# The Impact of Bowel Urgency on the Lives of Patients with Ulcerative Colitis in the US and Europe: Communicating Needs and Features of IBD Experiences (CONFIDE) Survey

C0363


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## BACKGROUND AND OBJECTIVES

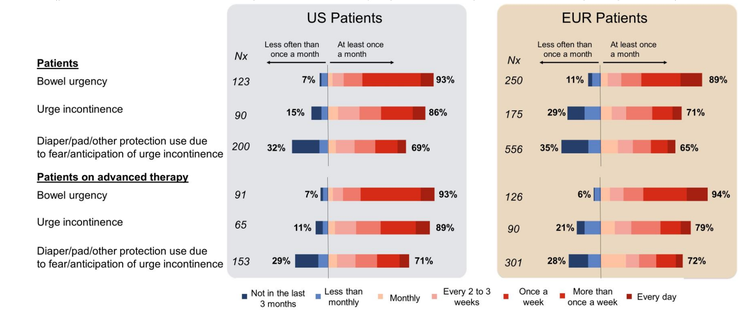
- Moderate to severe ulcerative colitis (UC) exerts a significant burden on patients' lives[1]
- Patients with UC report that bowel urgency has a substantial negative impact on their quality of life and psychosocial functioning[2], however, this symptom is missing from most disease activity indices
- The Communicating Needs and Features of IBD Experiences (CONFIDE) study aims to increase the understanding of the experience and impact of symptoms on patients' lives and elucidate any gaps in communication between healthcare professionals (HCPs) and patients with moderate to severe UC and Crohn's disease (CD) in the United States (US), Europe (EUR), and Japan
- These data focus on patients with moderate to severe UC in the US and EUR

## RESULTS

- A total of 200 US patients and 556 EUR patients completed the survey (Table 1)
- The top 3 symptoms experienced in the last month by US and EUR patients were diarrhoea (63% and 50%, respectively), bowel urgency (47% and 30%), and increased stool frequency (39% and 30%)
- 45% of US and 37% of EUR patients reported wearing a diaper/pad/protection at least once a week in the past 3 months due to fear/anticipation of urge incontinence (Figure 1)
- Among patients on advanced therapy, 47% of US and 38% of EUR patients reported wearing a diaper/pad/protection at least once a week in the past 3 months due to fear/anticipation of urge incontinence (Figure 1)

## KEY RESULTS

**Figure 1. Frequency of symptoms and use of diapers/pad/other protection over past 3 months**
(patients who have ever experienced the symptom or all patients for diaper question)




**Survey question: Patient survey question: How often did the following occur in the past 3 months?**
* Percentages are rounded and as a result totals may not add up to 100%

## CONCLUSIONS

- Bowel urgency, the second-most frequently reported symptom, has an extensive impact on the lives of patients with moderate to severe UC
- In this younger patient population, including patients receiving advanced therapies, almost two thirds of patients reported wearing diapers/pads/protection at least once a month in the past 3 months due to fear/anticipation of urge incontinence
- Among patients who have ever experienced urge incontinence, including patients receiving advanced therapies, over 70% of patients reported doing so at least once a month over the past 3 months
- Use of diaper/pad/protection in the past 3 months was more frequent among US patients potentially suggesting a greater impact on these patients
- Patients reported bowel urgency and fear of urge incontinence as the top reasons for declining participation in social events, work/school, and sports/physical exercise

## METHODS

- Online, quantitative, cross-sectional surveys were conducted in the US and Europe (EUR: France, Germany, Italy, Spain, and UK) with patients with self-reported, HCP-diagnosed moderate to severe UC
- Moderate to severe UC was defined using criteria based on previous treatment experience, steroid use, and/or hospitalization
- Data included patient perspectives on their UC symptoms and social life, work/school life, and ability to participate in sports/physical activities
- Patients were defined as ever experiencing bowel urgency or urge incontinence (bowel urgency related accidents) if they selected these symptoms in response to the survey question: "Which symptoms have you ever suffered from?"
- Descriptive statistics summarize the data

**Key patient eligibility criteria**

**Patient inclusion criteria**
- Male or female, aged ≥18 years
- Have an HCP diagnosis of UC (patient self-reported)
- Have active disease of at least moderate severity as defined by meeting at least one of the following criteria:
  - Received anti-TNF, anti-integrin, JAK inhibitor, anti-IL-12/23, or immunomodulator treatment within the last 12 months
  - Duration of steroid treatment of at least one month out of the last twelve months
  - Hospitalized for at least 4 consecutive weeks in the last 5 years

