

GASTROINTESTINAL SYMPTOMS MEASURE DIFFERENCES

A brief guide to differences between the PROMIS® Gastrointestinal Symptom Scales:

ADULT
PROMIS Scale v1.0 – Gastrointestinal Belly Pain 5a
PROMIS Scale v1.0 – Gastrointestinal Bowel Incontinence 4a
PROMIS Scale v1.0 – Gastrointestinal Constipation 9a
PROMIS Scale v1.0 – Gastrointestinal Diarrhea 6a
PROMIS Scale v1.0 – Gastrointestinal Disrupted Swallowing 7a
PROMIS Scale v1.1 – Gastrointestinal Gas and Bloating 13a
PROMIS Scale v1.0 – Gastrointestinal Gas and Bloating 13a*
PROMIS Scale v1.0 – Gastrointestinal Nausea and Vomiting 4a
PROMIS Scale v1.0 – Gastrointestinal Reflux 13a

*Retired measure

ABOUT GASTROINTESTINAL SYMPTOMS

The **PROMIS Gastrointestinal Belly Pain Scale** includes 5 items that assess the frequency, intensity, and quality of belly pain over the past 7 days. The items also address the bothersomeness and interference with daily activities that result from belly pain. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Bowel Incontinence Scale** includes 4 items that assess the frequency of bowel incontinence, soiling, and gas incontinence (i.e., stool leakage while passing gas) over the past 7 days. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Constipation Scale** includes 9 items that assess the frequency and intensity of constipation-related symptoms over the past 7 days. More specifically, the items address incomplete evacuation, rectal pain, straining, and hard stools, as well as the need for manual extraction of stool and the bothersomeness of these symptoms. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Diarrhea Scale** includes 6 items that assess the frequency, bothersomeness, and impact of bowel urgency over the past 7 days. Diarrhea refers to loose, watery stools, bowel urgency, and frequent bowel movements. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Disrupted Swallowing Scale** includes 7 items that assess the frequency of swallowing-related symptoms over the past 7 days. More specifically, the items address difficulty swallowing solid and soft foods, liquids, and pills, as well as throat/chest pain and the sensation of food being stuck in the throat/chest. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Gas and Bloating Scale** includes 13 items that assess the frequency, intensity, and severity of various gastrointestinal symptoms over the past 7 days. More specifically, the items address bloating (i.e., feeling pressure or fullness), bloating appearance (i.e., belly swollen or larger than usual size), flatulence

(i.e., passing gas), and abdominal sounds (i.e., gurgling or rumbling), as well as the predictability, bothersomeness, and interference with daily activities that result from these symptoms. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Nausea and Vomiting Scale** includes 4 items that assess the frequency of vomiting, nausea, and poor appetite, as well as the predictability of nausea, over the past 7 days. This measure is not disease-specific and is intended for adult respondents (ages 18+).

The **PROMIS Gastrointestinal Reflux Scale** includes 13 items that assess symptoms associated with stomach contents leaking backwards from the stomach into the esophagus over the past 7 days. More specifically, the items address the frequency of regurgitation, the experience of burning or a lump in the throat, burping, hiccupping, and excessive saliva production, as well as the bothersomeness that results from these symptoms. This measure is not disease-specific and is intended for adult respondents (ages 18+).

INTRODUCTION TO ASSESSMENT OPTIONS

There is one administration option for assessing adult PROMIS Gastrointestinal Symptoms (GI): fixed length scales. No computer adaptive test (CAT) is available. When administering a scale, instruct respondents to following the administration instructions in the scale. Some GI scales include instructions to skip non-relevant items (i.e., questions or statements).

VERSION DIFFERENCES

The PROMIS Gastrointestinal measures available at www.HealthMeasures.net and in the API (used by REDCap, Epic, and other 3rd party vendors) have slight modifications from the versions included in the Corrigendum in *The American Journal of Gastroenterology*. (Spiegel BMR, Hays RD, Bolus R, Melmed GY, Chang L, Whitman C, Khanna PP, Paz SH, Hays T, Reise S, Khanna D (2015). Corrigendum: Development of the NIH Patient-Reported Outcomes Measurement Information System (PROMIS) gastrointestinal symptom scales. *American Journal of Gastroenterology*, 110: 608. Doi:10.1038/ajg.2015.62).

The AJG scoring tables are different from the HealthMeasures' versions in this manual. AJG published a single summed score to scale score look-up table for each scale. Using a single look-up table provides a convenient best estimate for summed scores. But respondents who answered 5, 6, 7, 8, and 9 items (as might happen with the Constipation measure) could have the same summed score, but by means of different patterns. Consequently, this HealthMeasures manual includes additional tables for when a respondent correctly skipped items. This approach, while less convenient, provides an improvement in the T-score estimate relative to a single table.

The AJG summed score to scale score look-up tables start with sums of 0. As the lowest response score for any item is 1, it is not possible to produce a sum of 0. The HealthMeasures versions of scoring tables match the summed response scores possible from the print-ready versions of measures.

