



Patient and Health Care Professional Perceptions of the Experience and Impact of Symptoms of Moderate-to-Severe Crohn's Disease in US and Europe: Results from the Cross-Sectional CONFIDE Study

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Abstract

Background Crohn's disease (CD) significantly affects patients' health-related quality of life and well-being.

Aims Communicating Needs and Features of IBD Experiences (CONFIDE) survey explores the experience and impact of moderate-to-severe CD symptoms on patients' lives and identifies communication gaps between patients and health care professionals (HCPs).

Methods Online, quantitative, cross-sectional surveys of patients, and HCPs were conducted in the United States (US), Europe (France, Germany, Italy, Spain, United Kingdom), and Japan. Criteria based on previous treatment, steroid use, and/or hospitalization defined moderate-to-severe CD. US and Europe data are presented as descriptive statistics.

Results Surveys were completed by 215 US and 547 European patients and 200 US and 503 European HCPs. In both patient groups, top three symptoms currently (past month) experienced were diarrhea, bowel urgency, and increased stool frequency, with more than one-third patients wearing diaper/pad/protection at least once a week in past 3 months due to fear of bowel urgency-related accidents. HCPs ranked diarrhea, blood in stool, and increased stool frequency as the most common symptoms. Although 34.0% US and 27.2% European HCPs ranked bowel urgency among the top five symptoms affecting patient lives, only 12.0% US and 10.9% European HCPs ranked it among top three most impactful symptoms on treatment decisions.

Conclusion Bowel urgency is common and impactful among patients with CD in the US and Europe. Differences in patient and HCP perceptions of experiences and impacts of bowel urgency exist, with HCPs underestimating its burden. Proactive communication between HCPs and patients in clinical settings is crucial for improving health outcomes in patients with CD.

Keywords Bowel urgency · Crohn's disease · Health-related quality of life · Patient experience

Introduction

Crohn's disease (CD) is a chronic systemic inflammatory bowel disease, with a remitting and relapsing course, affecting the gastrointestinal tract [1, 2]. Common symptoms include abdominal pain and diarrhea, with or without blood and weight loss [3]. CD can be a progressive and debilitating disease, with 25–40% patients experiencing extraintestinal manifestations [4] and 20–40% patients having a lifetime risk of fistula development. Additionally, the disease burden can be compounded by symptoms such as fatigue, bowel urgency, and bowel urgency-related accidents [5, 6]. Treatment goals of CD include symptomatic, endoscopic, and steroid-free remission followed by improved health-related quality of life (HRQoL) [7, 8]. The Food and Drug

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Administration (FDA) guidelines have recently been updated to include bowel urgency as an important endpoint in CD [9]. However, although clinical guidelines from the American College of Gastroenterology and European Crohn and Colitis Organization include assessment of bowel urgency in ulcerative colitis (UC) [10, 11], they do not recommend bowel urgency as an outcome measure for CD [12, 13].

CD-associated physical and psychological symptoms substantially affect patients' HRQoL, even in the absence of active disease [14, 15]. Recent survey-based and qualitative studies have highlighted the substantial disease burden of CD [16] and differences in patient and physician viewpoints on the symptoms and their impact on the lives of patients with CD [17].

Moreover, disease-related issues impacting patient's HRQoL are not frequently discussed during health care professional (HCP)–patient interactions, with HCPs focusing primarily on the evaluation of more classic signs and symptoms and inflammatory biomarkers [18, 19]. This may result in patients' concerns remaining unaddressed, highlighting the possible communication gap between patients and HCPs [20]. To address the patients' most burdensome concerns, it is important to understand the gaps in communication and their impact on treatment decisions in a global population.

Although qualitative or survey-based studies have highlighted patients' experiences of CD symptoms, HCPs' perceptions, and gaps in HCP–patient communication, the understanding of patient experiences merits further exploration [17, 21, 22]. Previously reported UC data from the Communicating Needs and Features of Inflammatory Bowel Disease (IBD) Experiences (CONFIDE) study highlighted the burden and impact of bowel urgency on patients with UC and the communication gap between patients and HCPs in assessing and addressing bowel urgency [23]. However, the extent of severity, impact, and HCP–patient perceptions of bowel urgency in CD are unclear and might differ from those of UC. The current study aims to explore the experience and impact of moderate-to-severe CD symptoms on patients' lives and identifies communication gaps between patients and HCPs.

Methods

CONFIDE Survey

CONFIDE was a non-interventional observational study consisting of online, quantitative, cross-sectional surveys conducted among patients with moderate-to-severe UC or CD and prescribing HCPs managing UC and CD in the United States (US), Japan, and five European countries (France, Germany, Italy, Spain, and the United Kingdom [UK]). The patient and HCP survey questions included in

this study are provided as Appendix A. The details on the survey development, content, and data collection have been previously reported [23]. This article includes results from HCPs and patients with moderate-to-severe CD from the US and Europe.

Study Population

Patients were recruited via online patient panels and screened online to ensure only eligible patients were included. Adult patients with an HCP diagnosis of active CD of at least moderate severity (patient self-reported) who provided informed consent were included. Active disease of at least moderate severity was defined using the following criteria: received anti-tumor necrosis factor (TNF), anti-integrin, Janus kinase (JAK) inhibitor, anti-interleukin-12/23 (IL-12/23), or immunomodulator treatment in the last 12 months or received steroid treatment for at least 1 month out of the last 12 months or were hospitalized for at least four consecutive weeks in the last 5 years. Patients were excluded if they had undergone colectomy. Patients with a diagnosis of concomitant irritable bowel syndrome were no more than 20% of total patients in each country.

