Adaptation of the Treatment Satisfaction with Medicines Questionnaire (SATMED-Q) to Indonesian for Chronic Diseases Patients

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ABSTRACT

Background: National data indicate an increase in chronic disease prevalence. Therapeutic outcomes need to be assessed based on the aspects of the patient's psychology, including treatment satisfaction. In Indonesia, no native or cross-culturally adapted treatment satisfaction tool is available and validated for chronic disease patients. **Objectives:** The study is intended to conduct cross-cultural translation and adaptation of the Treatment Satisfaction with Medicines Questionnaire (SATMED-Q) into Indonesian and to evaluate the questionnaire's reliability and validity in the Indonesian context.

Methods: SATMED-Q translation and adaptation were conducted following a systematic procedure: forward translation, synthesis, backward translation, expert committee review, and pre-testing. The samples were hypertension and type 2 diabetes mellitus patients at the primary health care center. The internal consistency and knowngroup validity were analyzed statistically.

Results: A total of 45 participants were involved in the research to assess the reliability and validity of the translated questionnaire. Some grammatical changes were made on the forward translation, the back translation, and the expert committee review stage. The major changes were the definition of the Likert-type scale on each domain. The reliability test showed good consistency (Cronbach's alpha=0.842). Certain factors (gender and working status) showed known group validity, but not the number of antihypertensive or antidiabetic medications. Compared to individuals who took two medications, people who took one medicine indicated less satisfaction with their treatment

Conclusion: The translation and cross-cultural adaptation of the SATMED-Q to Indonesian was satisfactory. The Indonesian version of SATMED-Q was a reliable and valid instrument to assess treatment satisfaction.

Keywords: Chronic diseases; Cross-cultural adaptation; SATMED-Q; Treatment satisfaction

INTRODUCTION

World Health Organization (WHO) stated that in 2016, non-communicable diseases became one of the leading causes of death worldwide (around 71%), and most cases (around 80%) occurred in developing countries. Around 35% of them are due to heart and blood vessel disease, 12% due to cancer disease, and 6% due to diabetes disease. National Basic Health Research (Riset Kesehatan Dasar) 2018 data showed an increase in the prevalence of chronic diseases such as hypertension (from 25.8% to 34.1%), stroke (7 to 10.9 per mil), diabetes mellitus (6.9% to 10.9%), and chronic kidney disease (2.0 to 3.8 per mil).

Chronic disease prevalence and progression increase the cost of therapy.^{1–3} Many studies state the urgency of chronic disease management to maintain health, prevent complications, and achieve therapeutic

outcomes.⁴ Therapeutic outcomes need to be assessed from aspects of the patient's psychology, including treatment satisfaction. Good therapy management for chronic illness results in improved health outcomes, a lower cost of care, and higher patient satisfaction.³

Instruments are needed to assess treatment satisfaction in chronic disease patients. Some treatment satisfaction instruments have been developed, such as the Diabetes Treatment Satisfaction Questionnaire (DTSQ), SATMED-Q, and Treatment Satisfaction Questionnaire for Medication (TSQM). TSQM has been widely used to assess treatment satisfaction in many studies. ^{5,6} SATMED-Q is officially distributed by MAPI Research Trust. Many studies showed that the SATMED-Q in English is useful. ^{7,8} Research that compares the TSQM and SATMED-Q questionnaires states that compliance is associated with patient treatment satisfaction, either with the SATMED-Q or the TSQM. These two generic tools could be used to assess patients' treatment satisfaction. ⁹

In Indonesia, no native or cross-culturally adapted treatment satisfaction tool is available and validated to measure the treatment satisfaction of chronic disease patients. Cultural differences in perceptions of therapy and disease make this instrument should be translated and adapted systematically to be used in Indonesia.

The objectives of this research were to conduct a cross-cultural translation and adaptation of the SATMED-Q to Indonesian and to evaluate the reliability and validity of the pre-final questionnaire in a pre-test.

