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**TITLE PAGE**

**Title:** Using Patient-reported Outcome Measures in Gastroenterology: PROMISed Land or Road to Nowhere?

**Short “running” title:** PROs: PROMISed Land or Road to Nowhere?

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**Abbreviations:**

CI	confidence interval
GI	gastrointestinal
IBD	inflammatory bowel disease
IBS	irritable bowel syndrome

OR odds ratio

PRO patient-reported outcome

PROMIS patient-reported outcomes measurement  
information system

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**ABSTRACT**

Incorporating patient-reported outcomes (PROs) into clinical practice is advocated by some. However, the benefits remain uncertain. Almario *et al.* examined the impact of a gastrointestinal (GI) version of the patient-reported outcomes measurement information system (PROMIS<sup>®</sup>) on patient satisfaction, perception of doctors' interpersonal skills, and the likelihood of shared decision-making. Patients were allocated to complete GI PROMIS prior to their outpatient appointment, or usual management. Overall, uptake of GI PROMIS was poor and there was no difference in any outcome measure between those completing the questionnaire and those receiving usual management, suggesting PROs may be of limited utility in this setting.

A patient-reported outcome (PRO) is 'any report that comes directly from a patient about a health condition or its treatment, without interpretation of the patient's response by a clinician or anyone else'. (1) PROs comprise individual symptoms, or clusters of symptoms, that aim to capture the patient's illness experience, and may help healthcare providers to better understand symptoms from the patient's perspective. (2) Their use is advocated as an aid to the assessment of disease activity in conditions such as inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS), but also as an adjunct to standard clinical practice, in order to improve doctor-patient relations and patient satisfaction. Furthermore, the US Food and Drug Administration now support the use of PROs as endpoints in clinical trials of novel pharmacological therapies in gastrointestinal (GI) diseases. (3)

The National institutes of Health created the patient-reported outcomes measurement information system (PROMIS<sup>®</sup>) in 2004, (4) which was modified for use in GI disease in 2014. (5) This data collection tool comprises short questionnaires that are easily administered within the constraints of routine clinical practice, with the aim of providing a standardized set of PROs that can be used across the entirety of GI clinical and research practice. However, although the concept of integrating PROs into standard care is over a decade old, their impact on clinical outcomes remains poorly studied.

In this issue of *American Journal of Gastroenterology*, Almario *et al.* report data on the effect of the use of PROs on patient satisfaction, as well as the assessment of care provider interpersonal skills and shared decision-making at an initial visit in GI outpatient clinics.(6) The study was a pragmatic clinical trial, where patients in the intervention group received a letter inviting them to log on to an e-portal in order to complete a GI version of PROMIS (GI PROMIS), whereas those in the control group received usual management. Based on GI PROMIS responses, a symptom "heat map" and automated history of presenting illness was generated, which was available for the attending physician and patient to review

prior to, and during, the consultation. Following clinic review, participants were asked to complete post-visit questionnaires evaluating their satisfaction, their care provider's interpersonal skills, and their perceptions about ability to engage in shared decision-making.

In total, 594 patients were assigned to the intervention group, of whom only 221 (37.2%) accessed the e-portal and completed the GI PROMIS questionnaire. African Americans were significantly less likely to engage than White Caucasians (18.4% vs. 48.6%, odds ratio (OR) = 0.44; 95% confidence interval (CI) 0.26-0.74), and there was also a trend towards lower engagement in Latinos (19.7%, OR = 0.52; 95% CI 0.26-1.05). Only 112 (18.9%) of those in the intervention arm completed the GI PROMIS questionnaire, attended their clinic appointment, and completed the outcome questionnaire following their visit. In the control group, 502 patients were invited to participate. Of these, three (0.6%) had incomplete demographic data and were therefore excluded. In total, only 154 (30.9%) of the remaining 499 patients completed their post-visit questionnaires. Patients who were assigned to the intervention arm and who completed the GI PROMIS questionnaire were younger than the 154 in the control group who provided post-visit data (54.1 years vs. 58.7 years,  $P = 0.007$ ).

Comparison of outcome questionnaire responses between the intervention and control groups was undertaken using both an intention-to-treat analysis, where GI PROMIS responders who did not complete the outcome questionnaires were assumed to have the same responses as the control arm, and a per-protocol analysis. Overall, in both intention-to-treat and per-protocol analyses, the use of GI PROMIS had no effect on patient satisfaction, their opinions on the care provider's interpersonal skills, or their perception of the ability to engage in shared decision-making, when compared with control patients receiving usual management ( $P \geq 0.05$  for all comparisons).

Strengths of this study include it being conducted as part of usual clinical practice, meaning that the results are generalizable to other tertiary care referral populations, and the use of validated questionnaires to assess the endpoints of interest. However, there are also several limitations. The poor response rate to the invitation to complete the GI PROMIS questionnaire is a major issue as, if patients are not willing to engage with this system, then any potential benefits from its use will be reduced. Of those invited, less than 40% completed GI PROMIS, with the odds of African American invitees completing the questionnaire significantly lower than those of White Caucasians. Furthermore, GI PROMIS responders were significantly younger than controls, suggesting either that there was selection bias during recruitment into the intervention group, or that responders to GI PROMIS were younger than non-responders, thereby skewing the demographic comparison between the two groups, and potentially limiting the implementation of this intervention to young, White, "tech-savvy" individuals.

Based on these results alone, the use of PROs does not appear to improve patient satisfaction, perception of doctors' interpersonal skills, or the likelihood of shared decision-making between clinician and patient. However, the poor response rate to outcome questionnaires (51.6% in a self-selected intervention group and 30.7% in the control group) limits the validity of these findings. Furthermore, it may be that the standard of communication skills and shared decision-making in the four tertiary care referral centres used in this study was already extremely high, thereby reducing the likelihood of identifying a benefit of the PROMIS intervention. It would be premature, therefore, to assume that there are no benefits from applying this intervention in primary or secondary care.

Aside from the outcomes incorporated in the present study, the use of PROs may be of benefit in circumstances other than those examined by the authors. Although PROMIS was designed to aid improvement in patient outcomes, the impact of using it on other endpoints

could be studied. A reduction in mean consultation length in those patients who had completed GI PROMIS could improve efficiency and reduce costs in busy outpatient departments, but this was not examined. Moreover, the use of PROs in patients with chronic GI disorders may be of greater interest, as longitudinal alterations in PROs may prove a useful surrogate measure of the natural history of symptoms in chronic GI diseases such as IBS and IBD, as has been highlighted in other specialties. (7) Furthermore, incorporating PROs into long-term care pathways may aid the development of doctor-patient relationships over several consultations thereby improving the patient satisfaction, perception of doctors' interpersonal skills, and the likelihood of shared decision-making between clinician and patient.

In summary, this study demonstrates no beneficial effect of GI PROMIS on patient satisfaction, care provider interpersonal skills, or shared decision-making in gastroenterology outpatient clinics in tertiary care. However, inherent limitations of the study design and methodology employed, and the population participating, restrict the applicability of the findings. It may be that engagement with GI PROMIS would be greater in patients with chronic GI disorders, with beneficial effects arising as a consequence. The use of such tools in the longitudinal assessment of conditions, including IBS and IBD, is also of interest, although the sensitivity and specificity of individual PROs used in the formation of them, to date, has been shown to be poor in predicting disease activity. (8-10)

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