Hierarchical Construct Validity of the Treatment Satisfaction Questionnaire for Medication (TSQM Version II) among Outpatient Pharmacy Consumers

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ABSTRACT _

Objectives: The objectives of this study were twofold: 1) to evaluate the construct validity of the Treatment Satisfaction Questionnaire for Medication (TSQM v. II) using structural equation modeling (SEM); and 2) to assess its concurrent validity using medication adherence criteria. Methods: Pharmacy patients filling a new medication prescription (n = 342) were recruited from 14 Michigan pharmacies to participate in a 4-week treatment satisfaction study. The TSQM v. II was tested for model fit against an established theoretical model (the Decisional Balance Model of Treatment Satisfaction) using hierarchical confirmatory factor analysis (HCFA). Regression and discriminant analytic models were used to examine the criterion-related validity of the measure.

Results: An exploratory factor analysis, used for TSQM v. II item reduction, revealed a strongly dimensional instrument (Effectiveness, Side Effects, and Convenience) and explained 88% of total pooled variance. Results of an

HCFA using the final TSQM v. II items suggested a good model fit with the data (P > 0.54). In support of concurrent validity, the TSQM scales explained between 9% and 20% of the variance in dosing adherence and 60% of the variance in the likelihood of future use. Discriminant analysis demonstrated the superior classification power of the hierarchical model of treatment satisfaction over the discrete attribute model when predicting medication discontinuation.

Conclusions: The TSQM v. II has equivalent measurement characteristics as the TSQM v. I, yet uses four fewer items and more consistent wording. The value of the Decisional Balance Model for estimation of dosing adherence and medication persistence over time is discussed.

Keywords: compliance, medication adherence, patient reported outcomes, patient satisfaction, psychometric validation, structural equation model, treatment satisfaction.

Introduction

When evaluating the quality of programs, services, and products, patient satisfaction is a useful patient reported outcome (PRO). It serves four interrelated but distinct purposes, permitting: 1) evaluation of the acceptability of care or treatments from the patients' perspective; 2) comparison of health-care programs or treatment options; 3) identification of service or treatment approaches that require change; and 4) screening of patients who are likely

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to become nonadherent to care plans or medication regimens [1]. For these reasons, satisfaction measures are often used to plan health-care delivery systems and develop pharmaceutical products or medical devises [2–4]. Because of the breadth of treatment contexts in which such measures are used, the survey content of patient satisfaction measures is highly varied. As a result, at least one attempt has been made to cluster patient satisfaction measures based on the type of treatment experiences patients are asked to evaluate (e.g., satisfaction with medical device, TS-D, etc.) [5].

This article reports on the refinement and cross-validation of the Treatment Satisfaction Questionnaire for Medication version II (TSQM v. II). The original TSQM v. I was designed as a general measure of treatment satisfaction with medication (TS- S10 Atkinson et al.

M), suitable for use across a wide variety of medication types and illness conditions. Early development research, employing heterogeneous sampling across different chronic disease states, showed the TSQM v. I effectively operationalized the three most common dimensions on which patients' evaluate their medication (i.e., medication effectiveness, side effects of use, and convenience of use) [5]. In addition, there was preliminary evidence that an overall satisfaction rating, one that represented individual's balanced judgment across all three specific treatment attributes might be the most predictive indicator of patient satisfaction and adherence [6].

It is important to acknowledge that our focus on medication attributes is not a universally accepted standard. Others have proposed that satisfaction measures include questions about both the predictors and causal consequences of a patients' treatment experience. As a result, measures with hybrid causal structures often include questions on such topics as: the degree to which individuals' prior expectations for a medication are met [7], patients' willingness to recommend a medicine to others, and respondents' willingness to take a medication again [8-10]. It is our contention, however, that the inclusion of such predicating or consequential content reduces the precision of TS-M measures by blurring distinctions between more distally related causes and effects of TS-M. Perhaps the most problematic consequence is that poor measurement distinctions between causally related constructs impede conceptual advances with respect to prediction of the behavioral sequelae of patients' medication experiences.

Determinants of Treatment Satisfaction

Because of commercial interests in consumers' valuation of their product experiences, marketing research literature provides many of the betterdeveloped satisfaction assessment methodologies [11], whereas the psychology disciplines typically provide the theoretical basis for such activities [12]. A number of theoretical perspectives have been used to describe TS-M. Common to all of these, treatment satisfaction ratings are thought to be attitudinal responses arising from value judgments that patients make concerning specific treatment experiences and clinical encounters [13]. Thus, the core of the TS-M construct is the patients' evaluation of the attributes of their medication. Although patients' prior expectations about medication performance, past medication experience, relationship with the treating clinician, and level of medical knowledge are all thought to influence TS-M ratings; the measurement focus of TS-M is to characterize patients' assessment of their immediate treatment experiences.

Consequences of Treatment Satisfaction

A major consequence of patients' satisfaction or dissatisfaction with treatment is future product use. Satisfaction with medication attributes has been found to affect patients' dosing adherence and persistence with treatment over time. Such attributes include: the degree to which treatment is viewed as effective and reducing a threat to one's current or future health; the perception that a medication reduces symptoms of disease, the perceived tolerability of the medication in terms of side effects, and discomforts or complexities of medication use [14–16].

So as not to simplify matters, the causal predictors of medication adherence is not always so straight- forward. For example, an important moderator of treatment adherence is a patient's engagement with their clinician with regards to the treatment plan, which can foster an understanding of correct medication use and an awareness of the impact of medication adherence on treatment outcomes. When adequately informed, patients may be less likely to interrupt or discontinue their therapy [17,18]. Moreover, others have shown that psychiatric comorbidities, particularly depression and cognitive dysfunction, are significant predictors of noncompliance among patients on dermatologic, antiviral, and psychoactive medications [19-22]. Nonadherence when due to either lack of knowledge or impaired mental function might best be considered a result of "decisional impairment." In such situations, TS-M alone may inadequately or inconsistently account for observed variation in adherence behavior.

A final observation is that in the literature terms such as persistence, adherence, and medication compliance are often used interchangeably and loosely defined. Definitional precision in this area is important, because these terms appear to represent somewhat distinct sets of inconsistent medication behavior. Moreover, the various behavioral patterns of nonadherent or nonpersistent use (e.g., erratic use, incorrect administration, consistent but partial dosing, temporary discontinuation, and permanent discontinuation) may result from somewhat different causes.

A Decisional Balance Model of Treatment Satisfaction In the Decisional Balance Model of Treatment Satisfaction, decisions affecting adherence are influenced by individuals' value-weighted judgment of

positive and negative attributes of treatment. Among most patient groups the attribute of highest value is typically the perceived ability of treatment to mitigate the harms of untreated illness [23], while side effects, discomforts, and inconveniences are less heavily weighted. This would be expected because the need to treat illness is the primary driver of medication-related behavior; a necessity, which if met, allows patients to tolerate fairly burdensome side effects and inconvenient administration requirements. This may not always be the case, however, for example, when medication is taken to prevent a disease (e.g., a statin to control cholesterol) the risk of immediate illness may perceived to be low and thus treatment effectiveness would receive a lower value weighting than would the tolerability of side effects and inconveniences of medication use [5].

