

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

ALCOHOL USE

A brief guide to the PROMIS Alcohol Use instruments:

ADULT
PROMIS Item Bank v1.0 – Alcohol Use
PROMIS Short Form v1.0 – Alcohol Use 7a

ABOUT ALCOHOL USE

The PROMIS adult Alcohol Use item bank assesses drinking patterns (e.g. quantity and frequency of consumption, time spent drinking, episodes of heavy drinking), cue-based drinking (internal states and external contexts), cravings to drink (e.g. urgency, compulsivity), and efforts to control drinking (e.g. difficulty in limiting drinking) that indicate problematic drinking, particularly at the high end of the severity continuum. This bank, however, also provides good precision at moderate and low severity drinking levels (unlike many traditional measures of alcohol use and abuse). Although negative consequences are often associated with problem drinking, these consequences are assessed by a separate bank.

Alcohol Use instruments are available for adults (ages 18+).

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

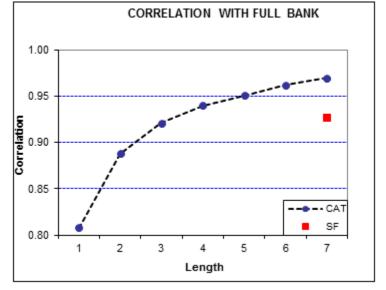
INTRODUCTION TO ASSESSMENT OPTIONS

There are two administration options for assessing Alcohol Use: short form 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 CAT, participant responses guide the system's choice of subsequent items from the full item bank (37 items in total). For both short form and CAT, participants are first asked to answer a screener question which inquires whether they have consumed any type of alcoholic beverage in the past 30 days. If a participant responds in the affirmative the remainder of the instrument is administered. If the participant responds in the negative the system by passes the remainder of the short form or CAT and moves on to the next instrument in the assessment. 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 Alcohol Use 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 alcohol use 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.

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Figure 1 illustrates the correlations (strength of relationship) of the full bank with CAT and with short forms of varying length. The correlation of CAT scores with the full bank score is greater than a short form of any length. A longer CAT or longer short form offers greater correlation, as well as greater precision. When evaluating precision, not all questions are equally informative. The flexibility of CAT to choose more informative questions offers more precision.



SCORING THE INSTRUMENT

<u>Short Form</u>: PROMIS instruments are scored using item-level calibrations. This means that the most accurate way to score a PROMIS

Figure 1

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.

For adults, each question 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 adult 7-item form, the lowest possible raw score is 7; the highest possible raw score is 35 (see short form scoring table in Appendix).

A score can be approximated if a participant skips a question. If items are missing, first check how many items were answered. For short forms with at least 5 items, confirm that 4 or 50% of items, whichever is greater, were answered. For example, a 4-item short form can only be scored with complete data. A 5-item short form can be scored as long as 4 items were answered. A 10-item short form can be scored as long as the participant answered at least 5 items. For branched instruments (e.g., Alcohol Use), the screening question is not used in calculating the score and therefore shouldn't be counted when assessing if the minimum number of items were answered. After confirming that enough responses were provided, sum the response scores from the items that were answered (not including any screening question). Multiply this sum by the total number of items in the short form. Finally, divide by the number of items that were answered. For example, if a respondent answered 5 of 8 questions and answered all items with the second lowest response option (2), you would sum all responses (10), multiply by the number of items in the short form (8) and divide by the number of items that were answered (5). Here (10x8)/5=16. If the result is a fraction, round up to the nearest whole number. This is a pro-rated raw score.

Again, the formula is:

(Raw sum x number of items on the short form) Number of items that were actually answered

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Locate the score conversion table in the Appendix and use this table to translate the total raw score or pro-rated 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. It is important to note that Assessment Center will convert a participant's pattern of responses to a standardized T-score after they have finished a CAT. The standardized T-score is reported as the final score for each participant.