METHODS

Study design

The SATMED-Q translation and cross-cultural adaptation followed a systematic and standard guideline that consisted of five steps: forward translation, synthesis, back-translation, expert committee review, and pretesting. To complete the direct/forward translation of questionnaire items, two independent and professional bilingual translators (in Indonesian) were chosen. One translator had a medical background, while the other had no previous knowledge about treatment or medication. They were provided with general instructions to confirm a similar questionnaire translation. The synthesis process was done by comparing the translated questionnaires to obtain a common Indonesian version. Discussion between translators and research team members was needed to reach a consensus when differences (discrepancies) were found. A synthesis questionnaire was arranged and documented. The synthesis questionnaire was arranged and documented.

The backward translation stage was performed by two different professional bilingual translators (in their native language). Both translators worked independently, had no medical background, and were unaware of the original English version to minimize bias. The back-translation questionnaire was then discussed by the translator and research team members A consistent translation is ensured via the back translation procedure. This is a validity checking procedure to ensure that the translated version accurately reflects the content of the source items. ¹⁰ An expert committee was chosen to combine all the translated versions into a prefinal questionnaire. The multidisciplinary expert committee consisted of a methodologist, language professional, translators, clinical psychologist, and health professionals (pharmacist and medical doctor). The committee identifies discrepancies between the translated and original versions of SATMED-Q and then discusses them. The discussion was mainly about idiomatic, semantic, and conceptual equivalences. Consensus was attained on a pre-final version of the SATMED-Q adapted to Indonesian. ¹⁰

A pre-test stage was performed to evaluate the equivalence, understandability, comprehensibility, and applicability of the translated version in the Indonesian context. After completing the question items in the questionnaire, the research team members conducted a short interview with each participant. The participants were asked several questions about the clarity and understandability of the instructions and question items, the usefulness of the questionnaire, their opinion about the duration of filling the questionnaire, the completeness of the questionnaire, and their suggestions for the questionnaire. All data then were discussed, and decisions were made on whether it was necessary to make changes to the questionnaire. The length of the questionnaire completion and interview was about 15-30 minutes per respondent.

Population and samples

The population of this study were hypertension and type 2 diabetes mellitus patients at primary health care centers. The samples of this study were hypertension and type 2 diabetes mellitus patients at primary health care centers who met the inclusion criteria. The inclusion criteria were patients aged \geq 18 years, the presence of chronic disease (hypertension or diabetes mellitus), able to read, able to communicate in the Indonesian language, and willing to be a research respondent by signing an informed consent. The exclusion criteria were patients with mental illness. Around forty people should ideally be tested. A total of 45 respondents (22 hypertension patients and 23 diabetes mellitus patients) participating in the chronic disease management

program (prolanis program) in the primary health care center in Jakarta were involved in the study. Patients were offered the chance to take part in the study during routine (monthly) prolanis meetings.

Study instruments

SATMED-Q was designed to assess treatment satisfaction in patients with chronic diseases receiving pharmacological therapy. The questionnaire comprises 17-item questions with six aspects: treatment effectiveness, undesirable side effects, the convenience of use, impact on daily activities, medical care, and global satisfaction, each of 3 questions except for the medical care dimension as many as 2 questions. Response options vary on a Likert-type scale (0 means not at all, 1 means a little bit, 2 means somewhat, 3 means quite a bit, 4 means very much). Item scoring reversion was found in the "undesirable side effects" dimension, with a "not at all" score was $4.^{11}$

The highest score was 68. A higher score means higher satisfaction with treatment. The score can be transformed to 0-100, using a formula¹¹:

$$Y' = \frac{(Yobs - Ymin)}{(Ymax - Ymin)} x 100 = Yobs x 1.471$$

Ymax = max score (68); Ymin = min score (0); Yobs = patient's score; Y' = transformed score

Unidimensional scales were correlated (Cronbach's alpha 0.813-0.912). SATMED-Q dimensions indicated significant but moderate correlations with TSQM dimensions (ranging from 0.577 to 0.680). Permission to perform language adaptation and to use the SATMED-Q attained from MAPI Research Trust.

