Assessing Person-Centered Health Outcomes in Adults with Inflammatory Bowel Disease (IBD)

These recommendations are offered as a starting point for consideration. They are not necessarily the best choices for every application and do not substitute for a comprehensive literature review.

Key Domains to Consider in IBD
IBD and its management can have a significant impact on an individual’s symptoms of belly pain, diarrhea, constipation, fatigue, pain interference, anxiety and depression, sleep disturbance, and ability to participate in social roles and activities. Patient-reported outcome (PRO) assessments of these domains in IBD have been used successfully in research settings. More recently, there has been a move to use PRO assessments in clinical trials, quality improvement initiatives, and healthcare delivery settings. This guidance includes relevant PROMIS® measures but does not include IBD-specific PRO measures.

Suggested HealthMeasures for Primary Domains in IBD

**Gastrointestinal – Belly Pain**
The Patient-Reported Outcomes Measurement Information System (PROMIS) Gastrointestinal – Belly Pain 5-item scale assesses the severity of belly pain in adult populations. It evaluates intensity, nature (sharp vs. dull), frequency, bothersomeness, and predictability (e.g. ability to tell in advance when a pain episode would occur) when measuring belly pain severity.

**Gastrointestinal – Diarrhea**
The PROMIS Gastrointestinal – Diarrhea 6-item scale assesses the frequency, form, bothersomeness, impact, controllability, and predictability of bowel urgency.

**Gastrointestinal – Constipation**
The PROMIS Gastrointestinal – Constipation 9-item scale assesses the frequency, intensity, bothersomeness, and/or impact the many facets of constipation, including incomplete evacuation, straining, infrequent stools, hard stools, associated symptoms of rectal pain, and need for manual maneuvers to facilitate stool evacuation.

Summary
- Recommended primary domains for IBD research or care include belly-pain, diarrhea, and constipation.
- Recommended secondary domains for IBD research or care include Fatigue, Pain Interference, Anxiety, Depression, Sleep Disturbance, Ability to Participate in Social Roles and Activities. (PROMIS-57 Profile may be used in lieu of individual instruments.)
- HealthMeasures offers brief, psychometrically sound measures for these domains.
- Recommended assessment times include those scheduled to capture the effects of treatment and disease course.
Suggested HealthMeasures for Secondary Domains in IBD

IBD may impact many aspects of a person’s physical, emotional and social functioning, which means that other health status and quality of life domains can also be significantly impacted and represent secondary domains worth assessment:

<table>
<thead>
<tr>
<th>Secondary HealthMeasures</th>
<th>Description</th>
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<tbody>
<tr>
<td>PROMIS Fatigue (FACIT-Fatigue) 13a short form or CAT</td>
<td>Assesses experience of fatigue (frequency, duration, and intensity) and the impact of fatigue on physical, mental, and social activities.</td>
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<tr>
<td>PROMIS Pain Interference 6a short form or CAT</td>
<td>Assesses the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities.</td>
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<td>PROMIS Anxiety 8a short form or CAT</td>
<td>Self-reported fear, anxious misery, hyperarousal, and somatic symptoms related to arousal.</td>
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<tr>
<td>PROMIS Depression 8a short form or CAT</td>
<td>Negative mood, negative views of self, negative social cognition, decreased positive affect and engagement.</td>
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<tr>
<td>PROMIS Sleep Disturbance 8a short form or CAT</td>
<td>Perceptions of sleep quality, sleep depth, and restoration associated with sleep.</td>
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<tr>
<td>PROMIS Ability to Participate in Social Roles and Activities 8a short form or CAT</td>
<td>Perceived ability to perform one’s usual social roles and activities (e.g., “I have to limit my regular family activities”)</td>
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<tr>
<td>PROMIS-57 Profile (8 items per domain)</td>
<td>In place of the individual measures above, the PROMIS-57 measures Physical Function, Fatigue, Pain Interference, Pain Intensity, Sleep Disturbance, Depression, Anxiety, Ability to Participate in Social Roles and Activities.</td>
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Assessment Times

Ideally, a pre-intervention assessment should be captured to serve as a reference point (i.e., baseline) for monitoring response to treatment, with a follow-up assessment post intervention. Assessment can also be used to measure stability and improvement in people with stable IBD.

Additional Information

The [www.HealthMeasures.net](http://www.HealthMeasures.net) website includes more information about measurement selection, data collection tools, scoring, and interpretation. Its [Search and View Measures](http://www.HealthMeasures.net) tool includes access to all HealthMeasures described here. A Forum allows for questions and responses from the HealthMeasures community. The HealthMeasures team is also available for collaboration or consultation via [help@healthmeasures.net](mailto:help@healthmeasures.net).