HCPs were recruited by an existing panel via e-mail invitation and were required to provide informed consent prior to screening. HCPs were included if they were gastroenterologists, internal medicine practitioners with gastroenterology focus, IBD nurse specialists, nurse practitioners, or physician assistants. Eligible HCPs were responsible for making prescribing decisions for at least 10 patients with CD, examined at least five patients diagnosed with moderate-to-severe UC and/or CD per month, and spent at least 50% of working time actively seeing patients. HCP and patient cohorts were independent from one another.

Statistical Analysis

Data were summarized using descriptive statistics, and no formal sample size estimations were performed. To allow descriptive analysis at the global and regional levels, a target of approximately 700 completed HCP interviews (200 in the US and 100 from each European country) and approximately 700 patients (200 patients with CD from the US and 100 patients from each European country) was set. Categorical and ordinal variables were presented as frequencies (HCPs or patients) and percentages. Continuous variables (e.g., age, time since diagnosis, and questions with numeric rating scale [NRS] responses) were presented as number of observations (HCPs or patients), means, and standard deviations. Direct comparisons between data from patients with UC and CD were not performed.

Ethical Considerations

The protocol and supporting data collection materials were approved by the Western Institutional Review Board (study number: 1307697). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and was consistent with Good Pharmacoepidemiology Practices and applicable laws and regulations of the countries where the study was conducted. All participants provided informed consent to participate in the study via an IRB-approved informed consent form. All data collection materials were structured such that no personally identifiable information (such as name, address) was directly captured from respondents. Data were anonymized to ensure that respondents could not be identified via linking data points. Patients and HCPs were paid a nominal honorarium for completing the survey.

Results

Demographics and Characteristics

Key patient and HCP demographics and characteristics are reported in Table 1. A total of 2706 patients with CD were contacted, of which 215 US (mean age: 40.9 years) and 547 European patients (38.0 years; France $N=130$, Germany $N=108$, Italy $N=91$, Spain $N=106$, UK $N=112$) with CD completed the surveys between July 01, 2021 and September 09, 2021. Of these, 54.9% of US and 55.4% European patients were male. In both US and European patients, corticosteroids (58.6% and 49.5%), and anti-TNF biologic therapy (43.3% and 52.8%) were the most common currently received CD treatments. A total of 58.1% US and 63.4% European patients were receiving advanced therapies (biologic therapy, biosimilars, or JAK inhibitors). Overall, 23.7% US and 16.1% European patients reported experiencing fistula-related symptoms around the anus/rectum (for example recurrent drainage or pain around the anus) in the past month.

Of the 840 physicians contacted, 200 US and 503 European HCPs (France $N=101$, Germany $N=101$, Italy $N=101$, Spain $N=100$, UK $N=100$) completed the surveys between May 28, 2021 and October 02, 2021. Overall, 78.0% US and 70.8% European HCPs surveyed were male, and 88.0% and 93.2% were gastroenterologists. Demographics and characteristics of patients and HCPs in each European country are presented in Supplemental Table 1.

Patient and HCP Perceptions on CD Symptoms

Diarrhea (55.3% and 54.7%), bowel urgency (42.3% and 38.0%), and increased stool frequency (40.0% and 36.6%) were the most common symptoms experienced by US and

European patients, respectively, in the last month (prior to survey completion) (Fig. 1A). Similarly, diarrhea (68.8% and 71.5%), bowel urgency (58.6% and 53.9%), and increased stool frequency (54.4% and 54.1%) were the top three symptoms ever experienced by the US and European patients, respectively. The top symptoms commonly experienced by patients in each European country in the past month are shown in Supplemental Fig. 1A. Patients receiving advanced therapies in US ($n=125$) and Europe ($n=347$) also reported these symptoms as the most experienced in the last month. The three most common HCP ranked symptoms reported by patients were diarrhea (67.0%), persistent abdominal pain (41.5%), and blood in stool (44.0%) in the US and diarrhea (66.2%), persistent abdominal pain (55.3%), and increased stool frequency (27.6%) in Europe (Fig. 1B). Bowel urgency was ranked among the top five most reported symptoms by 19.0% of US and 15.5% of European HCPs. The HCP-perceived most common symptoms reported by patients in each European country are shown in Supplemental Fig. 1B.

Diarrhea (68.9% and 74.9%), bowel urgency (61.9% and 70.8%), bowel urgency-related accidents (60.7% and 52.5%), increased stool frequency (54.7% and 54.7%), and blood in stool (49.5% and 50.2%) were reported as the top five symptoms with greatest impact by both US and European patients, respectively. (Fig. 1C). Diarrhea (71.5% and 73.2%), persistent abdominal pain (56.0% and 63.2%), blood in stool (48.0% and 33.8%), bowel urgency (34.0% and 27.2%), and increased stool frequency (39.0% and 37.2%) were reported as the most impactful symptoms by both US and European HCPs, respectively (Fig. 1D). Furthermore, persistent abdominal pain was ranked as more impactful by HCPs than patients. Patient- and HCP-reported symptoms with greatest impact in each European country are shown in Supplemental Fig. 1C, D.

