



Development and validation of the pain treatment satisfaction scale (ptss): a patient satisfaction questionnaire for use in patients with chronic or acute pain

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Received 26 June 2003; received in revised form 20 August 2004; accepted 1 September 2004

Abstract

The purpose of this study was to develop and validate a measure of patient satisfaction for patients receiving treatment for either acute or chronic pain: the Pain Treatment Satisfaction Scale (PTSS). Development of the initial questionnaire included a comprehensive literature review and interviews with patients, physicians and nurses in the United States, Italy and France. After initial items were created, psychometric validation was run on responses from 111 acute pain and 89 chronic pain patients in the United States. Analyses included principal components factor analysis tests of reliability, clinical validity and confounding. The hypothesized structure of the questionnaire was supported by statistical analyses, and seven overlapping or inconsistent items were removed. The multi-item domains of the final PTSS included 39 items grouped in five dimensions: information (5 items); medical care (8 items); impact of current pain medication (8 items); satisfaction with pain medication which included the two subscales medication characteristics (3 items) and efficacy (3 items); and side effects (12 items). Internal consistency reliability coefficients were good (ranging from 0.83 to 0.92). The test–retest reliability coefficients (ranging from 0.67 to 0.81) were good for all dimensions except medication characteristics (0.55). All dimensions except medical care discriminated well according to pain severity. The satisfaction with efficacy dimension, hypothesized to change in the acute pain population, indicated good preliminary responsiveness properties (effect size 0.37; $P < 0.001$). The PTSS is a valid, comprehensive instrument to assess satisfaction with treatment of pain based on independent modules that have demonstrated satisfactory psychometric performance.

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Keywords: Pain; Satisfaction; Questionnaire; Psychometrics; Health outcomes

1. Introduction

Pain is a subjective, personal, multidimensional experience that encompasses psychological, behavioral, affective, cognitive and sensory dimensions. Conventional measures of pain include verbal and numeric rating scales or visual analogue scales (VAS) (McDowell and Newell, 1996); generic quality-of-life instruments such as the Medical

Outcomes Study Short Form (SF-36) (Ware and Sherbourne, 1992), disease-specific measures such as the McGill Pain Assessment Questionnaire (Melzack, 1975) or the Brief Pain Inventory (Daut et al., 1983; Cleeland and Ryan, 1994), and newer augmented questionnaires such as the Treatment Outcomes in Pain Survey (TOPS) (Rogers et al., 2000a,b). The American Pain Society and the US Agency for Healthcare Research and Quality encourage the assessment of patient satisfaction with pain treatment (American Pain Society Quality of Care Committee, 1995; US Department of Health and Human Services, 1992). However, few of the available instruments for measuring patient satisfaction with pain treatment are comprehensive

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or have undergone psychometric testing (American Pain Society Quality of Care Committee, 1995; Carroll et al., 1999; McCracken et al., 1997; Payne et al., 1998; Ware et al., 1983) leading to the use of ‘homemade’ patient satisfaction measures in many studies (Hall and Dornan, 1988).

Patient satisfaction is the subjective, personal evaluation of treatment effectiveness, health service and health care providers. Satisfaction represents a complicated construct and it is inappropriate to reduce it to a single, one-dimensional item. From the patient’s perspective, satisfaction includes accessibility/convenience, availability of resources, continuity of care, efficacy, finances, humanness, information gathering, information giving, pleasantness of surroundings and quality/competence (Krowinski and Steiber, 1996). At its most basic level, satisfaction is a comprehensive evaluation of several dimensions of health care based on patient expectations and provider and treatment performance.

As an outcomes measure, patient satisfaction allows health care providers to assess the appropriateness of treatment according to patient expectations. In chronic diseases, where patients must live with treatment, patient satisfaction may be the distinguishing outcome among treatments with comparable efficacy (Weaver et al, 1997). Evidence suggests that patient satisfaction may be more sensitive to change than quality of life in clinical trials in chronic diseases (Weinberger et al., 1996).

Satisfaction with treatment provides information on treatment effectiveness (Cousins, 1994) and is believed to affect clinical outcome (Kehlet, 2002). High levels of patient satisfaction with medication correlate with treatment compliance, maintenance of a relationship with a specific provider and disclosure of important medical information (American Pain Society Quality of Care Committee, 1995). High levels of satisfaction have also been positively associated with good health status, fewer medical encounters and shorter hospital stays (McCracken et al., 1997). In contrast, dissatisfaction with medication may impact a patient’s likelihood to register formal complaints about services, engage in legal action against a clinic or provider or provide unfavorable publicity about a clinic (Carroll et al., 1999).

