CMRO

Current Medical Research & Opinion Volume 25, Number 10 October 2009

0300-7995
doi:10.1185/03007990903158430

Article 5023/416016
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Original article
Development of the Asthma Treatment Satisfaction Measure

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Mona L. Martin
Health Research Associates, Inc., Mountlake Terrace, WA, USA

Donald L. Patrick
University of Washington, Seattle, WA, USA

Donald M. Bushnell
Health Research Associates, Inc., Mountlake Terrace, WA, USA

Eli O. Meltzer
Asthma and Allergy Associates, San Diego, CA, USA

Benjamin Gutierrez
Bhash Parasuraman
AstraZeneca, Wilmington, DE, USA

Address for correspondence:
Mona L. Martin, RN, MPA, Health Research Associates, Inc. 6505 216th St. SW, Suite 105, Mountlake Terrace, WA 98043, USA.
Tel.: +1 425 775 6565; Fax: +1 425 775 6734; martin@hrainc.net

Key words:
Asthma – Outcome assessment – Patient satisfaction – Treatment outcome

Accepted: 2 July 2009; published online: 18 August 2009

Abstract

Objective:
Study aims were to develop and assess the measurement properties of a four-part treatment satisfaction measure for patients with asthma. The Asthma Treatment Satisfaction Measure (ATSM) incorporates specific attributes representing patient expectations, treatment preferences, self-reported treatment outcomes, and overall treatment satisfaction. This paper describes patients' ability to detect change in their satisfaction with asthma therapies using the ATSM.

Methods:
Adult patients with chronic asthma requiring a change in their asthma controller medications were recruited from sites in the US and Canada. Interviews were conducted with 22 patients to elicit areas important to patients in asthma treatment for measurement of satisfaction, providing the basis for the four-part questionnaire that was then tested for clarity. An additional 105 patients participated in the validation study and completed the first two parts of the ATSM (expectations and importance of treatment) at their initial visit (baseline) prior to a change in treatment. Parts 3 and 4 (treatment outcomes and treatment satisfaction) were completed after 4 weeks on the new treatment. A daily diary was completed by patients at home between visits. During clinical visits, patients also completed the Asthma Specific Quality of Life Questionnaire Standardized version assessing HRQL (AQLQ(S)), the Asthma Control Questionnaire 6-item version (ACQ-6), a 9-item asthma symptom checklist, items assessing symptom severity, and a single item overall rating of satisfaction (numerical analog scale between 0 and 10). Derived total satisfaction scores were compared to scores produced by the single global treatment satisfaction item using score variation and distribution plots.

Results:
Qualitative results identified 11 key attributes of asthma treatment. Internal consistency for the expectations, outcomes, and satisfaction parts of the measures (11 items each) were 0.73, 0.82 and 0.95, respectively. ATSM scores were able to discriminate between control and lack of control measured by ACQ-6 scores ($F = 30.09$; $p < 0.001$); between improvement, no change, or worsening of symptoms using the 4-week diary ($F = 7.05$; $p < 0.001$); between mild, moderate and severe levels of self-reported severity of asthma ($F = 2.07$; $p < 0.001$); and levels of self-reported health status ($F = 5.96$; $p < 0.001$). Compared to the single overall satisfaction item, the ATSM satisfaction score demonstrated a broader and more normal distribution. Irrespective of the variety of treatment regimens being changed from and changed to in the normal care setting, 4 of the 11 attributes still detected statistically significant differences in ($p < 0.05$) levels of patient satisfaction related to their new asthma treatment regimen.

Conclusion:
By augmenting a satisfaction rating with the constructs that help define satisfaction with treatment (expectation, importance and actual treatment experience), the ATSM scores demonstrated greater ability to detect changes in treatment and provide a potentially useful measurement system for pharmacologic evaluation. This study was conducted using a normal care setting to identify patients undergoing a change in treatment. Therefore, the main limitations were the inability to control for efficacy of treatment, and a relatively small sample. Several individual ATSM satisfaction scores were able to detect significant levels of patient satisfaction related to their treatment, while the global satisfaction scores were unable to detect any significant differences.

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Introduction

Patient satisfaction is a patient's subjective response to his or her evaluation of a treatment outcome, or its perceived quality. A person's expectation for the outcome of treatment, whether a specific mode of care, a prescribed behavioral change, or a drug therapy, is a key variable in customer satisfaction measurement in business and psychology[1]. End users of services are seen as having different expectations for services or products with a service quality gap between the expected 'what I want' and the perceived 'what I get'[2]. The early conceptual work by Weaver *et al.*[3] proposed the measurement of patient satisfaction as an indicator of healthcare quality. Research supports the relationship between patient satisfaction and treatment-related behaviors such as better adherence to treatment[4–8]. Several tools have been developed and tested for use in measuring patient satisfaction with drug therapy in general[9–12]. Multidimensional measures have been developed to measure other outcomes that are important to patients receiving treatment for their asthma[13–15]. The only measure found that addresses patient satisfaction with treatment for asthma was the 23-item Patient Satisfaction with Asthma Medication (PSAM). The PSAM was validated on a population of 53 adults with asthma who were participating in a clinical trial for inhaled medication. The PSAM has demonstrated acceptable measurement properties, but its content does not include patient expectations or importance values for treatment attributes. No data on patient satisfaction with a new asthma treatment have been reported to date[16].

Cleary and McNeil[17] discussed the importance of measuring patient satisfaction using multi-dimensional methods rather than global items. Their reasoning included the tendency of global measures to reflect numerous features of the treatment experience. Global measures often fail to detail the specific aspects of a treatment that may be associated with satisfaction or dissatisfaction and, therefore, generally have lower reliability and validity compared with multidimensional measures[4,13,18–21]. Furthermore, distributions of satisfaction ratings are commonly positively skewed with a majority of patients expressing high satisfaction. This might be due to social desirability factors, which may lead the patient to present more positive outcomes than are realistic to their actual experience.

