The Brief Pain Inventory User Guide



Charles S. Cleeland, PhD

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Chapter 1 Development of the Brief Pain Inventory

The Brief Pain Inventory (BPI) has become one of the most widely used measurement tools for assessing clinical pain. The BPI allows patients to rate the severity of their pain and the degree to which their pain interferes with common dimensions of feeling and function. Initially developed to assess pain related to cancer, the BPI has been shown to be an appropriate measure for pain caused by a wide range of clinical conditions. The BPI has been used in hundreds of studies. In some ways, the BPI is a "legacy" instrument— a self-report measure that has, over time, become a standard for the assessment of pain and its impact.

Background

In the late 1970s, it became increasingly evident that patients with cancer, especially the later stages of the disease, experienced incapacitating pain that was often poorly controlled. A constellation of events— the publishing of opinion pieces by prominent persons with cancer pain, the increasing advocacy of pain professionals and organizations for better cancer pain management, a growing awareness of the problem by national and international policy groups, and the simple recognition that pain often could be controlled— created the climate for a sustained effort to improve pain management for those with cancer.

A first step in this effort was to document the extent of poor pain management. The National Cancer Institute (NCI) and the Cancer Unit of the World Health Organization (WHO) wanted measurement instruments that would better capture the severity and impact of cancer pain and measure improvement in pain after changes in analgesic practice or implementation of new pain treatments. These instruments also needed to function well in large-scale national and international studies of the epidemiology of cancer pain.

With grant support from both the NCI and the WHO, the Pain Research Group at the University of Wisconsin Medical School-Madison, under the direction of Charles S. Cleeland, PhD, undertook a program to test and develop self-report measures of cancer pain and to apply them to studies of pain and its treatment in the United States and internationally. The Pain Research Group, now the Department of Symptom Research at The University of Texas M. D. Anderson Cancer Center, was also the WHO Collaborating Center for Symptom Research in Cancer.

Developing a Measurement Model and Items

Several existing pain measures (such as the McGill Pain Questionnaire; Melzack, 1975) were field-tested in interviews with cancer patients who had pain (N=50). Almost all of these measures had been designed to assess pain in patients with nonmalignant disease. The patients reported that the measures were too complex and too long, making them excessively burdensome for patients with high levels of pain. Patients also noted that the existing instruments included items not relevant to cancer patients and sometimes required responses that patients felt were ambiguous (Cleeland, 1984). Patients were also asked what questions they felt were the most important for communicating their experience of pain. The results of this study made clear that a new measurement instrument was needed.

The Pain Research Group planned a program to develop such an instrument. The aims were to have a scale that: (a) would take only a short time to complete; (b) would be easy for patients to understand; (c) could be self-administered for literate patients, or be completed by interview for illiterate or low-literacy patients; (d)

would be easily translated for non-English-speaking patients; and (e) would capture not only pain severity, but also the perception of how pain interfered with daily life.

Test Construction Standards

As a guide to scale construction, we used then-current psychometric standards found in the Standards for Educational and Psychological Tests published by the American Psychological Association, American Educational Research Association, and the National Council on Measurement in Education (1974). These standards included common elements of test validity (content, criterion, and construct) and reliability (internal consistency and test-retest). These standards had not been systematically applied in the development of the existing pain report scales.

Measurement Conceptualization: Multiple Dimensions of Pain

That pain is multidimensional was made clear during our patient interviews: patients reported that an adequate representation of pain required more than one simple measure of pain intensity. Melzack and Casey (1968) suggested that, based on the underlying neurophysiological mechanisms of pain, pain assessment should include three dimensions: sensory-discriminative, motivational-affective, and cognitive-evaluative. This approach to self-report measurement relied on three distinct patterns of responses to the words that patients used to describe their pain. However, the patients we interviewed had difficulty discriminating between the motivational-affective and cognitive-evaluative dimensions (Cleeland, 1989; Cleeland, 1990).

