Development of a New Questionnaire to Measure Satisfaction with Treatment with Medicines (SATMED-Q)

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OBJECTIVE A new generic questionnaire to measure Satisfaction with medicines is under construction. Item reduction and factorial validity are discussed.

INTRODUCTION

New advances in health care have shifted concern from infectious to chronic illnesses and therefore a new emphasis in the assessment of satisfaction with pharmaceutical treatment has risen. In Spain, there is no questionnaire available to assess satisfaction with treatment and so a new instrument is being built. Following the model proposed by Shiak and Rentz1, a six dimensional questionnaire is under construction. Item reduction and factorial validity of the new instrument are discussed here.

MATERIALS AND METHODS

Procedure

An expert panel was set up in order to advise in the design and follow up of the questionnaire construction process. The expert panel was composed by 3 medical doctors, 1 psychologist, 2 methodologist, 1 pharmacoepidemiologist and 1 clinic pharmacist.

A first approach was made considering the possibility of a linguistic adaptation of the TQM-SET Treatment Satisfaction Questionnaire for Medication (Version 1.3), a 9 items self reported questionnaire. After bibliographic review, the 5 dimensional model proposed by Shiak and Rentz1 was considered more suitable for the research aims.

A total of 4 focus groups constituted by (6-8) experienced patients were conducted: two groups of resident elderly people, one group of women in reproductive hormone substitution therapy, and one group of hypertensives patients.

A 36 items questionnaire was constructed and administered to a small sample of regular patients to check for response biases. Also time of response was recorded and additional 3 questions about comprehension, need of help, and need of clarification were included. The questionnaire was self reported under supervision by a health professional during an ordinary medical visit. The questionnaire was arranged around 6 main dimensions in the following order: 1.Efficacy and symptom relieve (5 items), 2.Ease and convenience (6 items), 3.impact on HRQL (4 items), 4.Satisfaction with medical care (4 items), 5.Medication Side Effects (8 items), and 6.Overall satisfaction (9 items), although additional dimensions could be latent in some items, i.e. Expectations towards treatment, Adherence, General health status, Willingness to recommend drug, and Available drug choices.

The questionnaire was administered to a representative sample of 156 patients for item reduction and dimension analysis. Since it was expected that all dimensions should relate between them, item analysis was conducted for the total questionnaire and within each conceptual dimension. Cronbach's alpha, item-total correlation, item deleted adjusted alpha, r-square item correlation, and bias statistics were computed. Also, a unidimensional exploratory factor analysis with principal components extraction was used to select those items composing each dimension. Items with communalities below the proportion of variance explained by the first eigenvalue were considered for deletion. A minimum of 3 items per dimension were desirable for proper dimension identification.

The reduced questionnaire was analyzed with exploratory factor analysis (EFA) and confirmatory factor analysis (CFA) in order to study the relations between dimensions. EFA was conducted using principal components extraction and Promax oblique rotation. The number of factors was determined using K1 rule and the Minimum Average Partial Method. CFA was estimated using Maximum Likelihood and allowing correlation between all factors.

The five dimensional solution was estimated using a CFA model using a validation sample. All factors were allowed to correlate but observed variables were allowed to load only in the theoretical latent factor. The estimation method used was GLS and factor variances were fixed to 1 in order to model the identified structure.

Patients and Sample

Four different samples were used. One sample of 12 patients used to assess usability and comprehension, a second sample of 24 patients included in the focus-groups sessions, a third sample was used for item reduction, and a fourth sample was used to confirm the instrument structure.

Two aspects were considered in the sample design: dimension construction and pathology representation. Based on the number of items conforming the questionnaire, a individual to item ratio above 3:1 is recommended and also sample sizes above 100 individuals. Since the questionnaire was composed by 36 items and using a ratio 4:1, a total of 144 individual were needed.

Given that the new instrument is to be used in general practice, 7 of the most prevalent pathologies were selected in order to capture patients from all of them. Also additional equally distributed strata for age (above 65 years old and younger of 65 years old) and gender were designed. Sampled pathologies were: Diabetes type II, Hypertension, Osteoarthritis, Prostate problems, EPOC/Arthritis, Depression, and Migraine. Patients were reminded to fill in the questionnaire trying to assess only one of their treatments (if they presented more than one). A total of 156 patients were included. The fourth sample was composed in a similar way as the data reduction sample, and was composed by 120 patients.

Patients were recruited at 4 primary care services (3 public and 1 private) and included by random sequential assignment and coverage of strata.

RESULTS

The initial 36 item questionnaire was reduced to a 14 form, composed by 5 dimensions, plus an additional 3 item dimension included to assess undesired pharmacological effects.

Five dimensions were found to be stable and well formed. Except the dimension of Medical care (2 items), the remaining dimensions were built up by 5 items each. The value for Cronbach's alpha was above 0.8 for all dimensions. Dimensions were correlated with each other suggesting that a summary global dimension can be achieved. Such dimension would explain 40% of the available variance, presented an alpha value of 0.881, and all items would load in it, with communalities ranging. 707-960.

A sixth dimension of Undesired Effects showed a marked floor effect. This dimension was kept in the questionnaire given that the new instrument is to be used in general practice, 7 of the most prevalent pathologies were considered for deletion. A minimum of 3 items per dimension were desirable for proper dimension identification.

New estimates of correlations between factors were obtained, with their associated significance values. The stronger relations found were between Efficacy and symptom relieve with Impact (rxy=0.661) and Overall satisfaction (rxy=0.52) and between Impact with Overall satisfaction (rxy=0.487) and with Medical care (rxy=0.328). Convergence was the more independent dimension, showing no significant relation with Medical care (rxy=-0.055, p = 0.931) and Impact (rxy=0.46, p = 0.089), and small relations with all other dimensions.

In the CFA model estimation, all factor loadings were significant (p < 0.001) and Goodness-of-fit-statistics were acceptable: Chi-square= 96.84 (df=38; p=0.010), Chi-square/df = 1.445, GFI = 0.880, AGFI = 0.811, CFI = 0.926, RMSEA = 0.062.

The questionnaire shows good reliability and validity properties. The 5+1 proposed dimensions are stable and well defined in a 17-item form. Results support that the questionnaire can be used to compute an overall meaningful score.

REFERENCES


Table 1. Pattern matrix (Promax factor loadings)