The Pain Treatment Satisfaction Scale (PTSS) was developed to assess satisfaction in patients with both acute and chronic pain. To establish the value of the questionnaire, a psychometric validation was performed, the results of which are the focus of this article.

2. Methods

2.1. Instrument development

The PTSS was developed based on semi-structured interviews with acute ($n=36$) and chronic pain ($n=24$)

sufferers, clinicians specializing in pain management ($n=24$) and three focus groups of nurses ($n=17$). Patients were recruited through the use of specialized agencies and newspaper advertisements. Acute pain patients were women suffering from dysmenorrhea or post-surgical patients who completed the interviews up to 72 h after their surgery. A patient interview guide, developed by three authors (E. Trudeau, C. Evans, P. Mertzanis), covered general health, impact of pain on a patient’s daily life, pain treatment, current pain medication and satisfaction with treatment. All patients had their diagnosis and treatment confirmed by their physician prior to being interviewed and provided their informed consent. Interviewers skilled in developing questionnaires conducted patient interviews and the focus groups in person. To facilitate the use of the PTSS internationally, interviews were conducted simultaneously in the United States, France and Italy. All physician interviews were conducted over the phone, utilizing a specifically designed telephone script. Each country contributed an equal number of clinicians and patients by pain type for the interviews.

After all interviews were conducted and transcripts created, summaries of the interviews were developed. A project team performed content analysis to determine item domains and generate potential items in each category.

The initial PTSS consisted of 69 items in seven hypothesized modules and seven external validation questions that could be administered separately. The modules were preliminarily titled general (7 items), information about pain and its treatment (5 items), medical care (5 items), current pain medication (11 items), pain medication route of administration (9 items with one skip pattern question), satisfaction with pain management and care (11 items) and side effects of medication (11 items). The seven stand-alone items query respondents on overall satisfaction and preference for treatment. One of the items was a question specific to treatment expectations, a known confounder in satisfaction assessments. The initial PTSS had a completion time of 10 min and utilized Likert-like response options (mainly on a five-point scale).

After completion of the initial interviews with patients and health care providers and development of the initial questionnaire items, the face validity of the initial PTSS was tested in the United States on 20 acute and chronic pain sufferers and four clinicians. Overall, both the patients and clinicians had positive opinions regarding the structure, understandability and intent of the questionnaire.

2.2. Validation study

The objectives of this study were to determine a consistent structure for the PTSS, develop a scoring algorithm, determine the appropriate number of items by domain and test its validity, reliability and responsiveness.

Two-hundred-fifteen US patients suffering from chronic or acute pain were recruited through newspaper advertisements and a clinical recruitment agency. Subjects who responded were asked several questions about their diagnosis and treatment to determine their eligibility. Eligible patients were sent a consent form for permission to contact their physician for further information on their diagnosis, treatment, pain severity and side effects.

Patients were included if they were 18 years of age or older, had a confirmed diagnosis of acute or chronic pain, experienced pain in the 72 h before screening for eligibility and within 1 week of the scheduled interview, were currently receiving pain treatment, would continue to receive treatment for the duration of the study, and were willing to participate in the entire study. Patients were excluded if they did not understand English or had a limitation or disability that would prevent them from participating.

Patients in the study were stratified into two groups: acute pain and chronic pain. The acute pain group included patients with post-surgical pain (dental, general, knee, hip and hand surgery, hernia repair, hysterectomy and bunionectomy) and those with dysmenorrhea. Chronic pain patients included those with osteoarthritis or rheumatoid arthritis and patients with cancer pain (breast, pancreatic, lung and colorectal).

The PTSS and a pain change question were administered to each study participant. The pain change question assesses whether the patient's pain changed over the previous 2 weeks. If there was no change in pain over the past 2 weeks patients indicated this and did not have to rate the degree of worsening or improvement. If the pain worsened the patient indicated by how much on a four-point scale (from a 'little worse' to 'a great deal worse'). If there was an improvement, the patient indicated by how much on a four-point scale (from a 'little better' to 'a great deal better'). The pain change item was developed specifically for this study based on findings from Guyatt et al. (2002). In addition, sociodemographic information was collected during screening or when the first set of questionnaires was completed. Patients at inclusion or at first administration completed two questions related to expectations of treatment and knowledge of treatment plan. Questionnaires were mailed to all participants and were returned in stamped, self-addressed envelopes. It required approximately 30 min to complete each set.