Consistent with a central premise of Expectancy Value Theory [12], an individuals' level of satisfaction with more important medication attributes will impact medication adherence to a greater extent than would satisfaction or dissatisfaction with a less important attributes of a medication. Thus, the important task of predicting adherence behavior is often hindered by the difficult task of accounting for value differences across individuals. Such difficulties contribute to imprecision in predictive models of medication adherence [2] and may help explain the difficulties many clinicians have at estimating a patient's level of compliance in the clinical setting [24,25].

Figure 1 depicts a hierarchical Decisional Balance Model of Treatment Satisfaction and medication adherence decisions based on patients' implicit valuation of three specific medication attributes. The model suggests that overall TS-M, as well as

resulting adherence behavior, is determined by patients' judgment of whether the positive value of treatment outweigh the negative value-associated harms and inconveniences of medication use. The relative values associated with these three attributes are not fixed across all patients and are influenced by numerous factors, as described throughout our review. Because they are not fixed weights across individuals, the use of any statistical estimate will perform more poorly than use of patients' own rating of overall value. Thus, ratings of Overall Satisfaction are sought from respondents to allow them to individually account for their own unique set of values. Moreover, the Decisional Balance Model predicts that an overall TS-M rating would be a better predictor of medication adherence than any specific TS-M dimensions (e.g., Effectiveness, Side Effects or Convenience). Of note, not all specific attributes of a medication may be influential in determining the balance of Overall Satisfaction, some attributes may only become relevant when they reach a tolerability or inconvenience "threshold" [26].

Using a cross-sectional study design, Atkinson et al. [2] found that the regression weights associated with models using the specific TSQM subscales (i.e., Effectiveness, Side Effects, and Convenience) to "predict" Overall Satisfaction scores differed according to illness condition, medication type, and the degree of perceived threat associated with the illness. Moreover, patients' Overall Satisfaction rating was a better "predictor" of ratings of their "likelihood to continue/discontinue using their medication" than were ratings on the more specific Effectiveness, Side Effects or Convenience TSQM scales. This observation was true irrespective of illness group or medication type.

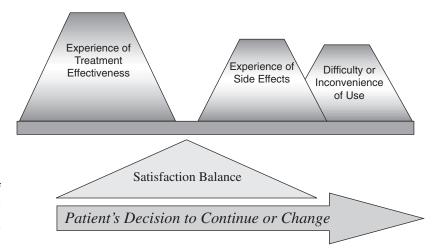


Figure I A Decisional Balance Model of Treatment Satisfaction depicting dimensions of treatment experience that are weighted to predict overall satisfaction and medication persistence.

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Among those with chronic conditions, low anticipation of an effective cure may act to reduce the value weight associated with medication effectiveness, thereby tipping the decisional balance toward the negative attributes of the medication such as ongoing side effects and inconvenience of long-term use. This may help explain why up to one half of patients with chronic illness end up making medication-related decisions, without seeking medical advice, and become nonadherent [27]. Over time, because greater emphasis is placed on dissatisfaction with side effects and inconvenience, poorer adherence may compromise the effectiveness of a medication, thereby speeding disease progression.

Study Objectives

Two objectives were originally identified for the current study:

- To evaluate the construct validity of a new version of the TSQM v. II using structural equation modeling (SEM), and;
- To examine, posteriori, associations between respondents' treatment satisfaction, dosing adherence and medication persistence.

Methods

Sample and Research Design

Pharmacists at 14 outpatient pharmacies in Michigan agreed to participate in, and recruit participants for, a 4-week study of consumers' satisfaction with a new medication. Study enrollment involved a rolling recruitment of any person, without respect to medical condition, who came to the pharmacy to fill a prescription for a medication they had never used before. Subjects had to be at least 18 years old, speak English, and consent to study participation. Participants were paid \$25 USD for their involvement in the study. This study was implemented with approval of the University of Michigan Institutional Review Board and an HIPAA compliance officer.

Consenting participants were given the option of completing the study survey materials either on the Internet or by hard copy paper forms. They were asked to complete one set of questionnaires before beginning their medication regimen (Time 1) and another set of forms 4 weeks later (Time 2). At baseline, the questionnaires gathered information about the type of medication, type of illness, level of information they obtained regarding their medication, demographics, insurance status, and their anticipations/expectations with respect to the new

medication. The 4-week follow-up questionnaires gathered information about participants' experience with their illness and medication (e.g., severity, duration, difficulty of use); their satisfaction on the Effectiveness, Side Effects, Convenience of use, and Overall Satisfaction scales of TSQM v. I and v. II candidate items; their adherence over the past month and their intent to continue using the medication in the future.

Psychometric and Statistical Methods

An initial Principal Components Exploratory Factor Analysis was performed using all original TSQM items and the newly reworded candidate satisfaction items. The best performing and conceptually true items were used to create revised scales for the TSQM v. II. Typical statistical parameters were used to evaluate item and scale performance, including factor loadings, internal consistency, distributional skew, and floor-ceiling effects.

Structural equation modeling (SEM) was used to confirm the hierarchical factor structure of the TSOM v. II. SEM is a class of statistical methods used to model the hypothetical relationships between observed and latent variables. The structural model to be tested is prespecified by defining the relationships among the variables and then tested by examining the fit between the specified model and the correlation or covariance patterns that are actually observed in the data sets. If the proposed model fits the observed data, it is said to be confirmed. The SEM software used was MX, a public domain application that is available for http://opal.vcu.edu/html/mx/ from mxhomepage.html. MX development is supported by an NIH grant (RR08123) and is provided through the Department of Psychiatry at the Medical College of Virginia [28].

Three broad criteria were used to judge the statistical significance and substantive meaning of the theoretical model. The first criterion involved global fit measures (RMSEA, CFI, NFI, chi-square). The second criterion was the statistical significance of individual parameter estimates for the paths in the model, computed by dividing the parameter estimates by their respective SE (compared with a *t*-value of 1.96 at the 0.05 level of significance). The third criterion considered the magnitude and direction of the parameter estimates.

The performance of both the original TSQM v. I and the TSQM v. II was evaluated by comparing the predictive power of specific TSQM scales with respect to respondents' Overall Satisfaction ratings as well as reports of actual and anticipated medica-

tion-related behavior (e.g., adherence, persistence, and likelihood to use the medication again).

Study Results

A total of 420 usable surveys were completed and returned by patients just before beginning their medication, with 342 of these also returning materials from the week 4 follow-up-resulting in a study completion rate of 81.4%. The demographic characteristics of participants completing the study using either the paper- (n = 248) or Web-based (n = 94) data collection methods are shown in Table 1. Overall, the mean age was 49.9 (SD 16.2) years with an age range of 18 to 88 years. There were roughly equal proportions of respondents in the low to middle household income levels, with fewer in the two highest income categories. The mean reported income, taking into account family size, was about \$24,500 (SD \$15.4 k). The sample was predominantly white people (~87%) with the other 13% being divided between African Americans, Native Americans, Hispanics, and Asian Americans. Those completing the study were somewhat older than the noncompleters (49.9 vs. 43.3 years, P < 0.001). No other differences were found between completers and noncompleters by race, education level or household income.