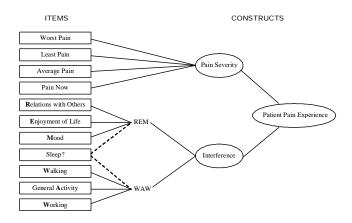
More commonly, researchers have found that two dimensions of pain self-report account for most of the variability in the way patients describe pain. Beecher (1959) called these dimensions "pain" and "reaction to pain"; Clark and Yang (1983) called them "sensory-discriminative" and "attitudinal." Following Beecher, we called these dimensions "sensory" and "reactive" (Cleeland, 1989).

Accordingly, our new questionnaire was developed to include items that reported the "sensory" dimension of pain (intensity, or severity) and the "reactive" dimension of pain (interference with

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daily function). We constructed four items to capture the variability of pain over time: pain at its "worst," "least," "average," and "now" (current pain). On the basis of patient interviews from additional field testing, we chose seven items that measured how much pain interfered with various daily activities, including general activity, walking, work, mood, enjoyment of life, relations with others, and sleep. Two subdimensions of pain interference were proposed: an affective subdimension (REM: relations with others, enjoyment of life, and mood) and an activity subdimension (WAW: walking, general activity, and work). The appropriate categorization of sleep within these two subdimensions was unclear.

A graphic representation of the conceptual framework for our measurement model is shown below. The model conforms to the U.S. Food and Drug Administration's Draft Guidance for Industry, Patient-reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims (Food and Drug Administration, 2006).



Early Version: The Wisconsin Brief Pain Questionnaire

The first version of our pain measure was the Wisconsin Brief Pain Questionnaire (BPQ; Daut & Cleeland, 1982; Daut, Cleeland, & Flanery, 1983). In the initial phase of scale development, 667 patients with cancer and 32 patients with rheumatoid arthritis were administered a three-page questionnaire and interviewed about the basic parameters of their pain (Daut et al., 1982). Patients who had experienced pain in the last month were asked to rate their pain intensity at its "worst," "average," and "now" and to rate the extent to which pain had interfered with activity and enjoyment of life. Patients were also asked to mark their pain location(s) on front/back body diagrams and to describe their perception of the cause of pain, the types of pain treatment they were receiving. and the amount of relief provided by their treatment. Patients were also asked to describe the quality of their pain by choosing words among a list of verbal descriptors derived from the McGill Pain Questionnaire (Melzack, 1975).

The design of the four-page BPQ was based on this initial questionnaire. In the BPQ, a 0–10 numerical rating scale was used to measure three pain severity items: "worst" in the past month, "average," and "now," where 0=no pain and 10=pain as bad as you can imagine. The interference items were measured using a five-option verbal descriptor scale, with ratings of 0=not at all, 1=a little bit, 2=moderately, 3=quite a bit, and 4=extremely. The recall period for both severity and interference scales was "in the last week." The BPQ also retained the body diagram from the initial questionnaire, along with word descriptors of pain quality and questions about types and effectiveness of pain treatment, the patient's perception of the cause of pain, and certain demographic information.

A second study (Daut et al., 1983) investigated the psychometric properties of the BPQ. This set of analyses was based on BPQ data obtained from more than 1200 patients with cancer at The University of Wisconsin Cancer Center. To determine test-retest characteristics of the BPQ, subsamples of patients completed the BPQ on two or more occasions. For comparison with other disease sites, a sample of patients with pain from rheumatoid arthritis was also surveyed.

Most of the patients were able to complete the BPQ by themselves with little or no instruction; others were interviewed to complete the questionnaire. A subset 25 patients completed both an interview-administered and self-administered version of the survey in counterbalanced order. We found little difference in ratings due to mode of administration. As expected, test-retest reliability varied by item. Short (days) test-retest reliability was 0.93 for "worst pain," but only 0.59 for "pain now." Preliminary exploration found that patient-reported pain severity and interference were directly associated with the use of opioid analgesics and the severity of disease.

The Brief Pain Inventory

The next iteration of our pain measure was the long form of the Brief Pain Inventory (BPI; Cleeland, 1989; Cleeland, 1990; Cleeland, 1991; Cleeland & Ryan, 1994). In this new instrument, we added the item "least pain" to the severity items and dropped the categorical rating scale for the interference items, in response to patient preference. The interference items were now presented with 0–10 scales, with 0=no interference and 10=interferes completely. The initial version of the BPI used a recall period of one week for both pain severity and pain interference ratings, included questions about medication use, and asked the patient to check potential pain quality descriptors that may describe their pain. The BPI long form also asked questions about the percentage and duration of pain relief and nonmedical methods used to relieve pain.