2.3. Psychometric testing

Gold standard psychometric tests and criteria (Nunnally and Bernstein, 1994; Streiner and Norman, 1995) were used to analyze the PTSS questionnaire. They included:

- Structure of the questionnaire
 - Principal components factor analysis (FA) with varimax rotation, item discriminant validity (item

correlates more with its own scale than with any other scale), item convergent validity (item correlates at or above 0.40 with its own scale after removing the item from the scale score and scale–scale correlations).

- Reliability
 - Internal consistency: the Cronbach α coefficient (Cronbach, 1951). A coefficient of ≥ 0.70 was considered to meet or exceed the standard criteria for reliability.
 - Test–retest reliability: intraclass correlation coefficient. An intraclass correlation coefficient of ≥ 0.70 provides confidence in test–retest reliability. Spearman correlation coefficients between the two assessments were also calculated as well as the Wilcoxon signed rank test to compare the two assessments.
- Clinical validity
 - This was assessed by describing and comparing baseline PTSS scores for subgroups of patients defined according to the following parameters: pain severity as assessed by the patient (rated as absent, very mild, mild, moderate, severe and very severe) and patient reports of treatment efficacy.
- Confounding
 - PTSS scores were analyzed for the confounding effect of a number of key variables, including gender, age, pain group, ethnicity, education and resource utilization.
- Responsiveness
 - Mean changes in PTSS scores according to change in pain were categorized as stable, worsened and improved.

Three population groups were defined to analyze the psychometric properties of the PTSS. The validation population was a selection of patients with exploitable PTSS data at baseline (i.e. completed questionnaires with less than 70% missing data). The test–retest population was a selection of chronic pain patients with exploitable PTSS questionnaires at both baseline and week 2. The responsiveness population was a selection of acute patients with exploitable PTSS data at both baseline and week 2.

2.4. Statistics

Descriptive statistics were calculated for continuous variables. For nominal and ordinal variables, the number of patients and the percentage for each response category were calculated. A FA was performed using the MINEIGEN criterion and by fixing the number of factors to the number of hypothesized dimensions. To compare groups of subjects for quantitative or ordinal data, Mann-Whitney-Wilcoxon tests were used to compare two groups, and Kruskal-Wallis tests were used to compare three or more groups. Categorical variables were compared among groups by a χ^2 test (or with the Fisher exact test whenever the underlying assumptions of χ^2 were not met). There was

no adjustment of threshold *P* values, since these analyses were exploratory in nature and *P* values were presented only as an indication of trend.

Data processing and most analyses were performed with SAS software (Statistical Analysis System, Version 8.2). Multitrait analyses (construct validity) and calculation of Cronbach α were performed using MAP-R (Multitrait Analysis Program) for Windows, Version 1.0.

3. Results

3.1. Subject characteristics

The initial validation study population was 215 patients. Among the 215 respondents, 209 returned the PTSS and one patient was not evaluable due to too many missing items; therefore, 208 patients were included in the final validation population with 111 patients from the acute pain group and 89 from the chronic pain group (eight patients had diagnoses of acute and chronic pain and were included when analyses were not stratified by type of pain). The test–retest population comprised 87 chronic pain patients (42% of total patients) and the responsiveness population included 107 acute pain patients (51% of total patients). The sociodemographics of the population are presented in Table 1. Only working status was significantly different between acute and chronic patients.

3.2. Structure of the questionnaire

The general health items and the stand-alone questions were not included in the FA as they provide complementary information to the PTSS. The FA led to the elimination of

7 items in the questionnaire because of similarity with concepts measured in other questions. Descriptions of the dimensions were adjusted to reflect this change; 39 items were grouped into five dimensions: satisfaction with current pain medication in two subscales: medication characteristics (3 items) and efficacy (3 items); side effects of medication (12 items); impact of current pain medication (8 items); medical care (8 items) and information about pain and its treatment (5 items). The main elements of the PTSS are presented in Table 2.

Table 3 provides results from the multitrait analyses based on the total sample with the new version of the PTSS (after item reduction). Only 2 items had a correlation coefficient of <0.40 . These items were from the side effect dimension. All items correlated better within their own dimension than with other dimensions.

