

# Pain assessment using the NIH Toolbox

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## ABSTRACT

**Objective:** Pain is an important component of health and function, and chronic pain can be a problem in its own right. The purpose of this report is to review the considerations surrounding pain measurement in the NIH Toolbox, as well as to describe the measurement tools that were adopted for inclusion in the NIH Toolbox assessment battery.

**Methods:** Instruments to measure pain in the NIH Toolbox were selected on the basis of scholarly input from a diverse group of experts, as well as review of existing instruments, which include verbal rating scales, numerical rating scales, and graphical scales.

**Results:** Brief self-report measures of pain intensity and pain interference were selected for inclusion in the core NIH Toolbox for use with adults. A 0 to 10 numerical rating scale was recommended for measuring pain intensity, and a 6-item Patient Reported Outcome Measurement Information System (PROMIS) short form for measuring pain interference. The 8-item PROMIS Pediatric Pain Interference measure was recommended as a supplemental measure. No specific measure was recommended for measuring pain intensity in children.

**Conclusions:** Core and supplemental measures were recommended for the NIH Toolbox. Additional measures were reviewed for investigators who seek tools for measuring pain intensity in pediatric samples. *Neurology*<sup>®</sup> 2013;80 (Suppl 3):S49-S53

## GLOSSARY

**DIF** = differential item function; **IRT** = item response theory; **NRS** = numerical rating scale; **PROMIS** = Patient Reported Outcome Measurement Information System; **VAS** = visual analog scale; **VRS** = verbal rating scale; **WBFRS** = Wong-Baker Faces Pain Rating Scale.

Pain is an important component of health and function. The NIH Toolbox somatosensation team took responsibility for considering the best methods for evaluating pain in the general population. In the International Classification of Functioning, Disability and Health, sensory functions and pain are grouped together as body functions; however, sensation of pain is distinguished from sensory functions such as proprioception or touch, as well as functions related to temperature and other stimuli.<sup>1</sup> The definition of somatosensory function includes the “detection, discrimination, and recognition” of pain (Dunn et al., this issue). However, pain is more than a biological process and can be integral to function, role participation, and overall quality of life. As such, its assessment often becomes a primary end point in clinical trials and treatment effectiveness studies. This led the Toolbox team to consider pain and its assessment in parallel with somatosensory function and to dedicate separate manuscripts to discussions of pain and somatosensation.

The science of pain measurement has benefited from recent advances in measurement approaches and applications.<sup>2-4</sup> The field of outcomes research has well-developed, self-reported pain measures that have been validated in a range of acute and chronic medical conditions. For this reason, the team chose not to develop new pain measures but to adopt existing instruments that would add to the battery of tests included in the NIH Toolbox. In this article, we describe the importance of pain to the assessment of health and discuss its multidimensional nature. We

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identify pain subdomains of particular interest to users of the NIH Toolbox and review current strategies for measuring those subdomains in adults and in children. This review is intended to provide users with a context for understanding the measurement of pain subdomains. Our recommendations for the NIH Toolbox core and supplemental measures of pain are summarized.

**PAIN AND HEALTH ASSESSMENT** Pain has been defined as an “unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.”<sup>5,6</sup> The International Association for the Study of Pain has called unrelieved pain “a major global healthcare problem.”<sup>7</sup>

Experiences and assessments of pain are often characterized as acute, chronic, or persistent.<sup>8</sup> Acute pain comes on abruptly and lasts a relatively short time. Such pain serves as a warning of an injury or sudden illness and may be mild or severe.<sup>9</sup> Chronic pain extends beyond the expected period of healing, often designated as persisting 6 months or more. A national survey estimated the point prevalence of chronic pain at >30%, with half of these reporting daily pain and 32% reporting 3-month average pain  $\geq 7$  on a scale of 0 to 10.<sup>10</sup> Not only is pain highly prevalent, its impact on quality of life is far-reaching. Pain interferes with sleep, makes activities of daily living more difficult, limits social engagement, and is financially burdensome to individuals and their families (see, for example, references 11–15). Furthermore, pain causes changes in neural function that outlast the precipitating disease or injury. Although typically triggered by injury or disease, chronic pain “becomes independent; it takes on a life of its own.”<sup>16</sup> Thus, pain has been described as “a disease in its own right.”<sup>16</sup> The prevalence, impact, and psychological and physiologic consequences of unrelieved chronic pain make it a critical domain in the assessment of health.

