

# The Real-World Global Use of Patient-Reported Outcomes for the Care of Patients With Inflammatory Bowel Disease

Jamie M. Horrigan, MD,\* Edouard Louis, MD, PhD,<sup>†</sup> Antonino Spinelli, MD, PhD,<sup>‡</sup>  
Simon Travis, DPhil, FRCP,<sup>§</sup> Bjorn Moum, MD, PhD,<sup>¶</sup> Jessica Salwen-Deremer, PhD,<sup>\*.1</sup>  
Jonas Halfvarson, MD, PhD,<sup>\*\*</sup> Remo Panaccione, MD, FRCPC,<sup>††,‡‡</sup> Marla C. Dubinsky, MD,<sup>§§</sup>  
Pia Munkholm, MD, DMSci,<sup>¶¶</sup> and Corey A. Siegel, MD, MS,<sup>\*,1D</sup> on behalf of the Patient Reported  
Outcomes Cluster of the International Organization for the Study of Inflammatory Bowel  
Diseases

\*Inflammatory Bowel Disease Center, Section of Gastroenterology and Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA

<sup>†</sup>Department of Gastroenterology, CHU Liège University Hospital, Liège, Belgium

<sup>‡</sup>Department of Biomedical Sciences, Humanitas University, IRCCS Humanitas Research Hospital, Milan, Italy

<sup>§</sup>Kennedy Institute of Rheumatology, Translational Gastroenterology Unit, and Biomedical Research Centre, University of Oxford, Oxford, UK

<sup>¶</sup>Department of Gastroenterology, Oslo University Hospital, Institute of Clinical Medicine, University of Oslo, Oslo, Norway

<sup>¶¶</sup>Department of Psychiatry, Section of Gastroenterology & Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA

<sup>\*\*</sup>Department of Gastroenterology, Faculty of Medicine and Health, Örebro University, Örebro, Sweden

<sup>††</sup>Department of Medicine, University of Calgary, Calgary, Alberta, Canada

<sup>‡‡</sup>Department of Community Health Sciences, University of Calgary, Calgary, Alberta, Canada

<sup>§§</sup>Department of Pediatrics, Susan and Leonard Feinstein IBD Center, Icahn School of Medicine, Mount Sinai, New York, New York, USA

<sup>¶¶</sup>Department of Gastroenterology, North Zealand Hospital, University of Copenhagen, Hillerød, Denmark

Address correspondence to: Corey A. Siegel, Inflammatory Bowel Disease Center, Section of Gastroenterology and Hepatology, Dartmouth-Hitchcock Medical Center, Lebanon, NH 03756, USA ([Corey.A.Siegel@hitchcock.org](mailto:Corey.A.Siegel@hitchcock.org)).

**Background:** Many patient-reported outcomes (PROs) have been developed for inflammatory bowel disease (IBD) without recommendations for clinical use. PROs differ from physician-reported disease activity indices; they assess patients' perceptions of their symptoms, functional status, mental health, and quality of life, among other areas. We sought to investigate the current global use and barriers to using PROs in clinical practice for IBD.

**Methods:** A cross-sectional survey was performed. An electronic questionnaire was sent to an international group of providers who care for patients with IBD.

**Results:** There were 194 respondents, including adult/pediatric gastroenterologists, advanced practice providers, and colorectal surgeons from 5 continents. The majority (80%) use PROs in clinical practice, 65% frequently found value in routine use, and 50% frequently found PROs influenced management. Thirty-one different PROs for IBD were reportedly used. Barriers included not being familiar with PROs, not knowing how to incorporate PRO results into clinical practice, lack of electronic medical record integration, and time constraints. Most (91%) agreed it would be beneficial to have an accepted set of consistently used PROs. The majority (60%) thought that there should be some cultural differences in PROs used globally but that PROs for IBD should be consistent around the world.

**Conclusions:** PROs are used frequently in clinical practice with wide variation in which are used and how they influence management. Education about PROs and how to use and interpret an accepted set of PROs would decrease barriers for use and allow for global harmonization.

## Lay Summary

Patient-reported outcomes (PROs) are standardized tools that generate numeric values representing patient perceptions of symptoms, functional status, mental health, and quality of life. In inflammatory bowel disease, it is necessary to identify practical PROs that represent what is most important to patients.