Correlations among scales were low (<0.50), except between medication characteristics and efficacy (0.64) and between medical care and satisfaction with medication (0.52) (Table 4).

3.3. Internal consistency

All Cronbach α coefficients all exceeded the standard criteria for reliability of ≥ 0.70 (Table 5).

3.4. Test–retest reliability

Test–retest reliability was assessed for patients with chronic pain (Table 5). The change in PTSS scores from baseline to week 2 was described for three subgroups of patients (worsened, stable and improved as defined by the pain change item). Only stable patients were the focus of

Table 1
Sociodemographic characteristics of the study population

		Acute		Chronic		Total		Test
		<i>N</i>	%	<i>N</i>	%	<i>N</i>	%	
Gender	Male	26	23	33	37	59	28	4.4286 ^a
	Female	85	77	56	63	143	69	
Race/ethnicity	White	93	84	76	85	170	82	0.0185 ^a
	African American or black	14	13	10	11	25	12	
	Hispanic/Spanish-American	1	1	3	3	4	2	
	Asian/Pacific Islander	1	1	–	–	1	0.5	
Education	Eighth grade or less	3	3	8	9	11	5	0.00 ^a
	High school diploma/GED	29	26	18	20	47	23	
	Vocational school	3	3	2	2	5	2	
	Some college or associate's degree	29	26	34	38	65	31	
	College degree	26	23	13	15	39	19	
Professional or graduate degree	19	17	14	16	33	16		
Work status	Not working	34	31	51	57	86	41	14.2158 [*]
	Working	75	67	37	42	113	54	

* $P < 0.01$.

^a Nonsignificant.

Table 2
Main elements of the PTSS

Scale	Lowest (0)	Highest (100)
Satisfaction with current pain medication	Dissatisfaction with the time it takes for the medication to work, the level and duration of pain relief, form of medication, frequency and amount of medication taken	Satisfaction with the time it takes for the medication to work, the level and duration of pain relief, form of medication, frequency and amount of medication taken
Efficacy subscale	Dissatisfaction with the time it takes for the medication to work, the level and duration of pain relief	Satisfaction with the time it takes for the medication to work, the level and duration of pain relief
Medication characteristics subscale	Dissatisfaction with form of medication, frequency and amount of medication taken	Satisfaction with form of medication, frequency and amount of medication taken
Side effects of medication	Bothered by 12 possible side effects (e.g. drowsiness, nausea, constipation)	No experience of bother or not bothered at all by 12 possible side effects (e.g. drowsiness, nausea, constipation)
Impact of current pain medication	Pain medication negatively impacts physical health, outlook, daily and leisure activities, relationships, mood, concentration and independence	Pain medication positively impacts physical health, outlook, daily and leisure activities, relationships, mood, concentration and independence
Medical care	Medical staff does not do their best, provide adequate follow-up, ask about pain. Dissatisfaction with amount of time devoted and care provided	Medical staff does their best, provides adequate follow-up, asks about pain. Satisfaction with amount of time devoted and care provided
Information about pain and its treatment	Too much information or not enough information regarding illness, cause of pain, treatment option, pain medication and side effects	Right level of information regarding illness, cause of pain, treatment option, pain medication and side effects

Table 3
Multitrait analyses of the final PTSS

Dimensions	No. of items	Range of correlation (item-scale)	Convergent validity test ^a		Discriminant validity tests ^b	
			Success/total	Success rate (%)	Success/total	Success rate (%)
Satisfaction with current pain medication	6	0.60–0.81	6	100	30	100
Medication characteristics subscale	3	0.60–0.82	3	100	15	100
Efficacy subscale	3	0.76–0.83	3	100	15	100
Medical care	8	0.42–0.75	8	100	40	100
Impact of current pain medication	8	0.58–0.81	8	100	40	100
Information about pain and its treatment	5	0.66–0.80	5	100	25	100
Side effects of medication	12	0.24–0.64	10	83	60	100

A Cronbach α coefficient of ≥ 0.70 is considered to meet or exceed the standard criteria for reliability.

^a Number of correlations that were ≤ 0.40 .

