were cancer patients over the age of 18 with any comorbidity such as hypertension or diabetes and simultaneous use of three or more drugs, or at the doctor's discretion based on the patient's medications. Participation of patients was voluntarily based on their written informed consent. General and clinical information about participants was gathered using face-to-face interviews or medical records. Total surveys returned for analysis numbered 50, with an overall survey response rate of 100% because of in-person interviews. Face and content validity and reliability (Cronbach's a = 0.84) of Persian version of CMM questionnaire was acceptable. All the qualification items for validation were acceptable without any change in questions. The Persian questionnaire has sufficient validity and reliability. Although the values obtained from the Cronbach's alpha and KMO tests are lower than the English version, this amount can be ignored, and it can be used. Additionally, in consideration of the differences between Iran and the United States health service systems, the difference in the number of components can be considered acceptable to help researchers more in interpreting the results.

Keywords: Persian version, 10-items patient satisfaction survey, Comprehensive medication management, Adherence

Introduction

Medication is a major component of 80% of treatment plans and has an impact on almost every aspect of a patient's life. In the US, it is anticipated that by 2021, there will be about 5 billion prescriptions filled annually, an increase of about 1 billion in just ten years [1].

According to a World Health Organization report, chronic disease treatment adherence in developed countries is around 50%, and non-adherence to treatment results in a decline in health status and an increase in medical care costs [2].

There is growing evidence that treatment failure and failure to meet clinical objectives are not primarily caused by non-adherence, which is frequently cited as the main problem with patients' medication use. More than half of the reported problems can be attributed to insufficient treatment, which is defined as using the incorrect medication, a different or unnecessary drug, or a dose that is too low [3]. As indicated by the report given by American Colleagues of Clinical Pharmacists (ACCP), the most widely recognized drug treatment issues are inadequate treatment (56.86%), non-adherence (14.89%), side effects (14.74%), high dose (6.83%) and unnecessary treatment (6.68%) [4, 5].

To ensure that the best medication has been selected for the right patient with the proper dose and considerations, it is necessary to review the patient's medication list and comorbidities [2].

Additionally, to achieve treatment objectives, it's critical to motivate patients to take their medications exactly as prescribed. This procedure is known as comprehensive medication management (CMM), and clinical pharmacists can implement it as trained and qualified specialists to monitor patients' treatment, enhance its quality, and ultimately increase patients' awareness of the disease. CMM may also lessen negative drug side effects and increase adherence to therapy. CMM assesses each patient's medications on an individual basis to determine whether the drug was properly chosen as a standard of care. When taking into account the patient's other medications and co-occurring diseases, is the desired medication safe? Is the patient able to take the medication for the intended therapeutic goal? [2]

Data show that offering CMM services helps the Medicare program avoid nearly 6 million doctor visits and 670,000 emergency room visits each year, saving the program more than $1.5 billion [3].

For pharmacists offering pharmacy services, a patient satisfaction tool is crucial for gauging quality and sustainability. A psychometrically sound survey for evaluating client satisfaction with CMM services has been developed by Jean Moon [6]. The purpose of this study is to validate Comprehensive Medication Management's 10-item Jean Moon Questionnaire for Iranian patients. It is assumed that this research achieves this objective because there aren't any appropriate Iranian methods to assess patients' comfort and confidence in their care as well as the effectiveness of the procedures used for medication management in Iran.

Materials and Methods

Survey development

The main survey has developed a patient satisfaction survey tool for comprehensive medication management (CMM) services, which are a relatively new standard for clinical practice.The survey consisted of 10 items related to 3 domains: medication-related needs, pharmacist-patient engagement, and overall satisfaction. The questionnaire was published in the Journal of Managed Care & Specialty Pharmacy in 2016 and it is one of the few questionnaires that have been specifically designed and tested for CMM services [6].

Two independent translators with fluency in Persian and English worked on the project and translated the questionnaire. The steps for validating this questionnaire are as follows: Translation and reinterpretation, face validity, content validity, reliability, and statistical analysis.

Survey composition

The final survey like the original version consisted of 10 questions, 9 of which used a scale from 1 to 4 (strongly agree, agree, disagree, strongly disagree) and asked patients to evaluate their experiences with the clinical pharmacist (supplementary 1). The final question asked patients to rate their overall quality of care and services on a Likert scale from 1 to 5 (excellent to poor).

Survey distribution

This single-center cross-sectional study was performed since June until September 2022 in the oncology clinic of our institution. Inclusion criteria were cancer patients over the age of 18 with any comorbidity such as hypertension or diabetes and simultaneous use of three or more drugs, or at the doctor's discretion based on the patient's medications. Participation of patients was voluntarily based on their written informed consent. General and clinical information about participants was gathered using face-to-face interviews or medical records.

