Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease.

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The objective of this study was to develop and psychometrically evaluate a general measure of patients' satisfaction with medication, the Treatment Satisfaction Questionnaire for Medication (TSQM).

The content and format of 55 initial questions were based on a formal conceptual framework, an extensive literature review, and the input from three patient focus groups. Patient interviews were used to select the most relevant questions for further evaluation (n = 31). The psychometric performance of items and resulting TSQM scales were examined using eight diverse patient groups (arthritis, asthma, major depression, type I diabetes, high cholesterol, hypertension, migraine, and psoriasis) recruited from a national longitudinal panel study of chronic illness (n = 567). Participants were then randomized to complete the test items using one of two alternate scaling methods (Visual Analogue vs. Likert-type).

A factor analysis (principal component extraction with varimax rotation) of specific items revealed three factors (Eigenvalues > 1.7) explaining 75.6% of the total variance; namely Side effects (4 items, 28.4%, Cronbach's Alpha = .87), Effectiveness (3 items, 24.1%, Cronbach's Alpha = .85), and Convenience (3 items, 23.1%, Cronbach's Alpha = .87). A second factor analysis of more generally worded items yielded a Global Satisfaction scale (3 items, Eigenvalue = 2.3, 79.1%, Cronbach's Alpha = .85). The final four scales possessed good psychometric properties, with the Likert-type scaling method performing better than the VAS approach. Significant differences were found on the TSQM by the route of medication administration (oral, injectable, topical, inhalable), level of illness severity, and length of time on medication. Regression analyses using the TSQM scales accounted for 40–60% of variation in patients' ratings of their likelihood to persist with their current medication.

The TSQM is a psychometrically sound and valid measure of the major dimensions of patients' satisfaction with medication. Preliminary evidence suggests that the TSQM may also be a good predictor of patients' medication adherence across different types of medication and patient populations.

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This article reports on the development and testing of the Treatment Satisfaction Questionnaire for Medication (TSQM) and builds on the conceptual framework of Treatment Satisfaction (TS) which is featured in a companion article entitled: "The Development of a Conceptual Framework for Treatment Satisfaction." (a manuscript currently under review). Within this paper, we will begin by reviewing current literature that highlights the clinical importance of TS, as well as some of the measurement challenges facing researchers in this field. This is followed by description of a two-stage TSQM item generation process that included both patient focus groups and patient interviews. The results section presents the analyses used for TSQM scale identification and psychometric testing. These results were based on a large sample of patients enrolled in the NFO World Group's Chronic Ailment Panel (NFO-CAP). Finally, in the discussion section we focus on the psychometric characteristics of the TSQM, the comparative performance of two different methods for item scaling, and the potential uses of TS assessment in clinical settings.

Those advocating collaborative (patient-caregiver) models of health care delivery suggest that patient reported outcomes (PROs), and particularly measures of patient preference, ought to play a central role in the planning and delivery of medical care [

A variety of models have been used to describe how patients' satisfaction with medical treatment impacts their health-related decision-making [

In addition to its impact on treatment outcomes within the clinical setting, TS results have been incorporated into decisions regarding pharmaceutical formularies and cost-effectiveness evaluations of managed care organizations [

Measurement challenges

Unfortunately, across most illness conditions TS and PS research has been consistently hampered by serious measurement problems, including; distributional skew, ceiling effects, and missing response data [

None of these scaling solutions, however, have been shown to wholly resolve the distributional problems associated with the cross-sectional measurement of TS and PS. Yet, there remains a persistent and largely unquestioned assumption that normal distributions of satisfaction scores can be obtained if only the construct were measured correctly. As a result, there are quite a few examples in the literature where patients' satisfaction ratings are suspect of social desirability or acquiescence responses bias [

An alternate mechanism may help explain the skewed distribution of TS-M ratings. Over time, clinical-selection may affect the composition of patient samples (sample drift) and result in a skewed cross-sectional distribution of satisfaction scores. It is hypothesized that such selection occurs over time as patients for whom a medication is working continue to take the medication, while those for whom it is not working, or for whom unpleasant side effects occur, seek alternative treatments. In general, one might expect sample drift to be greatest during the initiation of a new course of medication and, conversely, least when either a satisfactory medication has been found or when treatment alternatives have been exhausted. In the latter case, access to fewer treatment alternatives may be more likely among those with severe and persistent disease. Currently, it is unknown to what extent

these various influences shape the observed distribution of satisfaction results in cross-sectional patient samples.

Rationale for current study

Although numerous disease-specific measures of patients' TS and TS-M have been reported in the literature [

• To develop a conceptually and psychometrically sound general measure of TS-M, capable of assessing patients' satisfaction with various medications designed to treat, control, or prevent a wide variety of medical conditions; and

• To examine the performance of such an instrument with respect to scaling alternatives so as to maximize the precision and validity of the final measure.