^b Number of item-scale correlations with hypothesized dimension higher than with other dimension/total number of item-scale correlations.

test–retest analysis. For all dimensions except information, mean scores were not significantly different between baseline and week 2 ($P > 0.05$, Wilcoxon signed rank test). The intraclass correlation coefficient was greater than 0.70 for three of the scales: satisfaction with current medication, medical care and information. The side effects and impact of current medication had intraclass correlation coefficients of 0.67 and 0.68, respectively, indicating adequate confidence in test–retest reliability.

3.5. Clinical validity

All dimensions were significantly related to pain intensity immediately following treatment. PTSS scores were negatively correlated to pain severity. The highest correlation was obtained for the efficacy subscale and pain immediately following treatment.

The following variables were examined by PTSS dimension to test for known groups validity: pain severity

Table 4
Scale–scale correlation within the PTSS

Dimensions	Medication characteristics	Information	Medical care	Pain medication	Side effects	Efficacy of pain medication
Medication characteristics subscale	–					
Information about pain and its treatment	0.25	–				
Medical care	0.47	0.40	–			
Impact of current pain medication	0.36	0.16	0.27	–		
Side effects of medication	0.36	0.17	0.21	0.26	–	
Efficacy subscale	0.64	0.37	0.46	0.45	0.30	–
Satisfaction with current pain medication	–	0.36	0.52	0.45	0.39	–

Table 5
Internal consistency, reliability, clinical validity, discrimination and responsiveness in the PTSS

Scale	Internal consistency (Cronbach α)	Test–retest reliability in stable patient (intraclass correlation coefficient in stable patients)	Clinical validity (correlation with pain intensity after treatment; Spearman)	Discrimination power according to pain intensity after treatment (Kruskal-Wallis)	Responsiveness according to improvement in pain (signed rank test—effect size)
Satisfaction with current pain medication	0.90	0.74	–0.48	0.0001	0.0065, 0.35
Efficacy subscale	0.90	0.76	–0.53	0.0001	0.0041, 0.37
Medication characteristics subscale	0.85	0.55	–0.35	0.0001	0.0225, 0.22
Side effects of medication	0.83	0.67	–0.17	0.0191	0.0615, 0.24
Impact of current pain medication	0.92	0.68	–0.25	0.0073	NR
Medical care	0.86	0.81	–0.32	0.0002	NR
Information about pain and its treatment	0.89	0.76	–0.29	0.0009	NR

NR, Not relevant.

in the last week, pain severity 30 min after taking pain medication, level of pain in the last 24 h, level of pain right now, level of pain before asking the doctor for medication and level of pain before taking medication (all scored on a 0 to 10-point scale).

Scores were significantly lower (except medical care) in patients with severe pain in the last week, indicating less satisfaction, more burden and more impact of pain (Table 6). Scores were significantly lower in all scales ($P < 0.05$) in patients with severe pain after treatment. PTSS scores were systematically lower in patients reporting more severe pain for the three criteria used: pain in the last week, in the last 24 h and right now. The differences were significant for medication characteristics and side effects. Scores were not significantly different according to the level of pain before asking for medication and before taking a medication.

3.6. Responsiveness

The responsiveness of the PTSS was assessed for acute pain patients. The change in PTSS scores between baseline and week 2 was calculated for three patient subgroups (worsened, stable and improved, as defined by the pain change item). Only improved and worsened patients were assessed in the responsiveness analysis. No change was

expected in the information or medical care dimensions (Table 7).

The mean changes in PTSS scores were positive for the improved group of patients, with significant differences ($P < 0.05$; Wilcoxon signed rank test). In worsened patients, score changes were negative, as expected, but differences between the two assessments were not statistically significant. For pain medication and medical care dimensions, no trend was seen for either improved or worsened patients. However, on the information dimension worsened patients showed a tendency to improve their score, though results were not significant.

3.6.1. Confounding

The following potential confounders were examined: gender, age, pain group (chronic or acute), ethnicity, level of education, work status and prior resource use. Significant differences were found for type of pain on the information score, ethnicity on the information score and work status on the information score.

