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When does pain matter? Acknowledging the subjectivity of clinical significance.

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## **Introduction**

The IASP defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”, acknowledging that “pain is always subjective” [21]. This definition, based on individual differences in pain perception, is the cornerstone of pain research and practice and is consistent with personalized patient-centered care [22].

Health professionals frequently make judgments about the clinical significance of pain, either to assess treatment effectiveness or inform clinical decision-making. Judgments are highly individual, as patients with similar diagnoses may have diverse treatment needs. It follows that our conceptualization of clinically significant pain in research should be more personalized, as would be consistent with the IASP definition and good clinical practice.

The discussion of clinical significance in pain has largely centered on the assessment of treatment effectiveness [9,13]; however, also being used to categorize pain intensity [5,10]. Used in these ways, determining the clinical significance of pain is useful for describing pain prevalence or for judging treatment success. However, it begs the question: *when should pain be considered clinically significant?* How we address this question has significant implications for claims made about well managed versus undertreated pain.

Conceptualizing pain as a subjective experience leads us away from previous methods of determining clinical significance that rely on group-derived comparisons and apply uniform standards to all patients [23]. If pain is subjective, it follows that the clinical significance of pain should also be determined on an individual basis.

This review describes interpretations of clinical significance in pain, with particular

attention to assessing change in pain after treatment and for classifying pain levels. Existing group-based methods for determining clinical significance for both applications are reviewed, followed by the presentation of alternative and more personalized approaches. We advocate for these modified methods for determining clinical significance that offer greater sophistication in their respect for an individual's subjective experience of pain.

### **Clinical Significance and Pain Intensity**

Definitions of clinical significance have focused on whether an “intervention makes a real (e.g., genuine, palpable, practical, noticeable) difference in everyday life” [24, p.332]. Researchers have addressed the assessment of clinical significance because statistically significant findings do not always translate to meaningful differences in patients' lives.

Most interpretations of clinical significance center on the presence or reduction of symptomatology [14,23]; however, quality of life [18,25] and social validity [15] have been proposed as alternate markers of clinical significance. All are relevant to the multidimensional nature of pain, as improved physical and emotional functioning are desired treatment outcomes [9,31], as are the acceptability of pain treatment goals, procedures, and outcomes [11,30]. Consistent with this, the IMMPACT recommendations [9] guide measurement of multiple domains relevant to the clinical significance of any pain experience (e.g., intensity, physical and emotional functioning).

Pain intensity is but one facet of the pain experience, however it represents the most researched marker of clinical significance in pain research and practice [12,33]. Single-item pain intensity scales provide the simplest and most commonly used approach to quantify pain, offering utility given their high acceptance and convenience in clinical practice [30]. However, despite their widespread use, the usefulness of single-item pain rating scales has been questioned

given the lack of consistent meaning attributed to particular pain scores [19]. Individuals consider multiple factors (e.g., associated function, retrospective comparison) and attribute changeable personalized meaning to pain intensity ratings [6]. Therefore, researchers and clinicians should not presume to know the meaning of a subjective pain rating to the individual providing it. The proposed personalized methods are intended to improve existing approaches for determining the clinical significance of *pain intensity*, complementing measurement of other aspects of clinical significance (e.g., physical functioning).

### **Clinically Significant Change in Pain**

#### ***Reliable change***

The most commonly applied interpretation of clinical significance investigates the magnitude or percent change on a rating scale necessary for achieving clinically important differences (or minimum clinically significant difference). These studies typically measure the amount of change on a pain rating scale associated with descriptors such as “a little less” or “a little more” pain and define group averages of change as clinically significant across all respondents [16]. Such studies have been conducted across the lifespan using a variety of single-item pain rating scales [1,2,3,16,28].

Researchers have presumed achievement of universal standards with group-derived measures of reliable change. For example, an approximately 30 percent (or 2-point) reduction in pain intensity on an 11-point numeric rating scale was consistently demonstrated as clinically significant in adults with chronic pain across sex, age, treatment or placebo group, and chronic pain condition [13]. The IMMPACT recommendations use this approach, providing benchmarks for clinically important differences in treatment outcomes (i.e., 10-20% reflects minimally important changes,  $\geq 30\%$  reflects at least moderate clinically important differences, and  $\geq 50\%$

reflects substantial improvements [9]).

However, associations between changes in pain scores and patient definitions of clinical significance are not absolute [12]. This approach is problematic because it does not assess whether a group-determined change in pain is meaningful for any given individual. The individual's subjective experience is disregarded by considering patient needs as a group, inappropriately applying group-derived findings to the individual. Applying uniform degrees of clinically significant change across contexts and individuals is problematic given research challenging the linear and interval nature of self-report pain scales, suggesting that minimal clinically significant difference varies across the range of pain severity [2,30]. For example, a 30% change in pain may be more or less meaningful depending on the starting level of pain. More importantly, the minimum clinically significant difference can vary within the same individual, even over only a short period of time (e.g., 1.0-2.1/10 over 120 minutes) [1]. A 30% change in pain may be sufficient for an individual today, but may not be next week or next year.