Experience of Bowel Urgency

More than one-third of all patients reported that they could not defer defecation for more than 5 min when asked about deferral time (a measure of the urgency patients experience before bowel movements) in the last 3 days, while 2.8% US and 1.8% European patients reported sometimes not being able to make it to the bathroom in time (Fig. 2A). Patients who experienced bowel urgency in the past month were less able to defer their bowel movements (Fig. 2B). In the last month, most patients experiencing bowel urgency rated its severity as at least 7/10 using the 11-point Urgency NRS (range 0 [no urgency] to 10 [worst possible urgency]); mean Urgency NRS scores were similar among US and European patients (7.0 vs 6.7/10; Fig. 2C). Among the European countries, patients from France reported the highest mean Urgency NRS scores (7.2/10; Supplemental Table 2). Among patients who

Table 1 Demographics and characteristics of patients and HCPs

Patients		
	US patients (<i>N</i> =215)	European patients (<i>N</i> =547)
Mean age, years (SD)	40.9 (11.4)	38.0 (9.7)
Sex, <i>n</i> (%)		
Male	118 (54.9)	303 (55.4)
Female	97 (45.1)	244 (44.6)
Ethnicity, <i>n</i> (%)		
White	175 (81.4)	515 (94.1)
Hispanic/Latino	21 (9.8)	1 (0.2)
African American	12 (5.6)	-
Other ^a	7 (3.3)	31 (5.7)
Time since diagnosis of CD (mean years [SD])	8.7 (8.6)	9.2 (8.5)
Fistula-related symptoms ^b , <i>n</i> (%)	51 (23.7)	88 (16.1)
Current treatments, <i>n</i> (%)		
5-ASA	51 (23.7)	169 (30.9)
Corticosteroids	126 (58.6)	271 (49.5)
Immunomodulator	84 (39.1)	255 (46.6)
Anti-TNF biologic therapy	93 (43.3)	289 (52.8)
JAK inhibitor	18 (8.4)	47 (8.6)
Anti-IL-12/anti-IL-23 biologic therapy	18 (8.4)	69 (12.6)
Anti-integrin biologic therapy	43 (20.0)	154 (28.2)
Patients receiving advanced therapies ^c , <i>n</i> (%)	125 (58.1)	347 (63.4)
HCPs		
	US HCPs (<i>N</i> =200)	European HCPs (<i>N</i> =503)
Sex, <i>n</i> (%)		
Male	156 (78.0)	356 (70.8)
Female	40 (20.0)	139 (27.6)
Prefer not to say	4 (2.0)	8 (1.6)
Primary specialty ^d , <i>n</i> (%)		
Gastroenterologist	176 (88.0)	469 (93.2)
Internal medicine with GI focus/specialization	2 (1.0)	3 (0.6)
IBD nurse specialist	0	31 (6.2)
Nurse practitioner	11 (5.5)	0
Physician assistant	11 (5.5)	0
Year of qualification, <i>n</i> (%)		
Before 1985	22 (11.0)	57 (11.3)
1985–2018	173 (86.5)	434 (86.3)
After 2018	5 (2.5)	12 (2.4)

5-ASA 5-aminosalicylic acid; CD Crohn's disease; GI gastroenterology; HCP health care professional; IBD inflammatory bowel disease; IL interleukin; JAK Janus kinase; SD standard deviation; TNF tumor necrosis factor; UK United Kingdom; US United States

^aOther races included Asian–Indian subcontinent, Asian-other, Japanese, Korean, Middle Eastern, Afro-Caribbean, Native American, Mixed race, South-East Asian, and other

^bPatients who reported experiencing fistula-related symptoms around the anus/rectum (for example recurrent drainage or pain around the anus) in the past month

^cAdalimumab (including biosimilars), infliximab (including biosimilars), golimumab, certolizumab pegol, vedolizumab, natalizumab, ustekinumab, and tofacitinib

^dUS HCPs included nurse practitioners and physician assistants; UK HCPs included IBD nurse specialists