Methods & study design

Background item generation

The design of test items for the new instrument was based on a generalized conceptual framework of treatment satisfaction. The initial formation of the conceptual framework was grounded in a thorough review of the scientific literature that dealt with the core TS-M domains across a diversity of therapeutic areas. Subsequently, the draft conceptual framework was more fully elaborated using qualitative data from patient focus group interviews. Focus group participants (n = 30) were recruited to take part in one of three, two-hour sessions conducted in Los Angeles, Chicago, and Boston. Participants consisted of patients with at least one the following illness conditions: asthma, arthritis, cancer, cardiovascular disease, depression/anxiety, diabetes, infectious disease, migraine, and psoriasis. The focus group discussions were guided by a trained interviewer who, in accordance with established qualitative research procedures [

Over the course of the three focus group sessions, the discussion guide and conceptual framework on which it was based, were evolved through integration of the patients' perspectives from each preceding group. In this way the guide was iteratively refined to reflect the participants' perspectives. Once the framework was fully elaborated, the domains of TS-M included; (1) side effects, (2) symptom relief, (3) convenience, (4) effectiveness, (5) impact on daily life, and (6) tolerability/acceptability. Fifty-five draft TS-M items were designed to measure aspects of the conceptual framework and its domains. Further details of the qualitative methods and results can be found in a sister manuscript describing the development of the TS-M conceptual framework.

Initial item reduction and scaling (patient interviews)

In-depth patient interviews were conducted in order to reduce the 55-item pool by approximately half, leaving only those items that were most relevant across respondents. The interview sample consisted of 17 patients taking medication for the same conditions represented by focus group participants. During the 45–60 minute interviews, patients rated the importance or relevance of each item to their

satisfaction with their medication using a 5-point scale (where 1 was most important and 5 was not important at all). These ratings were used to select items that were most relevant across all illness groups. When items were ranked equally, the conceptual framework was used to help assure adequate representation of theoretical dimensions in the framework. The final test item pool contained 31 items.

Two scaling methods, visual analogue scaling (VAS) and Likert-type scaling, were considered for use in the final instrument. In order to compare the relative performance of the two methods, two sets of TSQM items were created that differed only in terms of the rating scale used. For both sets, TSQM items were scaled using either a 5-point or 7-point scale. Five-point scales were used for unidimensional continua (e.g. extremely to not at all), while 7-point scales were used for bipolar continua (e.g., extremely positive to extremely negative). This provided roughly equivalent rating intervals across items. Non-neutral midpoints were used for 7-point scales, resulting in a greater range of positive response options than negative options for these items. This approach has been suggested elsewhere as a way of helping to address scale resolution problems associated with the upper end of skewed distributions [

Psychometric testing and refinement (national panel survey)

The remaining sections of this article describe the reliability and validity characteristics of the test items and scaling methods using a large sample of patients participating in the NFO – World Group's CAP. The NFO CAP consists of over 250,000 people suffering from one or more of over 60 chronic ailments and conditions. The panel is a representative sampling of one out of every 191 households in America, prescreened for more than 50 pieces of demographic information so as to represent the demographic characteristics of the population of the citizenry of the USA (for more information see:

Patients were recruited for this portion of the study that had the same illness conditions as represented within the focus groups and interviews (anxiety/depression, arthritis, asthma, cancer, cardiovascular disease, diabetes, infectious disease, migraine, and psoriasis). They were also required to be at least 18 years of age, able to read English, and able to complete a questionnaire on-line. The broad sampling provided a range of treatment intents (i.e., curative, preventive and symptom management) as well as routes of medication administration (i.e., injection, oral, topical, inhalation).

Invitations were sent electronically to 10,000 NFO panel members across the United States. Participants that accessed the study site via the Internet were assessed for eligibility, equally stratified by illness condition and gender, and then randomly assigned into 1 of the 2 scale conditions (VAS or Likert-type scaling methods). Since many participants had multiple illness conditions, and were on several medications at the same time, respondents were helped to clearly identify which particular medication and illness condition were the subject of study. A total of 6,713 individuals responded (a response rate of 67.2%), from this pool individuals were sequentially offered the opportunity to participate based on the availability of participant slots in each stratum. Five hundred and eighty seven individuals passed screening and were enrolled, of these, 567 provided complete data sets, with 287 respondents in the VAS arm and 280 in the Likert-type arm.

In addition to completing the test items, respondents were asked to provide information about the length of time they had been on their medication, the method of its administration, the frequency and severity of any side effects they might have experienced, and the likelihood that they would continue to

take the medication given its current level of effectiveness and side effects. They were also asked about perceptions of their current state of health, the severity of their illness, and some basic socio-demographic information (e.g., age, gender, educational level, and ethnic background).

