# Treatment Satisfaction Questionnaire for Medication: Validation of the Translated Arabic Version among Patients Undergoing Warfarin Therapy in Saudi Arabia

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A B S T R A C T

**Objectives:** To validate the psychometric properties of the translated Arabic version of the Treatment Satisfaction Questionnaire for Medication (TSQM 1.4) for patients on warfarin therapy in Saudi anticoagulation clinics (ACCs). **Methods:** A cross-sectional survey was conducted at the Security Forces Hospital ACC in Riyadh, Saudi Arabia. It involved administering questionnaires related to patients' satisfaction and assessing adherence through interviews. The quality of the international normalized ratio control was assessed using the Rosendaal method. A psychometric evaluation of TSQM 1.4 was carried out, addressing internal consistency and known-groups and convergent validity. **Results:** A total of 101 patients completed the questionnaire with an 80% response rate. The independent Cronbach α values for the effectiveness, side effects, and global satisfaction domains were consistently higher than 0.75, demonstrating good internal consistency and suitability of these domains for application in the current patients' setting. When these domains were used together in a multivariable logistic regression model of adherence, the only domain that remained significant was TSQM effectiveness ($P = 0.017$). Interestingly, a higher likelihood of moderate to optimal international normalized ratio control was significantly and independently associated with increased satisfaction scores in the effectiveness and convenience domains, but not in the side effects and global satisfaction domains. **Conclusions:** This study provides evidence in favor of the reliability and validity of the Arabic version of TSQM 1.4 as a useful measure of satisfaction with anticoagulant therapy in patients visiting ACCs. The TSQM subscales in this patient setting seem to detect a clinically meaningful change over time, enhancing the potential of their use in routine practice.

Keywords: anticoagulants, clinical outcomes, patient-reported outcomes, Saudi Arabia, treatment satisfaction, warfarin.

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## Introduction

Vitamin K antagonists, or coumarin anticoagulants, including warfarin, have been used to treat thromboembolic disorders since the 1950s [1]. Despite the development of new alternatives—such as specific thrombin inhibitors such as dabigatran and rivaroxaban—warfarin therapy is still widely prescribed, for both newly diagnosed and long-term patients, particularly in low-income countries, because of its documented cost effectiveness [2,3].

Nevertheless, warfarin use is complicated by issues such as high interindividual variability caused by genetics, comorbid conditions, lifestyle, and diet. Currently, most clinical practice guidelines recommend beginning with a standard dose based on traditional warfarin-dosing protocols, which requires frequent monitoring of the coagulation rate using the international normalized ratio (INR) until the required coagulation rate is obtained [4–7]. It is, therefore, essential for health care services to provide high-quality anticoagulant education and monitoring to increase patients' adherence to and satisfaction with the therapy.

Previously, patients visiting a physician were referred to a laboratory for testing and then asked to return to the physician to complete the treatment cycle [8]. In the 1970s, however, anticoagulant clinics (ACCs) were established in the United States, and, currently, more than 1500 ACCs exist globally. Pharmacist-led ACCs have been shown to improve patient outcomes, increase safety, and reduce hospitalization [9,10].

ACCs are an example of a collaborative (patient-caregiver) model in the health care delivery system [11,12]. Therefore, upgrading the quality of health care provided in these clinics is dependent on patient-reported outcomes—particularly the measures reflecting patients' preferences [13].

Patient satisfaction reflects the patients' experiences with medical treatments, and it is essential for clinical research evaluation [14]. Health care economists have focused on satisfaction because of its well-documented impact on patients' future decisions, such as adherence and compliance with their habitual treatment [15]. Estimations may, however, vary, and they are influenced by a broad range of factors, including the nature and severity of disease condition(s), treatment(s) effectiveness, convenience, and impact on general well-being [16]. This has promoted the development and validation of several tools for satisfaction measurement, and some instruments focused on disease- [17,18] or treatment-specific measures of satisfaction [19].

Nevertheless, given the increasing use of long-term treatment for multiple chronic conditions (polypharmacy)—such as by those visiting ACCs—general measures, potentially applicable across a range of illnesses and medications, are required. Several general instruments have been developed to measure satisfaction with medications, with variable psychometric properties [20].