Based on conceptual models previously published by Weaver *et al.* (1997), and Patrick *et al.* (2003)[3,18], the authors developed a conceptual framework to address the need for a more sensitive approach to the assessment of patient satisfaction with treatment. Previous application of this work in the therapeutic area of migraine headaches resulted in a unique, four-part model that incorporated the impact of a patient's expectations about their new treatment, the importance they placed on various treatment attributes, their perceived treatment outcomes, and their rating of satisfaction for individual aspects of their treatment experience[18,19]. This model identified patient expectations as a key influence on perceived satisfaction with treatment.

The primary aim of this study was to use the conceptual model and scoring system previously applied in migraine headaches to develop a measure for assessing a patient's satisfaction with a specific treatment for asthma. This paper reports on the identification of attributes that were relevant and important to patients being treated for asthma, and presents an evaluation of measurement properties for the Asthma Treatment Satisfaction Measure (ATSM).

Methods

Qualitative development

In previously published work[20], 22 adult patients with chronic asthma requiring a change in their asthma controller medications were recruited from sites in the US and Canada. Published literature, expert opinion and existing treatment satisfaction questionnaires were used to help develop a qualitative interview guide. Individual interviews and focus groups were used to elicit areas of importance about patient satisfaction with their asthma treatment. Information from these initial interviews was used to develop 11 attributes of concern that would affect most patients, be important to patients being treated for asthma, would be likely to change with effective treatment, and would generate attribute-specific points of satisfaction with their new regimen of asthma treatment. A preliminary measure was drafted and pilot tested using an additional ten patients with asthma in order to evaluate the ATSM's clarity of language, relevance of content, comprehension of items, readability, overall burden, and feasibility.

Validation study

Two clinics in Toronto, Canada, were asked to identify and recruit a combined total of 50 asthma patients and an additional three sites were used in the US to recruit a combined 50 patients. Sites were instructed to include only patients who were not being successfully controlled on their current asthma medications and needed their treatment changed as a part of their asthma usual care process. Acceptable changes in maintenance medications were either from one inhaled corticosteroid to combination therapy, or from one combination therapy to another.

Patients were included if they were 18 years or older, had asthma for at least 1 year, and were switching to a new prescription for their inhaled asthma controller treatment. They were required to read and write English sufficiently

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well to self-administer the ATSM and other measures. Patients were excluded if they did not have a current prescription for a controller medication for their asthma, were changing to a rescue medication only, had a smoking history of greater than 10 pack-years (e.g., one pack of cigarettes a day for a year, for 10 years) in order to avoid complications with COPD or other chronic lung obstruction conditions, or had any other health problems (i.e., cancer) that may confound study results.

Staff at each clinic site screened patients from their normal patient flow for study eligibility and approached potential subjects to explain the requirements and purpose of the study and complete the informed consent process. At enrollment, patients were asked to complete parts 1 and 2 (expectations and importance) of the ATSM, as well as the Asthma Specific Quality of Life Questionnaire Standardized (AQLQ(S))[22], the Asthma Control Questionnaire 6-item version (ACQ-6)[23], items assessing symptom severity, and a 9-item asthma symptom checklist. Patients were sent home with a daily symptom diary to complete during their first 4 weeks on the new treatment regimen. One part of the diary was filled out daily (symptoms, nighttime awakenings, and rescue medication use) and the other part was done weekly (onset of effect, OEQ). Participants returned to clinic at 4 weeks and were given parts 3 and 4 (treatment outcomes and satisfaction) of the ATSM to complete along with the AQLQ(S), ACQ-6, 9-item symptom checklist, and an independent overall rating of satisfaction (numerical analog scale between 0 and 10).

Ethics approval was obtained for both the US and Canadian sites prior to recruiting patients. Weekly reminder calls by the clinical staff encouraged patient compliance with diaries, and appointment follow-up. At the close of the 4-week study, patients were given $125 for their participation.

Measures

The ATSM is a four-part assessment, each part addressing the following 11 basic attributes of treatment-related concerns:

(A) To have my new asthma maintenance medication relieve my symptoms quickly
(B) To have my asthma symptoms relieved
(C) To reduce my need to use rescue medication
(D) To prevent future asthma attacks
(E) To have this new asthma maintenance medication work each time
(F) To have feelings or sensations that tell me my new asthma maintenance medication is working
(G) To perform my daily activities and chores as if I do not have asthma
(H) To engage in my desired leisure activities as if I do not have asthma
(I) To manage my dosing according to my symptoms
(J) To have a new asthma maintenance medication that is convenient to use
(K) To have a new asthma maintenance medication with no side-effects

Part 1: The expectations of treatment for asthma (TE-A)

The 11 items in the TE-A correspond to the 11 main attributes of treatment satisfaction for asthma listed above, and are worded to express the attribute as an expectation (e.g., 'I expect this asthma maintenance treatment will. . .'). Each item has a 5-point response scale unique to what one would expect in a treatment with 1 being the worst case scenario (e.g., 'not change the frequency of my asthma attacks') and 5 being the best situation (e.g., 'totally prevent future asthma attacks'). This part of the ATSM addresses 'ideal expectations'.

Part 2: The importance ranking for asthma treatment (IR-A)

The IR-A ranks the 11 attributes by their importance to a patient'. A line is drawn from the attribute to a place on a 10-cm rating scale with 'As important as can be' at the top to 'Not important at all' at the bottom. The intersection of their drawn line and the 10-cm line gets scored on a 0- to 100-point scale.

Part 3: The outcomes of treatment for asthma (TO-A)

The 11 items in the TO-A express the patient's perception of their treatment outcome (e.g., 'This asthma maintenance treatment relieved my asthma symptoms'). Each item has a 5-point response scale indicating the actual outcome of the treatment with 1 being the worst-case scenario (e.g., 'did not relieve my asthma symptoms at all') and 5 being the best situation (e.g., 'totally relieved my asthma symptoms'). This part of the ATSM produces a self-report of treatment outcomes.