**Patient exclusion criteria**
- Have had a colectomy
- No more than 20% of full sample with concomitant irritable bowel syndrome diagnosis in each country

**Figure 2.** Key eligibility criteria for participation in the patient survey.

**Figure 3.** CONFIDE survey development.

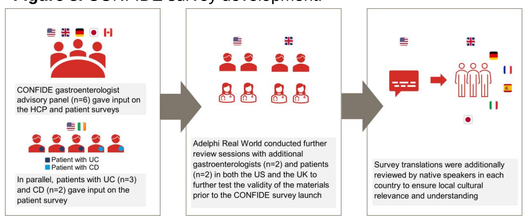
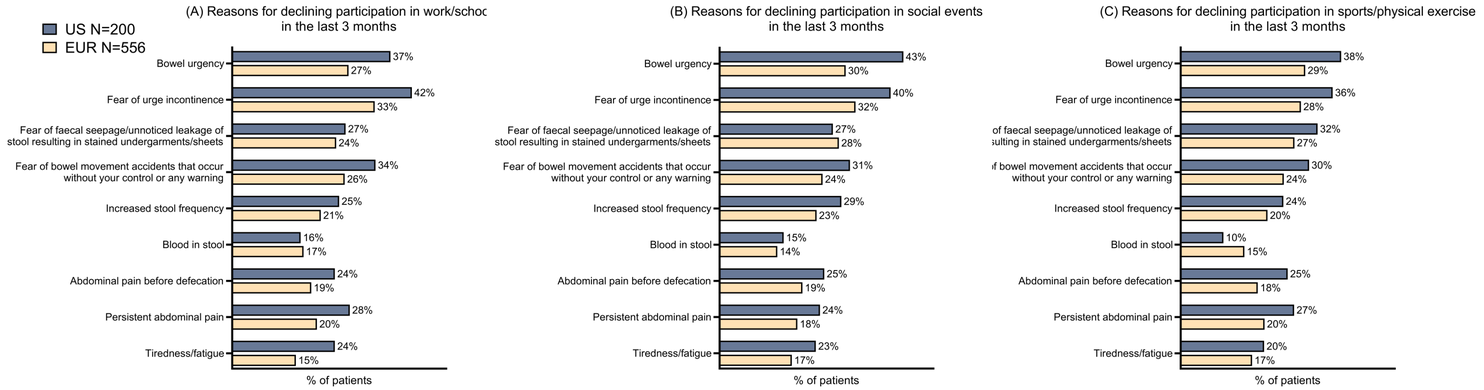



**Table 1.** Key patient demographics and characteristics*

| | US patients (N=200) | EUR patients (N=556) |
|---|---|---|
| **Sex at birth**, n (%)** | | |
| Male | 123 (62) | 319 (57) |
| Female | 77 (39) | 236 (42) |
| **Mean age (years)** | 40.4 | 38.9 |
| **Ethnicity, n (%)** | | |
| White | 155 (78) | 518 (93) |
| Hispanic/Latino | 23 (12) | 3 (1) |
| African American | 18 (9) | 0 |
| Japanese§ | 0 | 21 (4) |
| Other ethnicity† | 4 (2) | 14 (3) |
| **Mean time since diagnosis of UC (years)** | 7.9 | 7.9 |
| **Patients receiving advanced therapy‡, n (%)** | 153 (77) | 301 (54) |

**Figure 4.** Impact of UC symptoms on daily life




**Survey question:** In the last three months, have you declined participating in (A) Work/School (for example, academic, professional work), (B) Social events (for example meeting with friends or family), or (C) Sports/physical exercise due to any of the following reasons?
Patients selected reasons as shown in figure or "not declined participating in activities in the last 3 months".

*Percentages are rounded and as a result totals may not add up to 100%
** One EUR patient selected "Prefer not to say" in response to question on sex at birth
§ The CONFIDE study was also conducted in Japan and results will be presented in subsequent disclosures in the future
† Other ethnicity comprises Asian (US n=3, 1.5%; EUR n=5, 0.9%), Middle Eastern (US n=1, 0.5%), Korean (EUR n=2, 0.4%), Afro-Carribean (EUR n=4, 0.7%), and other (EUR n=3, 0.5%)
‡ adalimumab (including biosimilars), infliximab (including biosimilars), golimumab, certolizumab-pegol, vedolizumab, natalizumab, ustekinumab, and tofacitinib


## REFERENCES

1. Rubin, D.T., et al., Inflammatory bowel diseases, 2021. 27(12): p. 1942-1953.
2. Sninsky, J.A., et al., Official journal of the American College of Gastroenterology | ACG: doi: 10.14309/ajg.0000000000001685.