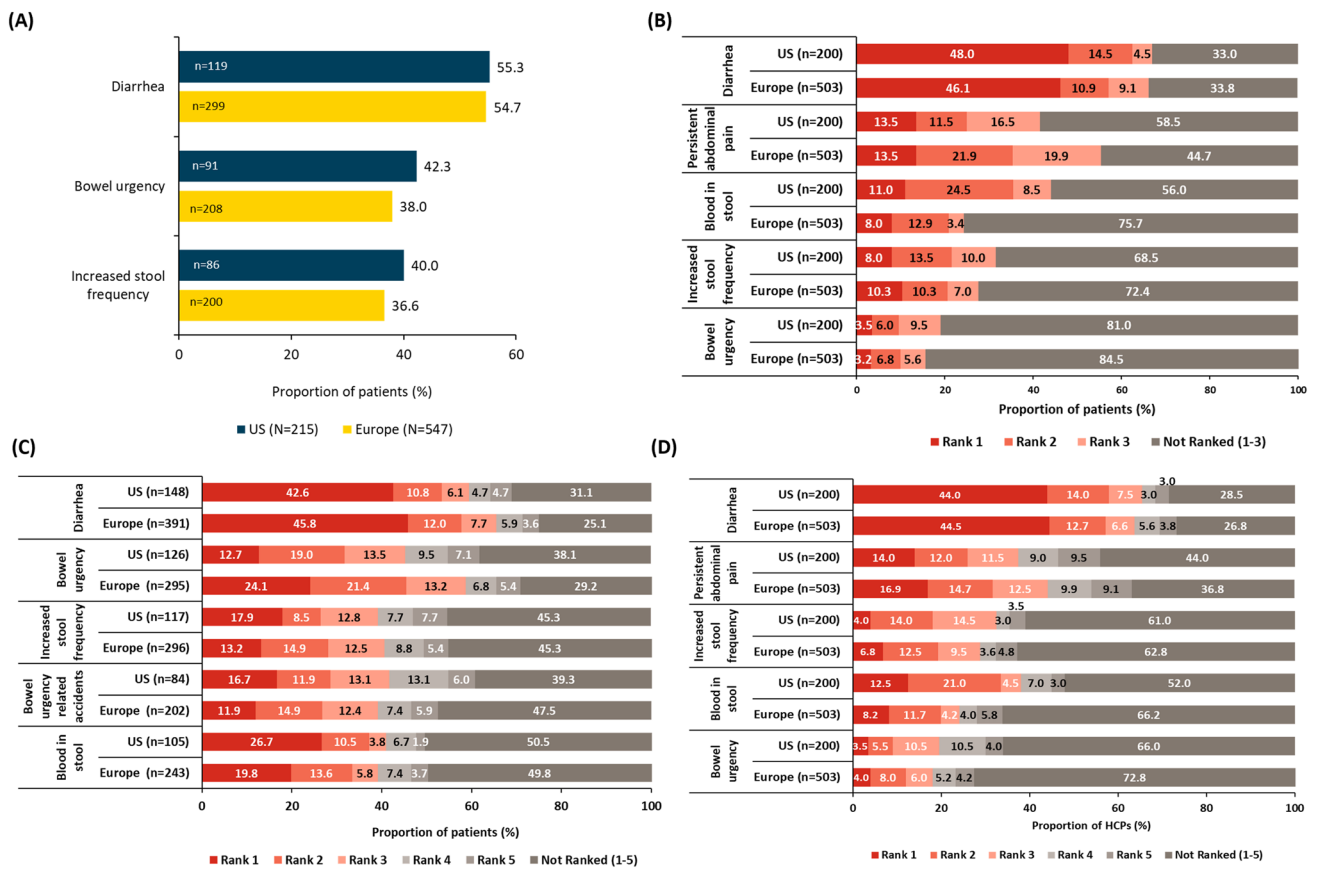


Fig. 1 Patient and HCP perceptions on CD symptoms. **A** The top three symptoms experienced by patients in the last month. Patients were asked which symptoms they currently suffer from (i.e., in the last month). Symptoms were selected from a list of 30 options. **B** The top five HCP-perceived most common symptoms reported by patients. HCPs were asked to rank the top five symptoms most

reported by patients. **C** Patient-reported symptoms with the greatest impact (of symptoms ever experienced). Patients were asked to rank the five symptoms that have the greatest impact. **D** HCP-perceived symptoms with the greatest impact on patients. HCPs were asked to rank the top five symptoms with the greatest impact on patients. *HCP* health care professional, *CD* Crohn’s disease, *US* United States

experienced bowel urgency in the last month, higher mean Urgency NRS scores were reported by those with shorter defecation deferral times (Fig. 2D). Among European patients, mean Urgency NRS scores were significantly higher in patients with a deferral time of < 5 min than in those with a deferral time of > 5 min (7.0 vs 6.5/10); however, this difference was not statistically significant among US patients (7.3 vs 6.7/10). Among the US (n = 126) and European (n = 295) patients who had ever experienced bowel urgency, most patients (US: 75.4%, Europe: 70.2%) reported experiencing bowel urgency at least once a week over the past 3 months (Fig. 2E). Among patients who had ever experienced bowel urgency and were receiving advanced therapies (US: n = 76, Europe: n = 189), 77.6% US and 69.2% European patients reported experiencing bowel urgency at least once a week in the past 3 months. Deferral of defecation times, Urgency NRS scores, and the frequency of bowel urgency among patients in each European country are presented in Supplemental Table 2.

Use of Diaper/Pad/Protection and Avoidance of Activities

Overall, 48.8% of US and 39.4% of European patients reported wearing diaper/pad/protection at least once a week in the past 3 months due to fear of bowel urgency-related accidents (Fig. 3A). Within European countries, diaper/pad/protection use of at least once a week in the past 3 months was highest in France (47.7%) and lowest in UK (31.2%) (Supplemental Table 3). Among patients receiving advanced therapies (US: n = 125; Europe: n = 347), 51.2% US and 45.2% European patients reported wearing a diaper/pad/protection at least once a week in the past 3 months due to fear bowel urgency-related accidents. Most patients reported declining participation in daily activities such as work/school (US: 80.5%, Europe: 76.1%), social events (US: 83.7%, Europe: 80.6%), and sports/physical exercise (US: 81.9%, Europe: 77.1%) due to CD in the last 3 months. Both US and European patients reported bowel urgency,