4. Discussion

Well-developed and validated patient satisfaction questionnaires that may be used in clinical trial and survey

Table 6
Mean (SD) PTSS scores at baseline according to pain severity in the last week

Scale	Severity			
	Very mild	Mild	Moderate	Severe
Satisfaction with current pain medication	80.06 (18.05)	74.20 (17.91)	61.54 (18.53)	59.63 (24.72)
Efficacy subscale	77.08 (24.70)	71.15 (22.88)	55.63 (21.63)	54.23 (28.93)
Medication characteristics subscale	83.04 (16.59)	77.24 (16.25)	67.15 (19.90)	64.58 (24.91)
Side effects of medication	91.43 (9.76)	88.08 (11.36)	78.49 (15.51)	75.60 (16.06)
Impact of current pain medication	73.26 (20.56)	73.34 (20.86)	62.94 (21.67)	55.15 (27.13)
Medical care	77.90 (18.42)	75.84 (18.26)	73.37 (16.89)	71.17 (24.15)
Information about pain and its treatment	75.45 (27.64)	71.54 (31.84)	57.84 (36.78)	53.93 (34.17)

Table 7
Effect size of the PTSS score change between baseline and week 2

Changes in scores, ES and SRM		Frequency baseline	Mean baseline	Mean week 2	STD change	ES	SRM
Efficacy subscale	Worsened	15	52.22	49.44	16.27	−0.09	−0.17
	Stable	22	62.12	63.64	17.75	0.07	0.09
	Improved	64	63.93	71.22	19.56	0.27	0.37
Satisfaction with current pain medication	Worsened	15	60.00	57.08	14.47	−0.13	−0.20
	Stable	24	67.88	66.25	13.01	−0.10	−0.13
	Improved	65	68.40	73.91	15.75	0.25	0.35
Side effects of medication	Worsened	15	82.78	81.72	10.15	−0.07	−0.10
	Stable	23	78.48	80.88	13.10	0.15	0.18
	Improved	64	81.07	83.36	9.63	0.15	0.24
Medication characteristics subscale	Worsened	14	69.05	64.88	19.54	−0.26	−0.21
	Stable	24	73.26	68.92	15.71	−0.29	−0.28
	Improved	64	72.40	76.17	16.99	0.18	0.22

ES, effect size; SRM, standardized response mean; STD, standard deviation.

research are in short supply. With few exceptions, there is a lack of rigor in the development of satisfaction questionnaires, and the measurement of treatment satisfaction has been characterized as poor (Weaver et al., 1997). This study presents the results of a methodologically rigorous process to develop and validate a questionnaire specifically for acute and chronic pain.

There are several different tools currently used to assess pain severity that have been adapted for use in satisfaction studies, such as the Faces Pain Rating Scale (FPRS), the Adjective Pain Rating Scale (APRS), the VAS (0–10 mm) and the Analogue Chromatic Continuous Scale (ACCS). Although some of these instruments have been adapted to measure satisfaction, they do not adequately address the multidimensional nature of satisfaction. Generic quality-of-life instruments, such as the SF-36, have been found to have substantial limitations in routine pain assessments in a pain clinic and contain no items directly related to treatment satisfaction (Rogers et al., 2000a). Disease-specific measures do not include information on satisfaction with treatment. The American Pain Society Patient Outcome Questionnaire (Ward and Gordon, 1996) is limited to 14 items, two of which deal with patients' satisfaction with how nurses and doctors treated their pain. As such, the instrument fails to capture the multidimensional nature of satisfaction assessments—the need to collect information on satisfaction with drug treatment, bothersomeness of side effects, satisfaction with information provided to patients, satisfaction with method of delivery and satisfaction with the results of treatment. The revised American Pain Society Outcome Questionnaire (APS-POQ) (McNeill et al., 1998) does measure satisfaction with the results of pain treatment, but excludes other aspects (except for satisfaction with nurse and physician care). The TOPS addresses satisfaction; however, only three of the 120 items deal with this area directly. Based on our initial interviews with a large number

of patients, clinicians and nurses, many more items are required to adequately assess satisfaction with pain treatments.

Patient satisfaction assessments are valuable for a number of reasons. First, satisfaction with treatment and care is related to adherence to clinician instructions, which is an important determinant of health outcomes (Fitzpatrick, 1991). Second, patient satisfaction assessments add another dimension to the understanding of patient outcomes. Although they are not objective and do not correspond directly to clinician assessments, the information captured goes beyond the rating of health care or health status (Ware et al., 1983). Third, feedback from patients may be used to alter and improve the quality of health care delivery (Fitzpatrick, 1991).

The PTSS may be used in randomized controlled trials, postmarketing surveillance research or in observational and survey studies. The PTSS, suitable for use in individual patients and for assessment in groups of pain sufferers, may also be used as separate modules or as an entire instrument. Additional testing of this modular approach is currently underway.