Part 4: The satisfaction with asthma treatment (PST-A)

The PST-A examines the patient's degree of treatment satisfaction as it corresponds to each attribute (e.g., 'Please rate your overall satisfaction with how often your new asthma medication worked'). Each item has a 0 to 10-point visual analog response scale with 0 being 'The most dissatisfied I could be' and 10 being 'The most satisfied I could be'. This part of the ATSM addresses satisfaction of the actual treatment experience.

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Other measures used to assess the measurement properties of the ATSM included:

(1) The Asthma Quality of Life Questionnaire Standardized form (AQLQ(S))[16], a 32-item measure covering four domains of health-related quality of life (HRQL) impairment (activity limitation, symptoms, emotional function, and environmental stimuli). Response options are on a 7-point scale where 1 indicates maximum impairment and 7 indicates no impairment. Scores are summed within each domain and expressed as a mean score for each domain with higher scores indicating 'less impairment' of HRQL.

(2) The Asthma Control Questionnaire (ACQ-6)[15], describing five symptoms and an additional item of clinical impairment that a patient with asthma may experience as a result of their disease. Response options are on a 7-point scale, with 1 representing the worst state and 7 representing the best state. Depending on the item, some scores need to be reverse scored prior to analysis.

(3) A set of 11 global satisfaction items (for comparison to the respective ATSM derived satisfaction score). Each item has a 0- to 10-point response scale with 0 being 'The most dissatisfied I could be' and 10 being 'The most satisfied I could be'.

(4) A 4-week Asthma Symptom and Medication Diary containing 8 items, including the use of rescue medication, night awakenings, oral steroid use, missed school or work, interrupted routine activities, doctor care, and a daily symptom score from 0 (no problem) to 3 (unable to do your normal activities or sleep).

(5) The Onset of Effect Questionnaire (OEQ)[24,25] containing a set of five questions to determine patient's perception of how they felt after taking the medication within the past week. Each item was rated on a 5-point response scale from 'strongly agree' to 'strongly disagree'.

(6) Severity was evaluated by asking patients to rate the severity of symptom flare-ups over the past week, on a 3-point scale (mild, moderate, or severe).

(7) Symptom-related checklist (the Asthma Symptom Frequency and Bothersomeness (ASFB)) uses a set of nine key symptoms frequently associated with asthma. It was designed specifically for this study by the development team based on patient feedback during the qualitative phase of the study and was reviewed by asthma experts. Each symptom has seven response options (along with an option of not having the symptom due to asthma) ranging from 1 (Not at all bothered) to 7 (A very great deal bothered). The final score is the sum of each symptom's bothersomeness response ranging from 0 (not having any symptoms) to 63 (being a very great deal bothered by all nine symptoms).

(8) Items addressing self-reported severity, self-reported health status, and the patient's self-reported ability to cope with their asthma management.

Statistical methods

Once collected by the clinical sites, the validation study case report forms were copied and sent to Health Research Associates (Seattle, WA, USA) where the data was entered and analyzed using SPSS for Windows, Version 10.1[26]. Descriptive tables were prepared to present demographic characteristics of the study population. Standard descriptive statistics were calculated for each of the convergent patient reported outcome (PRO) measures in order to identify ranges (minimum to maximum) and the distributions of response choices. Mean, standard deviations, median, and percentage of missing data were computed for each item.

Cronbach's alpha was used to assess internal consistency reliability for the expectations, outcomes and satisfaction sections of the measures, and to determine if the items within each scale were highly associated[27]. A high internal consistency suggests that the scale or subscale is measuring a single construct. A minimum correlation of 0.70 is necessary to claim the instrument is internally consistent and it is preferred to have alpha values between 0.80 and 0.90[27].

To assess convergent validity, Pearson correlations were used to assess convergent associations between the ATSM scores, the AQLQ(S), and the ACQ-6. Known groups' validity was evaluated using established cut-points on the AQLQ(S) and the ACQ-6.

Assessing known groups' validity involved testing various hypotheses about how the authors intuitively believe the ATSM scales should work. The authors compared treatment satisfaction by levels of HRQL (AQLQ(S), cut-point), asthma control (ACQ-6 cut-point), symptom change (4-week diary), self-reported severity, self-reported health, coping with asthma management, the 9-item symptom checklist (tertiles), and OEQ items 1 (Could tell that the medication was working) and 2 (Could feel that the medication began to work right away). ANOVAs with Student-Newman-Keuls (SNK) comparisons were performed to assess discriminant validity. Regression analysis was used to identify a proportionate contribution of the difference between outcomes/expectations and the importance rank on the final patient reported level of satisfaction.

The 4-week diary data was evaluated by week and expressed in totals except for the daily symptom score, which was evaluated as average score per week. The OEQ items were evaluated as single items and expressed

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as dichotomous variables, to denote that patients feel their medication working (strongly agree, somewhat agree = yes) or not (neither agree nor disagree, somewhat disagree, strongly disagree = no). Based on the ranking portion of the survey, the 11 attributes of the ATSM were ordered by importance to the patients.

The four parts of the ATSM were used to derive an augmented satisfaction score. Derived satisfaction scores were compared to scores produced by the single global treatment satisfaction item. Testing of the measurement properties of the ATSM was conducted using the scoring procedures developed in the previous work with this model in migraine headaches, the instrument review criteria developed by the Scientific Advisory Committee of the Medical Outcomes Trust[28] and the FDA PRO Draft Guidance[29,30].

Scoring methods

The scoring method from previous work[18,19] used regression analysis to identify the relative contribution of the differences between expectations and treatment outcomes and between the importance ranking and the final patient-reported level of satisfaction.