**Key Words:** Crohn's disease, ulcerative colitis, patient-reported outcomes (PROs), patient-centered care, inflammatory bowel disease (IBD)

## Introduction

Patient-reported outcomes (PROs) are standardized tools that generate numeric values representing the patient's perception of their symptoms, functional status, mental health, and quality of life, among other areas of their lives. PROs

differ from physician-reported disease activity indices as they are entirely patient reported and do not include any physical exam or laboratory findings. Initially, PROs were developed for research purposes but more recently have been used in clinical practice to help providers compare symptom burden

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### Key Messages

- What is already known? Many PROs have been developed for the care of patients with IBD for research and clinical purposes without agreement on which are best for clinical management.
- What is new here? PROs are frequently used in clinical practice with wide variation in which PROs are used and how they influence management.
- How can this study help patient care? Information on patterns of use and barriers to use of PROs in clinical practice is essential for development of a consolidated set of PRO tools.

and various health outcomes over time per the patient perspective.<sup>1,2</sup> In research settings, PROs are often combined with objective measures to assess disease activity and treatment response. Additionally, PROs are increasingly becoming required by regulatory agencies and may be used as primary endpoints in clinical trials.<sup>3,4</sup> PROs can range from a single question to lengthy questionnaires with complex scoring systems. While this complexity may not be a problem in the clinical trial setting, it may become difficult logistically in clinical practice.<sup>5,6</sup>

Inflammatory bowel disease (IBD) may deeply impact the quality of life of patients through the chronic nature of the disease and persistent symptoms. While providers caring often look to outcomes such as corticosteroid-free remission rates, emergency department visits, hospitalizations, surgery, and complications, patients with IBD especially value symptom burden and quality of life.<sup>7-9</sup> In multiple studies, fatigue was identified as the most bothersome symptom above bowel symptoms.<sup>10,11</sup> Fatigue affects >80% of patients with active disease and 50% of patients in clinical remission, which impairs quality of life and work productivity and functioning.<sup>12,13</sup> As clinical and diagnostic tests in IBD may not correlate with functional ability to perform daily activities, multiple generic and disease-specific PROs have become crucial tools for a comprehensive evaluation of the disease course.

Although many PROs have been developed for monitoring IBD, there are no clear recommendations on which PRO tools are best to monitor symptoms, measure the impact of IBD beyond symptoms, and are most important to patients to ultimately guide clinical care. IBD affects patients' quality of life beyond bowel symptoms and requires a holistic approach.<sup>14,15</sup> It can be difficult to sort out the unique impact of IBD on the patient, particularly in the context of chronic disease or behavioral health conditions. With increasing time pressure on patients and providers, we need clear and efficient ways to communicate patients' overall status. While there have been numerous PROs developed for monitoring disease severity and activity, quality of life, and functional status in IBD, there is very little guidance regarding which PRO best reflect patients' priorities and might be more appropriate to use over another.<sup>16-35</sup> Furthermore, we do not know if PROs are used differently globally. To our knowledge, there is no available information on who uses PROs, how they are used, which PROs are used most frequently, or barriers to their use for clinical

care in IBD. We performed this study to understand variation in the current global use of PROs for patients with IBD and to gain feedback on which PROs might be best to use in clinical practice.

### Materials and Methods

A cross-sectional survey was performed using a web-based questionnaire on REDCap (Nashville, TN, USA). To develop the questionnaire, we first created a domain table. The domains were: participant characteristics, prevalence of PRO use, reasons why providers do or do not routinely use PROs, and the desire to use and utility of PROs in practice. We then drafted specific aspects that were considered most important within each domain. The authors created a list of PRO tools that are known to be used for patients with IBD, and then generated the questionnaire using the domain table and PRO tool list. The questionnaire was uploaded into REDCap, and a small group of providers pilot tested the survey. Respondents were asked to broadly consider PROs as measures of the status of a patient's condition reported directly by the patient. To determine which PROs are used, we provided a list of 15 different PROs and also allowed participants to add in any other PROs that they use in practice. The 15 PRO tools that were offered included: patient report outcome (PRO) 2 and 3; simple clinical colitis activity index (SCCAI); survey index Crohn's disease activity index (CDAI); Manitoba IBD index; patient reported Harvey-Bradshaw index (HBI); short IBD questionnaire (IBDQ); IBD Disk; work productivity and activity impairment (WPAI) index; short health scale, facit-fatigue scale, patient-reported outcomes measurement information system (PROMIS)-10, general psychosocial well-being score (GPP), international consortium for health outcomes measurement (ICHOM) standard set, IBD Control, and EQ-5D-5L.