This version of the BPI proved to be too lengthy for repeated use in clinical monitoring or as a repeated measure in research. As a result, we developed a <u>shorter version</u> of the BPI. This version of the BPI retained the front and back body diagrams, the four pain severity items and seven pain interference items rated on 0–10 scales, and the question about percentage of pain relief by analgesics. The most important difference between the longer and shorter versions of the BPI is that the latter uses a 24-hour recall period.

Whereas the BPI long form is still used as a baseline measure in clinical trials, the shorter version has become the standard for use

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in clinical and research applications. The short form is typically what is referred to when the BPI is cited in research, and it is the version we describe below. Most psychometric evaluations of the BPI have been performed on the short form.

Scoring the Brief Pain Inventory as an Outcome Measure

A recent consensus panel recommended that the two domains measured by the BPI—pain intensity (severity) and the impact of pain on functioning (interference)—be included as outcomes in all chronic-pain clinical trials (IMMPACT, Turk et al., 2003). The IMMPACT panel (www.immpact.org) specifically identified the interference items of the BPI, rated on a 0–10 scale, as one of the two scales recommended for assessment of pain-related functional impairment (Dworkin et al., 2005).

How to Score the BPI: Pain Severity

The BPI assesses pain at its "worst," "least," "average," and "now" (current pain). In clinical trials, the items "worst" and "average" have each been used singly to represent pain severity. A composite of the four pain items (a mean severity score) is sometimes presented as supplemental information. The use of these single items is supported by the IMMPACT recommendations for assessing pain in clinical trials (Dworkin et al., 2005; Turk et al., 2006; Dworkin et al., 2008) and by the FDA Draft Guidance for Industry: Patient-Reported Outcome Measures (Food and Drug Administration, 2006). However, the BPI's developers recommend that all four severity items be used, because the models for validation of the BPI included all four items.

How to Score the BPI: Pain Interference

The BPI measures how much pain has interfered with seven daily activities, including general activity, walking, work, mood, enjoyment of life, relations with others, and sleep. BPI pain interference is typically scored as the mean of the seven interference items. This mean can be used if more than 50%, or four of seven, of the total items have been completed on a given administration.

We are exploring the utility of scoring the activity and affective dimensions described above (WAW and REM, see diagram [link]) as arithmetic means of these sets of items.

How to Score the BPI: Other Items

The item, "Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?" is a YES/NO preliminary screening question at the beginning of the BPI. This item is optional and we have not evaluated its psychometric properties. The BPI also asks the patient to indicate the percentage of relief provided by pain treatments or medications, but we have not found this item to be very useful in our studies.

Psychometric Properties of the Brief Pain Inventory

Dimensions of the BPI: Two-Factor Structure

Several approaches have explored the underlying dimensions of the BPI. As described above, the BPI was designed to capture two dimensions of pain: severity and interference. The BPI was also intended to capture two components of interference— activity and affect (emotions).

One of the first studies of the dimensions of the BPI compared the factor structure of four language versions of the BPI used to assess cancer pain in the United States, Mexico, the Philippines, and Vietnam (Cleeland, 1990). Factor analysis was applied to the matrix of intercorrelations of the item scores of each sample. For each language version, the same two factors emerged with an eigenvalue greater than 1: the first factor comprised the pain interference items and the second factor comprised the pain severity items. The similarity of the factor loading among the language versions indicated that patients experiencing cancer and pain, living in various countries and speaking various languages, responded to the items in a similar fashion.

This two-factor structure was confirmed in a large national study conducted in the U.S. by the Eastern Cooperative Oncology Group. Outpatients (N= 1261) with recurrent or metastatic cancer

from 80 centers were enrolled in the study (Cleeland et al., 1994). Factor analysis verified the two separate factors, pain severity and interference, found in the previous study. Internal stability (Cronbach alpha) was also examined in this study. Alphas showed good internal consistency, ranging from 0.80 to 0.87 for the four pain severity items and from 0.89 to 0.92 for the seven interference items. Subsequent data from studies of cancer patients in many countries and many languages have demonstrated high internal consistency and the robust nature of these two dimensions of the BPI.