With respect to the method of data collection, the online group was slightly younger than those

returning paper forms, 40 years (SD 12.6) versus 54 years (SD 16.0) (P < 0.001). A chi-square test also identified a significant gender difference between the collection methods (P = 0.02) with a greater proportion of females completing the paper surveys than males. Chi-square tests revealed no significant differences in the proportion of white people and African Americans using the online versus paper survey. On average, online responders tended to be better educated and have a greater household income than paper only responders (P < 0.001). An interesting observation was that all online respondents had at least a high school diploma.

Descriptive statistics for the key medication and illness characteristics of the sample are shown in Table 2. Conforming to what would be expected from a community sample, the average perceived symptom burden scores for the condition(s) being treated by the new medication was fairly low and the respondents' perception of their ability to cope with past side effects of previous medications was quite high. Participants, on average, indicated they were taking two other medications concurrently and were being treated for approximately two additional illness conditions. The vast majority of consumers in this study (93%) was required to take the new medication at least once a day and took this medication in an oral or topical form.

The sample was evenly divided between consumers being treated for chronic versus acute condi-

Table I Sample demographics

| | Paper survey (n = 248) | Used online only $(n = 94)$ | Total sample survey $(n = 342)$ |
|------------------------|------------------------|-----------------------------|---------------------------------|
| Age | | | |
| Mean (SD) | 53.6 (15.9) | 40.1 (12.6) | 49.9 (± 16.2) |
| Sex | , , | , , | , , |
| Male: female | 1:2 | 1:1.2 | 1:2.1 |
| Family size | | | |
| Mean (SD) | 2.31 (±1.2) | 2.7 (±1.2) | 2.42 (±1.2) |
| Median and range | 2 (1–6) | 3 (I-6) | 2.0 (I-6) |
| Race | , , | , , | , , |
| White people | 217 (87.9%) | 81 (86.2%) | 298 (87.4%) |
| African American | 14 (5.7%) | 3 (3.2%) | 17 (5%) |
| Hispanic | 7 (2.8%) | 0 (0%) | 7 (2.1%) |
| Native American | 9 (3.6%) | l (l.l%) | 10 (2.9%) |
| Other | 7 (2.8%) | 9 (9.5%) | 9 (2.6%) |
| Household income (\$)* | ` , | , | , |
| <25,000 | 70 (29.4%) | 13 (14.1%) | 83 (25.2%) |
| 25,000-49,999 | 62 (26.1%) | 18 (19.6%) | 80 (24.2%) |
| 50,000-74,999 | 57 (23.9%) | 21 (22.8%) | 78 (23.6%) |
| 75,000–99,999 | 24 (10.1%) | 22 (23.9%) | 46 (13.9%) |
| ≥100,000 | 25 (10.5%) | 18 (̀19.6%́) | 43 (13.1)% |
| Education | , , | , | ` , |
| No high school diploma | 21 (8.5%) | _ | 21 (6.2%) |
| High school graduate | 66 (26.7%) | 5 (5.3%) | 71 (20.8%) |
| Some college | 75 (30.4%) | 32 (34.0%) | 107 (31.4%) |
| College graduate | 47 (19.0%) | 27 (28.7%) | 74 (21.7%) |
| Postgraduate study | 38 (15.4%) | 30 (31.9%) | 68 (19.9%) |

^{*}Adjusted for number of dependents living at home.

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 Table 2
 Descriptive statistics of medication and illness characteristics

| Characteristics of treatment and illness | Response | | Frequency (%) |
|---|--|--|---|
| Medication dosage form | Oral Topical Inhalable Injectable Other | | 286 (84%) 37 (11%) 12 (4%) 5 (1%) 2 (<1%) |
| Duration of prescription | Less than a week 1-2 weeks 2-3 weeks 1-2 months >2 months | | 31 (13%) 69 (29%) 14 (6%) 24 (10%) 98 (42%) |
| Frequency of use | Several × daily Once a day Several × a week Once a week > I × a week | | 150 (46%) 168 (51%) 6 (2%) 2 (<1%) 1 (<1%) |
| Medication status at 4 weeks | Therapy finished Therapy ongoing Discontinued due to: Ineffective Side effects Inconvenient | | 95 (29%) 202 (61%) 21 (6%) 10 (3%) 3 (1%) |
| Nature of disease | Chronic Acute Unknown | | 150 (46%) 156 (48%) 21 (6%) |
| | Mean (±SD) | Minimum score | Maximum score |
| Mean adherence Coping with side effects of medications No. concomitant medications General attitudes toward medication Illness/symptom burden score Comorbidities | 4.55 (±0.57) 3.88 (±0.96) 2.51 (±3.06) 3.76 (±1.04) 1.99 (±0.87) Median = 1.6 | I (Low adherence) I (Not coping) 0 I (-) Attitude I (Low burden) 0 | 5 (High adherence) 5 (Cope very well) 20 5 (+) Attitude 5 (High burden) 14 |

tions, as a result, the numbers of respondents who were unsure about how long they would need to take the medication was equal to those taking medication for a delimited time period. At week 4, 95 (29%) had completed their course of medication. The mean self-reported adherence level after a month of using the new medication was high (9 out of 10). Only 34 (10%) study participants indicated that they had stopped therapy prematurely, the majority stopped as a result of lack of medication effectiveness, followed by problematic side effects and then inconvenience.

TSQM Version II: Content Modifications and Item Reduction

New item content for the TSQM v. II was based on respondents' feedback during earlier studies using the TSQM v. I. Suggestions were made about the "mental side effects" and "ease of use" items in the original instrument, and specifically: 1) The TSQM should ask about the impact of medication on emotional functioning, not just mental side effects; and 2) A question should be added to assess satisfaction with frequency of use. Changes were also made to

the item stems of five other questions to make their wording more consistent with the "satisfaction or dissatisfaction" stems used for other items in the instrument.

A principal components factor analysis (w/varimax rotation), involved all the proposed specific items in the TSQM v. II item pool (see Table 3), and resulted in the expected three factors (Eigenvalues > 1.0) that explained over 78% of the total pooled variance.

As a result of this factor analysis one Side Effect item was dropped because of poor factor loading. This item made reference to the impact of side effects on overall satisfaction and was not consistent with the other Side Effect items that addressed the symptom basis for dissatisfaction. A second item was also dropped from the Side Effects scale that asked about the "bothersomeness" of side effects. Although a sufficient Side Effects factor loading was found, earlier questions were raised during translation activities associated with the TSQM v. I about the meaning of "bothersomeness" in other non-English-speaking cultures and the cross-cultural adaptation of the concept proved difficult.