The Treatment Satisfaction Questionnaire for Medication (TSQM) [21] is not a disease-specific tool that permits comparisons across medication types and patient conditions. It was developed on the basis of an initial 55-item conceptual framework of treatment satisfaction grounded in a thorough review of related literature. The refinement process that led to TSQM version 1.4 included both patient focus groups and patient interviews [21]. A psychometric examination used groups of patients with diverse chronic diseases in America (arthritis, asthma, major depression, type 1 diabetes, high cholesterol, hypertension, migraine, and psoriasis). The final version included 14 questions in four domains: effectiveness (3 items), side effects (5 items), convenience (3 items), and global satisfaction (3 items). The TSQM scale was further refined by outpatient pharmacy consumers [22] and online among patients on antihypertensive medications [23]. The adherence outcome is a significant positive consequence of a patient's satisfaction [24]. The concurrent validity testing of TSQM domains provided evidence of correlation with various self-reported adherence indicators [22,23], with the side effects [22] and convenience scores [23] being the strongest predictors of the adherence outcome. The English version of TSQM 1.4 was translated into Arabic and adapted for evaluating treatment satisfaction in various settings, such as diabetes [25], hypertension [26], major depressive disorder [27], and renal transplant [28].

Further review of the literature reveals that many issues related to patients' general satisfaction with pharmacist-led ACCs' services remain under-reported [29–31]. Only a few studies on satisfaction with oral anticoagulant therapy used validated general and specific treatment satisfaction tools [32–35].

Moreover, to our knowledge, no studies in Arabian countries, in particular Saudi Arabia, estimate satisfaction with oral anticoagulants using TSQM or any other measurement scale.

Because validity and reliability evidence may not be generalized to new clinical settings, and the language of the TSQM questionnaire is not the first language of the population under study, researchers collected confirmatory data in their clinic [14]. Therefore, we use the translated Arabic version of the TSQM 1.4 for initial validation.

Three fundamental targets have been identified for the present study:

1. to validate the psychometric properties of the translated Arabic version of the TSQM 1.4 in patients on warfarin therapy in Saudi ACCs;
2. to explore the correlation between satisfaction and the efficacy of the oral anticoagulant drugs in terms of INR control; and

3. to investigate possible patients' demographic characteristics and clinical conditions that could have an impact on treatment satisfaction.

## Methods

### Study Design, Participants, and Setting

A cross-sectional study was conducted in the ACC at the Security Forces Hospital, Riyadh, Saudi Arabia, from June to November 2016. The study population involved patients receiving oral anticoagulants for any clinical indication and those who visited the clinic on a regular basis.

On the basis of the clinic's historical data, we estimated that 200 patients on warfarin therapy sought treatment in the chosen clinic. The calculated sample size was 103 (at 95% confidence level with 5% margin of error). The study procedures were conducted after obtaining the institutional review board approval according to national and local institutions' regulations. Informed written consent was obtained from patients who agreed to participate and were able to read the content included in the study tools. All participants were guaranteed anonymity and informed of the confidentiality of the results.

The study involved administering questionnaires concerned with patient satisfaction and assessing adherence in a face-to-face interview with each patient. The two assessments were administered together on the same day, which took approximately 30 minutes to complete.

Demographic details, patients' medical history, and drug regimens were obtained from the patients' medical records.

### Study Instruments

#### Treatment Satisfaction Questionnaire for Medication
The TSQM 1.4 is a generic and multilingual validated questionnaire developed for different patients and medications [21]. The researchers obtained an academic research license to use the translated Arabic version of the TSQM from Quintiles Strategic Research Services. The TSQM includes four essential domains of satisfaction with medications: effectiveness (items 1–3), side effects (items 4–8), convenience (items 9–11), and global satisfaction (items 12–14). The domain scores were calculated as recommended by the instrument's authors [22,23]. The scores for the domains ranged from 0 (extremely dissatisfied) to 100 (extremely satisfied).

#### Eight-Item Morisky Medication Adherence Scale
Medication adherence was evaluated using an Arabic version of the validated English version of the Eight-Item Morisky Medication Adherence Scale (MMAS-8) [25,36,37], which is a questionnaire with seven "yes or no" questions and one question answered on a five-point Likert scale. According to the scoring system, 8 denotes high adherence, 6 to less than 8 denotes medium adherence, and less than 6 denotes low adherence. Patients with low or medium adherence were considered nonadherent, whereas those with a total score of 8 were considered adherent.

#### INR control measures
All patients' INR readings, recorded in their hospital electronic files after the initiation of their oral anticoagulant therapy, were collected. For each patient, the quality of INR control was quantified by two different indicators: 1) the mean percentage time (in days) in the therapeutic range (TTR) using the Rosendaal method [38] and 2) the percentage of visits for which the INR readings were in the range (INR stability) using the Rose et al.