SLEEP-RELATED IMPAIRMENT

A brief guide to the PROMIS[®] Sleep-Related Impairment instruments:

ADULT	PEDIATRIC	PARENT PROXY
PROMIS Bank v1.0 – Sleep-Related Impairment PROMIS Short Form v1.0 – Sleep- Related Impairment 4a PROMIS Short Form v1.0 – Sleep- Related Impairment 8a	PROMIS Pediatric Bank v1.0 – Sleep- Related Impairment PROMIS Pediatric Short Form v1.0 – Sleep-Related Impairment 4a PROMIS Pediatric Short Form v1.0 – Sleep-Related Impairment 8a	PROMIS Parent Proxy Bank v1.0 – Sleep-Related Impairment PROMIS Parent Proxy Short Form v1.0 – Sleep-Related Impairment 4a PROMIS Parent Proxy Short Form v1.0 – Sleep-Related Impairment 8a

ABOUT SLEEP-RELATED IMPAIRMENT

The PROMIS Sleep-Related Impairment item banks focus on self-reported perceptions of alertness, sleepiness, and tiredness during usual waking hours, and the perceived functional impairments during wakefulness associated with sleep problems or impaired alertness. Though Sleep-Related Impairment does not directly assess cognitive, affective, or performance impairment, it does measure waking alertness, sleepiness, and function within the context of overall sleep-wake function. The Sleep-Related Impairment short form is universal rather than disease-specific. It assesses sleep-related impairment over the past seven days.

Sleep-Related Impairment instruments are available for adults (ages 18+), pediatric self-report (ages 8-17) and for parents serving as proxy reporters for their child (youth ages 5-17).

INTRODUCTION TO ASSESSMENT OPTIONS

There are two administration options for assessing Sleep-Related Impairment: <u>short form</u> and <u>computerized</u> <u>adaptive test (CAT)</u>. When administering a short form, instruct participants to answer all of the items (i.e., questions or statements) presented. With CAT, participant responses guide the system's choice of subsequent items from the full item bank (16 items in total). Although items differ across respondents taking 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 CAT. This guide provides information on all Sleep-Related Impairment short form and CAT instruments.

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 sleep-related impairment represented by all items in the item bank. When choosing between 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.

SHORT FORM DIFFERENCES

There are 2 adult short forms. Items were selected based on content and psychometric characteristics. Short form items are nested or overlap (e.g., an 8 item short form is the 4-item short form plus two additional items).

Pediatric and Parent Proxy Short Forms

There are 2 Pediatric and 2 Parent Proxy short forms. Items were selected based on content and psychometric characteristics.

Selecting a Short Form

In selecting between short forms, the difference is instrument length. The reliability and precision of the short forms within a domain is highly similar. If you are working with a sample in which you want the most precise measure, select the longest short form. If you have little room for additional measures but really wanted to capture something as a secondary outcome, select one of the shorter instruments (e.g., 4-item short form).

SELECTING A PEDIATRIC OR PARENT PROXY INSTRUMENT

In selecting whether to use the pediatric or parent proxy instrument for this domain, it is important to consider both the population and the domain which you are studying. Pediatric self-report should be considered the standard for measuring patient-reported outcomes among children. However, circumstances exist when the child is too young, cognitively impaired, or too ill to complete a patient-reported outcome instrument. While information derived from self-report and proxy-report is not equivalent, it is optimal to assess both the child and the parent since their perspectives may be independently related to healthcare utilization, risk factors, and quality of care.

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 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 4-item form, the lowest possible raw score is 4; the highest possible raw score is 16 (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

With the total raw score for a measure, locate the applicable score conversion table in the Appendix and use this table to translate the total raw score _i_nto 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 Sleep-Related Impairment 8a short form v1.0, a raw score of 10 converts to a T-score of 38.7 with a standard error (SE) of 4.2 (see scoring table for the 8a v1.0 short form in Appendix 1). Thus, the 95%

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confidence interval around the observed score ranges from 30.5 to 46.9 (T-score \pm (1.96*SE) or 38.7 \pm (1.96*4.2).

<u>CAT:</u> A minimum number of items (4 for adult and adult cancer CATs and 5 for peds and parent proxy CATs) must be answered in order to receive a score for the Sleep-Related Impairment CAT. 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 3.0 for adult and adult cancer CATs and 4.0 for peds and parent proxy CATs), or the participant has answered the maximum number of questions (12), whichever occurs first.

