PAIN QUALITY

A brief guide to the PROMIS[®] Pain Quality instruments:

ADULT	PEDIATRIC
PROMIS Scale v2.0 – Neuropathic Pain Quality 5a	PROMIS Pediatric Bank v2.0 – Pain Quality
PROMIS Scale v2.0 – Nociceptive Pain Quality 5a	PROMIS Pediatric Short Form v2.0 – Pain Quality – Affective 8a PROMIS Pediatric Short Form v2.0 – Pain Quality – Sensory 8a

ABOUT PAIN QUALITY

The adult PROMIS Pain Quality scales assess self-reported nociceptive pain and neuropathic pain.

- Nociceptive pain is caused by stimulation of peripheral nerve fibers (nociceptors) in the context of a normally functioning somatosensory nervous system. The PROMIS Nociceptive Pain Scale includes descriptors of pain sensations, such as "achy", "deep", "sore", and "tender", commonly reported by people with some qualities typical of nociceptive pain.
- Neuropathic pain is caused by damage to the peripheral somatosensory nervous system, part • of the nervous system involved in bodily feelings. This damage can be caused by an abnormality, trauma or disease. The PROMIS Neuropathic Pain Scale asks to what degree (from "not at all" to "very much") the respondent's pain shows gualities typical of neuropathic pain (i.e., felt "numb", "tingly", like "pins and needles", "stinging", or "electrical").

The pediatric Pain Quality measures assess specific physical sensations and affective components associated with pain. Because pain can be felt and described in so many ways, this category of pain contains a variety of attributes, such as perceived temperature (e.g., cold), sensations (e.g., throbbing), and perceived affective qualities of pain (e.g., uncomfortable).

The Pain Quality measures are universal rather than disease-specific. All assess pain quality over the past seven days. Pain quality instruments are available for adults (ages 18+) and pediatric self-report (ages 8-17).

INTRODUCTION TO ASSESSMENT OPTIONS

There is one administration option for assessing adult Pain Quality: fixed length scales. No computer adaptive test (CAT) is available. When administering a scale, instruct respondents to answer all of the items (i.e., questions or statements) presented.

There are two administration options for assessing pediatric Pain Quality: short forms and computerized adaptive test (CAT). When administering a short form, instruct participants to answer all of the items (i.e., questions or statements) presented. With a CAT, participant responses guide the system's choice of subsequent items from the full item bank (56 items in total). Although items differ across respondents taking a CAT, scores are comparable across participants. Some administrators may prefer 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. In these cases, or when paper administration is preferred, a short form would be more desirable than a CAT. This guide provides information on all pediatric Pain Quality short forms and a CAT instrument.



Whether one uses a short form or CAT, 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 quality represented by all items in the item bank. When choosing between a CAT and a short form, it is useful to consider the demands of computer-based assessment, and the psychological, physical, and cognitive burden placed on respondents as a result of the number of questions asked.

VERSION DIFFERENCES

Some PROMIS domains have multiple versions of instruments (i.e. v1.0, v1.1, v2.0). Generally, it is recommended that you use the most recent version available which can be identified as the instrument with the highest version number. In most cases, an instrument that has a decimal increase (v1.0 to v1.1) retains the same item-level parameters as well as instrument reliability and validity. In cases where a version number increases by a whole number (e.g., v1.0 to v2.0), the changes to the instrument are more substantial. PROMIS initially produced Pain Quality v1.0 for adults. This was a collection of items that were not calibrated but instead intended to be used descriptively or for further research. The v2.0 Neuropathic and Nociceptive Pain measures are calibrated and the preferred assessment tool.

SCORING THE INSTRUMENTS

<u>Scales and 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 use the HealthMeasures Scoring Service (<u>https://www.assessmentcenter.net/ac_scoringservice</u>) or a data collection tool that automatically calculates scores (e.g., Assessment Center, REDCap auto-score). This method of scoring uses responses to each item for each participant. We refer to this as "response pattern scoring." Because response pattern scoring is more accurate than the use of raw score/scale score look up tables included in this manual, it is preferred. Response pattern scoring is especially useful when there is missing data (i.e., a respondent skipped an item), different groups of participants responded to different items, or you have created a new questionnaire using a subset of questions from a PROMIS item bank.

To use the scoring tables in this manual, calculate a summed score. Each question usually has five response options ranging in value from one to five. To find the total raw score for a short form with all questions answered, sum the values of the response to each question. For example, for the v2.0 adult Nociceptive Pain 5-item form, the lowest possible raw score is 5; the highest possible raw score is 25 (see all short form scoring tables in Appendix 1). All questions must be answered in order to produce a valid score using the scoring tables. If a participant has skipped a question, use the HealthMeasures Scoring Service (https://www.assessmentcenter.net/ac_scoringservice) to generate a final score.

With the total raw score for a measure, locate the applicable score conversion table in Appendix 1 and use this table to translate the total raw score into a T-score for each participant. The T-score rescales the raw score into a standardized score with a mean of 50 and a standard deviation (SD) of 10. Therefore a person with a T-score of 40 is one SD below the mean.

For the adult PROMIS Nociceptive Pain 5a short form v2.0, a raw score of 10 converts to a T-score of 42.7 with a standard error (SE) of 4.0 (see scoring table for the 5a v2.0 short form in Appendix 1). Thus, the 95% confidence interval around the observed score ranges from 34.9 to 50.5 (T-score \pm (1.96*SE) or 42.7 \pm (1.96*4.0).