Table 3 Initial factor solution with all proposed items for version II of the TSQM

| | | Factors | |
|---|-------|---------|-------|
| TSQM version II items | I | II | III |
| Effectiveness | | | |
| Preventing or treating condition | 0.17 | 0.15 | 0.93 |
| Relief of symptoms | 0.17 | 0.16 | 0.94 |
| Time to start working (dropped) | 0.05 | 0.17 | 0.89 |
| Side effects | | | |
| Interference w/physical function | 0.89 | 0.00 | 0.17 |
| Interference w/mental function | 0.90 | 0.03 | 0.17 |
| Interference w/mood or emotions | 0.87 | 0.05 | 0.18 |
| Bothersomeness of side effects (dropped) | 0.88 | 0.03 | 0.19 |
| Side effects impact on overall satisfaction | 0.46 | 0.06 | -0.20 |
| (dropped) | | | |
| Convenience | | | |
| Ease of medication use | -0.07 | 0.79 | 0.18 |
| Planning for medication use | 0.07 | 0.92 | 0.11 |
| Frequency of medication use | 0.05 | 0.89 | 0.15 |
| Convenience of medication use (dropped) | 0.10 | 0.91 | 0.04 |
| Eigenvalues | 4.57 | 3.0 | 1.9 |
| Proportion of variance explained (%) | 38.1 | 24.7 | 15.8 |

An Effectiveness item that asks about "the time it takes for the medication to start working" was also dropped because it was thought to have different meanings in different treatment contexts. Translation consultants made a suggestion that assessment of satisfaction with a pain medication (for example) using this item would have a very different meaning if the respondent were taking an antidepressant.

Another item that was dropped from the Convenience scale asked generally about the "convenience" of taking a medication, while other items on the same scale ask about more specific causes of dissatisfaction (i.e., frequency of dosing, effort to plan, and difficulty of administration). While the general convenience item loaded strongly, it was thought that the more specific items adequately covered the construct of Convenience. In addition, some consideration was given to the relatively weak loading of the "difficulty of administration item" on the Convenience scale. It was not dropped, however, because the vast majority of respondents in this study were on medications in pill form. This current sample characteristic may have resulted in a somewhat weaker loading on the factor than would be observed in studies employing a more heterogeneous sampling of administration methods.

Finally, the Overall Satisfaction item "Confidence that the medication is a good thing" was dropped because it asked respondents about their confidence in their evaluation and not specifically for a judgment rating.

As later results will show, removal, addition, and refinement of the various TSQM items did not appear to result in significant performance differ-

ences between the two versions of the instrument. For reference purposes, Table 4 presents items of the TSQM v. I and the item pool that was considered for the TSQM v. II. Full versions of the TSQM can be found in Appendices A and B.

TSQM Version II: Scale Characteristics and Construct Validity

For the reasons stated various items were removed and the remaining eight specific items (i.e., addressing Effectiveness, Side Effects, and Convenience; TSQM v. I items 1, 2 and items 6, 7, 9, 10 with modified stems; along with the two new items addressing emotional side effects and frequency of administration) were reanalyzed. The final factor analysis converged in six iterations and the three factors (i.e., Effectiveness, Side Effects, and Convenience of Use) explained 88.3% of the total pooled variance with Eigenvalues greater than 1.3 (see Table 5).

Table 6 presents the intercorrelations between items in versions I and II of the TSQM. The bolded correlations highlight the associations between the five items that were reworded in version II to use a dissatisfaction stem. The rectangular boxes group correlations by the TSQM scale constructs (Effectiveness, Side Effects, Convenience, and Overall Satisfaction).

Tables 7 and 8 present item and scale statistics for both versions of the TSQM. No major differences were observed between the two versions with one exception. The Side Effects scale in version I had a lower proportion of individuals at the ceiling of the scale than version II (i.e., the proportion of individuals with scores of 100 on a scale from 0 to 100). This may have been due to differences in the stem wording between the two versions. Version I asked about dissatisfaction regarding symptom levels. It appears that approximately 13% of respondents reported side effects on version I that did not cause them any appreciable dissatisfaction.

TSQM Version II Hierarchical Confirmatory Factor Analyses

Figure 2 depicts a diagrammatic representation of the confirmatory factor analysis (CFA) of the TSQM v. II based on the Decisional Balance Model of Treatment Satisfaction. Global measures of goodness of model fit were evaluated. The chisquare statistic was not significant (chi-square value = 18.65, d.f. = 19, P = 0.46), indicating the model fit the data. The root-mean-square error of approximation (RMSEA) was virtually zero (90%)

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Table 4 Comparison of items in version I and version II of the TSOM

Original TSQM TSQM version II

- How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?
- 2. How satisfied or dissatisfied are you with the way the medication relieves your symptoms?
- 3. How satisfied or dissatisfied are you with the amount of time it takes the medication to start working?
- 4. As a result of taking this medication, do you currently experience any side effects at all?
- 5. 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 <u>physical</u> health and ability to function (i.e., strength, energy levels, etc.)?
- 7. To what extent do the side effects interfere with your mental function (i.e., ability to think clearly, stay awake, etc.)?
- 8. 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?
- 10. How easy or difficult is it to plan when you will use the medication each time?
- 11. How convenient or inconvenient is it to take the medication as instructed?
- 12. Overall, how confident are you that taking this medication is a good thing for you?
- 13. How certain are you that the good things about your medication outweigh the bad things?
- 14. Taking all things into account, how satisfied or dissatisfied are you with this medication?

<u>Same:</u> How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition?

<u>Same</u>: How satisfied or dissatisfied are you with the way the medication relieves your symptoms?

Dropped

<u>Same:</u> As a result of taking this medication, do you currently experience any side effects at all?

Dropped

Reworded: How dissatisfied are you by side effects that interfere with your physical health and ability to function (e.g., strength, energy levels)?

<u>Reworded</u>: How dissatisfied are you by side effects that interfere with your mental function (e.g., ability to think clearly, stay awake)?

<u>New</u>: How dissatisfied are you by side effects that interfere with your mood or emotions (e.g., anxiety/fear, sadness, irritation/anger)?

Dropped

<u>Reworded:</u> How satisfied or dissatisfied are you with how easy the medication is to use?

<u>Reworded:</u> How satisfied or dissatisfied are you with how easy it is to plan when you will use the medication each time?

<u>New:</u> How satisfied or dissatisfied are you by how often you are expected to use/take the medication?

Dropped

Dropped

<u>Reworded</u>: How satisfied are you that the good things about this medication outweigh the bad things?