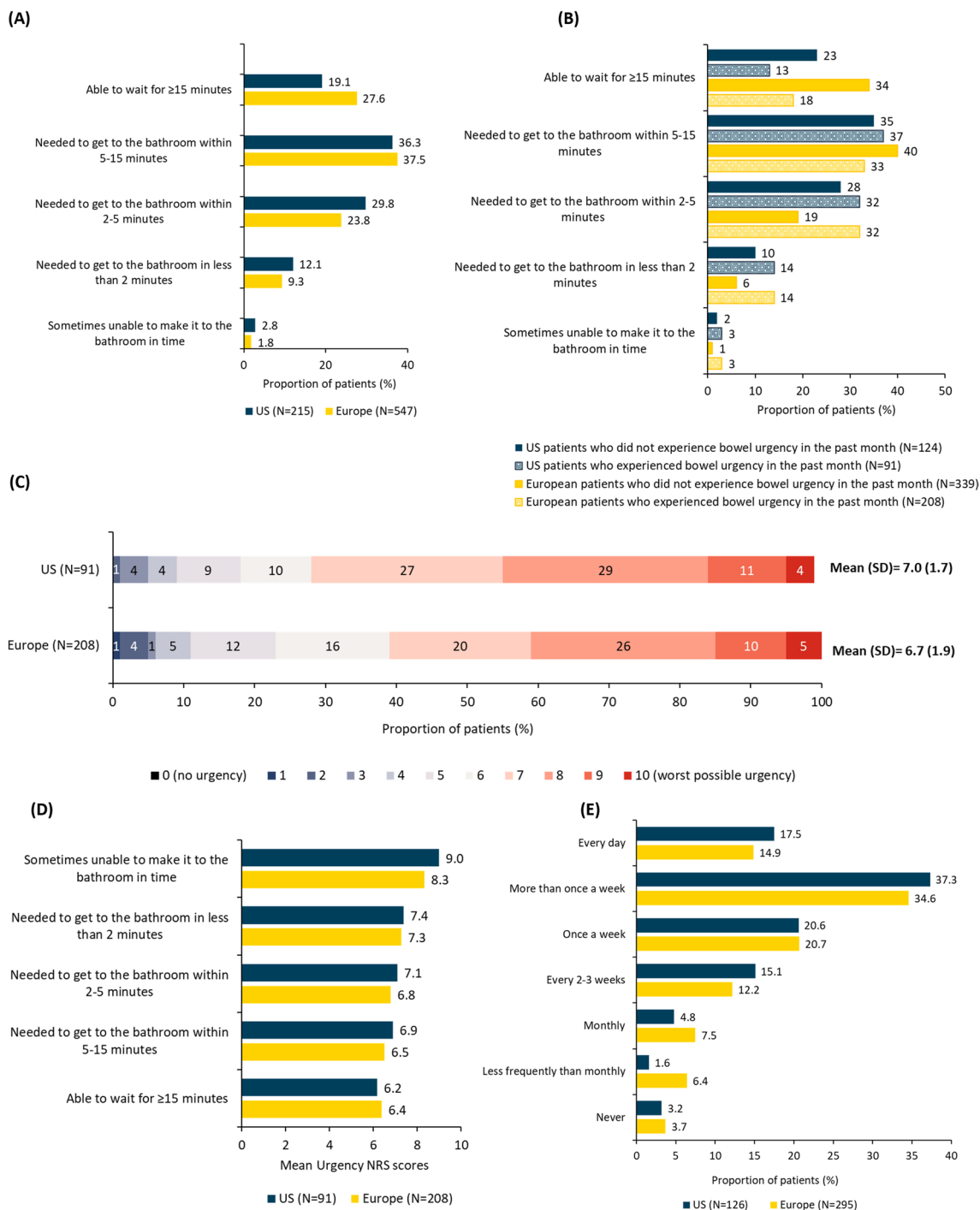


Fig. 2 Patient experience of bowel urgency. **A** Patients’ deferral time in last 3 days. Patients were asked how much urgency they had before bowel movements over the last 3 days. **B** Patients’ deferral time over the last 3 days in patients who experienced or did not experience bowel urgency in the past month among US and European patients. **C** Urgency NRS. Patients experiencing bowel urgency in the last month rated their urgency (sudden or immediate need) to have a

bowel movement in the last 3 days (from 0 [no urgency] to 10 [worst possible urgency]). **D** Mean severity of urgency before bowel movement by deferral time over the last 3 days among patients experiencing bowel urgency in the past month. **E** Frequency of bowel urgency in the past 3 months among patients who reported ever experiencing bowel urgency. *NRS* Numeric Rating Scale, *SD* standard deviation, *US* United States

fear of bowel urgency-related accidents, and fear of passive bowel movement accidents as the most common reasons for declining participation in work/school, social activities, and sports/physical exercise in the past 3 months (Table 2). Supplemental Fig. 2 shows the top reasons for declining participation in work/school, social events, and sports/physical exercise due to CD in each European country. Among patients who had ever experienced bowel urgency, 71.0% US and 76.0% of European patients reported that it negatively affected activities/decisions related to their work or school (Fig. 3B).

HCP–Patient Communication

Among patients who had ever experienced bowel urgency, 23.9% US and 40.1% European patients did not feel comfortable reporting bowel urgency to their HCP, with the most common reason being that they felt embarrassed to do so (Fig. 3C and Supplemental Fig. 3). When asked about the frequency of discussing bowel urgency with their HCPs, 41.8% US and 25.5% European patients reported discussing it at every appointment. Most of the patients (US: 73.6%, Europe: 73.5%) who reported not discussing bowel urgency at every appointment with their HCP would prefer to discuss it more frequently.

HCPs reported that the top three symptoms proactively discussed by them in routine appointments with patients with CD in the US were diarrhea (91.5%), blood in stool (85.5%), and increased stool frequency (80.0%), and in Europe, they were diarrhea (93.8%), increased stool frequency (83.5%), and persistent abdominal pain (75.9%) (Fig. 3D). A total

of 34.0% US and 39.8% European HCPs reported not proactively discussing bowel urgency with patients with CD at routine appointments. Of those who did not proactively discuss bowel urgency at routine appointments, 33.8% of US and 42.0% of European HCPs expected patients to bring this up if it is an issue (Fig. 3E).