Separate regressions were run for each of the 11 main attributes. For each attribute, the patient-reported (raw) satisfaction item was entered as the dependent variable and the independent variables were outcomes/expectation item differences and the item responses for importance ranking. This produced 11 pairs of regression coefficients (one for the difference in outcome/expectation and one for the importance rank for each attribute). The final value used for weighting the outcomes/expectation score was derived from averaging the regression coefficients for all of the differences in outcomes/expectations for each attribute. Similarly, the overall weight for the importance rank came from the process of identifying and averaging the regression coefficients of the importance rank for each attribute. Adjusted weight values derived from the regression analysis in this sample were 0.80 and 0.20 for outcomes/expectation difference and importance, respectively.

An exploratory factor analysis with varimax rotation was performed with the 11 attribute scores to evaluate the validity of a single overall score for treatment satisfaction. The sensitivity of the scoring method was assessed by comparing the distributions of the global and the derived ATSM satisfaction scores against normal curves.

Scoring steps

Step 1

A score was calculated using the two self-report parts of the measure for expectations and outcomes. Using the Bland and Altman[31] theory that two measures of the same or highly related theme should be subtracted from one another, expectation (with a 1–5 response option) was subtracted from outcome (also a 1–5 response scale). This number was then transformed to a 0- to 100-point scale with higher scores representing expectations met and lowers scores indicating expectations not met. The resulting variable represented the difference between what a patient thought would happen and what actually happened (expectation modified by treatment experience/outcome). This step operationalizes treatment satisfaction as dependent upon expectations.

Step 2

The adjusted treatment expectations variable (from step 1) and the raw values given by patients for importance ranking were each multiplied by the regression weights. These two values were then summed to represent 'modified expectations, adjusted further for importance.'

Step 3

The value derived in step 2 was then divided by 10 to create a variable on a 0–10 scale that could be used as the final value for modifying the raw satisfaction scores.

Step 4

The derived treatment satisfaction values were generated by multiplying the raw individual satisfaction scores from the fourth part of the measure (Satisfaction items) by the variable created in step 3 (both on 0–10 response scales).

Scoring formula

$$\text{Attribute score} = (((((((\text{out} - \text{exp}) + 4)/8) * 100) * 0.80) + (0.20 * \text{Imp}))/10) * \text{Satisfaction}$$

Scoring example

Using attribute A. To have my new asthma maintenance medication relieve my symptoms quickly.

Let's imagine a patient expects that their new asthma maintenance medication will relieve their asthma symptoms within 15 minutes (third response option; exp = 3). After the treatment experience, the patient indicated that their new asthma maintenance medication relieved my asthma symptoms within 30 minutes (fifth response option; out = 2). This patient ranked this attribute's importance as a 50 (on a 0–100 scale; Imp = 50), and rated their overall satisfaction with how quickly their new asthma maintenance medication worked as a 6

Table 1. Demographic characteristics of the study population.

Characteristic	USA ($n=50$)	Canada ($n=55$)	Total ($n=105$)
Age in years: mean (SD)	38.8 (15.9)	44.9 (13.8)	42.0 (15.0)
Gender: (% female)	62	70.9	66.7
Marital status			
(% married)	50	45.5	47.6
(% divorced/separated)	8	18.2	13.4
(% never married)	38	30.9	34.3
Education: (% college graduate)	46	65.5	56.1
Years since diagnosis: Mean (SD)	19.0 (13.4)	18.0 (13.9)	18.5 (13.6)
Self-rated health			
(% excellent/very good)	50	47.3	48.6
(% good)	40	36.4	38.1
(% fair/poor)	10	16.4	13.3

(on a 0–10 point numerical rating scale; Satisfaction = 6). Following the formula above, the attribute score would be: $(((((((2-3)+4)/8)*100)*0.80)+(0.20*50))/10)*6=24$.

Step 5

The final overall ATSM treatment satisfaction score was generated by summing the 11 different derived treatment satisfaction values generated in step 4. This final overall score represents patient expectations about their treatment, modified by the treatment experience, weighted by their adjusted importance values, and used to express a more sensitive expression of overall score for treatment satisfaction.

The recruitment for this study came from usual patient flow across several clinics using inclusion and exclusion criteria that were very specific regarding allowable treatment regimen changes. However, treatment itself was not controlled. This study sought to evaluate both the performance of the measure and the responses of the values in satisfaction with treatment as patients changed from one medication to the next.

The measurement model calls for a study design where the first two parts of the measure are administered prior to the onset of a new treatment and the remaining two parts at a later point in time. This allows the ATSM score to reflect a change related to a new treatment. Ability to detect change was evaluated by comparing ATSM scores and population groupings by changes to different medications.

Results

Population description

The mean age of the overall sample ($n=105$) at baseline was 42.0 years (SD ± 15.0), of whom 66.7% were female, 56.1% reported having graduated from college and 48.6% rated themselves as having excellent or very good heath. Table 1 summarizes the demographic characteristics of the validation study population. There were only minor variations between the groups recruited in Canada and the US. The US group had slightly fewer years of education, was slightly younger, and had fewer participating males. The Canadian population had more divorced participants and had slightly fewer participants reporting 'good to excellent' health status, but more reporting 'fair or poor' health status.

Scale results

In order to evaluate how important the 11 attributes were to patients, the responses from the first part of the ATSM were rank ordered (Table 2) by impact on patient satisfaction with treatment. The most important was 'To have my asthma symptoms relieved'. The least important attribute was 'To have feelings or sensations that tell me my new asthma maintenance medication is working'. While the individual ranges are quite wide, no attribute had a mean rank of less than 35 on a 0–100 scale.

Internal consistency results for the expectations, outcomes and satisfaction parts of the measure were $\alpha=0.73$, 0.82, and 0.95, respectively. The correlations between raw satisfaction scores for the 11 attributes and the ATSM adjusted satisfaction scores using Spearman methods was 0.92. The relatively high alpha values are consistent with the earlier development work and were expected due to the structure and design of the measure, the scoring, and the use of one variable to create the other.