After the patient enters the process, the necessary information about demographic characteristics such as sex, age, marital status, level of education and type of job, underlying diseases, type of medication (including supplements, traditional medicine, etc.), and type of cancer and related information, are gathered from the patient and entered into the form.

Validity and Reliability

This questionnaire's validation steps are as follows.

Translation and reinterpretation

Two independent translators with proficiency in Persian and English translated the questionnaire's English version into Persian in the first stage. The translated questionnaire was then reviewed in a meeting with the translators and the main researchers, and an initial common translation was obtained with the group's approval. Two additional translators—different from the originals—who are proficient in Persian and English were given the joint translation to be translated into English. The translation produced two distinct English translations. The two interpretations were looked at by a gathering of specialists and interpreters, contrasted, and the first variant of the English survey, and its shortcomings were analyzed and remedied and applied in the last Persian rendition of the poll.

Validity is the closeness of the deliberate size to the genuine size; to put it another way, the validity of a questionnaire means that the questions measure what we want to measure. [7]

Face validity (FV)

Face validity demonstrates the instrument's exterior quality; in other words, face validity answers the question of whether the questionnaire was created professionally or was presented carelessly and with a weak framework. Professional questions are expected to elicit more serious responses. To conduct the study in places where people speak a different language, a translated version of the questionnaire must be prepared.

According to experts, the degree of coordination between the content of the measurement tool and the objective of the research

is used to evaluate content validity. Two qualitative and quantitative methodologies are being investigated for this goal. During the quality evaluation of the material, the researcher asks the experts to provide the necessary feedback about the tool, and the necessary modifications are made depending on the experts' viewpoints.

In this study after confirmation of the face validity of the questionnaire, all items were qualitatively examined using a face-to-face structured interview with 20 patients with cancer under the services of clinical pharmacists. Each participant evaluated each item in terms of the relevance of the item, ease of answering the item, and ambiguous items and informed the researcher [7-9].

Content validity (CVR & CVI)

The concept and the tools used to convey it are important in content validity, and experts' opinions determine the validity of a good tool. In general, this kind of validity aims to determine whether or not the tool's content can accurately measure the specified objective. Concerning the selection of experts, two factors are essential: One is that the experts should include experts in both measurement and the content industry. The second point is about the number of experts to check content validity, which is suggested from 2 to 20 people. About the number, "Lin" suggests at least three people [10].

This study for checking the quantitative content validity used two indices such as Content Validity Ratio (CVR) and Content Validity Index (CVI).

Content Validity Ratio; CVR was designed by Lawshe. In this study, the expert panel of 7 members including clinical pharmacists, internal medicine specialists, and chemotherapists assessed the content validity. First, were requested from expert panels to select each question one of three items: "necessary", "useful but not necessary" or "not necessary". After that based on Lawshe's table, each item was accepted based on a total rate of ≥ 0.99 using this formula [11]:

$CVR = (N_{necessary} - N_{expert\ panel}/2) / (N_{expert\ panel}/2)$

Content Validity Index (CVI): For assessing CVI for each item requested from expert panels to rate each item in terms of relevancy, simplicity, and clarity based on the Likert scale (e.g. "1= not relevant, 2= somewhat relevant, 3= quite relevant and 4= completely relevant"). The CVI was calculated based on the number of experts who rated 3 or 4 divided by the total number of experts. The S-CVI is the average rating of relevancy, simplicity, and clarity. The value of S-CVI >0.79 was considered an acceptable value [12].

Reliability

Reliability refers to how dependably or consistently a test measures a characteristic. In this study, the reliability was assessed using Cronbach's alpha for measuring internal consistency. Cronbach's alpha value of 0.70 or above is considered an acceptable value. In this phase 50 patients filled out the validated questionnaire for assessing the reliability. About illiterate patients, the researcher read each item for patients, and the oral answers were inserted into the form by the researcher [13-15].

Statistical analysis

In this study, continuous variables were reported as mean and standard deviation, and the categorical variables were described as frequency and percentage (%). Quantitative content validity was assessed using the Content Validity Ratio (CVR) proposed by Lawshe with an acceptable value of 0.99 for a panel with seven experts and the Content Validity Index proposed by Waltz & Bausell with an acceptable value of 0.79 [11, 16].