Because pain has a variety of origins and expressions, it is best described as multidimensional.<sup>17</sup> Subdomains include pain intensity and temporal patterns, description and localization, and interference with quality of life, affect, and behavior. A full assessment of pain might include measures of each of these subdomains. For the purposes of the NIH Toolbox, investigators focused on the 2 most frequently assessed subdomains: pain intensity and pain interference.<sup>18</sup> Below we summarize common strategies for the measurement of pain intensity and interference within adult and pediatric populations.

**PAIN INTENSITY** **Measuring pain intensity of adults.** Pain intensity, defined as the “magnitude of experienced pain,”<sup>19</sup> is a narrow construct often measured using a

1-item scale. To measure pain intensity of adults, the most common strategies are verbal rating scales (VRSs), numerical rating scales (NRSs), visual analog scales (VASs), and graphical scales. With VRSs, participants select from among pain descriptors (e.g., mild, moderate, severe). VASs present a line on which respondents mark the point they believe most descriptive of their pain. The line has verbal descriptors, “anchors,” at the ends (e.g., “no pain” or “extreme pain”). Sometimes descriptors between anchors are included. NRSs ask respondents to pick a number that represents their pain level (e.g., 0–10). Graphical scales represent graduated levels of pain as drawings (e.g., faces) that express increasing levels of distress. Participants select the picture that best represents their level of pain. Graphical scales have verbal or numerical descriptors as anchors and may have one or more descriptors between anchors.

An extensive review on behalf of the European Palliative Care Research Collaborative examined 54 published studies that compared at least 2 of 3 different categories of scales (i.e., VRSs, VASs, NRSs) in acute or chronic pain.<sup>20</sup> Across the 54 studies, 131 unique measures were cataloged: 59 VASs, 39 VRSs, and 33 NRSs. Most of the reviewed studies recommended no particular category of pain-intensity scaling. Of those that did, 3 suggested a scale from a category other than NRSs, VRSs, or VASs; 11 recommended using NRSs; 7, VRSs; and 4, VASs. Correlations are typically high between scores from different kinds of pain-intensity measures,<sup>20</sup> but substantial nonequivalence between individual scores has been documented,<sup>21–24</sup> and this nonequivalence in scores varied in direction.<sup>22,23</sup>

**Measuring pain intensity of children.** Even more challenging than measuring the pain of adults is measuring pain intensity experienced and reported by children. Strategies include self-report, physiologic indicators, and behavioral measures (including proxy report).<sup>25–27</sup> These different approaches produce nonequivalent results that only weakly correlate with each other.<sup>26</sup> The weak associations suggest that they may be assessing distinct constructs.<sup>26</sup>

As with adults, self-report is accepted as the “gold standard” for measuring the pain intensity of children.<sup>25,28</sup> Graphical scales are arguably less abstract than NRS and VAS measures and often are used for measuring children’s pain intensity. There are a number of “faces pain scales” that include drawings of faces to suggest graduated levels of distress (e.g., smiling face at one end; face with tears at the other). Tomlinson et al.<sup>28</sup> conducted a review of self-reported pain-intensity measures for children and found that children prefer faces scales to other single-item measures. In their review, the Wong-Baker Faces Pain Rating Scale (WBFPRS)<sup>29</sup> was preferred by children in studies that compared more than one faces scale.

**NIH Toolbox pain-intensity measures.** For measuring the pain intensity of adults, the NIH Toolbox adopted a single-item measure for inclusion within its core battery of assessments. The item, “In the past 7 days, how would you rate your pain on average?” is scored on a 0 to 10 NRS in which 0 = no pain and 10 = worst imaginable pain. The 0 to 10 NRS is frequently used in clinical studies, and its validity has been demonstrated empirically.<sup>19</sup> Adding to its usefulness are estimations made within different clinical populations, based on the 0 to 10 scale, of cut-scores for different levels of pain (e.g., mild, moderate, severe).<sup>30–32</sup> However, this recommendation is qualified by the empirical findings of nonequivalence between individual scores.<sup>21–24</sup> No measure of pain intensity can fully capture individuals’ experiences of pain.

Although the NIH Toolbox only addressed assessment of average pain intensity, it is important to note that “worst pain” also has been suggested as a clinical trial end point.<sup>33,34</sup> Worst pain may be measured by substituting the phrase “on average” with a phrase such as “at its worst.”