Belly Pain: The AJG version of the Belly Pain measure includes one item that is an image of a belly with lines mapping out 9 areas. The image is interactive; the respondent is to select all of the areas of the belly that have pain. The number of areas is summed. Item-level parameters are then assigned to that summed value. The item thus contributes to the final T-score for Belly Pain. The version of Belly Pain available from HealthMeasures does not include this item. This item was removed due to the significant technology demands for implementing this idiosyncratic administration and scoring protocol in multiple data collection platforms, browsers, and apps. Additionally, APIs used to access to HealthMeasures in 3rd party data collection systems cannot control the

respondent's user interface. This means that the largest distributors of PROMIS measures – REDCap and Epic – will not support this item. Consequently, the item was removed. The remaining 5 items were recalibrated and made available as a 5-item scale.

Bowel Incontinence: The *AJG* version of Bowel Incontinence included an IRT-based T-score. The HealthMeasures version of the measure does not produce an IRT-based T-score. While the model fit was good, one of the items showed an extremely high discrimination parameter; for this reason, we are currently promoting simple summed scores for this measure. Further study to refine IRT-based scoring is welcome.

Gas and Bloating: In the *AJG* version of Gas and Bloating, a screener item (GISX94) has response scores of "1" and "2". These responses are not intended to be included in the summed score. To reduce the likelihood that users would add these responses in the summed score, they were modified to "A" and "B" in the versions distributed by HealthMeasures.net. The HealthMeasures version 1.0 of Gas and Bloating also incorrectly added skip logic to item 12 (GISX105) that allowed a respondent to skip item 13 (GISX109) after answering "Never."

PROMIS Scale v1.1 – Gastrointestinal Gas and Bloating 13a replaced PROMIS Scale v1.0 – Gastrointestinal Gas and Bloating 13a. The v1.1 measure removed the incorrect instruction on item 12 (GISX105) that had respondents who answered "Never" skip item 13 (GISX109). In the v1.1 measure, this error was removed. All respondents are asked to complete items 12 and 13. Removing the instruction altered the total number of items participants could complete when following skip logic correctly. Revised scoring tables were constructed and added to the Gastrointestinal Scoring Manual.

Reflux: The *AJG* version of Reflux includes one static image of the chest with a red area for the item "Look at the picture below. In the past 7 days, how often did you feel burning in the red area shown in the picture – that is, behind the breastbone?" The HealthMeasures version of Reflux available as a respondent-ready PDF via HealthMeasures.net uses the phrasing "Think of the area behind your breastbone (the area extending from the base of your throat to mid-chest). In the past 7 days... How often did you feel burning in the red area shown in the picture – that is, behind the breastbone?" The image is shown to the right of the response options. The electronic version of Reflux in HealthMeasures uses slightly different wording to support interfaces in which the image is not below, but next to the item, or not shown at all. We needed to make this modification. APIs used to access to HealthMeasures in 3rd party data collection systems (e.g., REDCap) do not support images. Therefore, the instruction before the item reads: "Think of the area behind your breastbone (the area extending from the base of your throat to mid-chest)." The item reads "In the past 7 days, how often did you feel burning in this area – that is, behind the breastbone?" The version of the scale without the image is named "PROMIS Scale v1.0 – GI Reflux no image 13a". If possible, use a version of the measure with the image. All versions use the same scoring.

SCORES

The PROMIS GI measures use a T-score centered on the U.S. General Population. This means that a score of 50 represents the average of the general population (and that 10 represents the standard deviation).

Important: *A higher PROMIS T-score represents more of the concept being measured.* For negatively-worded concepts like belly pain, bowel incontinence, constipation, diarrhea, disrupted swallowing, gas & bloating, nausea & vomiting, and reflux, a T-score of 60 is one SD worse than average. By comparison, a gastrointestinal symptom T-score of 40 is one SD better than average.

STATISTICAL CHARACTERISTICS

There are four key features of the score for GI measures:

- **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 ($T\text{-score} \pm (1.96 * SE) = 52 \pm 3.9 = 48.1 \text{ to } 55.9$).

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

PREVIEW OF SAMPLE ITEM

Figure 1 is an excerpt from the paper version of the 7-item Gastrointestinal Disrupted Swallowing Scale. This is the paper version format used for some of the Gastrointestinal Symptoms instruments.

In the past 7 days...		Never	Rarely	Sometimes	Often	Always
GISX31	How often did food get stuck in your chest when you were eating?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
GISX32	How often did food get stuck in your throat when you were eating?	☐ 1	☐ 2	☐ 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 www.healthmeasures.net.

Q: Are these instruments available in other languages?

These instruments are currently not available in other languages. The HealthMeasures website (<http://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/available-translations>) has 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 a scale. This can be scored using the Scoring Service (https://www.assessmentcenter.net/ac_scoringservice).