Compared to other European countries, a greater proportion of patients in Italy were not comfortable discussing bowel urgency with their HCPs. Among all European countries, embarrassment was the most common reason for not feeling comfortable in discussing bowel urgency with the HCPs (Supplemental Fig. 3D). HCP-reported most common symptoms proactively discussed at a routine appointment and the reasons HCPs do not discuss bowel urgency at routine appointments within each European country are presented in Supplemental Figs. 3E, F.

Most Impactful Symptoms on Treatment Decisions

When asked to rank the top three most impactful symptoms on their treatment decisions for patients with CD, both US and European HCPs ranked diarrhea (60.0% and 63.6%), blood in stool (51.5% and 34.6%), and persistent abdominal pain (40.0% and 45.3%) as most impactful (Fig. 3F). Although 34.0% US and 27.2% European HCPs ranked bowel urgency among the top five symptoms affecting patient lives (Fig. 1D), only 12.0% US and 10.9% European HCPs ranked it within the top three most impactful symptoms on treatment decisions (Fig. 3F). Supplemental Fig. 4 shows the most impactful symptoms on treatment decisions according to HCPs in each European country.

Table 2 Most common reasons for declining participation in work/school-related, social, or physical activities due to CD-related symptoms

Reasons	Patients (%) who declined participation in daily activities in the last 3 months					
	Work/school		Social events		Sports/physical exercise	
	US (N=215)	European (N=547)	US (N=215)	European (N=547)	US (N=215)	European (N=547)
Fear of bowel urgency-related accidents	87 (40.5)	169 (30.9)	80 (37.2)	156 (28.5)	84 (39.1)	146 (26.7)
Bowel urgency	83 (38.6)	151 (27.6)	69 (32.1)	160 (29.3)	67 (31.2)	141 (25.8)
Fear of passive bowel movement accidents	68 (31.6)	132 (24.1)	75 (34.9)	127 (23.2)	71 (33.0)	128 (23.4)
Persistent abdominal pain	57 (26.5)	126 (23.0)	56 (26.0)	129 (23.6)	57 (26.5)	125 (22.9)
Fear of fecal seepage/unnoticed leakage of stool resulting in stained undergarments/sheets	60 (27.9)	120 (21.9)	69 (32.1)	125 (22.9)	61 (28.4)	120 (21.9)
Increased stool frequency	64 (29.8)	134 (24.5)	64 (29.8)	159 (29.1)	67 (31.2)	132 (24.1)
Tiredness/fatigue	41 (19.1)	109 (19.9)	52 (24.2)	133 (24.3)	49 (22.8)	120 (21.9)
Abdominal pain before defecation	54 (25.1)	101 (18.5)	54 (25.1)	94 (17.2)	49 (22.8)	99 (18.1)
Blood in stool	53 (24.7)	87 (15.9)	51 (23.7)	80 (14.6)	45 (20.9)	76 (13.9)

