

Exploring Beyond the Gut: A Qualitative Study of Extraintestinal Symptoms in Ulcerative Colitis and Crohn's Disease

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OBJECTIVE



This study aimed to identify the extra-intestinal symptoms of Ulcerative Colitis (UC) and Crohn's Disease (CD) important to patients, through qualitative, open-ended concept elicitation interviews with patients and clinicians.

BACKGROUND

- UC and CD the two major forms of inflammatory bowel disease (IBD)¹, are characterized by symptoms of diarrhea, abdominal pain, fatigue, and weight loss.²
- Extra-intestinal symptoms can significantly complicate UC and CD, affecting multiple organ systems and underscoring the systemic implications of IBD.^{2,3}
- These symptoms, driven by genetic, environmental, and immunological factors, increase patients' disease burden and impact both quality of life and treatment.^{2,3}

RESULTS

Baseline characteristics

- The mean age of patients was 39.5 years for UC (n=12) and 40.3 years for CD (n=12) with an average time since diagnosis of 5.3 years and 10.3 years respectively (Table 1).

Table 1: Demographic and clinical characteristics: patients with UC and CD

Demographic characteristic	Patients with UC	Patients with CD
	Total (N=12)	Total (N=12)
Age, years, Mean (Median) [Range]	39.5 (36) [26-69]	40.3 (45.0) [22-54]
Gender, n (%)		
Male	5 (42)	4 (33)
Female	7 (58)	8 (67)
Race, n (%)		
White	7 (58)	10 (83)
Black or African American	3 (25)	2 (17)
Asian	2 (17)	1 (8)
Ethnicity, n (%)		
Not Hispanic or Latino	12 (100)	9 (75)
Time since CD diagnosis, years		
Mean (Median) [Range]	5.3 (4.2) [0.5-16.4]	10.3 (8.0) [2.5-28.8]
Number of current treatments, n		
1	10	11
2	2	1

UC: Ulcerative Colitis; CD: Crohn's Disease; n/ N: Number

- All clinicians were gastrointestinal specialists, with an average of 23.2 years managing patients with UC or CD (Table 2).

Table 2. Demographic characteristics: clinicians











Clinician Characteristics	Sample N=6 (%)
Medical specialty, n (%)	
GI specialist	6 (100)
Years working as a physician, Mean (range)	23.5 (11-32)
Years treating and managing patients with CD and UC, Mean (range)	23.2 (11-33)
Type of practice, n (%) *	
Private hospital	2 (33)
Specialist Center	1 (17)
Clinic	2 (33)
Other (private practice)	1 (17)

*Multiple responses could be selected; GI: Gastro-Intestinal; UC: Ulcerative Colitis; CD: Crohn's Disease; n/N: Number

Most frequently reported UC extra-intestinal symptoms by patients and clinicians

- Seven patients with UC reported extraintestinal symptoms, notably weight loss (n=4), fever (n=2), back pain (n=1), joint pain (n=1), and anemia (n=1) (Figure 1).
- Clinicians identified anemia and fever (n=3 each) in patients with UC, along with weight loss (n=2), joint pain, tachycardia and dehydration/electrolyte imbalance (n=1 each) (Figure 1).

Figure 1. Patient and clinician description of extra-intestinal symptoms of UC

Extra-intestinal symptoms of UC reported by patients	Extra-intestinal symptoms of UC reported by clinicians
 Weight loss (n=4) "Like, another sort of symptom is weight loss. That bothers me a lot, that I'm sort of, like, a lot thinner right now than I'd like to be."	 Anemia (n=3) "From our standpoint, we just can't stop the bleeding, and they become severely anemic, um, requiring transfusion."
 Fever (n=2) "When I started experiencing rectal bleeding, together with the fever and vomiting....I went to check out what was wrong."	 Fever or chills (n=3) "They might have fever, chills"
 Difficulty absorbing nutrients (n=2) "Oh, it's certainly made me much more careful about what I eat and affected my ability to get nutrition."	 Joint pain (n=1) "Occasionally fever, sometimes joint aches, joint pains, unexplained anemia, along with all of that."
	 Tachycardia (n=1) "I mean a patient with severe disease..do they have tachycardia?"
 Anemia (n=1) "I think is also a side effect tied to the bleeding is be-becoming anemic. Um, I have low-iron deficiency at this point and I'm anemic."	 Weight loss (n=2) "They may have abdominal pain; they may have weight loss..."
	 Dehydration and electrolyte imbalance (n=1) "They are losing a huge amount of fluids and electrolytes, by the frequent bowel habit..."