 $\underline{\underline{\mathsf{Same}}}.$ Taking all things into account, how satisfied or dissatisfied are you with this medication?

confidence interval [CI], 0.000–0.046) and, being less than 0.05, also indicated a good fit. Both the comparative fit index (CFI) value of 0.98 and the non-normed fit index (NNFI) value of 0.918

Table 5 Final factor solution of the content specific items of the TSOM version II

| | | Factors | |
|--------------------------------------|--------|---------|------|
| TSQM version II items | I | II | III |
| Effectiveness | | | |
| Preventing or treating condition | 0.16 | 0.14 | 0.96 |
| Relief of symptoms | 0.15 | 0.15 | 0.96 |
| Side effects | | | |
| Interference w/physical function | 0.88 | 0.02 | 0.14 |
| Interference w/mental function | 0.94 | 0.03 | 0.14 |
| Interference w/mood or emotions | 0.91 | 0.05 | 0.14 |
| Convenience | | | |
| Planning required for medication use | 0.06 | 0.93 | 0.15 |
| Frequency of medication use | 0.05 | 0.93 | 0.13 |
| Ease of medication use | -0.0 I | 0.89 | 0.13 |
| Eigenvalues | 3.4 | 2.3 | 1.3 |
| Proportion of variance explained (%) | 31.7 | 32.0 | 24.6 |

exceeded 0.90, suggesting a model with adequate fit. Overall, this set of five key global statistics confirmed that the proposed model fit the data well.

With respect to the model structure, the path coefficient between Overall Satisfaction and Effectiveness (0.96) was much greater than the weight of Side Effects on Overall Satisfaction (0.34) or Convenience (0.36), with Side Effects and Convenience loading equally Overall Satisfaction. The Side Effects dimension exhibited some measurement disturbance because the residual estimate for this latent variable could not be fixed at 1.00 without compromising the fit of the entire model. Allowing the parameter to float and to be estimated by the SEM software, the residual was estimated to be 0.40. This observation may be due to the fact that only 25% of the sample reported experiencing any side effects, thus influencing the overall structural fit of Overall Satisfaction on the three latent variables on Overall Satisfaction.

Table 6 Correlations between items in versions I and II of the TSOM

| TSQM version II | | | | | | | | | | |
|-----------------------------|-------------|----------|----------|------------|--------|---------|-----------|-----------|----------|--------|
| | Prevents or | Relieves | Physical | | | Ease of | Effort to | How often | Good vs. | All |
| TSQM version I | treats | symptoms | function | Mental | Mood | use | plan | used | Bad | things |
| | Effectiv | eness | | | | | | | | |
| Prevents or treats | _ | 0.94 | 0.30 | 0.32 | 0.31 | 0.24 | 0.25 | 0.28 | -0.7 I | -0.7 I |
| Relieves symptoms | 0.94 | _ | 0.30 | 0.32 | 0.32 | 0.26 | 0.26 | 0.29 | -0.69 | -0.72 |
| Time to start working | 0.81 | 0.84 | 0.19 | 0.19 | 0.20 | 0.25 | 0.27 | 0.29 | -0.59 | -0.62 |
| 5 | | | Si | de effects | | | | | | |
| Bothersome side effects | 0.25 | 0.25 | 0.82 | 0.69 | 0.73 | -0.0 I | 0.06 | 0.04 | -0.37 | -0.33 |
| Interfere physical function | 0.30 | 0.30 | 0.87 | 0.74 | 0.68 | 0.06 | 0.09 | 0.06 | -0.39 | -0.37 |
| Interfere mental function | 0.21 | 0.20 | 0.62 | 0.74 | 0.62 | 0.07 | 0.10 | 0.10 | -0.28 | -0.27 |
| SE impact on satisfaction | -0.05 | -0.06 | 0.26 | 0.29 | 0.24 | -0.0 I | 0.06 | 0.02 | 0.07 | 0.05 |
| • | | | | | | | Convenien | ce | | |
| Easy to use | 0.15 | 0.15 | 0.04 | 0.04 | 0.07 | 0.72 | 0.41 | 0.38 | -0.17 | -0.13 |
| Plan when to use | 0.19 | 0.17 | 0.07 | 0.09 | 0.13 | 0.53 | 0.70 | 0.57 | -0.26 | -0.22 |
| Convenient to take | 0.20 | 0.19 | 0.08 | 0.07 | 0.12 | 0.61 | 0.62 | 0.58 | -0.27 | -0.21 |
| | | | | | | | | | Over | all |
| Confident in benefits | -0.74 | -0.72 | -0.33 | -0.27 | -0.3 I | -0.26 | -0.30 | -0.28 | 0.80 | 0.66 |
| Good outweighs the bad | -0.69 | -0.65 | -0.29 | -0.22 | -0.29 | -0.33 | -0.3 I | -0.30 | 0.78 | 0.64 |
| All things into account | -0.7 I | -0.72 | -0.39 | -0.34 | -0.34 | -0.26 | -0.30 | -0.33 | 0.67 | - |

The Comparative Performance of Versions I and II of the TSQM

Table 9 compares the predictive power of the two versions of the TSQM based on regression analyses, using various aspects of satisfaction and adherence as dependent measures, specifically; Overall Satisfaction, participants' willingness to take the medication again, frequency of forgetting to take the medication, taking less medication than prescribed because of feeling better, and taking less medication than prescribed because they felt worse. The concurrent validity estimates and performance of both

Table 7 Item statistics of TSQM version II (n = 339)

| TSQM scale and items | Item means (SD) before transformation | Item-scale correlations* | Item correlation with overall satisfaction scale* |
|--------------------------------|---|-----------------------------|---|
| and items | transformation | Correlations | satisfaction scale |
| Effectiveness | | | |
| Prevents or treats condition | 2.82 (1.4) | 0.98 | 0.77 |
| Relieves symptoms | 2.88 (1.4) | 0.98 | 0.77 |
| Side effects | , | | |
| Interferes w/physical health | 1.34 (0.9) | 0.75 | 0.41 |
| Interferes w/mental function | 1.26 (0.7) | 0.66 | 0.34 |
| Interferes with mood | 1.27 (0.8) | 0.60 | 0.37 |
| Convenience | , | | |
| Effort to plan | 2.15 (1.1) | 0.74 | 0.25 |
| How often used | 2.16 (1.1) | 0.69 | 0.31 |
| Ease of use | 2.03 (1.1) | 0.62 | 0.33 |
| Overall satisfaction | , | | |
| Good outweighs the bad | 3.55 (1.2) | 0.88 | 0.88 |
| Taking all things into account | 2.90 (I.6) | 0.94 | 0.94 |

^{*}All items correlated with Overall Satisfaction at P-value < 0.05.

