



## Identifying important outcome domains for chronic pain clinical trials: An IMMPACT survey of people with pain

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### Abstract

This two-phase study was conducted to identify relevant domains of patient-reported outcomes from the perspective of people who experience chronic pain. In Phase 1, focus groups were conducted to generate a pool of patient outcome-related domains and their components. The results of the focus groups identified 19 aspects of their lives that were significantly impacted by the presence of their symptoms and for which improvements were important criteria they would use in evaluating the effectiveness of any treatment. Phase 2 was conducted to examine the importance and relevance of domains identified from a much larger and diverse sample of people with chronic pain. A survey was developed and posted on the American Chronic Pain Association website. Participants were asked to rate the importance of each item or domain identified by the focus groups on a scale of 0 to 10 (i.e., 0 = “not at all important” and 10 = “extremely important”). The survey was completed by 959 individuals. The results indicate that all 19 aspects of daily life derived from the focus groups were considered important with a majority of respondents indicating a score of 8 or greater. In addition to pain reduction, the most important aspects were enjoyment of life, emotional well-being, fatigue, weakness, and sleep-related problems. Chronic pain clearly impacts health-related quality of life. The results of the two phases of the study indicate that people with chronic pain consider functioning and well-being as important areas affected by the presence of symptoms and as appropriate targets of treatment. These multiple outcomes should be considered when evaluating the efficacy and effectiveness of chronic pain treatments.

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### 1. Introduction

Several guidelines have recommended a range of outcome measures to evaluate the effectiveness of treat-

ments for various chronic pain conditions (e.g., [3,10,11]). Most recently, the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommended a set of outcome domains and measures for chronic pain studies [13,23]. However, these recommendations were primarily based on the perspectives of clinicians and researchers. Given the broad impact of chronic pain on health-related quality of life (HRQoL) and other patient-reported outcomes (PROs), it is important to obtain the perspectives of individuals with chronic pain regarding what they consider the most relevant and important outcomes of treatments for chronic pain (cf. [1,21,26]).

IMMPACT was formed in 2002 to develop evidence-based consensus recommendations for the design and interpretation of clinical trials of treatments for patients with pain to expedite the evaluation of treatments and facilitate comparisons of study results [23]. Based on review of the literature and consensus discussions, six core outcome domains were recommended by IMMPACT for consideration in all clinical trials: pain, physical functioning, emotional functioning, participant ratings of global improvement, symptoms and adverse events, and participant disposition [23]. In subsequent IMMPACT recommendation [13,23], it was emphasized that the perspectives of *people who are experiencing chronic pain* must be determined. In particular, what are important concerns to these individuals that should be assessed to determine the efficacy and effectiveness of treatments in clinical trials?

Although there is a large literature examining the subjective experience of pain using narrative analysis, focus groups, in depth interviews, and questionnaires (e.g., [4,5,7]); there have been only limited attempts to clarify important outcomes in clinical trials from the perspective of those who experience persistent pain [6,22]. The results reported in both the Casarett et al. and Robinson et al. studies lend some support to the IMMPACT recommendation that chronic pain clinical trials should focus on other endpoints in addition to pain reduction. However, these studies have relied on patients seeking treatment at tertiary-care pain treatment programs and therefore may not be representative of the broader population of people experiencing chronic pain.

The purpose of the present study was to identify the domains of functioning that people with chronic pain consider important and that they can use as a basis for determining the value of and satisfaction with a treatment. The study consisted of two phases. Phase 1 used focus groups to identify outcome domains viewed as important to people with chronic pain. The identified outcome domains were then evaluated in the second phase, a web-based survey of a broad range of people with chronic pain.

## 2. Methods

### 2.1. Study design

Phase 1 used focus groups to identify important domains of PROs from the perspective of individuals seeking treatment for a range of chronic pain conditions. Findings from these focus groups were used to generate a pool of specific outcomes that were used in Phase 2. To examine the importance and relevance of these domains from a much larger and diverse sample of individuals with chronic pain, a web-based survey was developed and posted on a public website for people with chronic pain.

Institutional Review Board approval was obtained to comply with local human participant research requirements prior to study initiation. All participants gave informed consent before beginning study procedures.

