MOTILITY
MEASURING IBS
SYMPTOMS

Brennan Spiegel and colleagues have developed a framework for measuring IBS symptoms. “This study might be viewed as arcane or overly academic, but it’s not,” says Spiegel. “We believe this framework will be of value both to clinicians and clinical trialists.”

Currently, there are no existing end points for IBS trials that are approved by the FDA. “The FDA emphasizes that before a PRO (patient-reported outcome) can be made, investigators must develop a ‘conceptual framework’ upon which to ultimately build a PRO,” explains Spiegel.

The researchers therefore decided to create such a framework, following FDA guidance for developing PROs. They performed a systematic review of the literature on IBS questionnaires. They also conducted interviews with IBS patients in order to understand their illness experience in their own words. From this they developed a vocabulary that is consistent with what patients use to describe their symptoms.

“The main result of the study is the creation of a new conceptual framework for measuring IBS symptoms,” reports Spiegel. Other notable findings are that different patients mean different things when they refer to bloating, and that patients differentiate between the look and feel of bloating. Another important finding is that pain should be measured in terms of its intensity, frequency, impact, predicatability, bothersomeness and location. Furthermore, pain and discomfort are different. The term ‘discomfort’ should be downplayed as it is nonspecific. Clinicians frequently refer to ‘discomfort’; however, patients often have different beliefs about what this term means.

“The next step is to use this framework to help guide the development of a future PRO,” concludes Spiegel. “We hope this blueprint will help.”

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