Table 8 A comparison of scale characteristics between the TSQM v. I and v. II (n = 344)

| | Mean | (SD)* | No. | items | Chroni | oach's alpha† | Skewnes | s statistic | % C | eiling |
|-------------------------------------|------------------------------|------------------------------|------|--------|--------------|-------------------|----------------|----------------|--------------|--------------|
| TSQM version no. | V. I | V. II | V. I | V. II | V. I | V. II | V. I | V. II | V. I | V. II |
| Effectiveness | 68.23 (22.7) | 69.00 (23.7) | 3 | 2 | 0.95 | $r = 0.94^{\S}$ | -0.91 | -0.85 | 9.0 | 8.2 |
| Side effects [‡] | 90.38 (19.7) 62.26 (21.6) | 93.58 (15.9) 74.11 (22.8) | 4 | 3 | 0.88 | 0.91 | -2.68 -0.54 | -2.88 -0.85 | 74.0 6.7 | 76.7 20.4 |
| Convenience Overall satisfaction | 85.04 (16.2) 63.79 (26.2) | 81.39 (17.1) 72.08 (21.4) | 3 | 3 2 | 0.81 0.88 | 0.91 r = 0.88§ | -0.73 -0.73 | -0.84 -0.78 | 36.7 10.2 | 30.6 14.3 |

^{*}Scoring algorithms provide transformed scores between 0 and 100, these are presented along with the two versions of the TSQM in Appendices A and B. †Assessment of internal consistency is not computable with one item missing.

The scale mean, skew, and ceiling statistics are reported for the total sample as well as the subsample reporting any medication side effects (n = 85).

This statistic is not computable for scales employing two items, Spearman's correlation coefficients are used to approximate the strength of item association.

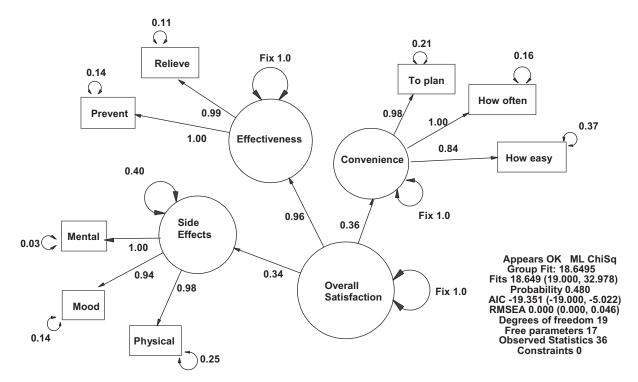


Figure 2 A hierarchical confirmatory factor analysis of the TSQM version II.

instruments were equivalent, with only slight differences in the statistical significance of scale Beta weights across analyses.

Overall Satisfaction scores were strongly predicted by all three specific TSQM v. II scales (Effectiveness, Side Effects, and Convenience), with Side Effects and Effectiveness scores being the strongest predictors. Participants' willingness to take their medication again was predicted predominantly by Overall Satisfaction, and less so by the Side Effects subscale. Respondents' who reported inconsistent medication use were less strongly predicted by this TSQM scale using either version of the instrument.

Completers versus Discontinuers

A final set of discriminant analyses were conducted to examine the ability of satisfaction scores to correctly classify those who completed their course of medication and those who did not (Table 10). Although both models were significant, the Discrete Satisfaction Model, consisting only of the three specific treatment satisfaction scales, demonstrated significantly less positive predictive power than the hierarchical Decisional Balance Model. These findings support the underlying premise of model, that the Overall Satisfaction is the strongest predictor of true cases of medication discontinuation.

Discussion

The psychometric performance of the new version of the TSQM is equivalent to the TSQM v. I, with the advantages of it being shorter and more consistently worded. Comparisons using results from the various regression analyses suggest that both versions perform equivalently when predicting measures of concurrent validity (i.e., patients' willingness to take the medication again, and various selfreported indicators of nonadherence). Moreover, results of the CFA provide fairly convincing evidence that the TSQM v. II precisely measures the dimensions described in the Decisional Balance Model of Treatment Satisfaction, on which both version of the instrument are based. Some disturbance in the model's Side Effects variable was observed, however, which suggests a need for more in-depth study of persons experiencing side effects. Only 25% of respondents in the current study experienced any side effects and the disturbance in the CFA model may have been in part due to distributional skew toward the highly satisfied range.

The loadings of the Effectiveness, Side Effects, and Convenience latent factors on the super-ordinate Overall Satisfaction factor support the hierarchical construct organization of the measure and the model provides a way to test predictions regard-

 $\textbf{Table 9} \quad \text{A performance comparison of the TSQM versions I and II}$

| | TSQM predictors o | f dependent criteria | R^2 for the | Comments | |
|---|---|---|---------------------|---|--|
| Dependent criteria | TSQM version I | TSQM version II | regression model | | |
| Overall satisfaction rating | Effectiveness: 0.63 (0.03), P < 0.000001 Side effects: 0.30 (0.04), P < 0.000001 Convenience: 0.13 (0.04), P < 0.001 | Effectiveness: 0.62 (0.03), P < 0.000001 Side effects: 0.33 (0.05), P < 0.000001 Convenience: 0.11 (0.04), P < 0.005 | 70% vs. 70% | The standardized beta weight for each scale, reflects the importance of that dimension (Effectiveness, Side Effects, and Convenience) and its impact on overall satisfaction with medication | |
| Would you take it again? | Effectiveness: 0.03 (0.05), n.s. Side effects: 0.10 (0.06), P = 0.06 Convenience: 0.07 (0.04), P = 0.09 Overall: 0.68 (0.06), P < 0.000001 | Effectiveness: 0.05 (0.05), n.s. Side effects: 0.14 (0.06), P < 0.01 Convenience: -0.002 (0.04), n.s. Overall: 0.67 (0.06), P < 0.000001 | 60% vs. 60% | Willingness to take the medication again, seemed to perform as a proxy for overall ratings of satisfaction with medication, possibly supporting a common appreciation of the relationship between satisfaction and future planning of medication-related behavior | |
| How often did you forget to take your medication? | Effectiveness: -0.02 (0.08), n.s. Side effects: -0.14 (0.06), P < 0.05 Convenience: -0.30 (0.05), P < 0.000001 Overall: 0.17 (0.09), n.s. | Effectiveness: 0.002 (0.06), n.s. Side effects: -0.12 (0.07), P = 0.09 Convenience: -0.31 (0.05), P < 0.000001 Overall: 0.16 (0.08), P < 0.05 | 8% vs. 9% | Convenience of use was the best predictor of the frequency with which respondents' forgot to take their medication | |
| Took less because felt better | | | 5% vs. 6% | Similarly, Convenience predicted taking less because they felt better, perhaps due reengagement with a busy life and the inconvenience of repeated dosing | |
| Took less because felt worse. Included only those indicating they had side effects (n = 88) | Effectiveness: 0.125 (0.04), P < 0.01 Side effects: -0.33 (0.05), P < 0.000001 Convenience: -0.18 (0.04), P < 0.00001 Overall: -0.18 (0.05), P < 0.001 | Effectiveness: 0.14 (0.04), P < 0.001 Side effects: -0.32 (0.05), P < 0.000001 Convenience: -0.10 (0.04), P < 0.01 Overall: -0.20 (0.05), P < 0.0001 | 26% vs. 23% | Quite a large amount of the variance in medication adherence was explained by participants' dissatisfaction with the side effects of their medication | |

n.s., not significant.