Dimensions of the BPI: Multidimensional Scaling of Interference We have also used multidimensional scaling (MDS) to examine the dimensions of the BPI. We used a four-country sample with BPI responses from patients with cancer and pain (Cleeland et al., 1996). In this MDS analysis, we focused on only the interference items of the survey. Our purpose was to explore potential linguistic and cultural differences in the report of pain interference.

As we had hypothesized, two dimensions of the interference scale were demonstrated. The first dimension consisted of patients' ratings of pain's interference with enjoyment of life, mood, and relations with others (REM, the affective cluster of interference items). A second dimension of interference ratings consisted of patients' ratings of pain's interference with walking, general activity, work, and sleep (WAW, the activity cluster of interference items). Subsequent studies of additional language versions (Hindi in Saxena, Mendoza, & Cleeland, 1999; Norwegian in Klepstad et al., 2002) have shown a similar decomposition of the interference items into the affective (REM) and activity (WAW) interference subscales.

In summary, there is strong psychometric support for the independent measurement of pain severity and interference in the BPI. In addition, there is provisional evidence that the interference items independently measure activity and affective interference.

Test-Retest Reliability

Values from any measure should not differ significantly between assessments. The underlying concept of a measure should not change between assessments. This psychometric concept applies to patient-report instruments and is examined by test-retest reliability.

The test-retest reliability of the BPI has been studied in cancer patients and other patients with pain. Initial short-term (1 day to 1 week) reliability for ratings of pain "worst" (0.93) and "usual" or "average" pain (0.78) in patients with cancer was high, which signals acceptable reliability. As expected, test-retest reliability for pain "now" severity ratings were lower (0.59), because pain intensity often changes over time (Daut et al., 1983).

Several more recent studies have found similar test-retest coefficients for these items. For example, Radbruch et al. (1999) examined test-retest coefficients in 109 outpatients in a German pain clinic, with the retest occurring 30 to 60 minutes after the first administration. Test-retest values were 0.98 for pain severity and 0.97 for pain interference. The individual item with the lowest value, 0.78, was pain "least."

Reliabilities have also been examined with daily administration of the BPI. In patients with osteoarthritis (Mendoza et al., 2006), testretest reliabilities of pain severity (pain "worst," "average," and "current") between consecutive daily administration for a week showed correlations ranging from 0.83 to 0.88. The test-retest reliabilities for pain interference ranged from 0.83 to 0.93, beginning at day 1 for the week.

In another study of patients who underwent coronary artery bypass graft, the test-retest reliability coefficients for pain severity ranged from 0.72 to 0.95 during assessment periods where postsurgical pain declined in an expected direction (Mendoza et al., 2004). Similarly, the test-retest reliability coefficients for pain interference ranged from 0.81 to 0.93 during the same assessment period.

Test-Retest Reliability and Alternate-Forms Reliability: the Hindi Translation

Finally, one study combined an examination of both test-retest reliability and alternate-forms reliability (Saxena et al., 1999). In this study, 100 patients with cancer who spoke both English and Hindi completed both language versions of the BPI on different days in a counterbalanced design. In addition to reporting reliability based on internal consistency, the study design allowed calculation of the alternate-forms reliability of the BPI. Treating the Hindi and English versions of the BPI as alternate test forms, the alternate-form reliabilities of the interference and severity subscales were 0.88 and 0.95, respectively. These reliabilities demonstrated that the Hindi and English versions could be substituted for one another in assessing the severity of pain and its impact in bilingual patients. These data also provided support for the high test-retest reliability of the BPI.

In summary, the BPI is reliable to the extent that high test-retest reliability and alternate-form reliability is demonstrated when pain is stable or when pain changes in a predictable way.

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Chapter 2 BPI References: Use of the BPI in Various Studies

The Brief Pain Inventory has been used in more than 400 studies worldwide. Here we present BPI references categorized by type of study.

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