This final version of this study was approved by the Dartmouth-Hitchcock Medical Center Human Research Protection Program (IRB# 02001062) with a waiver of consent documentation. Participants were provided with information about the study and proceeded on to questionnaires following receipt of this information. Members of the International Organization for the Study of Inflammatory Bowel Disease (IOIBD) were invited to participate and asked to share the survey with regional colleagues by email. After the first round of responses, a second query to the same distribution list was sent. The goal was to include a global population of pediatric and adult gastroenterologists, IBD advanced practice providers, and colorectal surgeons who see at least 10 patients with IBD each week. Participants were entered into the study over a 3-month time period.

Simple descriptive statistics were used to determine the global use and variations of PROs in clinical practice. The questionnaire is shown in [Appendix A](#).

### Results

There were 194 questionnaire respondents, including adult gastroenterologists (70%), colorectal surgeons (23%), pediatric gastroenterologists (6%), and other providers (3%). Most (71%) of the providers had more than 10 years of experience post training with 62% practicing at academic medical centers and 43% seeing greater than 20 patients with IBD per week ([Table 1](#)). There was global participation, with

**Table 1.** Demographics of questionnaire respondents.

Provider demographics	N	%
Overall	194	
Degree		
MD/DO/equivalent	179	92.3
Advanced practice providers	5	2.6
Other	19	5.2
Years of experience post-training		
<5 years	31	16
5–10 years	25	12.9
>10 years	138	71.1
Specialty		
Adult GI	135	69.6
Pediatric GI	11	5.7
Colorectal surgery	44	22.7
Other	4	2.1
Type of practice		
Academic medical center	123	63.4
Hospital-based practice	57	29.4
Private practice	10	5.2
Other	4	2.1
Volume of IBD patients seen per week		
<10 patients	56	28.9
10–20 patients	54	27.8
>20 patients	84	43.3
Continents represented		
Asia <sup>a</sup>	78	40
Europe <sup>b</sup>	60	31
North America <sup>c</sup>	35	18
Oceania <sup>d</sup>	12	6
South America <sup>e</sup>	10	5

Abbreviation: IBD, inflammatory bowel disease; GI, Gastroenterology.

<sup>a</sup>Japan, India, Bangladesh, Singapore, Vietnam, Malaysia, Burma, China, Kuwait, Nepal, and Qatar.

<sup>b</sup>United Kingdom, Sweden, Greece, Belgium, Ireland, Italy, Norway, Spain, Germany, Switzerland, Portugal, Austria, Czech Republic, Jersey, and Netherlands.

<sup>c</sup>United States, Canada, and Mexico.

<sup>d</sup>Australia and New Zealand.

<sup>e</sup>Brazil.

providers representing countries in 5 of the 7 continents, including Asia (40%), Europe (31%), North America (18%), Australia (6%), and South America (5%).

The majority (80%) of providers responded that they currently use PROs in clinical practice at least occasionally with categories being: with every patient, with most patients, with approximately half of patients, occasionally, and never. PROs were collected via paper questionnaires (57%), verbally in clinic (39%), electronic questionnaires through email or electronic medical record (24%), electronic questionnaire through a mobile phone/tablet application (13%), and verbally over the phone (6%). Participants who did and did not use PROs in their clinical practice did not differ significantly by volume of IBD patients seen per week ( $P = .36$ ), percentage of visits completed via telehealth ( $P = .87$ ), or time spent during a clinic visit with follow-up patients ( $P = .12$ ). However, they did differ significantly by years of experience post-training ( $P = .047$ ) and time spent with a new patient