Exploratory Factor Analysis (EFA) with principal components method and varimax rotation was performed to assess the multidimensional structure of the CMM questionnaire. Kaiser-Meyer-Olkin (KMO) measurement of sampling adequacy (> 0.6) and Barlett's test of sphericity (P_value <0.05) was used for confirming EFA [17].

The number of factors and eigenvalues were described using a scree plot. The reliability was assessed based on Cronbach's alpha. All of the statistical analysis was performed using SPSS version 21.

IRB Approval: this study was approved by IRB of our institution. (IR.SBMU.PHARMACY.REC.1401.139)

Results and Discussion

Demographics

The survey was distributed in person by the questioner to 50 patients, and all of the surveys were responded to, giving an overall response rate of 100 %. The demographic data is presented in **Table 1**.

40% of patients were female and 60% were male. 50% of patients were under 60 years old and the rest were over it. 82% of them were educated and 18% were illiterate. Types of cancers included Colorectal 64%, Gastric 16%, and other types 20%.

Table 1. General and clinical characteristics of participants.

Characteristics	Frequency (%) (N=50, 100%)
Gender	
Female	20 (40.00)
Male	30 (60.00)
Age (years)	
≤ 60	25 (50.00)
> 60	25 (50.00)
Marital status	
Married	43 (86.00)
Single	7 (14.00)
Type of job	
Employed	20 (40.00)
Housewife	19 (38.00)
Unemployed/retired	11 (22.00)
Level of education	
Illiterate	9 (18.00)
Lower than diploma	25 (50.00)
Diploma	9 (18.00)

Academic	7 (14.00)
Underlying diseases (Yes)	
Ischemic heart disease	4 (8.00)
Hypertension	20 (40.00)
Diabetes	11 (22.00)
Dyslipidemia	13 (26.00)
Thyroid dysfunction	13 (26.00)
Anemia	5 (10.00)
Psychological disorders	9 (18.00)
Others[1]	5 (10.00)
Type of cancer	
Colorectal	32 (64.00)
Gastric	8 (16.00)
Others [2]	10 (20.00)
Metastatic organs (Yes)	
Lymph	3 (6.00)
Lung	8 (16.00)
Liver	15 (30.00)
Type of medication (Yes)	
Psychotropic	15 (30.00)
Anti-reflux	27 (54.00)
Cardiovascular agents	32 (64.00)
Anti-diabetics agents	9 (18.00)
Anti-thyroid drugs	14 (28.00)
Others[3]	15 (30.00)

[1] such as seizure, Parkinson, benign prostatic hyperplasia, and rheumatoid arthritis

[2] such as Uterus, breast, thyroid, leiomyosarcoma, osteosarcoma, neck sarcoma, and acute myeloid leukemia

[3] such as supplements, prednisolone, and Tamsulosin

The mean age of participants was 56.52 ± 11.81 years.

Face and content validity

Face validity**:** According to the opinion of the 20 participants, none of the items were ambiguous and had a relatively good ease of answering.

Content validity**:** According to the results of **Table 2**, the evaluation of content validity of the entire scale (S-CVI) for each item has a score higher than 0.78, which means that each item is approved. On the other hand, regarding the content validity ratio (CVR) score, according to the Lawshe table, considering the panel of 7 experts, the score of all the items was above 0.99 and no question had the condition of leaving the review **(Table 2)**.

Table 2. The relevancy, simplicity, clarity, CVI, and CVR for the Persian version of the Patient Satisfaction Survey for Comprehensive Medication Management (CMM)

Item	Relevancy	Simplicity	Clarity	S-CVI for each item	CVR	Decision
Q1	0.85	0.85	0.85	0.85	1	Accept
Q2	1	0.85	1	0.95	1	Accept
Q3	1	1	1	1	1	Accept
Q4	1	1	0.85	0.95	1	Accept
Q5	0.85	1	1	0.95	1	Accept
Q6	1	0.85	1	0.95	1	Accept
Q7	0.85	0.71	1	0.85	1	Accept
Q8	1	1	1	1	1	Accept
Q9	1	1	1	1	1	Accept
Q10	1	1	1	1	1	Accept

Factor analysis

Construct validity results: According to the results of the sampling adequacy test (KMO) regarding the 10-question CMM questionnaire, the value of the index was estimated as 0.66 (greater than the standard limit (0.6)), which indicates the appropriateness of the determined sample size for factor analysis. Also, the result of Bartlett's test of sphericity is statistically significant, which means there is a significant relationship between variables (questionnaire items) ($\chi 2 = 249.799$, P-Value<0.001). According to the results of factor analysis, the three components that have eigenvalues greater than one estimate only 70.62% of the total variance **(Table 3)**.