CONCLUSIONS



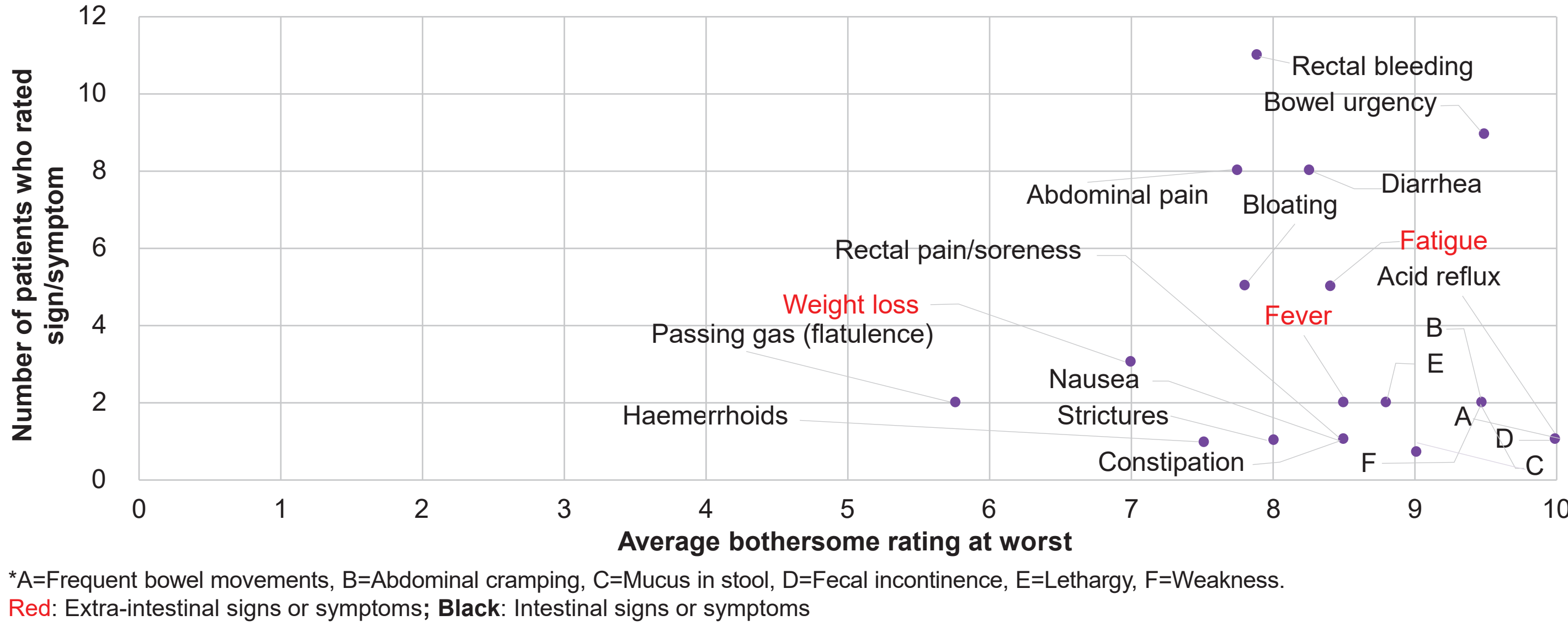
The study underscores the diverse, systemic nature of UC and CD extraintestinal symptoms and emphasizes the need for holistic care and improved data collection to inform current and future treatment approaches.

METHODS

- Concept elicitation interviews were conducted with an Institutional Review Board-approved semi-structured interview guide to explore the diversity of extra-intestinal symptoms experienced by patients with UC or CD.
- Participants aged ≥18 years with a diagnosis of moderate-to-severe UC or CD (n=12 each), and clinicians (n=6) experienced in treating UC and/or CD in the United States were included in the study.
- UC or CD signs and symptoms mentioned by >75% of participants with an average rating of ≥5 on a 0-10 rating scale were considered salient.
- Interview transcripts were analyzed using Atlas.ti software (Version 9).

- At its worst, no extraintestinal symptom of UC met the salience threshold (Figure 2).