 Table 10
 Prediction of medication persistence using two models of treatment satisfaction

| Model | Variable | Wilks' lambda | F-value | P-value |
|---|--|----------------------------------|--|----------------------------------|
| Discrete satisfaction model | Effectiveness Side effects Convenience | 0.861 0.808 0.751 | | 0.000001 0.000001 0.66 |
| | Total model Predicted/actual discontinued: 14/34 = 41% | 0.751 | $F_{3,339} = 37.5$ Predicted/actual persisted: $302/309 = 98\%$ | P < 0.0001 |
| | False positives: 20/34 = 59% | | False negatives: 7/309 = 2% | |
| Hierarchical decisional balance model | Effectiveness Side effects Convenience Overall satisfaction | 0.653 0.665 0.658 0.751 | | 0.62 0.01 0.11 0.000001 |
| | Total model Predicted/actual discontinued: 24/34 = 71% False positives: 10/34 = 28% | 0.653 | $F_{3,338} = 44.9$ Predicted/actual persisted: $300/310 = 97\%$ False negatives: $10/310 = 3\%$ | P < 0.00001 |

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ing patient medication adherence. As expected, given that the primary reason for taking a medication is illness cure/prevention or symptom relief, the loading of the Effectiveness variable on Overall Satisfaction was strongest. Side Effects and Convenience were about equally loaded on Overall Satisfaction suggesting, in this sample, an equal impact of these medication attributes on Overall Satisfaction.

Finally, evaluation of the importance of a hierarchical Decisional Balance Model was demonstrated using discriminant analysis. The use of specific dimensions of satisfaction with medication attributes (i.e., Effectiveness, Side Effects and Convenience) to identify individuals who discontinued medication use was not nearly as strong as a model that included participants' evaluation of their Overall Satisfaction (41% vs. 71% correct classification or positive predictive value to predict nonpersistent individuals). The power of the hierarchical model was particularly impressive given that only about 10% of individuals in the total sample were nonpersistent. Granted, because treatment satisfaction measures at week 4 were administered after discontinuation, the predictive validity of this model needs to be assessed using a prospective research design. Nevertheless, there is little reason to believe that TSQM measurements at week 4 would differ significantly from respondent ratings of dissatisfaction just before discontinuation of the medication.

Limitations of the Current Study and Future Directions

Various limitations with respect to study design and sample selection may have impacted the psychometric parameter estimates and the generalizability of results: 1) the short study duration may have truncated the sampling frame (right censoring persistence data) and affected the frequency and reasons for discontinuations (e.g., discontinuations due to loss of medication ineffectiveness); 2) the simultaneous measurement of TS-M and dosing adherence and persistence with medication over time, may have introduced some response consistency due to recall bias, increasing the observed correlation between satisfaction and self-reported adherence and persistence. More detailed prospective studies are needed in which TS-M data are collected regularly over time and can be used to temporally predict discontinuation (nonpersistence) or nonadherence with the medication regimen before they occur; 3) resulting from the select outpatient samples, caution must be used when using the current scale statistics and CFA to estimate sample parameters for other studies. For example, in other

research involving patients with chronic illness, satisfaction with Side Effects appeared to weigh more heavily on judgments of Overall Satisfaction than did Convenience; and 4) the low incidence of side effects made it difficult to precisely fit the Side Effects latent variable within the confirmatory SEM model, without allowing for some measurement disturbance. Moreover, it is less than ideal that the confirmatory SEM analysis was conducted using observed variables that had been preselected based on earlier EFA results. As a result, additional studies are required to replicate the hierarchical model and provide adequate sampling of persons with side effects to allow for subsample modeling. A final note is that data were not gathered with respect to patients' level of difficulty with self-administration of medication—a consideration that might be particularly important for certain types of delivery methods among persons with impaired administration abilities.

Conclusions

This study provides convincing evidence in support of the reliability and validity of the TSQM v. II. The hierarchical Decisional Balance Model of Treatment Satisfaction shows particular promise as a theoretical tool for prediction of treatment dosing adherence and medication persistence over time.

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Appendix A

TSQM (Version I): Treatment Satisfaction Questionnaire for Medication

Rights to the TSQM v. I and TSQM v. II are shared by Quintiles Strategic Research Services and Pfizer Inc. For permission to use approved formatted versions of the instruments as well as obtaining numerous translations, please contact Shoshana Colman, PhD, Quintiles Strategic Research Services, 475 Brannan Street, Suite 430, San Francisco, CA 94107; Voice: 415.633.3243; Fax: 415.633.3133; shoshana.colman@quintiles.com

| | How satisfied or dissatisfied are you with the |
|----|--|
| | ability of the medication to prevent or treat |
| | your condition? |
| | □1 Extremely Dissatisfied |
| | □2 Very Dissatisfied |
| | □3 Dissatisfied |
| | □4 Somewhat Satisfied |
| | □5 Satisfied |
| | □6 Very Satisfied |
| | □7 Extremely Satisfied |
| 2. | How satisfied or dissatisfied are you with the |
| | way the medication relieves your symptoms? |
| | □1 Extremely Dissatisfied |
| | □2 Very Dissatisfied |
| | □3 Dissatisfied |
| | □4 Somewhat Satisfied |
| | □5 Satisfied |

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| 3. | □6 Very Satisfied □7 Extremely Satisfied How satisfied or dissatisfied are you with the amount of time it takes the medication to start working? □1 Extremely Dissatisfied □2 Very Dissatisfied □3 Dissatisfied □4 Somewhat Satisfied □5 Satisfied □6 Very Satisfied □7 Extremely Satisfied | 10. | □6 Very Easy □7 Extremely Easy How easy or difficult is it to plan when you will use the medication each time? □1 Extremely Difficult □2 Very Difficult □3 Difficult □4 Somewhat Easy □5 Easy □6 Very Easy □7 Extremely Easy How convenient or inconvenient is it to take |
|----|---|-----------------------|---|
| 4. | As a result of taking this medication, do you experience any side effects at all? 1 Yes 0 No | 11. | the medication as instructed? □1 Extremely Inconvenient □2 Very Inconvenient □3 Inconvenient |
| 5. | How bothersome are the side effects of the medication you take to treat your condition? □1 Extremely Bothersome □2 Very Bothersome □3 Somewhat Bothersome □4 A Little Bothersome □5 Not at All Bothersome | 12. | □4 Somewhat Convenient □5 Convenient □6 Very Convenient □7 Extremely Convenient Overall, how confident are you that taking this medication is a good thing for you? □1 Not at All Confident |
| 6. | To what extent do the side effects interfere with your physical health and ability to function (i.e., strength, energy levels, etc.)? □1 A Great Deal □2 Quite a Bit □3 Somewhat □4 Minimally □5 Not at All | 13. | □2 A Little Confident □3 Somewhat Confident □4 Very Confident □5 Extremely Confident How certain are you that the good things about your medication outweigh the bad things? □1 Not at All Certain □2 A Little Certain |
| 7. | To what extent do the side effects interfere with your mental function (i.e., ability to think clearly, stay awake, etc.)? □1 A Great Deal □2 Quite a Bit □3 Somewhat □4 Minimally □5 Not at All | 14. | □3 Somewhat Certain □4 Very Certain □5 Extremely Certain Taking all things into account, how satisfied or dissatisfied are you with this medication? □1 Extremely Dissatisfied □2 Very Dissatisfied □3 Dissatisfied |
| 8. | To what degree have medication side effects affected your overall satisfaction with the medication? □ 1 A Great Deal | | □4 Somewhat Satisfied□5 Satisfied□6 Very Satisfied□7 Extremely Satisfied |
| | □2 Quite a Bit □3 Somewhat □4 Minimally □5 Not at All | score shou EFFI | LE SCORING ALGORITHM: TSQM Scale es range from 0 to 100 and no computed score ld be lower or higher than these limits. ECTIVENESS: ([(Item $1 + Item 2 + Item 3) - 3$] |
| 9. | How easy or difficult is it to use the medication in its current form? □1 Extremely Difficult □2 Very Difficult □3 Difficult □4 Somewhat Easy □5 Easy | If or 2? + SIDF divid | led by $18) \times 100$ ne item is missing: ([(Sum of Item 1? + Item Item 3?)) - 2] divided by $(12) \times 100$ E EFFECTS: ([Sum of Item 5 to Item 8) - 4] led by $16) \times 100$ ne item is missing: ([(Sum of Item 5? to Item - 3] divided by $12) \times 100$ |