PROMIS Patient-Reported Outcomes Measurement Information System

<u>CAT:</u> A minimum number of items (5) must be answered in order to receive a score for Pain Quality. The response to the first item will guide the system's choice of the next item for the participant. The participant's response to the second item will dictate the selection of the following question, and so on. As additional items are administered, the potential for error is reduced and confidence in the respondent's score increases. CAT will continue until either the standard error drops below a specified level (on the T-score metric 4.0), or the participant has answered the maximum number of questions (12), whichever occurs first.

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. You can read more about the calibration and centering samples on HealthMeasures.net (<u>http://www.healthmeasures.net/score-and-interpret/interpret-scores/promis</u>). 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 quality, a T-score of 60 is one SD worse than average. By comparison, a pain quality T-score of 40 is one SD better than average.

STATISTICAL CHARACTERISTICS

There are four key features of the score for Pain Quality:

- **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 SE²).
- **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/SE²).
- 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 [±] (1.96*SE) = 52 [±] 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 is an excerpt from the paper version of the adult five-item Neuropathic Pain Quality Scale. This is the paper version format used for all Pain Quality instruments.



In the past 7 days					
	Not at all	A little bit	Somewhat	Quite a bit	Very much
PAQUALISF Did your pain feel sore?		2	3	4	5
PAGUALOBY Did your pain feel tender?			3	4	5

Figure 1

FREQUENTLY ASKED QUESTIONS (FAQs)

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

Review the HealthMeasures website at <u>www.healthmeasures.net</u>.

Q: Do I need to register with PROMIS to use these instruments?

No.

Q: Are these instruments available in other languages?

No. However, periodically check the HealthMeasures website (<u>http://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/available-translations/117-available-translations</u>) for current information on PROMIS translations.

Q: Can I make my own short form?

Yes, custom short forms can be made by selecting any items from an item bank. This can be scored using the Scoring Service (<u>https://www.assessmentcenter.net/ac_scoringservice</u>).

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?

To learn more about research on the meaning of a change in scores, we suggest conducting a literature review to identify the most current information. The HealthMeasures website (<u>http://www.healthmeasures.net/score-and-interpret/interpret-scores/promis</u>) has additional information on interpreting scores.

APPENDIX 1 - SCORING TABLES

Nociceptive Pain Quality 5a – Adult v2.0			
Short Form Conversion Table			
Raw Score	T-score	SE*	
5	30.3	5.4	
6	34.5	4.6	
7	37.0	4.4	
8	39.1	4.2	
9	41.0	4.1	
10	42.7	4.0	
11	44.4	3.9	
12	45.9	3.9	
13	47.5	3.9	
14	49.0	3.9	
15	50.5	3.9	
16	52.0	3.9	
17	53.6	3.9	
18	55.2	4.0	
19	56.8	4.0	
20	58.6	4.0	
21	60.5	4.0	
22	62.5	4.2	
23	64.9	4.3	
24	67.7	4.5	
25	71.8	5.2	
*SE = Standard Error on T-score metric			



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Neuropathic Pain Quality 5a – Adult v2.0		
Short Form Conversion Table		
Raw Score	T-score	SE*
5	37.0	6.0
6	42.9	4.1
7	45.2	4.0
8	47.1	3.8
9	48.8	3.6
10	50.4	3.4
11	51.8	3.3
12	53.1	3.2
13	54.4	3.2
14	55.6	3.2
15	56.9	3.2
16	58.1	3.2
17	59.3	3.3
18	60.6	3.3
19	61.9	3.4
20	63.3	3.5
21	64.8	3.6
22	66.3	3.7
23	68.1	3.8
24	70.4	4.1
25	74.1	4.9
*SE = Standard Error on T-score metric		



Pain Quality - Sensory 8a - Pediatric v2.0			
	Short Form Conversion Table		
Raw Score	T-Score	SE*	
8	32.2	5.5	
9	36.6	4.5	
10	38.9	4.3	
11	40.7	4.1	
12	42.2	3.9	
13	43.7	3.7	
14	45.0	3.6	
15	46.2	3.5	
16	47.3	3.4	
17	48.4	3.3	
18	49.4	3.2	
19	50.3	3.2	
20	51.2	3.1	
21	52.1	3.1	
22	53.0	3.1	
23	53.9	3.0	
24	54.7	3.0	
25	55.6	3.0	
26	56.5	3.0	
27	57.3	3.0	
28	58.2	3.1	
29	59.1	3.1	
30	60.0	3.1	
31	60.9	3.2	
32	61.9	3.2	
33	62.9	3.3	
34	64.0	3.4	
35	65.2	3.5	
36	66.5	3.7	
37	67.8	3.8	
38	69.3	4.0	
39	71.0	4.1	
40	74.5	4.8	
*SE = Standard Error on T-score metric			

Pain Quality - Affective 8a - Pediatric v2.0			
Short Form Conversion Table			
Raw Score	T-Score	SE*	
0	34.6	5.7	
1	39.9	4.4	
2	43.5	3.6	
3	46.5	3.1	
4	49.0	2.9	
5	51.4	2.9	
6	54.0	3.3	
7	57.5	4.2	
8	63.0	5.80	
*SE = Standard Error on T-score metric			