Table 3. The total variance explained results for the Persian version of the Patient Satisfaction Survey for Comprehensive Medication Management (CMM)

	Initial eigenvalues			Extraction sums of squared loading			Rotation sums of squared loading		
Item	**Total**	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**	**Total**	**% of Variance**	**Cumulative %**
Q1	4.216	42.155	42.155	4.216	42.155	42.155	3.518	35.177	35.177
Q2	1.748	17.484	59.639	1.748	17.484	59.639	2.435	24.347	59.524
Q3	1.099	10.985	70.625	1.099	10.985	70.625	1.110	11.101	**70.625**
Q4	0.940	9.399	80.024						
Q5	0.575	5.751	85.775						
Q6	0.511	5.111	90.885						
Q7	0.381	3.812	94.698						
Q8	0.244	2.445	97.142						
Q9	0.189	1.895	99.037						

Q10	0.096	0.963	100.00

The Scree plot shows the eigenvalue in each of the extracted components, which starts from the largest eigenvalue and its trend is always downward. The eigenvalue of the fourth factor is less than 1 **(Figure 1)**.

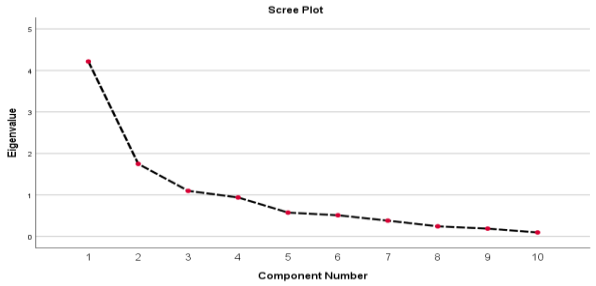

Figure 1. The rock diagram (pebble) of the eigenvalue

According to the results of **Table 4**, a total of 50 people participated in the reliability check of this questionnaire and there was no missing data among the answers. After checking the reliability of the 10-question questionnaire, the value of Cronbach's alpha was 84%, which indicates that the questionnaire has relatively favorable reliability. According to the examination of each question, it can be seen that each question has a relatively favorable correlation with other questions, and by removing each question, the variance has not changed significantly, nor has there been a significant change in the increase of Cronbach's alpha by removing the questions. Therefore, it can be concluded that there is no need to remove a specific question and all questions have a good connection. **(Table 4)**

Table 4. Corrected item-to-total correlation and Cronbach's alpha (α) of the Persian version of the Patient Satisfaction Survey for Comprehensive Medication Management (CMM)

Items	Responses	N (%)	Scale mean if the item deleted	Scale variance if item Deleted	Corrected item-total correlation	α if the item deleted	Total Cronbach's alpha for 10 items
Q1	Strongly disagree	0 (0.00)	34.04	6.121	0.540	0.827	0.840
	Disagree	2 (4.00)					
	Agree	11 (22.00)					
	Strongly agree	37 (74.00)					
Q2	Strongly disagree	0 (0.00)	34.00	6.449	0.479	0.832	
	Disagree	1 (2.00)					
	Agree	11 (22.00)					
	Strongly agree	38 (76.00)					
Q3	Strongly disagree	0 (0.00)	33.88	6.965	0.423	0.835	
	Disagree	0 (0.00)					
	Agree	7 (14.00)					
	Strongly agree	43 (86.00)					
Q4	Strongly disagree	0 (0.00)	33.98	6.632	0.473	0.831	
	Disagree	0 (0.00)					
	Agree	12 (24.00)					
	Strongly agree	38 (76.00)					
Q5	Strongly disagree	0 (0.00)	33.98	6.551	0.513	0.827	
	Disagree	0 (0.00)					
	Agree	12 (24.00)					
	Strongly agree	38 (76.00)					
Q6	Strongly disagree	0 (0.00)	33.90	6.949	0.401	0.837	
	Disagree	0 (0.00)					
	Agree	8 (16.00)					
	Strongly agree	42 (84.00)					
Q7	Strongly disagree	0 (0.00)	33.98	6.306	0.636	0.816	
	Disagree	0 (0.00)					
	Agree	12 (24.00)					
	Strongly agree	38 (76.00)					
Q8	Strongly disagree	0 (0.00)	34.04	5.917	0.691	0.809	
	Disagree	1 (2.00)					
	Agree	13 (26.00)					
	Strongly agree	36 (72.00)					
Q9	Strongly disagree	0 (0.00)	33.96	6.447	0.587	0.821	
	Disagree	0 (0.00)					
	Agree	11 (22.00)					
	Strongly agree	39 (78.00)					
Q10	Poor	0 (0.00)	33.90	6.541	0.629	0.819	
	Faire	0 (0.00)					
	Good	0 (0.00)					
	Very good	8 (16.00)					
	Excellent	42 (84.00)					