Data collection

The sampling method used was consecutive sampling. All subjects who met the inclusion criteria were included in the study until the required number of subjects was met. Patients who met the inclusion criteria were asked to complete the adapted version of the questionnaire (result from the expert committee review) and to answer questions in the interview. All data then were discussed, and decisions were made on whether it was necessary to make changes to the questionnaire.

Data analysis

The clarity and understandability of the instructions and question items, the usefulness of the questionnaire, their opinion about the duration to fill the questionnaire, and the completeness of the questionnaire, were analyzed descriptively to obtain the percentage of frequency distribution.

Reliability is defined as the consistency and repeatability of a method in measuring something. It is considered reliable if consistent results can be attained by applying the same methodology under similar conditions and across time. Reliability refers to the stability, consistency, and repeatability of results in quantitative studies. The type of reliability test being used was internal consistency reliability, which was assessed using Cronbach's alpha. The coefficient of reliability ranges from 0 to 1 (perfect reliability is represented as 1). 13,14 A questionnaire is considered to be reliable if Cronbach's alpha is > 0.7. $^{13-15}$

Validity is often defined as the degree to which an instrument measures what it is intended to measure. Validity tests are divided into four: content validity, face validity, construct validity, and criterion validity. ¹³ When a test or questionnaire can distinguish between two groups that are known to differ on the relevant measure, it is said to possess known-groups validity, a form of construct validity. ¹⁶

RESULTS AND DISCUSSION

Translation and cross-cultural adaptation

The forward translation was performed without major difficulty. Based on Table I some diction issues were found in both translations, such as in title (treatment), in Likert-type scale (a little bit, somewhat, quite a bit, very much), in section 2 (the effectiveness of the medication), in question item number 4, in question item number 5, in question item number 6, in section 3 (the ease of use the medication), in question item number 7, in question item number 8, in question item number 9, in section 4 (medication's impact), in question item number 10, in question item number 11, in question item number 12, in question item number 14 (the right way), in item number 16 (treatment), and in item number 17 (treatment). The research team members then formulated the diction and discussed the items with the translator in more detail. The translator approves the changes compiled by the researchers. Furthermore, the agreed term to be changed was in section 2 (relieve,