### 2.2. Phase 1: focus groups

#### 2.2.1. Participants

Potential participants were recruited from 4 clinics (2 tertiary-care pain clinics, 1 oncology clinic, and 1 research clinic) in Round Rock TX, Jacksonville FL, Trenton NJ, and Annapolis MD during June and July 2003 to participate in focus group sessions regarding their experience of chronic pain. A site investigator from within each clinical site served as the primary contact person for the study. The site investigator identified potential participants using a screening form to ensure that participants met all pre-specified criteria. To be eligible, participants had to be at least 21 years of age; have a history of chronic pain for the past 6 months; and be able to speak and understand English. Those who met eligibility criteria were provided an explanation of the purpose of the study and, if they agreed to participate, completed an informed consent form. A total of 31 individuals participated in one of four focus groups.

Background characteristics of the 31 participants in the focus groups are presented in Table 1. These participants were 52 years of age on average, and 71% ( $n = 22$ ) were female. Eighty-seven percent ( $n = 27$ ) were Caucasian and 13% ( $n = 4$ ) were Asian, and 81% ( $n = 25$ ) of the participants were living with a spouse or partner. Nearly half of the participants (48%,  $n = 15$ ) reported that they had attended “some college,” 19% ( $n = 6$ ) had attained a college degree, and the remaining 16% ( $n = 5$ ) reported having a high school degree. With respect to employment status, 32% ( $n = 10$ ) of study participants indicated that they worked full-time, and approximately 42% ( $n = 13$ ) did not work at all because they were disabled. Focus group participants reported having chronic pain for an average of 8 years and being under the care of a physician for their pain for an average of 7 years.

#### 2.2.2. Structure of focus groups

Focus group meetings were held at times and locations convenient to participants. To facilitate in-depth discussion, four separate 90 minute sessions were led by a moderator trained in qualitative research methods. All sessions were audiotaped with permission from the participants. Specific questions were designed to maintain the focus of the discussion on pain and

Table 1  
Demographic and clinical characteristics of study participants

Item	Focus group N = 31	Web survey N = 959
<i>Age (years) (mean, SD)</i>	51.3 (13.34)	45.6 (11.59)
<i>Gender (n, %)</i>		
Female	22 (70.96)	691 (72.05)
Male	9 (29.04)	268 (27.95)
<i>Race (n, %)</i>		
Caucasian	27 (87.09)	886 (92.39)
Black or African-American	0 (0)	20 (2.09)
Asian or Asian-American	4 (12.90)	5 (0.52)
Hispanic or Latino	0 (0)	23 (2.40)
Other	0 (0)	25 (2.61)
<i>Marital status (n, %)</i>		
Never married	–	154 (16.06)
Married	–	599 (62.46)
Separated	–	17 (1.77)
Divorced	–	163 (17.00)
Widowed	–	26 (2.71)
<i>Living situation</i>		
Living alone	6 (19.35)	–
Living with spouse/partner	25 (80.65)	–
<i>Employment (n, %)</i>		
Employed, full-time	10 (32.25)	330 (34.41)
Employed, part-time	2 (6.45)	32 (3.34)
Employed, part-time because of pain	0 (0)	43 (4.48)
Homemaker	0 (0)	31 (3.23)
Student	1 (3.22)	20 (2.09)
Unemployed	3 (9.67)	17 (1.77)
Unemployed because of pain	–	125 (13.03)
Retired	5 (16.12)	40 (4.17)
Disabled	13 (41.93)	78 (8.13)
Disabled because of pain	–	231 (24.09)
Other	0 (0)	12 (1.25)
<i>Education (n, %)</i>		
Elementary/primary school	0 (0)	9 (0.94)
Secondary/high school	5 (16)	193 (20.13)
Some college	15 (48.39)	377 (39.31)
College degree	6 (19.3)	247 (25.76)
Postgraduate degree	0 (0)	119 (12.41)
Other	0 (0)	14 (1.46)
<i>Duration of pain (years) (mean, SD)</i>	8.2 (9.40)	8.31 (8.01)
<i>Time treated for chronic pain (years) (mean, SD)</i>	7.1 (9.98)	5.93 (6.50)

“–” denotes that item was not asked in demographic questionnaire.

maximize consistency across the focus groups. A discussion outline served as a question and prompt guide. The discussions addressed symptoms of pain, impact of pain on daily life, and experiences with treatments. Participants were given an honorarium of \$50 to compensate them for their time and travel expenses.

### 2.2.3. Data analysis

A content analysis approach was used to analyze the data from the focus group sessions [2,20]. Two investigators systematically reviewed the transcripts and tapes to identify general themes, recurrent words, issues, and concerns from the focus

group sessions. Findings from the initial focus groups were used to generate an item pool of outcomes relevant to individuals who have chronic pain using the question structure detailed below.