CD Crohn’s disease; US United States

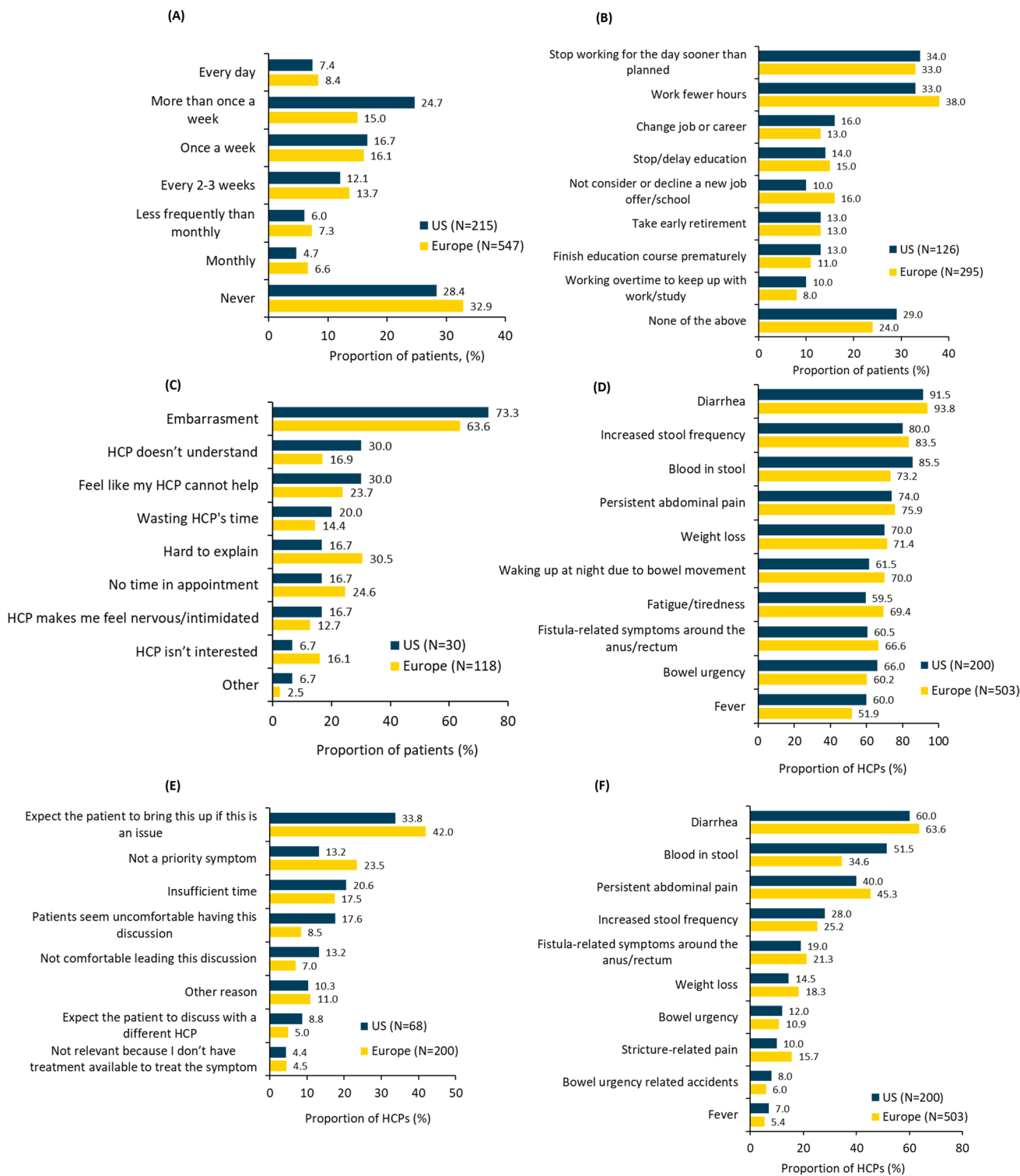


Fig. 3 Impacts of bowel urgency on daily lives of patients and HCP–patient communication. **A** Frequency of diaper/pad/other protection use due to fear/anticipation of bowel urgency-related accidents. **B** The impact of bowel urgency experience on work/school (among patients who ever experienced bowel urgency). **C** Reasons for patients feeling uncomfortable reporting bowel urgency to HCPs. **D** HCP-reported

symptoms proactively discussed at a routine appointment. **E** Reasons for HCPs not proactively discussing bowel urgency in routine appointments. **F** HCP-perceived most impactful symptoms on treatment decisions. HCPs were asked to choose from a list of possible symptoms the top three most impactful on treatment decisions. *HCP* health care professional, *US* United States

Discussion

This study provided important insights into the experience and burden of CD-related symptoms on patients in the US and Europe. Despite a high proportion receiving advanced therapies, patients with moderate-to-severe CD continued to experience symptoms that substantially affected their HRQoL. The results also highlighted the communication gap between patients and HCPs and discrepancies between their perceptions on the most impactful CD symptoms.

Bowel urgency was identified among the top three most common patient-reported CD symptoms in both US and Europe, even among those who were receiving advanced therapies. In addition, bowel urgency was among the most impactful symptoms experienced by patients in both geographic populations. These findings were similar to those of previous studies that identified bowel urgency as a common and bothersome symptom in patients with CD [5, 24–27]. In the IBD Global Assessment of Patient and Physician Unmet Need Surveys (GAPPS) including large cohorts of patients with UC or CD from the US and Europe, bowel urgency was the top symptom affecting the HRQoL of patients [17]; however, this survey did not investigate the severity, impacts, and experiences of bowel urgency among patients with UC or CD. To the best of our knowledge, this is the first study to investigate experience of bowel urgency and its impacts on HRQoL in a large global cohort of patients with CD.

Almost half of US patients and over one-third of European patients overall reported wearing a diaper/pad/protection at least once a week in the past 3 months due to fear or anticipation of bowel urgency-related accidents. Given the young mean age of patients in this study, the frequency of diaper/pad/protection use even among patients receiving advanced therapies suggests the severe impacts of bowel urgency and bowel urgency-related accidents. Given the large proportion of patients with CD who use diaper/pads/other protection, even those on advanced therapies, diaper/pads/other protection use can become a simple metric for assessing the quality of care. Similar findings observed among patients with UC [23] emphasize the similarities in the experiences and burden of bowel urgency in UC and CD, despite the clinical differences between the diseases. More than a third of patients in both US and Europe reported that in the past 3 days, they could not defer defecation for more than 5 min, with some patients not being able to make it to the bathroom in time. These results highlight the significant burden of bowel urgency and the extent to which it can affect the lives of patients. The fear of having bowel urgency-related accidents has been reported to be as debilitating as having an accident. It severely affects patients' ability to perform daily activities and has significant emotional and psychosocial effects [28].

The CONFIDE survey also evaluated the impact of CD symptoms on the daily lives of patients with CD. Most patients reported declining participation in work/school, social events, and sports/physical exercise due to their CD-related symptoms. Bowel urgency and bowel urgency-related accidents were reported by the patients as the most common reasons for avoiding such activities. Moreover, more than two-thirds of patients who ever experienced bowel urgency reported that it negatively impacted their work or education. These findings are in agreement with previous studies, as well as with the results observed among patients with UC [23, 28].