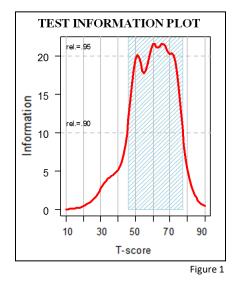
For most PROMIS instruments, a score of 50 is the average for the United States general population with a standard deviation of 10 because calibration testing was performed on a large sample of the general population. You can read more about the calibration and centering samples on HealthMeasures.net (<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 Sleep-Related Impairment, a T-score of 60 is one SD worse than average. By comparison, a Sleep-Related Impairment T-score of 40 is one SD better than average.

STATISTICAL CHARACTERISTICS

There are four key features of the score for Sleep-Related Impairment:

- 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.

In Figure 1 (adult 8a short form), the two dotted horizontal lines each represent a degree of internal consistency reliability (i.e., .90 or .95) typically regarded as sufficient for an accurate individual score. The shaded blue region marks the range of the scale where measurement precision is comparable to the reliability of .90 for the eight-item form. Figure 1 also tells us where on the scale the form is most informative based upon the T-score. This form would typically be more informative than a Sleep-Related Impairment form with fewer items.

PROMIS - Sleep-Related Impairment

Figure 2 is a sample of the statistical information available in Assessment Center for the Sleep-Related Impairment CAT. More information is available at <u>HealthMeasures.net</u>.

		Scalin	g Mod	lel Us	ed	For Ca	librati	on	Gra	ded	Re	spo	onse	Mode
	1	Fotal I	lumb	er of	Iter	ns		1	16					
				S	am	nle			N		۵In	ha	Reli	ability
					_	p Calib	ration			52 (-			ability
					Sco	ore Dis	tributi	one						
		Mean	SD	P5		P10	P25	P5	0	P7	5	P	90	P95
	Raw	34.84	13.2	3 18	.45	20.00	24.00	32.	00	44.	00	54	.00	61.00
	Scale	50.00	9.81	. 34	.59	37.41	43.03	49.	52	56.	89	63	.18	66.73
													Min	Max
Scale :	Score	10.0	20.0	30.0	40.	.0 50.0	60.0	70.	0 8	80.0	90	0.0	10.	90.0
SE		2.20	.90	.40	.30	.20	.20	.20		30	.8	0		
Reliability .00 .13 .8			.80	.90	.97	.97	.97		91	.3	5			

PREVIEW OF SAMPLE ITEM

Figure 3 is an excerpt from the paper version of the eight-item short form. This is the paper version format used for all Sleep-

Related Impairment instruments. It is important to note, CAT is not available for paper administration.

	In the past 7 days					
		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep10	I had a hard time getting things done because I was sleepy		2 2	3	4	5
Sleep11	I had a hard time concentrating because I was sleepy		2 2	— 3	— 4	5

Figure 3

FREQUENTLY ASKED QUESTIONS (FAQ)

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?

Yes! Look at the HealthMeasures website (<u>www.healthmeasures.net</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.

4/14/2020

- 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.

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APPENDIX-SCORING TABLE

Short Fo	rm Conversio	n Table			
Raw Score T-score SE*					
4	36.2	6.2			
5	42.4	4.6			
6	47.1	3.6			
7	50.1	3.3			
8	52.7	3.1			
9	54.8	3.0			
10	56.7	2.9			
11	58.6	2.9			
12	60.5	2.8			
13	62.3	2.7			
14	64.0	2.7			
15	65.8	2.7			
16	67.6	2.7			
17	69.4	2.7			
18	71.5	2.8			
19	74.0	3.1			
20	77.7	3.8			



Sleep-Related Impairment 8a				
	m Convers	ionTable		
Raw				
Score	T-Score	SE*		
8	30.0	5.4		
9	35.2	4.6		
10	38.7	4.2		
11	41.4	3.8		
12	43.6	3.6		
13	45.5	3.4		
14	47.3	3.1		
15	48.9	2.9		
16	50.3	2.7		
17	51.6	2.6		
18	52.9	2.6		
19	54.0	2.5		
20	55.1	2.5		
21	56.1	2.5		
22	57.2	2.5		
23	58.2	2.4		
24	59.3	2.4		
25	60.3	2.4		
26	61.3	2.4		
27	62.3	2.3		
28	63.3	2.3		
29	64.3	2.3		
30	65.3	2.3		
31	66.3	2.3		
32	67.3	2.3		
33	68.4	2.3		
34	69.5	2.3		
35	70.7	2.4		
36	71.9	2.5		
37	73.4	2.6		
38	75.0	2.8		
39	76.9	3.1		
40	80.1	3.9		
	ard Error on 1			
	dult version			

Note: The Sleep-Related Impairment 8a table was revised on 5/22/2014. Instruments scored prior to this date should be re-scored using this table.