### 2.3. Phase 2: web-based survey

A web-based survey was conducted using the items generated from the focus groups to examine the importance of the outcomes and their components from a much larger and diverse sample of persons with chronic pain. The survey included items identified by the initial chronic pain focus groups as well as ancillary measures of HRQoL for purposes of exploratory analyses.

#### 2.3.1. Measures

For the items generated by the focus groups, participants were asked to rate the importance of each in terms of how their life was impacted by pain on a scale of 0 to 10, where 0 represents “not at all important” and 10 represents “extremely important.” In addition, participants were asked to list other aspects of their daily life affected by pain that were not included in the questionnaire.

To characterize the sample of patients, several validated and reliable scales were also included. Average pain during the past week was assessed using an 11-point numerical rating scale, where 0 represented “no pain” and 10 represented “pain as bad as you can imagine.” Two scales from the Brief Pain Inventory (BPI; [8,9]), pain severity and pain interference, and the interference scale from the Multidimensional Pain Inventory (MPI; [15]), were also included. The BPI 7-item interference scale was used to assess how much during the past week pain interfered with general activity, mood, walking ability, work, relations with other people, sleep, and enjoyment of life, on a rating scale that ranged from 0 (does not interfere) to 10 (completely interferes). The 9-item MPI interference scale [15] was included to address overall pain interference with day-to-day activities, work, social/recreational activities, household chores, and friendships with non-family members, with responses based on a 7-point scale (0–6).

The Medical Outcomes Study 12-Item Short Form Health Survey (SF-12) was included as a generic HRQoL measure that contains 12 questions considered valid for assessing treatment outcomes that focus on the physical and mental components of a disease [27]. Items from the National Health Interview Survey were used to assess the number of days during the past four weeks participants missed work, were late to work, spent part or all of the day in bed, and were kept from usual activities due to their pain [17].

#### 2.3.2. Survey participants

The American Chronic Pain Association (ACPA) is a non-profit organization dedicated to providing education and support to people with chronic pain to help them better manage their pain and their lives. An invitation to complete the survey was posted on the ACPA website. Those experiencing chronic pain were invited to complete a screening form to ensure that they met all pre-specified criteria. To be eligible for the study, participants had to be 21 years of age or older and have at least one chronic pain condition for at least 3 months prior to par-

ticipating in the survey. Those who met eligibility criteria were provided further explanation of the study and asked to complete an informed consent form. After obtaining informed consent, participants immediately began the survey. The survey was posted on the website of the ACPA from November 2004 to January 2005.

A total of 1407 individuals met study eligibility criteria and were invited to participate in the survey. Of these, 1148 agreed to participate and started to complete the survey. Among these 1148 respondents, 189 were excluded from the analysis because of incomplete data (i.e., less than 50% of items were completed) or inconsistent responses between the screening questions and the survey related to select demographic and clinical characteristics; this resulted in a final sample size of 959 participants.

Among study participants, 72% ( $n = 691$ ) were female and the mean age was 45 years ( $SD = 11.59$ ) (Table 1). Ninety-three percent ( $n = 886$ ) of the sample was Caucasian, 2% ( $n = 23$ ) Hispanic or Latino, and 2% ( $n = 20$ ) African-American; 62% ( $n = 599$ ) were currently married, 17% ( $n = 163$ ) were divorced, and 16% ( $n = 154$ ) reported that they were never married; the remaining participants were either separated (2%) or widowed (3%). With respect to employment status, 34% ( $n = 330$ ) were employed full-time. Over one-third of the participants were either unemployed due to pain (13%,  $n = 125$ ) or disabled due to pain (24%;  $n = 231$ ). Among study participants, 39% ( $n = 377$ ) reported that they had completed some college, 26% ( $n = 247$ ) had a college degree, and 20% ( $n = 193$ ) had a high school education.

On average, study participants indicated that the duration of their pain was 8 years ( $SD = 8.01$ ) and that they had been treated by a physician for their pain for 6 years ( $SD = 6.50$ ). When asked to indicate the types of pain conditions they currently have, with the stipulation that they could only choose up to 3 conditions, 55% ( $n = 523$ ) of study participants reported that they had low back pain, 46% ( $n = 441$ ) reported neck or shoulder pain, 39% ( $n = 378$ ) reported neuropathic pain, 28% reported fibromyalgia, 23% ( $n = 216$ ) reported migraine or other chronic headache, and 19% ( $n = 184$ ) reported osteoar-

thritis (Table 2). Five percent of study participants reported that they had rheumatoid arthritis and less than 1% reported cancer.