**Table 2.** Patient-reported outcomes (PROs) currently used in clinical practice.

PRO tool	Proportion of providers using each PRO (%)
Patient-reported Harvey–Bradshaw index (HBI)	17.5
Simple clinical colitis activity index (SCCAI)	16.8
Survey index Crohn’s disease activity index (survey index CDAI)	15.8
PRO2 or PRO3	13.0
Short IBDQ	7.7
IBD Disk	4.9
Short health scale	4.2
EQ-5D-5L	3.2
IBD Control	3.2
Work productivity and activity impairment (WPAI) questionnaire	2.1
Facit-fatigue scale	1.4
General psycho-physical well-being score (GPP)	1.1
PROMIS-10	1.1
Manitoba Inflammatory Bowel Disease Index	1.1
ICHOM Standard Set	0.7
IBD Qorus	0.7
Modified Pouchitis Disease Activity Index (m-PDAI)	0.7
IBDnow	0.4
IBD-STAR	0.4
Hospital Anxiety and Depression Scale (HADS Scale)	0.4
IBDQ-32 (32-item IBD questionnaire)	0.4
Novel Integral Disease Activity Index of UC	0.4
6 Point Mayo	0.4
Mayo Score	0.4
Partial Mayo Score	0.4
Pediatric Crohn’s Disease Activity Index (PCDAI)	0.4
Pediatric Ulcerative Colitis Activity Index (PUCAI)	0.4
Perianal Disease Activity Index (PDAI)	0.4
Lichtiger Index	0.4
Mobile Health Index for UC and CD	0.4
Öresland score	0.4

Abbreviation: IBD, inflammatory bowel disease.

Questionnaire respondents were allowed to respond with more than one PRO tool.

( $P = .011$ ). Specifically, providers who did not use PROs had more years of experience and spent more time with patients during the first visit.

There were 31 different PROs that providers reportedly used for patients with IBD with the most commonly used PROs being patient-reported HBI, SCCAI, survey index CDAI, PRO2 or PRO3, short IBDQ, and IBD Disk (Table 2). Of the providers who used PROs, perceived value of PROs differed significantly based on frequency of use ( $P < .001$ ). Specifically, on a scale from 1 (never) to 10 (always),

providers who used PROs occasionally valued them less ( $M = 6.11$ ,  $SD = 1.74$ ) than those who used them half or most of the time ( $M = 7.22$ ,  $SD = 1.36$ ) or all the time ( $M = 8.62$ ,  $SD = 1.39$ ). Similarly, influence of PROs on patient management also differed based on frequency of use ( $P < .001$ ). On the same 1–10 scale, providers who used PROs occasionally were influenced by them less ( $M = 5.61$ ,  $SD = 1.61$ ) than providers who used them half or most of the time ( $M = 6.45$ ,  $SD = 1.39$ ) or all the time ( $M = 7.62$ ,  $SD = 1.44$ ). Most providers who use PROs found value in using PROs in clinical practice (answered 7–10 on Likert scale). Half of the providers found that PROs frequently (answered 7–10 on Likert scale) influence management of patients with IBD.

Of the providers who use PROs, 64% use PROs to start discussions with the patient on specific issues, 50.8% use PROs to guide treatment changes, 21.4% use PROs to guide diagnostic testing, and 11.9% collect them but do not use them as part of clinical care (Figure 1A). Providers who reported they use PROs in clinical practice indicated that they would use PROs more often if they were better incorporated into the electronic medical record (63.3%), if it was known which PROs were most beneficial (38.3%), and if research studies showed a benefit to using PROs (38.3%) (Figure 1B).

For providers who never use PROs, the most significant barriers were not being familiar with PROs (53), not knowing how to incorporate the results of PROs into clinical practice or management (33%), lack of integration into the electronic medical record (28%), and time constraints (20%) (Figure 2A). These providers would consider using PROs if research studies showed a benefit to using PROs in clinical practice (62%), if they were easily incorporated into the electronic medical record (59%), if they had the resources to implement and act on the responses (54%), if they knew how to interpret PRO results (39%), and if they knew which PROs were the most beneficial (36%) (Figure 2B).