Limitations

Our study, while offering valuable insights, has several limitations that should be considered when interpreting the results. Firstly, being a single-center study, the findings might not be generalizable to other institutions or broader regions. The cross-sectional design captures data at one specific point in time, preventing us from observing changes or trends over extended periods. With a sample size of 50 surveys, the results, though indicative, might have been more robust with a larger and more diverse participant pool. Relying on patient-reported outcomes introduces the potential for recall and social desirability biases. Additionally, while the aim was to validate the Persian version of the patient satisfaction survey, there might be cultural or linguistic nuances that the study did not fully account for. The specific inclusion criteria, focusing on certain patient demographics, might have introduced a selection bias. Lastly, without a comparison group using the original version of the

survey, we lack a direct benchmark for understanding potential discrepancies or similarities in patient responses.

This study was aimed at Validation of the Persian Version of the 10-Item Jean Moon Questionnaire in Iranian patients by Comprehensive Medication Management. The validity and reliability of variables were evaluated. Since the CVR, CVI, and impact scores of all items of the translated questionnaire were above the defined criteria, their content and face validity were confirmed. Furthermore, the internal consistency and reliability of the Persian version of the 10-Item Jean Moon Questionnaire like the original English version were good.

Due to several searches among multiple references, it's been found that the questionnaire was conducted only in the USA and subsequently by this research in Iran.

According to the results, the evaluation of content validity of the entire scale (S-CVI) for each item has a score higher than 0.78, which means that each item is approved and no question had the condition of leaving the review.

After checking the reliability of the 10-question questionnaire, the value of Cronbach's alpha was 0.84, which indicates that the questionnaire has relatively favorable reliability. In the English version (USA) the single factor Cronbach's alpha of two separate surveys was 0.95 and 0.96 [6]. It shows that the English questionnaire has more reliability but the value of the Persian questionnaire is acceptable.

In the English version, The Kaiser-Meyer-Olkin measure for sample adequacy for two different health services was 0.87 and 0.93. Principal component factor analysis (PCA) revealed only 1 factor and accounted for 66.4% of the variance in the first survey (eigenvalue=6.6) and 69.3% in the second survey (eigenvalue=6.9). No other components had eigenvalues>1. In addition, the scree plot showed a break after the first factor for both surveys. All 10 items were loaded to the first factor, with a loading greater than 0.75 for the first and 0.76 for the second. The revealed factor was labeled "patient satisfaction," and the single factor Cronbach's alpha of the first survey was 0.95, and the second survey was 0.96.

For evaluating the Construct validity results of the Persian version, according to the results of the sampling adequacy test (KMO), the value of the index was estimated as 0.66 (greater than the standard limit (0.6)), which indicates the appropriateness of the determined sample size for factor analysis. Also, the result of Bartlett's test of sphericity is statistically significant, which means there is a significant relationship between variables (questionnaire items) ($\chi 2 = 249.799$, P-Value<0.001).

Regarding the difference between English and Persian questionnaires the (KMO) value of the English one is better but the three components of the Persian one because of its component's alignment, can describe it better [6].

According to the results of factor analysis, the three components that have eigenvalues greater than one estimate only 70.62% of the total variance. Due to the basic and rotated Component Matrix, we can assume three components can explain 70.62% of the total variance and components had eigenvalues greater than 1. So, we can propose below titles for them:

Sense of comfort and confidence which derived from questions 4,7,8,9,10

The practical procedure derived from questions 1,2,6

Optimization which derived from questions 3 and 5

The scree plot shows the eigenvalue in each of the extracted components and almost it's values difference began from first to third component. Totally, all items above indicate despite one component that identified for English version which labeled "patient satisfaction", the Persian version has three components with the proposed labels "Sense of comfort and confidence", "Practical procedure" and "Optimization".

Conclusion

"Considering all the above explanations, it can be concluded that the Persian questionnaire has sufficient validity and reliability to be carried out. Although the values obtained from the Cronbach's alpha and KMO tests are lower than the English version, this amount can be ignored and it can be used. Additionally, in consideration of the differences between Iran and the United States health service systems, the difference in the number of components can be considered acceptable to help researchers more in interpreting the results."

Acknowledgments: None

Conflict of interest: None

Financial support: None

Ethics statement: None

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