Respondent characteristics

Respondents' ages ranged from 18 to 88 years, with a mean of 50.5 (SD 13.0), which did not differ significantly from the total NFO representative sampling (mean 48.8, SD 13.4). Thirty nine percent of respondents indicated that they had received four or more years of college education, and 60.1% stated that they were employed full-time. The educational proxy for socioeconomic status was roughly equivalent for the original NFO recruitment sample (31%). Table

TSQM Validation Survey: Respondent Characteristics (n = 567)

Major Route of Admin:

High Cholesterol (n = 75)

Construct dimensionality of the TSQM

Multi-step exploratory factor analyses (EFA) were employed to investigate the construct validity of the TSQM. Two separate EFAs were conducted, one using global TS-M items, and another using items that referred to more specific domains of medication experiences (e.g., Effectiveness, Side effects, Convenience) [

A first EFA employed principal components extraction and a subsequent orthogonal varimax rotation of the more specific TS-M items. This resulted in a three-factor solution that accounted for 68.3% of the total variance. Items with the greatest loadings on these factors were then selected for inclusion in the final TSQM scales. The three factors in the final solution converged in five iterations, possessed Eigenvalues greater than 1.7 and explained 75.6% of the overall variance (see Table

Loadings of Treatment Satisfaction with Medication Items (n = 567)

Side effects 1: Side effects interfere with physical function

Side effects 2: Bothersomeness of side effects

Side effects 3: Side effects interfere with mental function

Side effects 4: Side effects impact overall satisfaction

Effectiveness 1: Ability to prevent or treat the condition

Effectiveness 2: Ability to relieve symptoms

Effectiveness 3: Time it takes medication to start working

Convenience 1: Convenience of administration

Convenience 2: Ease/Difficulty of planning

Convenience 3: Ease/Difficulty following schedule

75.6% of Total Variance Explained; by Factor I (28.4%), Factor II (24.1%) and Factor III (23.1%)

A second EFA (principal component extraction and varimax rotation) was conducted using responses to five global satisfaction items, comprising a conceptually distinct second order factor of TS-M. Three items with the highest loadings were selected for final inclusion. The final solution was unidimensional (Eigenvalue = 2.3), with factor loadings between .86 and .90, which explained 79.1% of the total variance. The three items asked about were; 1) the confidence individuals had in the benefits of the medication, 2) their comparative evaluation of the benefits versus drawbacks of the medication, and 3) their overall satisfaction with the medication. The final instrument (see Table

Final Items for the Treatment Satisfaction Questionnaire for Medication (TSQM)

How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?

How satisfied or dissatisfied are you with the way the medication relieves your symptoms?

How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?

As a result of taking this medication, do you currently experience any side effects at all?

How bothersome are the side effects of the medication you take to treat your condition?

To what extent do the side effects interfere with your

To what extent do the side effects interfere with your

To what degree have medication side effects affected your overall satisfaction with the medication?

How easy or difficult is it to use the medication in its current form?

How easy or difficult is it to plan when you will use the medication each time?

How convenient or inconvenient is it to take the medication as instructed?

Overall, how confident are you that taking this medication is a good thing for you?

How certain are you that the good things about your medication outweigh the bad things?

Taking all things into account, how satisfied or dissatisfied are you with this medication?

* These items are scaled on a seven point bipolar scale from 'Extremely Satisfied' to 'Extremely Dissatisfied'. **Item #4 is a dichotomous response option with a conditional skip to item #9.

Interscale correlation matrices* for VAS/Likert-type methods

Effectiveness (EFFECT)

* Spearman correlations are significant at the .0001 level (2-tailed); **VAS sample (n = 287); ***Likert type sample (n = 280)

Scale characteristics and scaling comparisons

The performance of the two scaling methods was evaluated based on the strength of the factorial solution and the estimates of internal consistency of resulting TSQM scales. The factorial dimensionality and item loading order were the same using either scaling dataset. However, the strength of the factorial solution and Cronbach's Alpha coefficients were greater when using the Likert-type results compared to the VAS results. As expected, the score distributions resulting from both scaling methods were characterized by ceiling effects and skew that plague this class of PRO instrumentation (Table

The Distributional and Scale Characteristics of the TSQM

% Scores at Scale Ceiling

Likert Method (n = 280)

** Skewness Standard Error VAS Method = .14, Likert-type Method = .15

Possible reasons for the distributional skew of SIDEF were explored further. The removal of respondents who reported rare or very infrequent side effects from the sample resulted in an essentially normal distribution (skew = -.13, <4% of scores at ceiling value). This suggested that respondents appropriately provided high satisfaction ratings in situations where the side effects of the medication were very infrequent. Thus, the skew and ceiling effects associated with this particular scale do not seem to be simply due to problems associated with an uninterpretable respondent bias.

Medication and illness characteristics associated with treatment satisfaction

No significant differences in mean TSQM scale scores were observed by gender or education level. Significant differences in satisfaction levels were found on all TSQM scales by route of medication administration (Figure

Mean Medication Satisfaction Levels by Route of Administration Notes

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[Content truncated for PDF size. Full text available at: https://www.ncbi.nlm.nih.gov/pmc/articles/398419/]

Citation

Atkinson MJ, Sinha A, Hass SL, Colman SS, Kumar RN, Brod M, Rowland CR. Validation of a general measure of treatment satisfaction, the Treatment Satisfaction Questionnaire for Medication (TSQM), using a national panel study of chronic disease.. Health Qual Life Outcomes. 2004. DOI: 10.1186/1477-7525-2-12