### 2.3.3. Data analysis

The primary objective of Phase 2 was to identify PRO domains that are important to people with persistent pain. Descriptive statistics (frequency of endorsement of each response option) were used to determine the importance ratings of items identified during the focus groups by the different pain conditions. Descriptive statistics are presented for items included in the web-based survey. All analyses are based on actual response data; no responses were imputed.

## 3. Results

### 3.1. Phase 1: focus groups

Overall, focus group participants indicated that they experience pain on a daily basis, with most participants indicating that their pain was constant and others indicating that it “comes and goes” throughout the day either spontaneously or as a result of activities. For some, the nature of their pain varied in terms of location (depending on point of pressure for some) and sensation, whereas for others the location and sensation were predictable (i.e., “I always feel it in my feet” or “in my stomach like its burning”). Pain impacted on a number of aspects of participants’ lives, which are described below and organized by common themes of the discussions.

#### 3.1.1. Pain-related symptoms

A general feeling of overall weakness and malaise was commonly reported by focus group participants. Several noted that they were limited to a single activity each day, and many would “pick a goal each day.” For example, “if you go grocery shopping, you can’t cook that day” or “since I came to the focus group today, that’s it; I am spent and will spend the rest of the day in bed resting.” Fatigue and lack of energy were also commonly reported symptoms, apparently due in part to problems with sleep. Some participants noted trouble falling asleep due to pain, whereas others indicated that although they could fall asleep, they often “wake up hurting” in the night. Several participants indicated that once they woke in the night, they had difficulty falling back asleep and would wake up in the morning feeling “just as tired as when I went to bed.” Symptoms related to cognitive functioning were also experienced, particularly among those with fibromyalgia, who reported often experiencing a “fog” and forgetting “common words” or what they were doing or going to do next. Problems concentrating during periods of severe pain were experienced by the majority of those who participated in the focus groups.

Table 2  
Type and number of reported pain conditions: web survey<sup>a</sup>

Chronic pain condition	Total <i>N</i> (%)
Migraine or other chronic headache	216 (22.5)
Rheumatoid arthritis	50 (5.2)
Osteoarthritis	184 (19.2)
Pain related to cancer	8 (0.8)
Lower back pain	523 (54.5)
Neck or shoulder pain	441 (46.0)
Fibromyalgia syndrome	269 (28.1)
Painful diabetic neuropathy	26 (2.7)
Other neuropathic pain (nerve damage)	352 (36.7)
Other	201 (21.0)
<i>Number of pain conditions reported by participants</i>	
1	174 (18.1%)
2	259 (27.0%)
3	526 (54.8%)

<sup>a</sup> Participants were able to indicate no more than 3 different pain conditions.

When asked what participants would like most from new treatments, the responses were varied. Answers included: “Getting restful sleep;” “Having more energy;” “I would love to be able to clean my house;” “Being able to take a 2-h trip;” “Just 2 h of anything and I could go for sure, and just pick up and take off without thinking that I’m going to pay for this tomorrow;” “To have better control and stop taking so many pills.”

### 3.1.2. Physical activities

All participants indicated that their pain condition had a negative impact on their overall physical functioning. For most of the focus group participants, basic physical movements caused severe pain, including walking, sitting for any length of time (i.e., more than 30–45 min), and bending over. Limitations in self-care activities were especially prevalent among those with fibromyalgia and pain associated with cancer, with comments such as “everything is hard work for us – tying shoes or putting a blouse on.” Although a few participants reported that they were able to do moderate activities, such as standing for relatively long periods of time at work or “climbing stairs to get to their office,” most indicated that they were incapable of performing such activities. Nearly all participants were unable to do any strenuous activities, especially those that included any “lifting.”

### 3.1.3. Family life

Pain and pain-related symptoms appeared to have had a profound effect on participants’ family life, including spousal relationships, caring for their family members (children, spouses), and intimacy. A number of participants were frustrated that their spouses did not understand their condition but instead blamed them “for being just lazy” and wondered why they had to “sleep all the time.” Women with children expressed distress that they were unable to care for their children at times since they were not able to “lift or carry them” and had to spend so much of their time “resting.” With respect to intimacy, most participants noted that their sex lives were severely impacted by their pain, either because of loss of libido or because “even though you want the intimacy, when you’re having pain, it’s not number one on your list.”