For the adult PROMIS Alcohol Use 7a short form, a raw score of 10 converts to a T-score of 49.4 with a standard error (SE) of 2.7 (see scoring table for the 7a short form in appendix). Thus, the 95% confidence interval around the observed score ranges from 44.1 to 54.7 (T-score \pm (1.96*SE) or 49.4 \pm (1.96*2.7).

For pro-rated scores, this calculation assumes that responses are missing at random. This isn't always true. Therefore, use caution when interpreting the final pro-rated T-score.

<u>CAT</u>: A minimum number of items (4 for adult) must be answered in order to receive a score for Alcohol Use CAT. The first item is selected because it provides the most information about the U.S. general population. The response to this item will guide the system's choice of the next item for the participant. The participant's response to this 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, 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. However, Alcohol Use instruments were not calibrated on a national sample and so a score of 50 represents the average of the calibration sample which was generally more enriched for chronic illness. As these instruments, a score of 50 likely represents somewhat sicker people than 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 Alcohol Use, a T-score of 60 is one SD higher than average. These individuals have more alcohol consumption, cravings, or difficulty controlling their drinking. By comparison, an Alcohol Use T-score of 40 is one SD below average. These individuals have less alcohol use, cravings or difficulty controlling their drinking.

STATISTICAL CHARACTERISTICS

There are four key features of the score for Alcohol Use:

- **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/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).

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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 2 (Adult 7a 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 seven-item form. Figure 2 also tells us where on the scale the form is most informative based upon the T-score.

More information is available online via Assessment Center (assessmentcenter.net).

PREVIEW OF SAMPLE ITEM

Figure 3 shows an adult Alcohol Use item from the full item bank 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 4 is an excerpt from the paper version of the adult seven-item short form. This is the paper version format used for all Alcohol Use instruments. It is important to note, CAT is not available for paper administration.

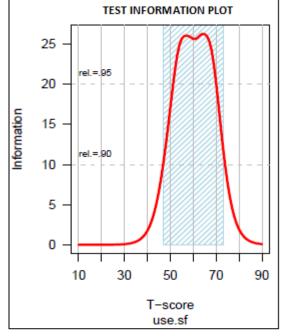
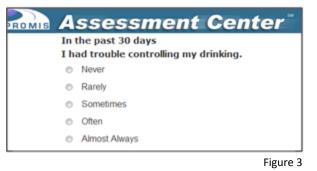


Figure 2



	In the past 30 days	Never	Rarely	Sometimes	Often	Almost always
CONS01	I spent too much time drinking	1		3	4	5
CONS07	I drank heavily at a single sitting	1	2	3	4	5

Figure 4

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 <u>nihpromis.org</u> or <u>assessmentcenter.net</u>. To learn more, contact <u>help@assessmentcenter.net</u>.

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

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 <u>assessmentcenter.net</u>.

Q: Are these instruments available in other languages?

Yes, these instruments are 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 Alcohol Use 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

Alcohol Use 7a						
Short Form Conversion Table						
Raw Score	T-Score	SE*				
7	38.9	5.9				
8	45.2	3.6				
9	47.6	3.1				
10	49.4	2.7				
11	50.9	2.5				
12	52.1	2.3				
13	53.2	2.2				
14	54.2	2.1				
15	55.1	2.1				
16	56.0	2.0				
17	56.9	2.0				
18	57.7	2.0				
19	58.6	2.0				
20	59.4	2.0				
21	60.2	2.0				
22	61.0	2.0				
23	61.8	2.0				
24	62.6	2.0				
25	63.4	2.0				
26	64.2	2.0				
27	65.1	2.0				
28	66.0	2.0				
29	66.9	2.1				
30	67.8	2.1				
31	68.9	2.2				
32	70.1	2.4				
33	71.5	2.6				
34	73.2	2.9				
35	76.7	4.0				
*SE= Standard Error on T-score metric						

Adult version

Note: The Alcohol Use 7a table was revised on 5/22/2014. Instruments scored prior to this date should be rescored 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.