Convergent validity

Prior to analysis, the authors predicted that the ATSM scores would be strongly correlated to both AQLQ(S) and ACQ-6 measures ($r>0.50$). Specifically, ATSM scores were expected to be more highly associated with the AQLQ(S) *activity limitation* and *symptoms* domains.

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Table 2. Attributes rank ordered (by mean importance rank).

Attribute	*n*	Min	Max	Mean	SD
To have asthma symptoms relieved	105	33.0	100.0	86.0	14.1
To prevent future asthma attacks	104	5.0	100.0	82.2	21.2
To perform daily activities as if no asthma	105	3.0	100.0	80.7	23.7
To engage in desired leisure activities as if no asthma	104	1.0	100.0	75.6	26.5
To reduce need to use rescue medication	104	2.0	100.0	74.6	27.8
To have new asthma maintenance med relieve symptoms quickly	105	0.0	100.0	70.3	27.6
To have new asthma maintenance med work each time	104	3.0	100.0	64.1	25.0
To have new asthma maintenance med with no side-effects	104	0.0	100.0	53.5	30.7
To have new asthma maintenance med that is convenient to use	103	0.0	99.0	41.3	27.7
To manage my dosing according to my symptoms	94	0.0	100.0	41.3	30.1
To have feelings/sensations that tell me med is working	105	0.0	99.0	35.0	29.1

Attributes are ranked via a 10 cm rating scale with 'As important as can be' at the top to 'Not important at all' at the bottom. The intersection of their drawn line and the 10 cm line gets scored (on a 0- to 100-point scale).

Table 3. Convergent validity of the derived ATSM score.

	Derived ATSM score correlated† with	
	ACQ-6, AQLQ(S), OEQ, ASFB collected during follow-up visit	Difference of baseline and follow-up measures (ACQ-6, AQLQ(S), OEQ, ASFB)
AQLQ(S) – symptoms	0.61**	0.34**
AQLQ(S) – activity limitation	0.65**	0.35**
AQLQ(S) – emotional function	0.52**	0.36**
AQLQ(S) – environmental stimuli	0.50**	0.32**
AQLQ(S) – total	0.65**	0.37**
ACQ-6 – total	−0.62**	−0.38**
OEQ item 5		−0.22*
ASFB – symptom bother	−0.59**	−0.23*

†Correlations are Pearson coefficients.
*Correlation is significant at the 0.05 level; **Correlation is significant at the 0.01 level.
ATSM, Asthma Treatment Satisfaction Measure; QLQ(S), Asthma Quality of Life Questionnaire Standardized version; ACQ-6, Asthma Control Questionnaire 6-item version; OEQ item 5, Satisfied with how quickly felt the medication begin to work; ASFB, Asthma Symptom Frequency and Bothersomeness.

Table 3 shows the relationship between both the AQLQ(S) and the ACQ-6 with the derived ATSM scores at follow-up as well as the correlation between derived ATSM and difference between AQLQ(S), ACQ-6, symptom checklist, and OEQ baseline and follow-up measures. Strong correlations ($r > 0.50$) were observed between the derived ATSM score and AQLQ(S) domains, ACQ-6, OEQ item 5, and symptom checklist. Since derived ATSM score was a function of expectations and importance at baseline, and outcomes and satisfaction at follow-up; the authors examined the correlation between derived ATSM score and the difference in scores between baseline and follow-up for AQLQ(S), ACQ-6, symptom checklist and OEQ-item 5. As shown in Table 3, significant correlations were observed between derived ATSM and all the domains examined.

Known groups validity

Table 4 shows mean ATSM scores by scores from the AQLQ(S). There is a strong trend that satisfaction is higher in those patients with better quality of life, with significant differences seen between levels of AQLQ(S) change. Using published results indicating cut points for the AQLQ(S)[33]. Table 4 also shows two separate comparisons. The ATSM is able to discriminate between totally-controlled asthma versus not totally controlled ($p < 0.001$) and well-controlled asthma versus not well-controlled ($p < 0.001$). The ATSM is also able to distinguish between changes in symptoms using the symptom score data from the 4-week diary. Scores were significantly lower for those subjects indicating a worsening of their symptoms ($p < 0.001$). Significant differences were also found when looking at satisfaction by self-reported severity, self-reported health status, and the patient's self-reported ability to cope with their asthma management.

The 9-item Asthma Symptom checklist was also used to evaluate the ability of the ATSM to discriminate between known groups. Table 5 shows the ATSM treatment satisfaction scores in relation to bothersomeness of individual symptoms at the 4-week follow-up visit. Across all symptoms, treatment satisfaction (ATSM scores) were significantly lower as the ratings of degree of symptom-bother increased.

Sensitivity of the scoring algorithm

ATSM scores were compared to those from an independent global satisfaction item using the same 0–10 scale as the satisfaction part of the ATSM. The primary difference between the two scores is that the independent global item scores have not been adjusted to account for the impact of other important causes of treatment-related satisfaction (importance of attributes, expectations, and perceived outcomes). Pearson correlations between the single global items and the scores from the raw ATSM satisfaction component and the final adjusted ATSM score were 0.88 and

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0.86, respectively ($p<0.001$). For each of the 11 attributes, the augmented ATSM satisfaction score demonstrated a broader distribution versus the single satisfaction item. The range of the ATSM score distributions are shown in Table 6 in comparison to the narrow distribution of scores from the single independent global satisfaction item.

The sensitivity of the scoring method can further be demonstrated by Figures 1 and 2. Compared with the single satisfaction item, the ATSM scores are more normally distributed (single item median = 9, IQR = 3; overall ATSM median = 45.9, IQR = 17.1). Figure 1 shows the frequency of the independent global satisfaction item. The distribution is skewed to the right, with most of the participants reporting higher levels of satisfaction. Figure 2 shows the frequency of the augmented ATSM satisfaction score in the same population, which approximates a normal distribution.