Table I. The grammatical changes in the translation process

Section	Original version	The agreed version
The forward translation		
Title	Medicine treatment satisfaction	Kepuasan penggunaan obat
Likert-type scale	a little bit, somewhat, quite a bit, very much	Sedikit, kadang-kadang, cukup, sangat
Section 2 (medicine	Its capacity to treat your condition and	Yaitu kemampuannya mengobati
effectiveness)	relieve your symptoms	kondisi Anda dan meringankan gejala
Question item number 4	The medicine I am taking relieves my symptoms	Obat yang saya minum meredakan gejala saya
Question item number 5	I am satisfied with the time it takes for the medicine to start to work	Saya puas dengan waktu yang diperlukan obat sampai mulai berefek
Question item number 6	I feel better now than I did before starting the treatment	Sekarang saya merasa lebih baik daripada sebelum menggunakan obat
Section 3 (the ease of use	The convenience and ease of use of the	Kenyamanan dan kemudahan
the medication)	medicine	penggunaan obat
Question item number 7	I find that taking my medicine is practical for me	Saya merasa penggunaan obat ini praktis
Question item number 8	I find it easy to use/take the medicine in its present form (taste, size, etc.)	Saya merasa mudah menggunakan obat dengan bentuk yang sekarang (rasa, ukuran, dll.)
Question item number 9	The timetable for taking the medicine suits me	Saya merasa cocok dengan jadwal penggunaan obat
Section 4 (medication's impact)	The impact of the medicine	Dampak obat
Question item number 10	Thanks to the medicine I am taking, it is easier for me to do my leisure and free time activities	Saya lebih mudah melakukan kegiatan di waktu luang dan waktu santai setelah menggunakan obat ini
Question item number 11	Thanks to my medicine, it is easier for me to take care of my personal hygiene	Saya lebih mudah menjaga kebersihan diri setelah menggunakan obat ini
Question item number 12	Thanks to my medicine, it is easier for me to perform my daily activities	Saya lebih mudah melakukan kegiatan sehari-hari saya setelah menggunakan obat ini
Question item number 14	My doctor has informed me about the right way to treat my medical condition	Dokter telah memberitahukan cara yang tepat untuk mengobati kondisi medis saya
Question item number 16	I feel comfortable with my treatment	Saya merasa nyaman dengan pengobatan saya
Question item number 17	In general, I feel satisfied with the treatment	Secara umum, saya merasa puas dengan pengobatan ini
The expert committee revie	w	
The Likert-type scale on	0= not at all, 1= a little bit, 2=	Tidak sama sekali, sedikit, kadang-
the domain "undesirable	somewhat, 3= quite a bit, 4= very much	kadang, cukup, sangat
side effects" and	•	- · · · · ·
"treatment effectiveness"		
The Likert-type scale on	0= not at all, 1= a little bit, 2=	Sangat tidak setuju, tidak setuju, netral,
the domain "convenience	somewhat, 3= quite a bit, 4= very much	setuju, dan sangat setuju
of use", "impact on daily	, , , , , , , , , , , , , , , , , , , ,	, , <u> </u>
activities", and "global satisfaction"		
The Likert-type scale on	0= not at all, 1= a little bit, 2=	Tidak pernah, jarang, kadang-kadang,
the domain "medical care"	somewhat, 3= quite a bit, 4= very much	sering, selalu

translated as "meringankan"). The detailed grammatical changes are presented in Table I. On the back translation process, researchers and translators ensure that there are no differences in meaning between the synthesis results and the original version in English. To obtain a comprehensive and understandable questionnaire, some minor changes were made due to linguistic problems and cultural differences. It was important to make some adjustments to the wording both on the instructions and the question items, considering the Indonesian language and culture. These translation and adaptation challenges should be carefully confronted to confirm the equivalence of the questionnaire. 17–19

The expert committee consists of 7 persons (1 methodologist, 1 language professional, 2 translators, 1 clinical psychologist, 1 pharmacist, and 1 medical doctor). Before the discussion, the expert committee was given the original and translated versions of SATMED-Q. Alterations were made and documented during the discussion. Major changes from this stage were the definition of the Likert-type scale on each domain (0= not at all, 1= a little bit, 2= somewhat, 3= quite a bit, 4= very much), which on domain "undesirable side effects" and "treatment effectiveness" become "tidak sama sekali, sedikit, kadang-kadang, cukup, sangat" sequentially, while on domain "convenience of use", "impact on daily activities", and "global satisfaction" become "sangat tidak setuju, tidak setuju, netral, setuju, dan sangat setuju", and on domain "medical care" become "tidak pernah, jarang, kadang-kadang, sering, selalu". After discussion, the revised document was sent to the expert committee and then asked to be checked by the experts. Some experts made corrections to the questionnaire. The pre-final document is then signed by the expert committee.

The translated version of SATMED-Q in Indonesian (pre-final document) was administered to 45 respondents in a primary health care center in Jakarta. The patient's characteristics (socio-demographic and clinical) are described in Table II.

Based on Table II, most of the respondents were female (73.3%) with a mean of age 57.9 (SD 9.8) years. Many patients had a low-middle level of education (75.6%), didn't work (53.3%), the common diagnosis was diabetes mellitus (51.1%) with a duration of disease less than 5 years (60.0%), had comorbidity/complications (53.3%), and single-use of antihypertension/antidiabetic drugs (55.6%). Unfortunately, many respondents (64.4%) still cannot manage the disease (uncontrolled blood pressure/fasting blood glucose).

Table III presented the clarity and understandability of the instructions and question items, the usefulness of the questionnaire, their opinion about the duration of filling the questionnaire, and the completeness of the questionnaire based on the pre-test stage.