Bowel urgency was among the patient- and HCP-perceived most impactful symptoms; however, it was neither among the HCP-reported top three symptoms that impacted treatment decisions nor among those most proactively discussed at routine appointments. When asked about the reasons for not discussing bowel urgency during clinic visits, HCPs reported that they expected the patients to bring it up if it is an issue, while patients reported feeling embarrassed discussing it. Among patients who experienced bowel urgency, less than half of US and almost a quarter of European patients reported discussing bowel urgency at every HCP appointment. Further, most patients who did not discuss bowel urgency at each appointment wished to do so, illustrating the gap in communication between the patients and HCPs, resulting in misalignment of treatment priorities. In a study from the IBD GAPPS survey, similar differences of perspectives between patients and HCPs were reported among patients with CD, where more patients than HCPs perceived a high burden of bowel urgency as its impact on HRQoL [17]. Although the IBD GAPPS survey highlighted the discrepancies between patient and HCP perceptions of bowel urgency in both UC and CD, the misalignment was greater in CD. Further research is needed to identify and address the communication gaps between patients and HCPs to effectively treat the symptoms that are most important for the patients. Additionally, for better disease management, there is a need to create awareness among HCPs about the symptoms and their importance for patients.

Although the impacts and experiences of bowel urgency were broadly similar among US and European patients, some numerical differences were noted. A greater proportion of European patients ranked bowel urgency among the most impactful symptoms than US patients. In contrast, a greater proportion of US patients ranked bowel urgency-related accidents among the most impactful symptoms. In contrast, a lower proportion of European HCPs ranked bowel urgency and bowel urgency-related accidents as the most impactful symptom for patients with CD. Notably, a greater proportion of US patients reported that they needed to get to the bathroom within 2–5 min, and a smaller proportion reported being able to defer their bowel movement for ≥ 15

min, indicating a more severe experience of bowel urgency among US patients. A greater proportion of US patients reported wearing diaper/pad protection at least once a week due to fear of bowel urgency-related accidents. A greater proportion of European patients reported not feeling comfortable discussing bowel urgency with their HCPs. While a greater proportion of US patients reported embarrassment as a reason for discomfort in discussing bowel urgency with the HCPs, a greater proportion of European patients reported not knowing how to explain it to their HCPs. It is important to note that US and European patients were not statistically compared; the findings may be influenced by different work and school environment, differences in the lifestyle of patients in the countries, and differences in the availability of bathroom facilities.

Overall, the findings of the CONFIDE survey highlight the importance of assessment of bowel urgency in CD, which is often overlooked in clinical settings. Although recent FDA draft guidelines have recognized bowel urgency as an “additional symptom of CD identified by subjects as important,” it is infrequently included as an endpoint in clinical trials. In addition, although a few patient-reported outcome (PRO) measures include bowel urgency (Urgency NRS, Symptoms and Impacts Questionnaire for CD [SIQ-CD], Crohn’s Disease Patient-Reported Outcomes Signs and Symptoms [CD-PRO/SS] diary, and Crohn’s Disease Diary) [25, 27, 29–31], there are no disease-specific tools for assessing the experience and impact of bowel urgency, except the Urgency NRS, which evaluates severity of bowel urgency [29]. Taken together, there is a need for standardization of assessment of bowel urgency by development of validated questionnaires and PRO measures and to include bowel urgency and bowel urgency-related accidents in clinical trial assessments [32].

Limitations

This study had several limitations. First, back-translations of the surveys were not performed. The translations were performed by a translation agency and validated by comparing to the original English version by native speakers who had a specialty in the medical field. Second, eligibility of patients, diagnosis of concomitant irritable bowel syndrome, and survey responses were self-reported and consisted primarily of their retrospective assessment. This could potentially result in recall bias and adversely affect data reliability. Third, because only the patients who completed the survey were included, the results might have been biased to include patients who are more active in managing their disease and communicating with HCPs. Fourth, participation was influenced by willingness to complete the survey, so patient participants may not reflect the general population with moderate-to-severe CD. Fifth, the survey included a

question on perianal fistula-related symptoms; however, the presence of fistula and disease location was not explored in the survey. Sixth, direct comparisons between data from patients with UC and CD were not included in this study and will be considered for future analyses. Last, this study is limited to patients with “moderate-to-severe” CD in the US and Europe; therefore, the results may not represent the full CD population worldwide.

Conclusions

Patients with moderate-to-severe CD experience symptoms that severely affect HRQoL, despite receiving advanced therapies. Bowel urgency and bowel urgency-related accidents were the most commonly reported symptoms that impact patients’ lives. However, bowel urgency was not prioritized by most HCPs during routine appointments and when making treatment decisions. This highlights the communication gap and misalignment of patients and HCPs’ perceptions of symptoms, such as bowel urgency, which are impactful and important to treat. Responsive and reliable PRO measures for evaluating bowel urgency are needed to provide evidence of treatment benefits in clinical trials and facilitate patient–HCP communication in clinical practice.

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Declarations

Competing interests DTR, Personal fees: Abbvie, Pfizer, Lilly, Janssen, Bristol-Myers Squibb; Grants and personal fees: Takeda; and Board of Trustees, Crohn’s & Colitis Foundation (no compensation), CFO, Cornerstones Health (non-profit organization). TH, Personal fees: Abbvie GK, EA Pharma, Janssen Pharmaceutical K.K, JIMRO, Mitsubishi-Tanabe, Mochida Pharmaceutical, Pfizer Japan, Sandoz K.K, Takeda Pharmaceutical, Zeria Pharmaceutical, Celltrion Healthcare Japan, Eli Lilly Japan, Gilead Sciences, Miyarisan Pharmaceutical, Alfresa Pharma Corporation, Kyorin Pharmaceutical; Grants: JIMRO, Mochida Pharmaceutical, Zeria Pharmaceutical, Miyarisan

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