Table 4. Known groups validity of the derived ATSM score by score.

	n	Derived ATSM score mean (SD)
Derived ATSM scores by the AQLQ(S) change score		
AQLQ(S) total change score category		
F-stat: 3.069* ($p=0.052$)		
Improvement (change ≥ 0.50)	45	45.8 (11.0)
No change (change = −0.49–0.49)	34	40.6 (14.5)
Deterioration (change ≤ 0.50)	6	35.12 (7.2)
ATSM scores by the ACQ-6 cut point		
ACQ-6 cut point (at follow-up)		
Totally controlled asthma		
F-stat: 30.093*** ($p<0.000$)		
Yes ≥ 0.5 ($n=34$)		50.9
No < 0.5 ($n=51$)		37.7
Well controlled asthma		
F-stat: 45.477*** ($p<0.000$)		
Yes ≥ 1.0 ($n=51$)		49.0
No < 1.0 ($n=34$)		33.8
ATSM scores by change in daily symptom scores		
Daily symptom score change from week 1 to week4		
*F-stat: 7.049** ($p<0.001$)*		
Improvement (change ≥ 1)	40	44.7 (11.3)
Remaining the same (change = 0)	28	46.2 (12.1)
Worsening (change ≤ 1)	17	33.4 (12.5)
ATSM scores by self-report severity		
Self-reported asthma symptom severity		
F-stat: 27.7, $p<0.001$		
Mild ($n=17$)		46.3 (9.1)
Moderate ($n=36$)		44.5 (12.0)
Severe ($n=32$)		39.4 (14.4)
ATSM scores by self-reported health		
Self-rated health		
F-stat: 5.595 ($p<0.005$)		
Excellent/very good ($n=42$)		46.3 (11.11)
Good ($n=32$)		41.9 (13.4)
Fair/poor ($n=11$)		33.0 (10.8)
ATSM scores by self-reported ability to cope with condition		
How well to cope asthma management		
F-stat: 5.494 ($p<0.006$)		
Very well ($n=24$)		49.5 (7.9)
Well/moderately well ($n=48$)		41.1 (12.2)
Somewhat/not well ($n=13$)		37.5 (16.7)

Ability to detect change

Table 7 shows the US, Canadian, and total group distribution across changes in medication categories. A large group of patients (46%) came into the study on an inhaled corticosteroid. The majority of patients (82.5%) changed from their previous regimen to a combination therapy.

The ATSM was designed to generate individual scores for each of the 11 individual attributes, as well as an overall satisfaction score. To evaluate a patient's ability to detect changes in medication, both the ATSM satisfaction scores and the global item scores were compared for groups changing to the two primary types of combination therapy, budesonide/formoterol fumarate dehydrate (Symbicort,

Table 6. Summary of global satisfaction score and derived ATSM score.

Global satisfaction score	Derived ATSM score range
2	9.32–16.04
3	15.11–23.37
5	18.97–29.74
6	28.13–52.49
7	31.34–43.06
8	25.95–48.46
9	32.94–53.91
10	43.63–62.95

Table 5. ATSM item scores by symptom bothersomeness (ASFB).

Symptom bothersomeness score (ASFB)	ATSM item score Mean (SD)						*F*-stats
	ASFB-response: No symptoms		ASFB-response: Hardly/somewhat/ moderately bothersome		ASFB-response: Good deal/great deal/ very great deal bothersome		
Tightness in chest	49.7 (11.1)	$n=18$	42.9 (11.7)	$n=59$	28.1 (10.2)	$n=8$	9.765***
Shortness of breath	48.0 (12.1)	$n=17$	44.2 (11.2)	$n=58$	27.2 (10.4)	$n=10$	11.764***
Wheezing	45.7 (11.2)	$n=35$	41.8 (13.4)	$n=47$	29.0 (0.8)	$n=3$	3.013*
Breaking out in sweat	46.0 (10.7)	$n=62$	34.7 (14.5)	$n=18$	34.3 (13.1)	$n=5$	7.933***
Coughing or choking	46.2 (11.8)	$n=34$	42.1 (12.2)	$n=44$	32.4 (14.1)	$n=7$	3.917**
Difficulty breathing	49.9 (10.3)	$n=29$	41.3 (10.3)	$n=50$	23.2 (16.9)	$n=6$	16.511***
Panic, fear	45.3 (11.3)	$n=68$	33.7 (13.9)	$n=16$	28.1 (.)	$n=1$	7.315***
Dizziness, light headed	45.6 (11.2)	$n=62$	39.2 (11.8)	$n=19$	19.2 (8.5)	$n=4$	11.674***
Tiredness, low energy	48.7 (9.3)	$n=40$	39.7 (12.4)	$n=36$	30.7 (14.2)	$n=9$	12.029***

*Significant at the 0.10 level; **Significant at the 0.05 level; ***Significant at the 0.01 level.

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AstraZeneca International, Wilmington, Delaware, USA) and fluticasone propionate/salmeterol (Advair, GlaxoSmithKline, United Kingdom)

Table 7 shows the results of the each of the 11 attributes across the various groupings of medication change. This analysis was carried out by country in order to account for any differences in the sample. Statistical differences were seen using the derived ATSM score that were not seen using only the global satisfaction items. In both Canada and the US, attribute 1 (ability to manage dose according to symptoms) showed statistically significant results in treatment satisfaction following a switch to either budesonide/formoterol fumarate dehydrate or fluticasone propionate/salmeterol from a previous treatment. Significant differences were also found in the US population for treatment changes to these two treatments with the ATSM attribute scores for A (quick relief), C (reduce need for rescue medication), D (prevent future asthma attacks). Tables 8a and 8b show the results by medication groups and change in therapy.