There were several limitations to this study. The validation study was conducted only in the United States. Whether these results are generalizable to other countries will require additional testing. A second limitation is that participants for both the development and validation populations consisted of a convenience sample of subjects. Although we were able to confirm diagnosis of pain with physicians, there is no guarantee that this sample is representative of the general acute and chronic pain populations. A third limitation to this study is that due to the limited sample size we were unable to split the sample by acute and chronic pain patients and re-run our analyses separately. We feel that by following a rigorous approach to the development of the questionnaire, with 60

patient and 41 health care provider interviews, we minimize the chance that the questionnaire is only applicable to one group. However, to answer this question definitively additional testing is required. Currently, several large scale trials with the PTSS are underway and we hope to report the results of this additional testing at a later date.

The test–retest reliability was good for all scales except the medication characteristics sub-scale. We are unsure as to why there is only a weak to moderate correlation. Perhaps some patients switched or titrated their medication in the intervening period and this led to a change in response. In addition, the effect size for responsiveness was only moderate. This is a potential shortcoming of the PTSS and may be due to the wide distribution in this relatively small sample, which will tend to decrease the effect size. Another possibility is that there is residual pain that leads to residual dissatisfaction. Despite this, almost all variables related to clinical severity correlated with the PTSS scores at baseline in the direction expected, and potential confounding was limited to the information scale (ethnicity, type of pain and

work status) or resource utilization factors. The PTSS has good test–retest reliability, and analysis of responsiveness to change over time indicated that the scores for efficacy of pain medication, side effects and medication characteristics were responsive to change. More research is needed to test the responsiveness of the PTSS before the final properties can be confirmed.

The results of this work indicate that the PTSS is a valid instrument that will be useful for further assessment of patient satisfaction in pain therapy in a variety of settings.

Acknowledgements

This study was made possible by a grant from Pfizer Inc. and Pharmacia Corporation.

Appendix

The Pain Treatment Satisfaction Scale

General

1. In general do you feel that your health is: *(check one)*

- ₁ Excellent ₂ Very Good ₃ Good ₄ Fair ₅ Poor

The following statements ask you about the level of pain that you suffer from. On a scale from 0 to 10, with 0 representing “no pain” and 10 representing the “worst pain possible,” please circle the number that represents:

2.	How much pain you had in the last week.	0	1	2	3	4	5	6	7	8	9	10
	No pain											Worst pain possible
3.	How much pain you had in the last 24 hours.	0	1	2	3	4	5	6	7	8	9	10
	No pain											Worst pain possible
4.	How much pain you have right now.	0	1	2	3	4	5	6	7	8	9	10
	No pain											Worst pain possible
5.	The level of pain you reach before asking your doctor for medication.	0	1	2	3	4	5	6	7	8	9	10
	No pain											Worst pain possible
6.	The level of pain you reach before taking your medication.	0	1	2	3	4	5	6	7	8	9	10
	No pain											Worst pain possible

Information About Pain and Its Treatment

The following questions ask about your **pain and its treatment**. Please answer each question below by checking the box that best represents your opinion (check only one box per question).

How much information would you have liked to have received about each of the following:		I would have liked much more information	I would have liked a little more information	The amount of information was right for me	I would have liked less information	I would have liked no information
7.	My illness or injury	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
8.	The cause(s) of my pain	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
9.	Treatment options for my pain	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
10.	Pain medication, in general	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
11.	Possible side effects of pain medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Medical Care

The following statements ask about your **medical care**. Please answer each question below by checking the box that best represents your opinion (check only one box per question).

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
12.	It is easy to ask the medical staff questions.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
13.	The medical staff always do their best to keep me from worrying.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
14.	The medical staff is willing to provide me with the pain medication that I feel I need.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
15.	The medical staff provide adequate follow-up care.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
16.	The medical staff does not ask me about the pain I experience.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Current Pain Medication

The following statements are about your **current pain medication**. Please answer each question below by checking the box that best represents your opinion (check only one box per question).

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
17.	My pain medication has a positive effect on my physical health .	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
18.	My pain medication helps me have a better outlook on life .	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
19.	My pain medication allows me to perform my daily activities more easily.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
20.	My pain medication allows me to participate in my leisure activities more often.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

21.	My pain medication helps me do things independently .	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
22.	My pain medication allows me to have better relationships with others .	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
23.	My pain medication improves my mood .	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
24.	My pain medication allows me to concentrate better.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Pain Medication Route of Administration

How is your current pain medication administered? Please check all that apply and complete those sections.