As seen in Table III most participants understand the instructions and the question items of the questionnaire. Two respondents (4.4%) reported question number 5 was ambiguous, besides, one respondent (2.2%) stated that question number 1 was not clear.

Although three participants experienced difficulties in answering question items number 1 and 5, the research team members decided not to change the diction of the questionnaire (question number 1 translated as "efek samping obat mengganggu aktivitas fisik saya", question number 5 translated as "saya puas dengan waktu yang diperlukan obat sampai mengatasi keluhan") since only a little number of respondents (2-4%) that not clearly understand in 1 question (of 17 questions). Question number 5 has been reformulated from the stages of forward translation, back translation, and expert committee review.

The survey found that 91.1% of respondents stated the questionnaire is useful. In their opinion, the questionnaire provides information on how satisfied they are with the current treatment. A treatment satisfaction questionnaire can be used as a tool to identify what factors interfere with a patient's medication adherence. Unfortunately, 8.9% of respondents who didn't find the SATMED-Q useful, didn't report the reason behind the answer.

All patients answered all questions, this response rate is satisfactory. Most of the respondents (80.0%) were satisfied with the duration of completing the questionnaire. Based on respondents, the duration of completing the questionnaire is not too long, making it practicable to be applied in any health service facility, such as in a primary health care center where a patient's available time is limited. All respondents (100.0%) reported that the questionnaire was complete. However, some respondents suggest that the number of questions should be reduced.

Reliability test

Internal consistency reliability was used in this study. The Cronbach's alpha value of the Indonesian version of SATMED-Q was 0.842 for the total scale, which indicates good consistency. Cronbach's alpha value above 0.7 is considered good reliability.^{20,21} The SATMED-Q is considered one of the instruments suitable to assess treatment satisfaction in chronic disease patients since similar results found in some research conducted

Table II The patient's characteristics (socio-demographic and clinical)

Parameter	N (%)	
Age		
< 60 years	24 (53.3)	
≥ 60 years	21 (46.7)	
Mean ±SD	57.9 ± 9.8	
Gender		
Male	12 (26.7)	
Female	33 (73.3)	
Level of Education		
Low-middle (elementary-high school)	34 (75.6)	
High (diploma-college)	11 (24.4)	
Working status		
Not working	24 (53.3)	
Working	21 (46.7)	
Diagnose		
Hypertension	22 (48.9)	
Diabetes Mellitus	23 (51.1)	
The presence of comorbid/complications		
Without comorbid/complications	21 (46.7)	
With comorbid/complications	24 (53.3)	
Duration of disease		
< 5 years	27 (60.0)	
≥ 5 years	18 (40.0)	
Blood pressure/fasting blood glucose		
Uncontrolled	29 (64.4)	
Controlled	16 (35.6)	
Number of antihypertension/antidiabetic drugs		
1	25 (55.6)	
2	18 (40.0)	
3	2 (4.4)	

in chronic disease patients such as diabetes mellitus and hypertension stated that the SATMED-Q indicated good consistency and reliability (>0.87, 0.916, 0.879, and 0.847 respectively). 7,9,12,22

Validity test

Known-group validity was used to assess construct validity in this study. Known-group validity was found in 4 domains, i.e.: gender, working status, diagnosis, and number of antihypertension/antidiabetic drugs (p <0.05). Certain factors (gender and working status) showed known group validity, but not the number of antihypertensive/antidiabetic medications. Compared to individuals who took two medications, people who took one medicine indicated less satisfaction with their treatment.