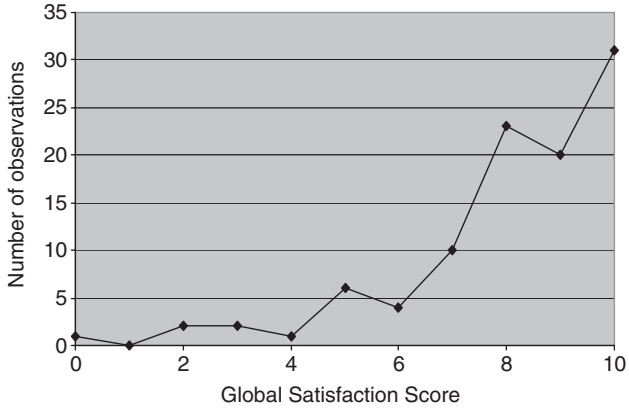

Figure 1. Frequency of global satisfaction scores.

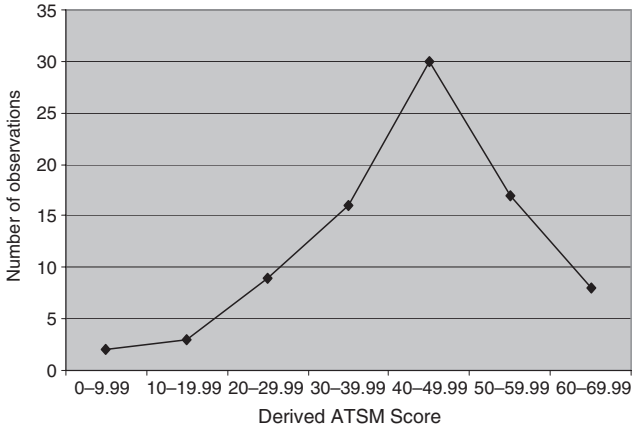

Figure 2. Frequency of derived ATSM scores.

Discussion

Until recently, information on patient satisfaction with drug therapy delivery system for asthmatics was not well researched. A review of the literature shows that several studies evaluating patient satisfaction with asthma therapies are developing and using self-reporting patent questionnaires as a component. One recently published study has developed the 'Onset of Effect Questionnaire'[24,32] to measure patient's perception and satisfaction with feeling an asthma medication working right away. Two other studies developed measures to assess the degree of satisfaction regarding available inhalation devices: the 'Feeling of Satisfaction with Inhaler (FSI-10)', a self-completed questionnaire to assess patient opinions regarding ease or difficulty of use, portability, and usability of devices for delivery of inhaled corticosteroids[34]; and the 'Satisfaction with Inhaled Asthma Treatment Questionnaire (SATQ)', patients' satisfaction with inhaled medication that strongly reflects the severity of asthma exacerbations as assessed by means of the spirometry[35]. The focus of these studies remains on the ability of the patient to easily identify and understand differences in their satisfaction with delivery mechanisms (such as inhalers), but not necessarily on their ability to compare the efficacy of one medication with another. All these studies are providing options for end points in clinical trials involving patients with asthma care. Ultimately, the data derived from these questionnaires could provide a basis for a more comprehensive asthma education program for patients with asthma.

Building on prior studies that measured treatment satisfaction in migraine headaches, the authors modified the content and scoring to develop a measure that was relevant and valid for use in evaluating patient satisfaction with asthma treatment. The overall hypothesis was that by including the impact of multiple variables driving satisfaction, a more sensitive and meaningful score would be developed to reflect asthma treatment satisfaction, thus providing a more useful measurement for pharmacologic evaluation. Convergent associations with other standard asthma specific measures and with key self-reported constructs were all strong. ATSM scores were able to discriminate between control and lack of control measured by ACQ-6 scores, between self-reported improvements, no change, or worsening of symptoms using the 4-week diary; between mild, moderate and severe levels of self-reported severity of asthma; and between different levels of self-reported health status. Compared to the single overall satisfaction item, the augmented ATSM satisfaction scores demonstrated a broader distribution and were more normally distributed.

Based on the 2006 FDA Draft Guidance on PRO measures, in order to support a claim based on a portion of a multi-item instrument, the development and validation

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Table 7. Derived ATSM scores for individual items and raw satisfaction score by treatment.