Figure 2. Salience graph of signs and symptoms of UC, as rated at worst



Most frequently reported CD extra-intestinal symptoms by patients and clinicians

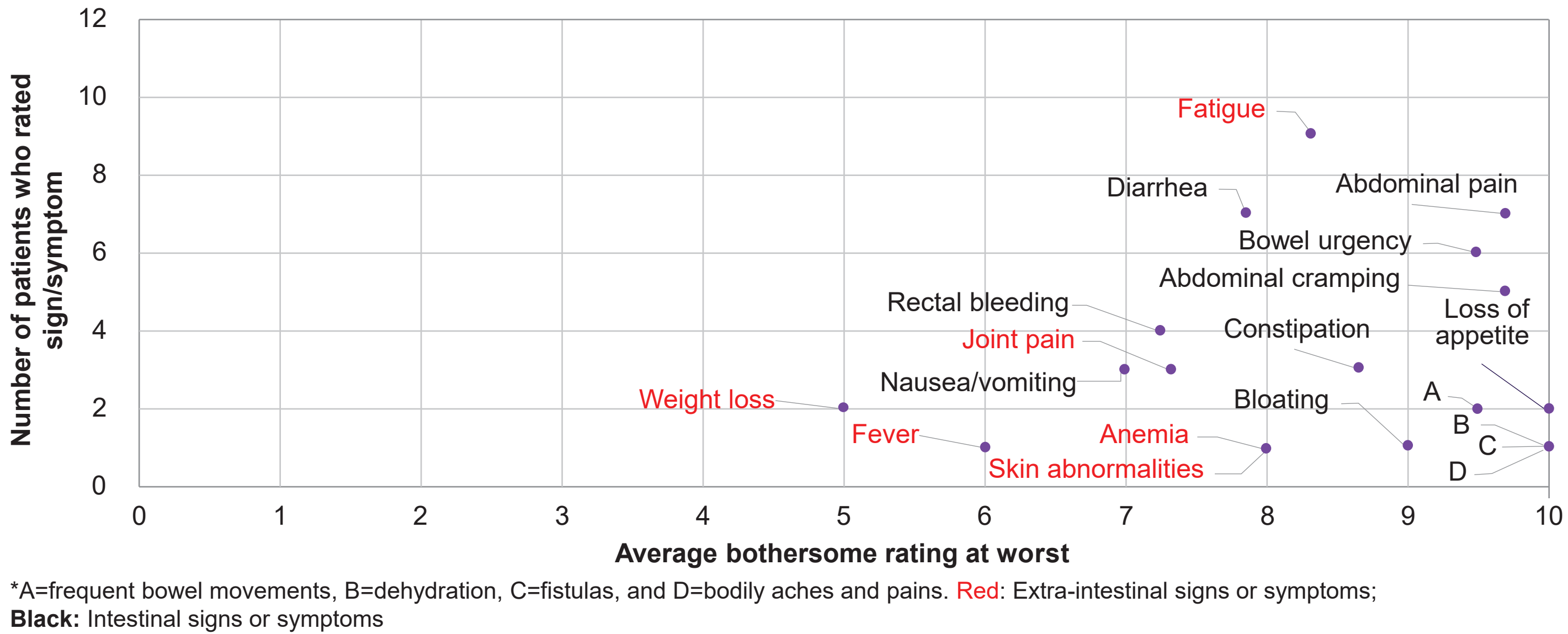
- All patients with CD (n=12) experienced extraintestinal symptoms, notably fatigue (n=11), anemia, weight loss (n=4 each), dizziness (n=3), feeling cold (n=2), difficulty absorbing nutrients and other symptoms including increased infections, dehydration, fever, infertility, malaise, and skin abnormalities (n=1 each) (Figure 3).
- Clinicians noted dermatological issues (n=2), fever and chills, eye diseases, and rheumatological manifestations (n=1 each) in patients with CD (Figure 3).

Figure 3. Patient and clinician description of extra-intestinal symptoms of CD

Extra-intestinal symptoms of CD reported by patients	Extra-intestinal symptoms of CD reported by clinicians
 Fatigue/tiredness/low energy (n=11) "I'm always fatigued... I'm just always tired no matter how much sleep I get or how much iron is in my body..."	 Skin diseases/dermatological (n=2) "Sometimes, extraintestinal manifestations, especially of...dermatological nature, present as well."
 Anemia (n=4) "I also have iron deficiency anemia as a result of my Crohn's."	 Eye diseases (n=1) "More rarely, eye and skin, you know, involvement and things...."
 Weight loss (n=4) "If I started to get sick, um, I would lose – I, I got all the way down to 116lbs, um, during a flare-up."	 Rheumatological manifestations (n=1) "Sometimes, extraintestinal manifestations, especially of rheumatological nature, present as well."
 Dizziness (n=3) "Sometimes there'd be a lot of blood, and I'd get lightheaded."	 Fever and chills (n=1) "Not that uncommon to have fever and chills."
 Feeling cold (n=2) "I get, like, really cold, that's the nutrition and iron."	 Generalized inflammatory response (n=1) "Kind of, a generalized inflammatory response, if you will, blood in the stool and, um, a fecal urgency."
 Difficulty absorbing nutrients (n=2) "I feel like that's [fatigue] also accentuated with having a colon where I don't absorb nutrients...it's a battle against physiology."	 Weight loss (n=1) "Usually abdominal pain, change in their bowel habits, sometimes nausea, um, rectal bleeding, weight loss."

- At its worst, patients with CD rated fatigue as the most bothersome extra-intestinal symptom (8.3 on a 0-10 scale) (Figure 4).

Figure 4. Salience graph of signs and symptoms of CD, as rated at worst



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CONFLICTS OF INTEREST

GD and SK are employees of Clarivate and received funding from Sanofi to conduct this research project, they may hold stock or stock options. KJ was a former employee at Sanofi and may hold stock or stock options. LL is an employee of Sanofi and may hold stock or stock options. EBH is a consultant for Sanofi.

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