## DISCLOSURES

Stefan Schreiber reports consultancies and lectures from AbbVie, Amgen, Arena, BMS, Celltrion, Falk, Fering, Galapagos/Gilead, Genentech/Roche, Lilly, Janssen, MSD, Pfizer, and Takeda. Marla C. Dubinsky reports consultancy fees from AbbVie Inc., Arena Pharmaceuticals, Boehringer Ingelheim International GmbH, Bristol-Myers Squibb Company, Celgene Corporation, Eli Lilly and Company, F. Hoffman-La Roche Ltd., Genentech Inc., Gilead, Janssen Global Services, LLC, Pfizer Inc., Prometheus Biosciences, Takeda Pharmaceuticals USA Inc. and UCB SA. David T. Rubin has received consulting fees from AbbVie, Alimentiv Inc., Altrubio, Arena Pharmaceuticals, Aslan Pharmaceuticals, Athos Therapeutics, Bellatrix Pharmaceuticals, Boehringer Ingelheim, Ltd., Bristol-Myers Squibb, Celgene Corp/Syneos, ClostraBio, Connect BioPharma, EcoR1, GalenPharma/Atlantica, Genentech/Roche, Gilead Sciences, Ironwood Pharmaceuticals, Iterative Scopes, Janssen Pharmaceuticals, Lilly USA, LLC, Materia Prima, Pfizer, Prmomedicus Biosciences, Takeda, and Techlab, Inc; grant support from Takeda; has a stock agreement with Altrubio; is on the board of trustees of the American College of Gastroenterology; and is the Co-Founder and CFO of Cornerstones Health, Inc. Toshifumi Hibi reports grants from Otsuka Holdings; grants and personal fees from AbbVie GK, JIMRO, Kyorin, Mitsubishi Tanabe Pharma, Mochida Pharmaceutical, Takeda Pharmaceutical and Zeria Pharmaceutical; and personal fees from Aspen Japan K.K, BMS, Celltrion, EA Pharma, Eli Lilly, Ferring, Gilead Sciences, Janssen, Kissei Pharmaceutical, Nichi-Iko Pharmaceutical, Nippon Kayaku and Pfizer, outside the submitted work. Remo Panaccione has received consulting fees from AbbVie, Abbott, Alimentiv (formerly Robarts), Amgen, Arena Pharmaceuticals, AstraZeneca, Bristol-Myers Squibb, Boehringer Ingelheim Celgene, Celtrion, Cosmos Pharmaceuticals, Eisai, Elan, Eli Lilly and Company, Ferring, Galapagos, Genentech, Gilead Sciences, Glaxo-Smith Kline, Janssen, Merck, Mylan, Oppilan Pandion, Pharma, Pandion Pharma, Pfizer, Progenity, Protagonist Therapeutics, Roche, Satisfai Health, Sandoz, Schering-Plough, Shire, Sublimity Therapeutics,Theravance Biopharma, UCB, Takeda Pharmaceuticals; speaker fees from AbbVie, Arena Pharmaceuticals, Celgene, Eli Lilly and Company, Ferring, Gilead Sciences, Janssen, Merck, Pfizer, Roche, Sandoz, Shire, Takeda Pharmaceuticals; research/educational support from AbbVie, Ferring, Janssen, Pfizer, Takeda; and has served on an advisory board for AbbVie, Amgen, Arena Pharmaceuticals, Bristol-Myers Squibb, Celgene, Celtrion, Eli Lilly and Company, Ferring, Galapagos, Genentech, Gilead Sciences, Glaxo-Smith Kline, Janssen, Merck, Mylan, Oppilan Pharma, Pandion Pharma, Pfizer, Sandoz, Shire, Sublimity Therapeutics, Theravance Biopharma, Takeda Pharmaceuticals. Christian Atkinson is an employee of Adelphi Real World, and a paid consultant to Eli Lilly and Company in connection with the development of this publication. Alison Potts Bleakman, Cem Kayhan, Theresa Hunter Gibble, Eoin J. Flynn, and Christophe Sapin are employees and stockholders at Eli Lilly and Company. This study was sponsored by Eli Lilly and Company. Medical writing services were provided by Angela O'Sullivan, PhD and employee of Eli Lilly and Company, and was funded by Eli Lilly and Company. This study was previously presented at the United European Gastroenterology Week (UEGW) 2022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