The 11 individual item attributes	USA						Canada					
	Derived ATSM score for individual attribute			Global satisfaction score for individual attribute			Derived ATSM score for individual attribute			Global satisfaction score for individual attribute		
	Change from any treatment to budesonide/ formoterol fumarate dehydrate ($n=10$)	Change from any treatment to fluticasone propionate/ salmeterol ($n=26$)	*F*-test	Change from any treatment to budesonide/ formoterol fumarate dehydrate ($n=10$)	Change from any treatment to fluticasone propionate/sal-meterol ($n=26$)	*F*-test	Change from any treatment to budesonide/ formoterol fumarate dehydrate ($n=34$)	Change from any treatment to fluticasone propionate/sal-meterol ($n=10$)	*F*-test	Change from any treatment to budesonide/ formoterol fumarate dehydrate ($n=34$)	Change from any treatment to fluticasone propionate/sal-meterol ($n=10$)	*F*-test
	Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
A. Asthma maintenance medication relieve my symptoms quickly	52.2 (19.4)	41.0 (16.2)	3.047*	8.4 (1.9)	7.4 (2.0)	2.126	40.5 (19.6)	31.3 (15.4)	1.874	7.0 (2.8)	6.2 (1.9)	0.384
B. Asthma symptoms relieved	63.7 (12.7)	54.9 (14.8)	2.783	8.7 (1.4)	8.1 (1.7)	0.905	49.9 (18.2)	42.2 (16.6)	1.438	7.5 (2.4)	7.1 (2.2)	0.666
C. Reduce need to use rescue medication	55.3 (14.6)	42.9 (17.2)	4.058*	8.9 (1.5)	8.1 (1.9)	1.558	34.3 (19.2)	32.4 (19.2)	0.077	6.8 (3.1)	6.9 (2.2)	0.919
D. Prevent future asthma attacks	68.8 (18.9)	54.4 (19.4)	4.027*	9.2 (1.4)	8.6 (1.6)	1.002	45.4 (22.7)	43.7 (17.6)	0.047	7.0 (2.9)	7.3 (2.5)	0.749
E. Have this asthma maintenance medication work each time	50.5 (16.4)	45.6 (14.3)	0.759	8.9 (1.7)	8.3 (1.9)	0.828	40.3 (17.2)	34.9 (14.6)	0.810	7.8 (2.4)	7.3 (2.1)	0.560
F. Have feelings/sensations that tell me my new asthma medication is working	32.2 (20.4)	27.6 (15.2)	0.526	6.8 (2.8)	7.2 (2.6)	0.133	27.7 (12.9)	29.8 (22.1)	0.147	6.5 (2.5)	6.1 (2.9)	0.649
G. Perform daily activities as if do not have asthma	51.7 (13.1)	49.5 (11.0)	0.242	8.8 (1.9)	8.8 (1.4)	0.000	42.9 (15.7)	38.6 (14.7)	0.579	7.9 (2.4)	7.9 (2.1)	0.989
H. Engage in desired leisure activities as if do not have asthma	50.9 (13.2)	47.2 (8.9)	0.981	8.8 (1.9)	8.8 (1.3)	0.003	41.7 (16.5)	35.0 (14.7)	1.309	7.8 (2.4)	7.6 (2.1)	0.794
I. Manage dosing according to symptoms	44.9 (20.8)	30.1 (14.4)	5.539**	8.0 (2.3)	7.4 (2.4)	0.559	37.3 (17.2)	26.3 (17.7)	2.940*	7.5 (2.5)	6.7 (2.3)	0.364
J. Have asthma maintenance medication that is convenient to use	44.6 (16.8)	40.6 (16.2)	0.423	8.5 (2.1)	8.5 (2.3)	0.002	36.3 (12.5)	30.5 (15.8)	1.458	7.8 (1.7)	7.2 (2.6)	0.377
K. Have asthma maintenance med with no side-effects	44.3 (17.0)	49.8 (11.9)	1.211	8.3 (2.8)	9.2 (1.2)	1.877	47.8 (14.8)	39.7 (14.5)	2.192	8.4 (1.8)	7.4 (2.6)	0.154

*Significant at the 0.10 level; **Significant at the 0.05 level.

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Table 8a. Numbers of participants by change of asthma medication category.

	USA ($n=50$)		Canada ($n=53$)		Total ($n=103$)	
	Previous prescription	New prescription	Previous prescription	New prescription	Previous prescription	New prescription
Inhaled corticosteroid (ICS)	50%	20%	41.5%	15.1%	45.6%	17.5%
Combination therapy	38%	80%	43.4%	84.9%	40.8%	82.5%
Rescue medications	8%	–	11.3%	–	9.7%	–
Other medication/no meds	4%	–	3.8%	–	3.9%	–

Table 8b. Patient medication categories.

		Frequency	Percent	Valid percent	Cumulative percent
Valid	No change	1	1.0	1.0	1.0
	Advair to Symbicort	14	13.3	13.6	14.6
	Advair plus to Symbicort	11	10.5	10.7	25.2
	Others to Symbicort	19	18.1	18.4	43.7
	Others to Advair	36	34.3	35.0	78.6
	Others to others	22	21.0	21.4	100.0
	Total	103	98.1	100.0	
Missing	System	2	1.9		
Total		105	100.0		

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process should ensure that the measure was appropriately developed to perform in this manner and that the measurement supports the claimed concept. The ATSM is comprised of 11 different attributes that are supported by qualitative work with patients being treated for chronic asthma and it is designed to be used as individual attribute scores, thus enhancing the ability to more specifically assess pharmacologic compounds with different benefit and risk profiles.

Conclusion

The data presented in this report demonstrate that the ATSM has good psychometric performance, is more comprehensive than a single global satisfaction item, and is able to reflect differences in satisfaction with changes in therapeutic strategies, unlike scores from a single global item. While an overall Treatment Satisfaction Score can be generated for the ATSM, further investigation is needed in order to understand the relationship between overall satisfaction and individual scores using analytic techniques like factor analysis.

Due to the subjective and multi-dimensional nature of treatment satisfaction, it may not be possible to derive a clinical interpretation of satisfaction scores. Significant differences in satisfaction between treatment groups should be both appropriate and sufficient to show favorable and non-favorable patient impressions about their choice of care. Responder analysis of more satisfied patients might shed further light on groups that might be predicted to have greater degrees of satisfaction with specific compounds, but the definition of responders and non-responders would need to be explored specific to each treatment agent.

These data show the ATSM to be a reliable and valid measure of patient satisfaction with their asthma treatment. Because it was developed based on patient information regarding the important attributes for any treatment they might receive for their asthma, its application is potentially broader than only drug therapy. The ATSM can be used in studies with relatively low overall burden to patients. It is feasible for use in clinical trials, and offers the advantage of greater sensitivity to changes in treatment than a single global item was able to provide. By augmenting the rating with constructs that help define satisfaction with treatment (expectation, importance and actual treatment experience), the ATSM scores are able to demonstrate a greater ability by the healthcare provider and the patient to detect differences in satisfaction with change in medication, thus providing a more useful measurement for pharmacologic evaluation.

Transparency

Declaration of funding

This study was funded by AstraZeneca, which markets budesonide/formoterol fumarate dehydrate

Declaration of financial/other relationships

B.G. and B.P. have disclosed that they are employees of AstraZeneca. D.L.P. has disclosed that he is a consultant for AstraZeneca. E.O.M. has disclosed that he has received grants

from, and serves as a consultant to, numerous pharmaceutical companies. D.M.B. and M.M. have no relationships to disclose.

All peer reviewers receive honoraria from CMRO for their review work. Peer reviewer 1 has disclosed that he/she has received grants from Lilly and is on the speakers' bureau of Pfizer. The other peer reviewer has disclosed that he/she has no relevant financial relationships.

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