### 3.1.4. Social/recreational activities

Social and recreational activities with friends and family were also negatively affected. Participants in the focus groups indicated that changes in pain were often unpredictable, and most expressed the same fears: “You’re afraid to commit because you do not know how you are going to feel;” “I can’t plan anything;” “I can’t predict what it is going to be like in 2 h from now.” In addition, participants had difficulty attending

social events that required sitting for any length of time (e.g., sporting events, vacation travel) or standing at social gatherings.

### 3.1.5. Emotional well-being

Overall, participants were generally distressed about their condition, the perception family members and friends had of them (i.e., “lazy”), and what the future would hold for them. As one participant explained, “As of right now, we don’t know what tomorrow will bring.” In general, there was a feeling of despair about the future and a general belief that the pain was now a part of their lives, with one participant emphasizing: “And while you’re spending this money (on treatment) and you’re in pain, it is not like anything we’re going to do will change the outcome. It’s not going to change anything. It’s not going to change the pain. It’s not going to change what is happening.”

Based on the findings from the focus groups, a total of 19 important aspects of daily life affected by pain were identified and included in the web survey. These aspects addressed outcome domains and components, including sleep, sex life, employment, home care, relationships, family life, social and recreational activities, physical activities, emotional well-being, fatigue, weakness, and cognitive functioning.

## 3.2. Phase 2: web survey

### 3.2.1. Validated pain measures

**3.2.1.1. Pain severity.** The mean score for average pain was 7.39 (SD = 1.57) on the BPI, suggesting that many study participants were experiencing severe pain [16,18,19,28], on average, during the prior week (Table 3).

**3.2.1.2. Interference with functioning.** Mean scores for the BPI and the MPI interference scales were 8.77 (SD = 1.91, range 0–10) and 4.77 (SD = 1.18, range 0–6), respectively, suggesting that pain very significantly interfered with general activities, mood, walking ability, work/housework, social/recreational activities, relations/friendships, sleep, and enjoyment with life (Table 4). Mean scores for the SF-12 Physical Summary

Table 3  
Mean scores of pain and HRQoL measures

Item	N	Mean	SD
BPI interference (range 0–10)	877	7.77	1.91
MPI interference (range 0–6)	847	4.77	1.18
SF-12 physical component summary	636	29.96	7.80
SF-12 mental component summary	636	35.08	10.80
# Bed days (past 30 days)	866	8.76	9.62
# Activity limitation days (past 30 days)	856	15.54	10.30

BPI, Brief Pain Inventory; MPI, Multidimensional Pain Inventory; SF-12, Short-Form 12.

Table 4  
Mean importance ratings of patient reported outcomes

Patient outcome area	N	Response 8–10 percent	Scale <sup>a</sup> mean (SD)
1. Falling asleep at night	823	66.7	7.8 (2.78)
2. Staying asleep at night	823	74.8	8.3 (2.45)
3. Sex life	823	51.9	6.6 (3.49)
4. Taking care of family such as children, spouses, parents or other relatives	823	60.6	7.1 (3.36)
5. Relations with family, relatives or significant others	823	66.0	7.7 (2.75)
6. Relations with friends	823	55.8	7.2 (2.76)
7. Employment	823	67.2	7.6 (3.25)
8. Household activities (cleaning, cooking, running errands)	823	67.0	7.9 (2.36)
9. Planning activities	823	52.2	7.0 (2.87)
10. Participating in family events/ activities	823	64.3	7.7 (2.67)
11. Participating in recreational and social activities	823	63.3	7.7 (2.61)
12. Physical activities (walking, climbing stairs, bending, squatting, lifting)	823	78.1	8.4 (2.33)
13. Hobbies	823	54.4	7.1 (2.86)
14. Enjoyment of life	823	84.4	8.8 (2.05)
15. Emotional well-being (feeling sad, depressed, less motivated)	823	79.6	8.6 (2.27)
16. Fatigue, feeling tired	823	84.0	8.8 (2.01)
17. Weakness	823	75.3	8.3 (2.42)
18. Difficulty concentrating	823	71.3	8.0 (2.62)
19. Difficulty remembering things	823	65.4	7.6 (3.06)

<sup>a</sup> Responses based on a 0–10 scale, where 0 represents “not at all important” and 10 represents “extremely important”.

