Patient-Reported Outcomes Measurement Information System
Dynamic Tools to Measure Health Outcomes From the Patient Perspective

PAIN INTENSITY

A brief guide to the PROMIS Pain Intensity instrument:

ADULT
PROMIS Scale v1.0 - Pain Intensity 3a

ABOUT PAIN INTENSITY

The PROMIS Pain Intensity instrument assesses how much a person hurts. Patients are usually able to provide quantitative pain intensity estimates relatively quickly, and most measures of pain intensity tend to be closely related to one another. This suggests that pain intensity is a fairly homogeneous dimension, and one that is relatively easy for adults to identify and gauge. The Pain Intensity short form is universal rather than disease-specific. The first two items within the short form assess pain intensity over the past seven days while the last item asks patient to rate their pain intensity "right now".

Pain Intensity instrument is available for adults (ages 18+).

(For complete definition see http://nihpromis.org/measures/domainframework2*)*

INTRODUCTION TO ASSESSMENT OPTIONS

There is one administration options for assessing Pain Intensity: <u>short form</u>. When administering the short form, instruct participants to answer all of the items (i.e., questions or statements) presented. Short forms are preferable when administrators wish to ask the same question of all respondents or of the same respondent over time, to enable a more direct comparability across people or time, or when paper administration is preferred.   When one uses this short form, the score metric is Item Response Theory (IRT), a family of statistical models that link individual questions to a presumed underlying trait or concept of pain intensity represented by all items in the item bank.

SHORT FORM DETAILS

The Pain Intensity short form (3a) was constructed by the domain team with a focus on representing the range of the trait and also representing the content of the item bank. Domain experts reviewed short forms to give input on the relevance of each item. Psychometric properties and clinical input were both used and likely varied in importance across domains.

SCORING THE INSTRUMENT

<u>Short Forms</u>: PROMIS instruments are scored using item-level calibrations. This means that the most accurate way to score a PROMIS instrument is to utilize scoring tools within Assessment Center or API that look at responses to each item for each participant. Data collected in either of these platforms will automatically score in this way. We refer to this as "response pattern scoring." Response pattern scoring can be used when data was collected on paper or in another software package through the <u>Assessment Center Scoring Service</u>. Because response pattern scoring is more accurate than the use of raw score/scale score look up tables, it is preferred. However, if you aren't able to use response pattern scoring, you can use the instructions below which rely on raw score/scale score look-up tables.

Each question has five response options ranging in value from one to five. To find the total raw score for the short form, sum the values of the response to each question. For example, the lowest possible raw score is 3; the highest possible raw score is 15 (see all short form scoring tables in Appendix). All questions must be answered in order to produce a valid score

For the PROMIS Pain Intensity 3a short form, a raw score of 10 converts to a T-score of 54.5 with a standard error (SE) of 2.9 (see scoring table for the 8b short form in appendix). Thus, the 95% confidence interval around the observed score ranges from 48.8 to 54.5 (T-score $\pm$ (1.96*SE) or 54.5 $\pm$ (1.96*2.9).

For most PROMIS instruments, a score of 50 is the average for the United States general population with a standard deviation of 10 because calibration testing was performed on a large sample of the general population. The T-score is provided with an error term (Standard Error or SE). The Standard Error is a statistical measure of variance and represents the "margin of error" for the T-score.

Important: *A higher PROMIS T-score represents more of the concept being measured.* For negatively-worded concepts like Pain Intensity, a T-score of 60 is one SD worse than average. By comparison, a Pain Intensity T-score of 40 is one SD better than average.

STATISTICAL CHARACTERISTICS

There are four key features of the score for Pain Intensity:
- **Reliability**: The degree to which a measure is free of error. It can be estimated by the internal consistency of the responses to the measure, or by correlating total scores on the measure from two time points when there has been no true change in what is being measured (for z-scores, reliability = $1 - SE^2$).
- **Precision**: The consistency of the estimated score (reciprocal of error variance).
- **Information:** The precision of an item or multiple items at different levels of the underlying continuum (for z-scores, information = $1/SE^2$).
- **Standard Error (SE):** The possible range of the actual final score based upon the scaled T-score. For example, with a T-score of 52 and a SE of 2, the 95% confidence interval around the actual final score ranges from 48.1 to 55.9 (T-score $\pm$ (1.96*SE) = 52 $\pm$ 3.9 = 48.1 to 55.9).

The final score is represented by the T-score, a standardized score with a mean of 50 and a standard deviation (SD) of 10.