- Orally (pills, capsules, liquid, etc.) GO TO SECTION A
- By intravenous injections GO TO SECTION B
- By patches GO TO SECTION C

SECTION A

TO BE ANSWERED BY PATIENTS TAKING **ORAL** PAIN MEDICATION

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
25.	My oral pain medication is easy to swallow.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
26.	My oral pain medication leaves an after-taste.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

SECTION B

TO BE ANSWERED BY PATIENTS TAKING **INTRAVENOUS (IV)** PAIN MEDICATION

How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
27.	My IV pain medication works quickly.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
28.	My IV pain medication hurts when it is injected.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
How much do you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
29.	My IV injections leave too many bruises.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

SECTION C

TO BE ANSWERED BY PATIENTS TAKING **PATCH** PAIN MEDICATION

How much you agree or disagree with each of the following statements:		Strongly agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
30.	My patch pain medication irritates my skin.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

31.	My patch pain medication is easy to apply to my skin.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
32.	My patch pain medication is easy to take off.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
33.	My patch pain medication falls off easily.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Side Effects of Medication

The following statements ask about **side effects** of your current pain medication. Please answer each question below by checking the box that best represents your opinion (check only one box per question).

Because of your pain medication, how much were you bothered by the following:		Did not experience	Not bothered at all	A Little bothered	Moderately bothered	Quite bothered	Extremely bothered
34.	Unintentional weight gain	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
35.	Excessive fatigue	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
36.	Drowsiness	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
37.	Inability to concentrate	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
38.	Nausea	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
39.	Diarrhea	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
40.	Dizziness	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
41.	Constipation	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
42.	Skin rashes	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
43.	Stomach aches	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
44.	Heartburn	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
45.	Vomiting	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

Satisfaction with Current Pain Medication and Care

The following statements are about your satisfaction with your **current pain medication and the care you receive**. Please answer each question below by checking the box that best describes your level of satisfaction (check only one box per question).

How satisfied are you with each of the following:		Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
46.	The information that you received about your pain and its treatment	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
47.	The amount of time that doctors devoted to you during their visits/consultations	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
48.	The care provided by the nurses for your pain and its treatment	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
49.	The form of your medication (for example, pill, capsule, patch or injection)	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
50.	How often you take your medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
51.	The amount of pain medication you take	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

How satisfied are you with each of the following:		Very satisfied	Satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
52.	The time that it takes your pain medication to work	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
53.	The level or amount of pain relief provided by your pain medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
54.	The duration of pain relief provided by your pain medication	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

55. **Overall**, how satisfied are you with your current pain medication?
₁ Very Satisfied ₂ Satisfied ₃ Neither satisfied nor dissatisfied ₄ Dissatisfied ₅ Very Dissatisfied

56. **Overall**, how does your **level of pain relief** meet your expectations of pain relief?
₁ Greatly exceeds my expectations ₂ Somewhat exceeds my expectations ₃ Meets my expectations ₄ Does not quite meet my expectations ₅ Does not meet my expectations at all

57. Do you think that your current pain medication **could be** more effective in relieving your pain?
₁ Yes, definitely ₂ Probably yes ₃ I don't know ₄ Probably not ₅ Definitely not

58. Would you like to **continue** taking your current pain medication?
₁ Yes, definitely ₂ Probably yes ₃ I don't know ₄ Probably not ₅ Definitely not

59. Some people say that they get nervous at the thought of taking a pain medication for a **short time period**. Please check the closest description of how nervous you feel about taking your current pain medication for a short time period.
₁ Not at all nervous ₂ A little nervous ₃ Moderately nervous ₄ Very nervous ₅ Extremely nervous

60. Some people say that they get nervous at the thought of taking a pain medication for a **long time period**. Please check the closest description of how nervous you feel about taking your current pain medication for a long time period.
₁ Not at all nervous ₂ A little nervous ₃ Moderately nervous ₄ Very nervous ₅ Extremely nervous

61. Have you ever **used** another pain medication?
 Yes No

If Yes, overall, how would you compare your current pain medication with the other one?

₁ This medication is much better than my other one
₂ This medication is somewhat better than my other one
₃ This medication is about the same as my other one
₄ This medication is somewhat worse than my other one
₅ This medication is much worse than my other one

Thank you for your help.

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