We also investigated comfort level with the 6 most commonly used PROs in providers who did and did not use them in practice. Comfort level with the patient-reported HBI, SCCAI, CDAI, and SIBDQ did not differ significantly based on provider use (all  $P$  values  $>.33$ ). Providers who used PROs were significantly more comfortable with the PRO2/PRO3 ( $P < .001$ ) and the IBD-Disk ( $P < .001$ ) than providers who did not use PROs in their practice.

Most providers (91%) thought that it would be beneficial to have an accepted set of PROs that were consistently used for the care of patients with IBD. Suggested currently available PRO tools to be used in clinical practice are shown in Table 3. Half of the participants thought these currently available PROs were acceptable either alone or in combination for clinical practice, and 10% responded that a new PRO tool needed to be created specifically for certain subgroups of patients with IBD. These included patients with stomas, those status post ileal pouch-anal anastomosis surgery, and patients with perianal disease. The majority of respondents (60%) thought that there should be some differences in PROs used globally to fit with regional/ethnic/cultural differences, but that the PROs for IBD should be consistent around the world.

## Discussion

In a global cohort of gastroenterology providers, PROs were frequently used in clinical practice for the care of patients

with IBD, but there was wide variation in which PROs were used and how they influenced patient management. Providers often do not know how to interpret the various PROs and there is no guidance as to which PROs are most clinically valuable. Six PROs that were most frequently suggested by providers to be used in practice include PRO2/PRO3, SCCAI, patient-reported HBI, survey index CDAI (patient-reported), short IBDQ, and IBD Disk (Table 2).

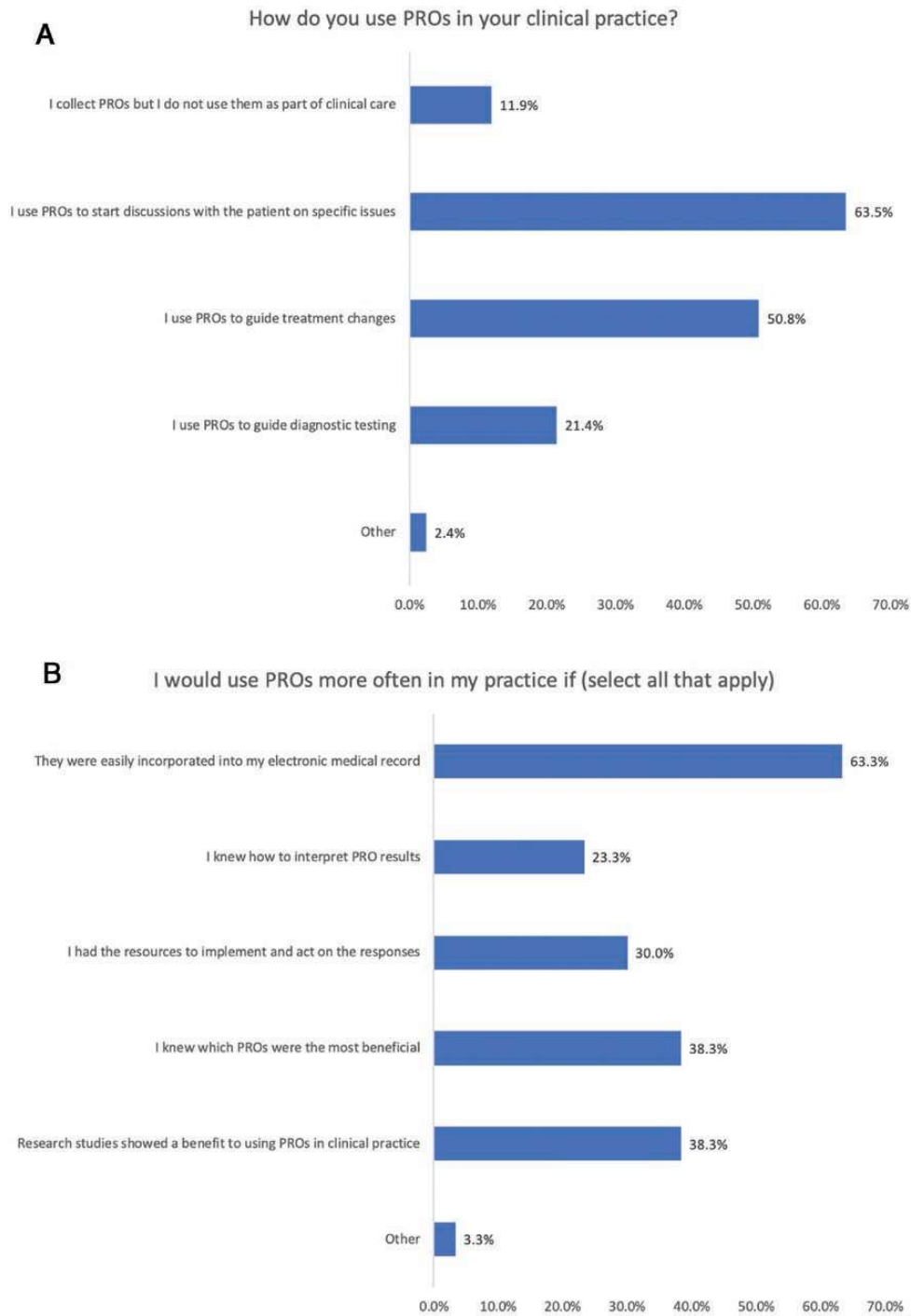
PROs have been used and validated for use in clinical trials relating to IBD and there are a number of publications showing associations between PROs and disease activity in both ulcerative colitis and Crohn's disease.<sup>36,37</sup> However, data are lacking on the current use of PROs in routine clinical management, how they reflect what is most important to patients, and if they are associated with outcomes over time.