Component (PSC) and Mental Summary Component (MSC) scores were 29.96 (SD = 7.80) and 35.08 (SD = 9.62), respectively, which are significantly lower than norms for the United States general population. Study participants acknowledged that they were kept from their usual activities due to pain for 16 days on average during the preceding month. In addition, they reported spending on average 9 days in bed for all or part of the day during the past month due to their pain. Among the study participants who indicated that they worked for pay ( $n = 388$ ), the average number of days they missed work due to pain during the prior month was 3.3 days (SD = 5.76) and they were late for work due to pain an average of 4 days. During the past six months, 65% ( $n = 560$ ) of survey participants indicated that their overall pain had worsened, whereas 25% ( $n = 216$ ) reported no change.

### 3.2.2. Importance ratings of outcome domains and components

The importance ratings of outcome domains and components indicated that all of the assessed items were considered important to people with chronic pain

(Table 4). Mean scores ranged from 6.6 (SD = 3.49) for sex life to 8.8 (SD ≤ 2.05) for fatigue/feeling tired and for enjoying life in general. Items with a mean score of 8.0 or higher included enjoyment of life in general (mean 8.8; SD = 2.05), fatigue (mean 8.8; SD = 2.01), emotional well-being (8.6; SD = 2.27), weakness (mean 8.3; SD = 2.42), and staying asleep at night (mean 8.3; SD = 2.45). Other aspects of daily life mentioned by the participants include travel and getting around the community (i.e., driving, commuting) (2.3%), activities of daily living (i.e., bathing, grooming) (1.4%), and problems with self-esteem (1.1%).

Table 5 contains the mean importance ratings by pain condition. Scores were generally consistent across the different pain conditions.

## 4. Discussion

This study identified the aspects of daily life that individuals experiencing chronic pain consider important in evaluating the consequences of their condition. In health outcomes research, patients' perspectives are considered essential for understanding the impact of a medical condition on their lives. In our focus groups, we identified 19 different aspects of daily life that people being treated for diverse chronic pain conditions believed were impacted by their symptoms and would be important in evaluating the effectiveness of treatments for their pain. The importance of these items was confirmed in the web-based survey completed by a much larger and diverse sample of people with chronic pain. The focus group and survey responses confirm that people with chronic pain reported that most if not all aspects of their lives are significantly affected by chronic pain, particularly enjoyment of life in general, emotional well-being, fatigue, weakness, and sleep-related problems. The results support suggestions regarding the importance of assessing the patient with chronic pain and not just the pain [25]. Future studies should focus on the relative importance of each of the identified outcome domains from the patient's perspective.

The results of the present study were generally consistent with previous research in highlighting pain reduction, improvement in physical functioning, sleep, and fatigue as treatment outcomes that are important from the perspective of patients [6,22]. Casarett et al. [6] observed that when patients ( $n = 40$ ) who were already taking opioids and were still seeking treatment at an anesthesiology-based pain clinic reviewed vignettes describing various treatments, 80% reported that decreased pain, 32% improvement in sleep, and 30% improvement in activities of daily living were important outcomes. More recently, [22] surveyed 110 pain patients with diverse chronic pain syndromes seeking treatment to determine how important and how much change would be required to establish treatment success

