



GASTROINTESTINAL SYMPTOMS MEASURE DIFFERENCES

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

| ADULT |
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| 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 v1.0 – Gastrointestinal Gas and Bloating 13a* |
| PROMIS Scale v1.1 – 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 assesses the severity of belly pain in adult (18 years+) populations over the past 7 days. The Gastrointestinal Belly Pain Scale is not disease-specific and is multifaceted, thus is able to measure belly pain as it varies in location, intensity, and quality. The intensity, nature (sharp vs. dull), frequency, bothersomeness, and predictability (e.g., ability to tell in advance when a pain episode would occur) all contribute towards belly pain severity. Involvement of more abdominal regions is related to higher pain severity.

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. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Constipation Scale assesses the frequency and intensity of incomplete evacuation, rectal pain, straining, and hard stools, as well as the need for manual extraction of stool. This scale also assesses the degree of bother and interference from these symptoms. All items use a 7 day reporting period. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Diarrhea Scale contains items focused on capturing the frequency, form, bothersomeness, impact, controllability, and predictability of bowel urgency during the past 7 days. Diarrhea refers to loose, watery stools, urgency, and frequent bowel movements. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Disrupted Swallowing Scale includes 7 items that assess 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. The PROMIS Gastrointestinal Disrupted Swallowing Scale assesses the frequency of these swallowing-related symptoms during the past 7 days. The measure is not disease specific and is intended for adult respondents (18+).



The PROMIS Gastrointestinal Gas and Bloating Scale assesses the frequency and intensity/severity of 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). The scale also assesses the degree of bother and interference with daily activities resulting from bloating and swelling. All items assess these experiences over the past 7 days. The measure is not disease specific and is intended for adult respondents (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. The measure is not disease specific and is intended for adult respondents (18+).

The PROMIS Gastrointestinal Gastroesophageal Reflux Scale assesses symptoms associated with stomach contents leaking backwards from the stomach into the esophagus. The scale assesses the frequency of regurgitation, experience of burning or a lump in the throat, burping, hiccupping, and excessive saliva production in the past 7 days. The scale also assesses the amount of regurgitation experienced as well as the degree of bother from burping or experiencing a lump in the throat, also reported over the past 7 days. The measure is not disease specific and is intended for adult respondents (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 of Gas and Bloating also has item 12 (GISX105) use “If Never, you are finished” and skip item 13. This skip logic is not included in the *AJG* version of the measure.

PROMIS Scale v1.1 – Gastrointestinal Gas and Bloating 13a replaced PROMIS Scale v1.0 – Gastrointestinal Gas and Bloating 13a. The v1.0 measure included an incorrect instruction with item GISX105 to skip the following question (GISX109) if a respondent selected “Never.” This error was removed in v1.1.

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 includes 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. Now, 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 the red area shown in the picture – that is, behind the breastbone?” The image is included in the print-ready version of the scale at HealthMeasures.net. The image is excluded from systems using the API (e.g., REDCap). 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-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. More information is available at HealthMeasures.net.

PREVIEW OF SAMPLE ITEM

Figure 1 is an excerpt from the paper version of the seven-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 <u>chest</u> when you were eating? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 5 |
| GISX32 | How often did food get stuck in your <u>throat</u> when you were eating? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | <input type="checkbox"/> 3 | <input type="checkbox"/> 4 | <input type="checkbox"/> 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_scoringervice).