### ***Personalizing pain relief***

We propose two ways for achieving more personalized assessment of clinically significant change in pain. The first represents a minor modification in reporting practices. The IMMPACT recommendations guide researchers to report the proportion of individuals achieving the group-derived benchmarks for clinically important change in pain [9]. A more personalized approach would require researchers to report the proportion of individuals achieving their *own* individually measured clinically important change in pain as a measure of treatment success. Clinically important change for each individual would be measured within each study at treatment outset, using methods for determining minimal clinically significant change as in previous work [1,2,3,16,28]. In this way, researchers assess whether each patient achieves the

minimum amount of change in pain that is meaningful to them.

An alternate approach is Goal Attainment Scaling (GAS) [37]. Individuals specify personalized goals for treatment and rate the personal importance of each goal. Using a preset scoring formula that accounts for the importance of each goal, treatment success is based on to what degree patients achieve their goals. This approach has the advantage of being able to integrate various aspects of clinical significance, allowing the individual to weigh the importance of pain relief in relation to other areas (e.g., improved function). For example, an individual could strive for a 4-point reduction in pain intensity, but still rate an achieved 2-point reduction as somewhat successful, rating a second goal of improved function as more important. By providing a single score, GAS accommodates highly individualized goals, while remaining comparable between individuals or groups.

### **Clinically Significant Levels of Pain**

#### ***Reliable cut points and normative reference groups***

Classifying pain of particular intensity as clinically significant has become important for interpreting pain prevalence rates and directing further treatment [5,10]. The aforementioned approaches assessing the importance of change in pain ignore whether post-treatment levels of pain remain clinically significant to the individual and warrant further intervention.

Studies have used set, but inconsistent cut points for identifying clinically significant levels of pain that have been determined in relation to reports of pain severity (i.e.,  $\geq 3/6$  reflects moderate-severe pain; [5]) or based on associations with other aspects of clinical significance, such as function (e.g., children reporting pain  $> 3/10$  had more difficulty ambulating, eating, and playing; [10]). Using group data, statistically optimal cut points for classifying pain intensity as mild (1-3/10), moderate (4-6/10), or severe (7-10/10) have been derived based on associations

with pain interference [20].

This approach is problematic as valuable information about individual experience is lost. Classifying pain intensity based on associations with pain-related disability underestimates known variability in experience, ignoring that individuals can experience improved functioning despite a lack of reduction in pain severity – a benefit of many psychological interventions for chronic pain [35]. Furthermore, determining cut points from group data by its very nature leads to misclassification of individuals. VAS scores greater than 30mm captured only 85% of patients reporting moderate pain on a 4-point categorical pain rating scale (misclassifying 15%) [4]. If used as the basis for treatment decisions, misclassified individuals may receive inadequate or unneeded intervention. Additionally, statistically-derived cut points are highly dependent on the measures used and study sampling. Pain severity cut points for discriminating pain-related disability have varied between chronic pain conditions and, more importantly, within condition depending on sample characteristics [32,38].

Several authors have recommended determining clinical significance by comparing individual outcomes to a normative reference sample, determining the likelihood of that individual falling within the normal or well-functioning range [14,26]. In this way, cut points have been used to classify patients after treatment as “improved but not recovered” [23]. However, appropriate implementation of this method requires adequate norms for both well-functioning and dysfunctional populations [23]. Although pain is common throughout the lifespan [27,29,34], healthy “pain-free” populations may not serve as an appropriate normative reference group. Returning to a generally pain free life may be unrealistic for individuals with chronic pain or who require frequent medical intervention. Difficulty selecting appropriate normative reference groups is a criticism of this approach to determining clinical significance in



other disciplines [36]. Perhaps most problematically, no indication is provided as to when individuals desire intervention for their pain.

### ***Personalizing pain severity***

We propose the assessment of individual pain treatment thresholds as a more personalized approach, providing a marker of the clinical significance of pain intensity *for a specific patient* at the time of assessment [7,17]. Using the same pain rating scale as used to assess pain intensity, pain treatment thresholds ask the patient to rate how much pain they consider manageable, above which they desire intervention. By comparing intraindividual pain treatment threshold to pain intensity ratings, claims can be made about the adequate management of pain (i.e., pain above the pain treatment threshold is considered clinically significant).

Compared with other determinations of clinical significance, pain treatment thresholds take into account each individual's experience of pain and their unique desire for treatment, eliminating inappropriate generalizations of group-derived cut points to the individual. When measured concurrently with each pain assessment using the same measurement tool, this approach adeptly accommodates idiosyncratic use of pain rating scales over time based on context and changing pain experiences [1,6]. The noted variability in pain treatment thresholds (e.g.,  $M=1.85-2.54/6$  for three postoperative days, [7];  $M=3.2/6$ , [17]) does not reduce the utility or validity of this approach given that individual measurements are applied only to that individual. To date, pain treatment thresholds have been used in two studies of pediatric post-operative pain [7,17].

### **Summary**

Farrar [12] stated, "it is up to the investigator to provide guidance as to the level of pain or change in the level of pain that should be considered clinically important to the study

subjects” (p. 163). This perspective inherently contradicts the subjective nature of pain and we advocate for a more patient-centered approach focused on the meaningfulness of an outcome to a particular individual. The goal in assessing the clinical significance of pain is not whether the individual achieves what is satisfactory for *most* people, but whether they reach what is meaningful to them. We proposed more personalized approaches for determining clinical significance that prioritize the individual’s own experience of pain against which claims of treatment effectiveness and continued treatment decisions are determined. These are most consistent with the individualized nature of clinical care and the IASP definition of pain.

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