Table 5  
Mean importance ratings by pain condition<sup>a</sup>

Item	Migraine <i>N</i> = 190 mean (SD)	RA <i>N</i> = 46 mean (SD)	OA <i>N</i> = 158 mean (SD)	Low back pain <i>N</i> = 453 mean (SD)	Neck or shoulder <i>N</i> = 382 mean (SD)	Fibromyalgia <i>N</i> = 227 mean (SD)	Neuropathy <i>N</i> = 320 mean (SD)
1. Falling asleep at night	7.9(2.61)	7.8(2.57)	7.8(2.57)	8.0(2.70)	7.8(2.72)	8.3(2.66)	8.0(2.71)
2. Staying asleep at night	8.3(2.33)	8.6(2.52)	8.7(1.96)	8.5(2.18)	8.3(2.36)	8.8(2.00)	8.3(2.59)
3. Sex life	6.7(3.56)	6.2(3.26)	6.2(3.54)	6.9(3.45)	6.6(3.42)	6.5(3.53)	6.9(3.47)
4. Taking care of family such as children, spouses, parents or other relatives	7.3(3.27)	6.1(3.77)	6.4(3.54)	7.5(3.20)	7.0(3.43)	7.3(3.29)	7.1(3.44)
5. Relations with family, relatives or significant others	8.0(2.44)	7.8(2.44)	7.7(2.70)	7.9(2.55)	7.6(2.81)	8.4(2.14)	7.7(2.94)
6. Relations with friends	7.4(2.57)	6.9(2.61)	7.0(2.66)	7.3(2.66)	7.2(2.73)	8.0(2.31)	7.3(2.86)
7. Employment	7.9(2.77)	7.9(3.09)	7.2(3.45)	7.6(3.24)	7.8(3.00)	8.0(2.94)	7.3(3.54)
8. Household activities (cleaning, cooking, running errands)	7.9(2.30)	7.6(2.63)	8.0(2.02)	8.2(2.20)	7.9(2.33)	8.4(1.92)	7.9(2.49)
9. Planning activities	7.2(2.66)	6.3(3.09)	7.2(2.86)	7.2(2.74)	7.0(2.83)	7.3(2.59)	7.1(3.01)
10. Participating in family events/activities	7.9(2.52)	7.2(2.70)	7.8(2.41)	7.8(2.63)	7.6(2.74)	8.3(2.26)	7.8(2.74)
11. Participating in recreational and social activities	7.7(2.67)	6.6(3.12)	7.8(2.40)	7.9(2.47)	7.7(2.63)	8.1(2.41)	7.7(2.64)
12. Physical activities (walking, climbing stairs, bending, squatting, lifting)	8.2(2.48)	8.0(2.57)	8.7(2.12)	8.7(2.06)	8.4(2.27)	8.6(2.06)	8.5(2.48)
13. Hobbies	6.9(2.97)	6.6(2.95)	7.3(2.67)	7.2(2.80)	6.9(3.01)	7.5(2.48)	7.1(3.00)
14. Enjoyment of life	9.0(1.80)	8.0(2.74)	8.8(1.88)	9.0(1.95)	8.7(2.22)	9.0(1.93)	8.8(2.14)
15. Emotional well-being (feeling sad, depressed, less motivated)	8.8(2.03)	8.0(2.37)	8.7(1.90)	8.7(2.21)	8.5(2.36)	8.9(2.03)	8.7(2.28)
16. Fatigue, feeling tired	9.2(1.29)	8.7(1.96)	8.8(1.95)	8.9(1.87)	8.8(1.97)	9.1(1.70)	8.7(2.18)
17. Weakness	8.7(1.97)	8.2(2.39)	8.3(2.27)	8.5(2.23)	8.3(2.42)	8.5(2.27)	8.4(2.47)
18. Difficulty concentrating	8.6(2.01)	7.8(2.23)	8.0(2.45)	8.0(2.64)	8.1(2.55)	8.5(2.25)	8.1(2.66)
19. Difficulty remembering things	8.2(2.52)	7.2(3.02)	7.2(3.03)	7.6(3.05)	7.7(2.90)	8.4(2.40)	7.9(3.03)

<sup>a</sup> Importance ratings based on scale of 0 to 10, where 0 represent “not at all important” and 10 represents “extremely important”.

<sup>b</sup> “Painful diabetic neuropathy” and “other neuropathy” were combined.

for (1) pain, (2) emotional distress, (3) interference, and (4) fatigue. The results supporting the importance of improvement in mood and physical functioning in this study are consistent with the results of the current study. Casarett et al., however, reported that only 8% of their sample viewed emotional functioning and only 30% rated physical functioning as important end-points, in contrast to Robinson et al. who found that 65% indicated that reduction in emotional distress and 66% considered physical functioning necessary for a successful outcome. Consistent with the results of the present study, Casarett et al. found that sleep was considered an important end-point by 30% of patients.

The discrepancies noted between the [6,22] studies and the current results are likely associated with the very different methods used to elicit patients' beliefs about which outcomes are important. In contrast to Phase 2 of the current study, which recruited a web-based community sample, Casarett et al. and Robinson et al. included treatment-seeking patients. The instructions in the Casarett et al. study prompted certain types of responses (i.e., outcomes in relation to opioids) and Robinson et al. asked patients to respond to a set of outcomes that were specified a priori. In the current study, we used focus groups to generate the outcomes and identified a broad set of 19 different areas aspects of daily life that were then rated by a large sample of people with pain drawn from the community. We also invited participants in the web-based survey to note any areas that were not included in the list.