Research shows that women were more satisfied with the therapy they were undergoing. This result was different from other research which states that women were more dissatisfied with the therapy they received. A study confirmed that there were gender differences in the clinical response to and perception of both disease and treatments between men and women, adding to the numerous gender post hoc analyses of the Meta-GeM project, an Italian gender medicine program that has evaluated gender differences in several observational real-life studies. This suggests again that gender attention may be necessary to provide tailored therapeutic options. ²³

According to a study, having no job was linked to noticeably poorer treatment satisfaction scores.²⁴ These results were contradictory to this study (unemployed expressed higher treatment satisfaction). The possibility was that most respondents in this study were elderly patients who participated in the chronic disease management program (prolanis program) where patients regularly participated in activities at the community

Table III The pre-test stage results

Topic	N (%)
The clarity and understandability of the instructions and question	items
Instructions	45 (100.0)
Question number 1	44 (97.8)
Question number 2	45 (100.0)
Question number 3	45 (100.0)
Question number 4	45 (100.0)
Question number 5	43 (95.6)
Question number 6	45 (100.0)
Question number 7	45 (100.0)
Question number 8	45 (100.0)
Question number 9	45 (100.0)
Question number 10	45 (100.0)
Question number 11	45 (100.0)
Question number 12	45 (100.0)
Question number 13	45 (100.0)
Question number 14	45 (100.0)
Question number 15	45 (100.0)
Question number 16	45 (100.0)
Question number 17	45 (100.0)
The usefulness of the questionnaire	
Useful	41 (91.1)
Not useful	4 (8.9)
The duration to fill out the questionnaire	
Appropriate	36 (80.0)
Not appropriate (too long)	9 (20.0)
The completeness of the questionnaire	
Complete	45 (100.0)
Incomplete	0 (0.0)

health center and received education from health workers which then contributed positively to therapeutic outcomes to improve the patient's quality of life.

This research indicated that diabetes mellitus patients were more satisfied with their treatment than hypertension patients. This result was in contrast with the research that assessed treatment satisfaction in patients with diabetes, arterial hypertension, and heart failure. Based on that study, diabetes mellitus patients were less satisfied than hypertension patients (SATMED-Q total scores were 73.81 and 76.1 respectively).⁷ Another study found that in the patients who were not satisfied with the treatment, the number of daily insulin injections was noticeably higher.²⁵ Data in this study showed that all patients used oral antidiabetic drugs (without the use of insulin). This was most likely what caused the level of treatment satisfaction in diabetes mellitus patients to be high.

The number of antihypertension/antidiabetic drugs affects treatment satisfaction. Some research stated that a large amount of medication had significantly lower treatment satisfaction. ^{26,27} This is in line with this research result on patients using 3 drugs, which has the lowest score of treatment satisfaction. The older age group was disproportionately affected by polypharmacy, which can result in poor adherence, prescription errors, drug interactions, and avoidable adverse drug events (ADEs), which can cause a variety of issues. An ADE is a side effect that regular medication dosages might have that raises morbidity and mortality. It has significant financial ramifications as well. ²⁸ Unique findings were found in patients with 2 drugs, where treatment satisfaction was higher than patients with 1 drug.

Based on research conducted in hypertension, type 2 diabetes mellitus, and heart failure patients, noteworthy (p < 0.05) independent variables that raised the SATMED-Q score and, consequently, improved treatment satisfaction were age, medication adherence, level of education, 7 and perceived medication

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effectiveness.²⁹ The question items in the questionnaire were on 6 domains: treatment effectiveness, undesirable side effects, convenience of use, impact on daily activities, medical care, and global satisfaction. Treatment effectiveness, convenience of use, and impact on daily activities will increase medication adherence, while undesirable side effects will decrease medication adherence. Treatment effectiveness will increase perceived medication effectiveness.

The limitation of this study is only two chronic diseases are included (hypertension and diabetes mellitus). A more heterogeneous disease, a larger number of samples, and detailed psychometric properties are needed to generalize the results better.

CONCLUSION

The cross-cultural adaptation and translation process of the SATMED-Q to Indonesian was performed successfully. The Indonesian version of SATMED-Q was a reliable and valid instrument to assess treatment satisfaction.

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STATEMENT OF ETHICS

The study obtained research ethical approval from the UHAMKA health research ethics committee (protocol number: 03/23.02/02308), dated February 27th, 2023.

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

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