PREVIEW OF SAMPLE ITEM

Figure 1 shows a Pain Intensity item from the short form as it would appear to a study participant during data collection in Assessment Center. Several formats for presenting the items are available for computer-based administration through Assessment Center (see FAQ section).

Figure 1

Figure 2 is an excerpt from the paper version of the three-item short form.
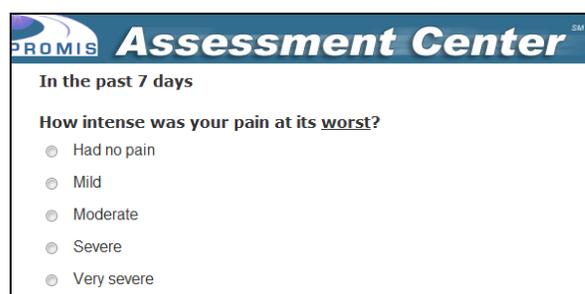
In the past 7 days…		Had no pain	Mild	Moderate	Severe	Very severe
PAINQU6	How intense was your pain at its worst?........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Figure 2

FREQUENTLY ASKED QUESTIONS (FAQ)

Q: *I am interested in learning more. Where can I do that?*

All instruments are available on the PROMIS website through Assessment Center, which houses all PROMIS instruments for each domain.

Assessment Center is a free online research management tool. It enables researchers to create study-specific websites for capturing participant data securely. Studies can include measures within the Assessment Center library, as well as custom instruments created or entered by the researcher. PROMIS instruments (short forms, CATs, profiles) are a central feature of the instrument library within Assessment Center. Any PROMIS measure can be included in an online study or downloaded for administration on paper.

Detailed statistical information and development history about PROMIS items and instruments are available for review at nihpromis.org or assessmentcenter.net. To learn more, contact help@assessmentcenter.net.

Q: *Do I need to register with PROMIS to use this instrument?*

Yes, to get a copy of these instruments, we ask that you register with Assessment Center and endorse the PROMIS Terms and Conditions of Use, so that we are better able to track who has accessed instruments for research. Assessment Center is available at assessmentcenter.net.

Q: *Is this instrument available in other languages?*

This instrument is currently available in Spanish in Assessment Center. The PROMIS group is also working to translate this form into other languages. Information on available translations is updated periodically at http://nihpromis.org/measures/translations.

Q: *Can I make my own short form?*

Yes, custom Pain Intensity short forms can be made by selecting any items from the item bank. Instructions for creating a custom short form in Assessment Center can be found in the Assessment Center User Manual https://www.assessmentcenter.net/UserManuals.aspx.

Q: *How do I handle multiple responses when administering a short form on paper?*

Guidelines on how to deal with multiple responses have been established. Resolution depends on the responses noted by the research participant.

- If two or more responses are marked by the respondent, and they are next to one another, then a data entry specialist will be responsible for randomly selecting one of them to be entered and will write down on the form which answer was selected. *Note: To randomly select one of two responses, the data entry specialist will flip a coin (heads - higher number will be entered; tails – lower number will be*

entered).To randomly select one of three (or more) responses, a table of random numbers should be used with a statistician's assistance.

- If two or more responses are marked, and they are NOT all next to one another, the response will be considered missing.

Q: *What is the minimum change on a PROMIS instrument that represents a clinically meaningful difference?*

This question is related to an area of active research in the PROMIS network, namely the determination of the "minimally important difference" or "MID" for a PROMIS instrument. A manuscript in the *Journal of Clinical Epidemiology* outlines the process for MIDs for adult PROMIS measures and estimates the MIDs for six PROMIS-Cancer scales: Yost, K. J., Eton, D. T., Garcia, S. F., & Cella, D. (2011). Minimally important differences were estimated for six PROMIS-Cancer scales in advanced-stage cancer patients. *Journal of Clinical Epidemiology, 64(5)*, 507-16.

As described in that manuscript, the MID is a tool to enhance the interpretability of patient-reported outcomes and is often defined as the "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" (Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Controlled Clinical Trials* 1989; 10(4):407-415).

APPENDIX- SCORING TABLE

Pain Intensity 3a Short Form Conversion Table		
Raw Score	T Score	SE*
3	30.7	4.5
4	36.3	3.1
5	40.2	3
6	43.5	3
7	46.3	3
8	49.4	2.9
9	52.1	2.8
10	54.5	2.9
11	57.5	3.1
12	60.5	3.1
13	64.1	3.8
14	67.4	4.2
15	71.8	5

*SE=Standard Error on Tscore metric

Adult version