A study by Wong et al found that it was feasible to collect the ICHOM Standard Set for IBD through a web-based questionnaire longitudinally and track meaningful metrics for patients, such as quality of life measures. The PROs also found a higher proportion of patients reporting prolonged corticosteroid use than providers expected, identifying the need for further education to reduce corticosteroid use. This may not have been as promptly identified without the use of PROs.<sup>9</sup>

As patient-centered care become a focus across disciplines of medicine, PROs will become more important. To allow this evolution to occur and to amplify the patient voice, we need to find ways to use PROs efficiently in day-to-day practice. Importantly, the field needs to rally behind PROs that broadly reflect patients' priorities, but which can be administered quickly and interpreted easily by providers at in person or telemedicine visits.

It is important for PROs to be valid, reliable, and consistent for use in research and clinical settings. Certain PROs are limited by cost, length of questionnaire, lack of provider education on interpretation, and questionable validity and reliability. For example, the IBDQ-32 is commonly used in research settings, but it is a lengthy questionnaire and costly to use. IBD Control is commonly used in clinical settings, especially as it includes questions about what the patients would like to discuss at their appointment, rendering it less relevant for use in research.<sup>38</sup> PROs allow us to learn more about quality of life, disability, and symptom burden in our patients, which most patients report valuing. However, the currently available PROs are largely focused on gastroenterology symptoms and may or may not reflect how IBD impacts all of the aspects of an individual patient's life to appropriately guide management. The future use of PROs should improve quality measures and allow us to provide more value-based, patient-centered care.<sup>7–9</sup>

While we were able to include providers from many regions of the world, there are still many countries that are not represented. Furthermore, the respondents were generally seeing a high volume of IBD patients weekly and from academic medical centers. Thus, our results may not be generalizable to providers who care for a smaller number of IBD patients or work in community practices. Although it is possible PROs are used more often by non-IBD specialists, we suspect that our results overrepresent the true use of PROs in daily practice. Going forward, it will be important to educate all gastroenterologists who care for IBD patients in academic centers and the community about PROs, as a measure to enhance patient engagement as well as improve the ability