Our findings are consistent with the core outcome domains and measures recommended by IMMPACT for evaluating chronic pain interventions [13,23]. In addition to confirming the importance of pain relief and improvement in physical and emotional functioning, our results expand on the IMMPACT domains by highlighting fatigue, sleep, home and family care, social and recreational activities, interpersonal relationships, and sexual activities.

It has long been emphasized that chronic pain can cause severe emotional, physical, economic, and social problems for patients, disrupt family roles and relationships, destroy careers, and cause individuals to withdraw from society (e.g., [24]). We also found that people with chronic pain consider that increased functioning, reduction in feelings of fatigue and weakness, and improved sleep are important outcomes of treatment. Previous studies have also documented the profound effects that chronic pain has on mood, personality, and social relationships, as well as the concomitant experiences of depression, sleep disturbance, and decrease in overall function experienced by this patient population (cf. [12,14]). Our study is the first, however, to quantify the importance of these adverse effects and confirm these results among a large and diverse chronic pain sample with data obtained from nearly 1000 participants repre-

senting multiple chronic pain conditions. The large sample size made it possible to examine the patient-identified outcomes across a wide range of pain conditions, and the results suggested that the importance of the outcome domains was consistent across pain conditions.

As expected, the people with chronic pain participating in this study were more impaired in their health status compared with the general population. Baseline mean PCS scores were 30.0 in this sample with chronic pain, which is two standard deviations lower than the mean in the United States general population [27] and indicates that the participants in this study have significant impairments in their physical functioning. The participants in this study have scores that are nearly 1.5 standard deviations below the MCS scores reported in the United States general population, which provides further confirmation on the magnitude of the impact of chronic pain on overall emotional well-being.

There were several limitations of our study. The participants in the focus groups were all seeking treatment at specialized pain facilities and may not be representative of people with chronic pain who are not currently seeking treatment or those who receive treatment from primary care physicians or specialists outside a pain clinic setting. However, the results of the web survey provide confirmation that the domains identified as important by the treatment-seeking focus group participants are more generally reflective of what is important to people with persistent pain. There was a lack of variability in the ratings of importance with most areas rated as very important to patients. Although it is possible that respondents did believe that all of the items were this important to them, it is also possible that these ratings reflect a general response set.

Results from our web survey are based on self-selected participants who were familiar with ACPA and had the computer skills necessary to log on to the ACPA website. Those who completed the 40-min survey were generally younger (mean age 46 years), Caucasian, and well-educated. There was no attempt to obtain verification of patient diagnosis. Nor was it possible for us to confirm that the respondents to the web-based survey experienced chronic pain themselves, as opposed to being the responses of significant others who were familiar with chronic pain. The findings of this study may not be generalizable to minority groups, the elderly, and those lacking access to the Internet or who do not use it. Our results, however, are consistent with those obtained from the focus groups' participants for whom we did have a clinical diagnosis and with the two previous studies that had similar objectives [6,22].

Despite its limitations, our study identified important domains of PROs among individuals with chronic pain from the perspective of a large, diverse sample of people with chronic pain and confirms the domains recommended by IMMPACT for evaluating the efficacy and



effectiveness of treatments for chronic pain. The results also further clarify and expand on these domains and can be used to help identify appropriate measures to provide improved treatment outcomes for the chronic pain population. Comprehensive and psychometrically-sound PRO measures, consistent with the multiple impacts of pain on everyday life, are needed to evaluate pharmacologic and other interventions for chronic pain [23]. The results of this study can further focus efforts aimed at identifying relevant outcome domains from the perspective of people with chronic pain and thereby expedite the development of more effective treatments for chronic pain.

We want to emphasize that just because patients view various outcomes as important in their own experience of pain does not necessarily mean that treatments for pain must have a beneficial effect on all of these outcomes. For example, if a treatment is developed to improve pain (or another specific pain-related outcome), it may be unrealistic to expect it to have beneficial effects not only on that specific outcome but also on other outcomes that patients would consider important. Just because patients desire change in various pain-related aspects of their functioning does not mean that the efficacy or effectiveness of a pain treatment should be measured by its effects on these other outcomes if the pain treatment was designed, for example, to only have an analgesic benefit. Knowledge of the pain-related outcomes that patients consider important, however, has the potential to greatly improve assessments of whether the impact of a pain treatment includes beneficial effects on patient well-being and health-related quality of life and in so doing can improve the validity of comparisons of the overall benefits of treatment.

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