Conversion table applies only when ALL items on the short form have been answered. T-score metric is a linear transformation from the IRT theta scale: T-score=10*theta+50.

Short Form Conversion Table							
Raw Score	Raw Score T Score T Score SE* Theta Score						
4	38.3	6.0	-1.17				
5	44.7	4.1	-0.53				
6	47.8	3.7	-0.22				
7	50.6	3.1	0.06				
8	52.9	2.9	0.29				
9	55.1	2.8	0.51				
10	57.2	2.8	0.72				
11	59.5	2.9	0.95				
12	61.9	2.9	1.19				
13	64.1	3.0	1.41				
14	66.1	3.1	1.61				
15	68.4	3.0	1.84				
16	70.7	3.0	2.07				
17	73.0	3.1	2.3				
18	75.7	3.3	2.57				
19	79.6	3.9	2.96				
*Standard Error on T-score metric							

Pediatric v1.0 – Sleep-Related Impairment 4a

Short Form Conversion Table						
Raw Score	T Score	T Score SE*	Theta Scor			
8	37.4	5.7	-1.26			
9	43.3	3.8	-0.67			
10	45.9	3.3	-0.41			
11	48.1	2.8	-0.19			
12	49.7	2.5	-0.03			
13	51.2	2.3	0.12			
14	52.5	2.2	0.25			
15	53.7	2.1	0.37			
16	54.8	2.1	0.48			
17	55.9	2.1	0.59			
18	57.0	2.1	0.7			
19	58.1	2.1	0.81			
20	59.2	2.1	0.92			
21	60.3	2.1	1.03			
22	61.5	2.2	1.15			
23	62.7	2.2	1.27			
24	63.9	2.2	1.39			
25	65.1	2.3	1.51			
26	66.2	2.3	1.62			
27	67.4	2.3	1.74			
28	68.6	2.2	1.86			
29	69.7	2.2	1.97			
30	70.9	2.2	2.09			
31	72.0	2.2	2.2			
32	73.1	2.2	2.31			
33	74.2	2.2	2.42			
34	75.4	2.3	2.54			
35	76.6	2.3	2.66			
36	78.0	2.4	2.8			
37	79.6	2.6	2.96			
38	81.4	2.8	3.14			
39	84.0	2.9	3.4			

Pediatric v1.0 – Sleep-Related Impairment 8a

Parent Proxy v1.0 – Sleep-Related Impairment 4a						
Short Form Conversion Table						
Raw Score	T Score	T Score SE*	Theta Score			
4	40.0	6.4	-1			
5	46.7	4.4	-0.33			
6	50.7	3.7	0.07			
7	54.0	3.0	0.4			
8	56.5	2.8	0.65			
9	58.7	2.8	0.87			
10	61.1	2.8	1.11			
11	63.7	2.9	1.37			
12	66.4	2.9	1.64			
13	68.9	3.1	1.89			
14	71.3	3.1	2.13			
15	73.8	3.0	2.38			
16	76.1	2.9	2.61			
17	78.4	3.0	2.84			
18	80.9	3.2	3.09			
19	84.3	3.0	3.43			
*Standard E	rror on T-sco	re metric				

Parent Proxy v1.0 – Sleep-Related Impairment 8a						
Short Form Conversion Table						
Raw Score	T Score	T Score SE*	Theta Score			
8	37.9	6.1	-1.21			
9	43.8	4.5	-0.62			
10	47.0	3.9	-0.3			
11	49.6	3.3	-0.04			
12	51.7	2.8	0.17			
13	53.5	2.5	0.35			
14	55.0	2.3	0.5			
15	56.4	2.3	0.64			
16	57.7	2.3	0.77			
17	58.9	2.3	0.89			
18	60.2	2.3	1.02			
19	61.5	2.3	1.15			
20	62.9	2.3	1.29			
21	64.3	2.3	1.43			
22	65.6	2.3	1.56			
23	67.0	2.4	1.7			
24	68.4	2.4	1.84			
25	69.8	2.4	1.98			
26	71.2	2.4	2.12			
27	72.6	2.4	2.26			
28	73.9	2.3	2.39			
29	75.3	2.3	2.53			
30	76.6	2.3	2.66			
31	77.9	2.4	2.79			
32	79.2	2.5	2.92			
33	80.6	2.6	3.06			
34	82.1	2.7	3.21			
35	83.7	2.7	3.37			
36	85.3	2.5	3.53			
37	86.6	2.2	3.66			
*Standard E	rror on T-sco	ore metric				