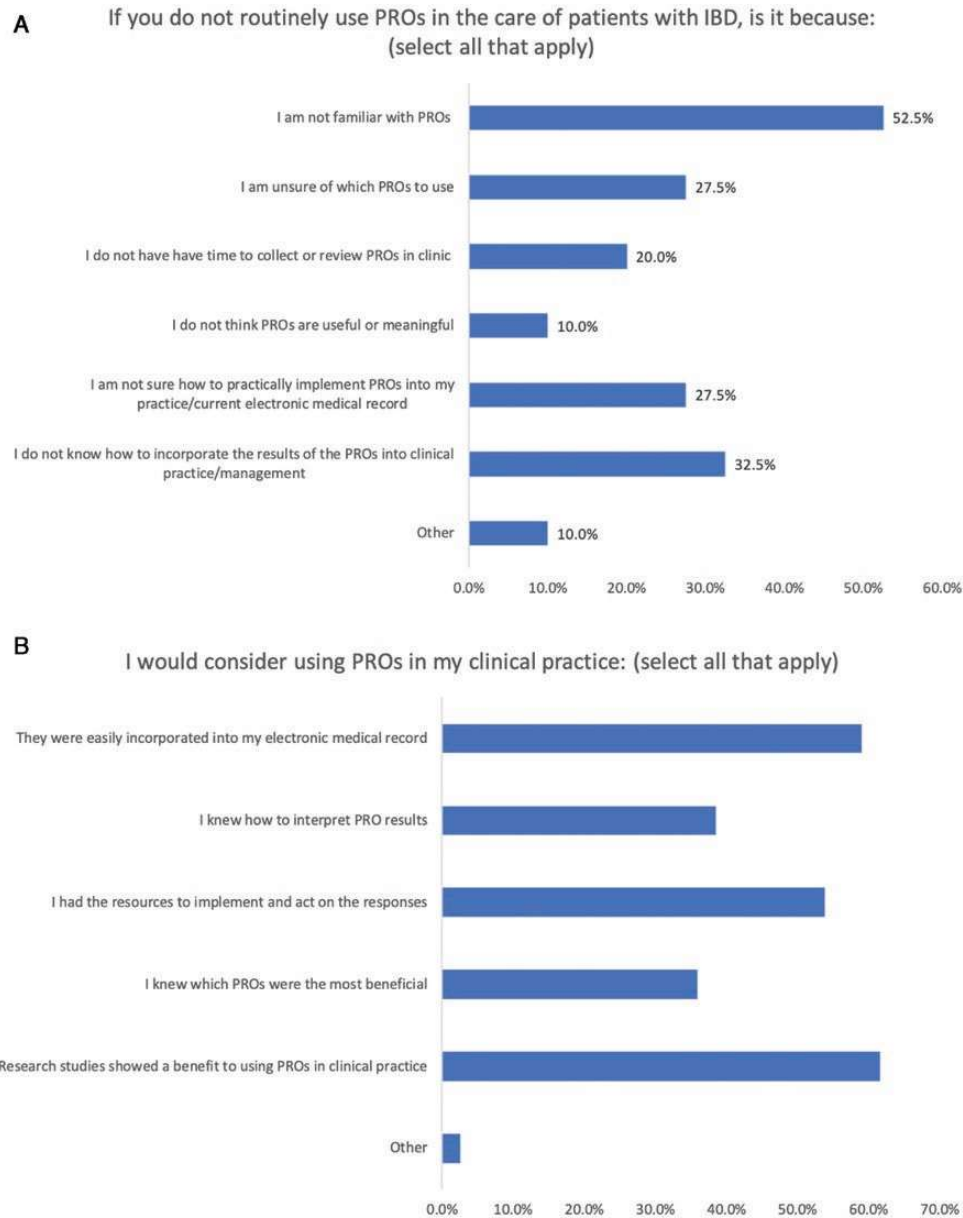
**Figure 1.** Provider perceptions of using PROs in clinical practice. A, How PROs are used in clinical practice. B, Reasons why providers would use PROs more often. Abbreviation: PRO, patient-reported outcome.

to transfer information regarding patient status between providers.

If we want to increase the utilization of PROs in the future and have a consistent set used globally, we need to identify a small subset of candidates that are practical, reflective of the broad impact of IBD on our patients, and easy for providers. Furthermore, as a field we need to specify the circumstances in which PROs should be used and define how to best incorporate them into practice. This subset can be validated with providers and patients while testing different methods for implementation and measuring their

impact on care, how PROs correlate and complement each other, and which dimensions of PROs are most important to patients and providers. We also need to create or refine PROs for special populations of patients that have historically been left out of PRO development including those with stomas, ileal pouch-anal anastomoses, proctitis, extraintestinal manifestations, and other less common disease states.