For the measurement of children’s pain intensity, no specific supplemental measure was identified for the NIH Toolbox. Although research indicates that children prefer a faces scale,<sup>28</sup> the WBFPRS has weaknesses. The anchor faces of the WBFPRS (a smiley face and a face with tears) may confound affect with pain intensity, especially in younger children.<sup>28</sup>

**PAIN INTERFERENCE MEASUREMENT** Pain interference may be thought of as a functional consequence of pain intensity. There is substantial empirical and clinical evidence that the 2 are distinct constructs and that each provides valuable information.<sup>18</sup> Pain intensity is a relatively narrow domain, but pain interference is broader, multifaceted, and associated with pain disability. The subdomains typically tracked by self-reported pain interference measures include impact on physical function, work, recreation, social activities, family roles, activities of daily living, and sleep.

**Measuring pain interference in adults.** There are many published measures of pain interference for use in adult populations (see, for example, references 35–38). However, with few exceptions,<sup>3,35,39</sup> pain interference measures have been developed using classic test theory approaches. Compared with classic psychometric approaches, newer strategies such as item response theory (IRT) allow for finer-grade evaluations of measures. Psychometric assessments are made at the individual item level, not at the scale level as with classic test theory. Furthermore, the precision of scores at different levels of pain interference can be assessed with IRT methods by calculating scale information.<sup>40</sup> The Patient Reported Outcome Measurement Information

System (PROMIS) initiative applied IRT methods in developing the PROMIS Pain Interference item bank.<sup>3</sup> As described on the PROMIS Web site (<http://www.nihpromis.org>), “The pain interference item bank measures the self-reported consequences of pain on relevant aspects of one’s life. This includes the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities ...”

**Measuring pain interference in children.** Although substantial psychometric attention has been given to the measurement of children’s pain intensity, the same is not true of the measurement of children’s pain interference. Two exceptions are the Child Activity Limitations Interview<sup>41</sup> and the PROMIS Pediatric Pain Interference Scale.<sup>42</sup> An advantage of the PROMIS scale over the Child Activity Limitations Interview is the fact that it was developed using modern psychometric methods (IRT), and the items of the bank were tested for differential item function (DIF) between boys and girls of differing ages. DIF exists when, *after holding level of pain interference constant*, the probabilities of different responses to an item vary by subgroup. DIF is a threat to measurement validity because the trait being measured should drive how respondents answer a question, not their membership in a particular demographic or clinical subgroup. An 8-item subscale assesses pain impact on children’s sleep, attention, mobility (e.g., walking, running, standing), ability to have fun, schoolwork, and affect (e.g., anger when in pain). A recently published study with 8- to 17-year-old children with cancer found evidence for the feasibility and validity of the PROMIS pediatric measures, including the PROMIS Pain Interference measure.

**NIH Toolbox pain interference measures.** For the measurement of pain interference in adults, the NIH Toolbox adapted the PROMIS Pain Interference v1.0–Pain Interference 6a (<https://www.assessmentcenter.net>). The 6 items of this short form ask, “How much did pain interfere with: a) your day to day activities, b) work around the home, c) your ability to participate in social activities, d) your household chores, e) the things you usually do for fun, and f) your enjoyment of social activities?” Each item is scored from 1 to 5, where 1 = not at all, 2 = a little bit, 3 = somewhat, 4 = quite a bit, and 5 = very much. The item set in short form 6a includes 6 of the 10 most “discriminating” items in the item bank; that is, the items that best distinguish among different levels of pain interference. Items with greater discrimination yield more precision in estimating individuals’ pain interference levels.

The NIH Toolbox adopted the PROMIS Pediatric Pain Interference measure for use in measuring self-reported pain interference in children. To date, clinical validity of this measure has been evidenced in children

aged 8 to 17 years. Future studies need to evaluate whether the measure retains its validity and feasibility in younger clinical populations.

**CONCLUSION** In this article, we present a context for understanding the importance of pain and review strategies for its measurement. Two measures were adopted into the NIH Toolbox core battery for adults: a 0 to 10 NRS for measuring pain intensity and a 6-item PROMIS Pain Interference short form. The PROMIS Pediatric Pain Interference is included as a supplemental measure for measuring children's pain interference. No particular scale for measuring pain intensity in pediatric populations was recommended.

#### AUTHOR CONTRIBUTIONS

Dr. Cook: manuscript concept and design. Dr. Dunn, Dr. Griffith, Dr. Morrison, Dr. Tanquary, Dr. Sabata, Dr. Victorson: domain conceptualization and critical review of the manuscript for important intellectual content. Dr. Carey: study supervision, domain conceptualization and critical review of the manuscript for important intellectual content, domain conceptualization, and critical review of the manuscript for important intellectual content. Dr. MacDermid, Dr. Dudgeon, Dr. Gershon: study supervision, domain conceptualization and critical review of the manuscript for important intellectual content.

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