| livid f o Item OVE First Then | IVENIENCE: ([Sum of Item 9 to Item 11) – 3] led by 18) × 100 ne item is missing: ([(Sum of Item9? to 11?)) – 2] divided by (12) × 100 IRALL SATISFACTION recode Item14_recode = (Item14 – 1) × 5/6 le: ([Sum of Item 12 to Item 14) – 3] divided by × 100 | 5. | □4 Slightly Dissatisfied □5 Not at all Dissatisfied How dissatisfied are you by side effects that interfere with your mental function (e.g., ability to think clearly, stay awake)? □1 Extremely Dissatisfied □2 Very Dissatisfied □3 Somewhat Dissatisfied |
|--|---|-----|---|
| | y one Item is missing: ([Sum of Item 12? to Item | | □4 Slightly Dissatisfied |
| | -2] divided by (8) × 100 | | □5 Not at all Dissatisfied |
| | | 6. | How dissatisfied are you by side effects that interfere with your mood or emotions (e.g., |
| Д рр | endix B | | anxiety/fear, sadness, irritation/anger)? |
| rso/ | M (Version II): Treatment Satisfaction | | □1 Extremely Dissatisfied □2 Very Dissatisfied |
| _ | tionnaire for Medication | | □3 Somewhat Dissatisfied |
| - | ts to the TSQM v. I and TSQM v. II are shared | | □4 Slightly Dissatisfied |
| | uintiles Strategic Research Services and Pfizer | | □5 Not at all Dissatisfied |
| | For permission to use approved formatted ver- | 7. | How satisfied or dissatisfied are you with how |
| | of the instruments as well as obtaining numer- | | easy the medication is to use? |
| ous t | ranslations, please contact Shoshana Colman, | | □1 Extremely Dissatisfied |
| | Quintiles Strategic Research Services, 475 | | □2 Very Dissatisfied |
| | nan Street, Suite 430, San Francisco, CA | | □3 Dissatisfied |
| | 7; Voice: 415.633.3243; Fax: 415.633.3133: | | ☐4 Somewhat Satisfied |
| | nana.colman@quintiles.com. | | □5 Satisfied |
| 1. | How satisfied or dissatisfied are you with the | | □6 Very Satisfied |
| | ability of the medication to prevent or treat | 0 | □7 Extremely Satisfied |
| | the condition? | 8. | How satisfied or dissatisfied are you with how |
| | ☐1 Extremely Dissatisfied | | easy it is to plan when you will use the med- |
| | ☐2 Very Dissatisfied ☐3 Dissatisfied | | ication each time? |
| | ☐4 Somewhat Satisfied | | □1 Extremely Dissatisfied □2 Very Dissatisfied |
| | □5 Satisfied | | □3 Dissatisfied |
| | □6 Very Satisfied | | □4 Somewhat Satisfied |
| | □7 Extremely Satisfied | | □5 Satisfied |
| 2. | How satisfied or dissatisfied are you with the | | □6 Very Satisfied |
| | way the medication relieves symptoms? | | □7 Extremely Satisfied |
| | □1 Extremely Dissatisfied | 9. | How satisfied or dissatisfied are you by how |
| | □2 Very Dissatisfied | | often you are expected to use/take the |
| | □3 Dissatisfied | | medication? |
| | □4 Somewhat Satisfied | | □1 Extremely Dissatisfied |
| | □5 Satisfied | | □2 Very Dissatisfied |
| | □6 Very Satisfied | | □3 Dissatisfied |
| | □7 Extremely Satisfied | | □4 Somewhat Satisfied |
| 3. | As a result of taking this medication, do you | | □5 Satisfied |
| | experience any side effects at all? | | □6 Very Satisfied |
| | □1 Yes | | □7 Extremely Satisfied |
| | □0 No | 10. | How satisfied are you that the good things |
| 4. | How dissatisfied are you by side effects that | | about this medication outweigh the bad things? |
| | interfere with your physical health and ability | | ☐1 Extremely Dissatisfied |
| | to function (e.g., strength, energy levels)? | | □2 Very Dissatisfied |
| | □1 Extremely Dissatisfied □2 Very Dissatisfied | | □3 Dissatisfied □4 Somewhat Satisfied |
| | □3 Somewhat Dissatisfied | | □ 5 Satisfied |
| | Joint what Dissatisfied | | _o outioned |

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| | □6 Very Satisfied | EFFECTIVENESS: ([(Item 1 + Item 2) – 2] divided |
|-----|---|---|
| | □7 Extremely Satisfied | by $(12) \times 100$ |
| 11. | Taking all things into account, how satisfied | SIDE EFFECTS: ([Sum of Item 4 to Item 6) – 3] |
| | or dissatisfied are you with this medication? | divided by $12) \times 100$ |
| | □1 Extremely Dissatisfied | If one item is missing: ([(Sum of the two completed |
| | □2 Very Dissatisfied | items) – 2] divided by $(8) \times 100$ |
| | □3 Dissatisfied | CONVENIENCE: ([Sum of Item 7 to Item 9) $- 3$] |
| | □4 Somewhat Satisfied | divided by $18) \times 100$ |
| | □5 Satisfied | If one item is missing: ([(Sum of the two completed |
| | □6 Very Satisfied | items) – 2] divided by $(12) \times 100$ |
| | □7 Extremely Satisfied | GLOBAL SATISFACTION: ([Sum of Item 10 to |
| | | Item 11) – 2] divided by 12) \times 100 |

SCALE SCORING ALGORITHM: TSQM Scale scores range from 0 to 100 and no computed score should be lower or higher than these limits.