In conclusion, PROs are often used in clinical practice, but there is wide variation in which PROs are used, how reflective they are of what is most important to patients, and how they



**Figure 2.** Providers who do not routinely use PROs. A, Reasons why providers do not use PROs in clinical practice. B, Scenarios in which they would consider using PROs. Abbreviation: PRO, patient-reported outcome.

impact management of patients with IBD. The next steps include identifying a practical set of PROs that are acceptable to patients and providers and to include patient populations who have been excluded in the past. Then, education around how to implement and interpret an accepted set of PRO tools in routine clinical practice would allow for global harmonization and an opportunity to learn from a globally diverse patient population.

### Supplementary Data

Supplementary data is available at *Crohn's and Colitis* 360 online.

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### Authors' Contributions

J.M.H.: study design, analysis and interpretation, manuscript development and writing. E.L., A.S., S.T., B.M., J.H., and R.P.: study design, manuscript development and review. J.S.-D.: analysis and interpretation, manuscript development and review. M.C.D.: study design, analysis and interpretation,

**Table 3.** Suggested currently available patient-reported outcome (PRO) tools to be used in clinical practice for the care of patients with IBD.

PRO tool	Proportion of providers recommending each PRO tool (%)
PRO2 or PRO3	15.41
Simple clinical colitis activity index (SCCAI)	14.86
Patient-reported Harvey–Bradshaw index (patient-reported HBI)	14.59
Survey index CDAI	10.81
Short IBDQ	10.27
IBD Disk	7.30
IBD Control	4.05
Facit-fatigue scale	4.05
Other	3.78
Short health scale	3.24
EQ-5D-5L	2.70
General psychological well-being score (GPP)	2.43
Manitoba Inflammatory Bowel Disease Index	2.43
Work productivity and activity impairment (WPAI) questionnaire	1.89
PROMIS-10	0.01
ICHOM Standard Set	0.01

Abbreviation: IBD, inflammatory bowel disease. Questionnaire respondents were allowed to respond with more than one PRO tool.

manuscript development and review. C.A.S.: study design, analysis and interpretation, manuscript development and writing.

### Conflicts of Interest

J.M.H.: None declared. E.L. has served as a consultant to AbbVie; as a speaker for AbbVie, Janssen, Fresenius-Kabi, and Takeda; as a speaker for AbbVie, Falk, Ferring, Janssen, Pfizer, Galapagos, and Takeda; received research grants from Janssen, Pfizer, Ferring, Falk, AbbVie, and Takeda; received educational grants from AbbVie, Janssen, Fresenius-Kabi, and Takeda; has served on the advisory committee for AbbVie, Celgene, Ferring, Janssen, BMS, Pfizer, and Takeda, Galapagos, Gilead, Arena, Eli Lilly. A.S. has served as a consultant to Johnson & Johnson and Takeda. S.T. has served as a consultant for Abacus, AbbVie, Actial, ai4gi, Alcimed, Allergan, Amgen, Apexian, Aptel, Arena, Asahi, Aspen, Astellas, Atlantic, AstraZeneca, Barco, Biocare, Biogen, BLPharma, Boehringer Ingelheim, BMS, Buhmann, Calcico, Celgene, Cellerix, Cerimon, ChemoCentryx, Chiesi, CisBio, ComCast, Coronado, Cosmo, Ducentis, Dynavax, Elan, Enterome, EQrX, Equillium, Falk, Ferring, FPRT Bio, Galapagos, Genentech/Roche, Genzyme, Gilead, Glenmark, Grunenthal, GSK, GW Pharmaceuticals, Immunocore, Immunometabolism, Indigo, Janssen, Lexicon, Lilly, Medarex, Medtrix, Merck, Merrimack, Mestag, Millenium, Neovacs, Novartis, Novo Nordisk, NPS-Nycomed, Ocera, Optima, Origin, Otsuka, Palau, Pentax, Pfizer, Pharmaventure, Phesi, Phillips, P&G,

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### Data Availability

Data not publicly available.

### References

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