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Background

- Crohn's disease (CD), an inflammatory bowel disease, can significantly impair patients' health-related quality of life (HRQoL).^{1,2}
- For the effective management of CD, understanding the priorities of the patients is crucial.²

Objective

• The objective of this study was to develop a comprehensive conceptual model (CM) of the patient experience of CD by identifying the symptoms and impacts experienced by adults with CD in the United States (US).

Methods

- In this qualitative study, concept elicitation interviews were conducted among patients aged ≥18 years with a diagnosis of moderate-to-severe CD and clinicians experienced in treating CD in the US.
- IRB-approved semi-structured interviews were conducted online to explore CD symptoms and their impact on patients' HRQoL.
- Interview transcripts were analyzed using Atlas.ti software (Version 9).

Results

Baseline characteristics

- Twelve patients with a mean age of 40.3 years (range: 22–54 years) were included.
- Six gastroenterologists, with an average practice duration of 23.5 years, participated in the study (**Table 1**).

Table 1. D	emographic	and clinics	al charact	arietice

Patient characteristi	CS
Demographic characteristics	(N = 12)
Age, years, Mean (Median) [Range]	40.3 (45.0) [22–54]
Female, n (%)	8 (67)
Race, n (%)*	
White	10 (83)
Black or African-American	2 (17)
Asian	1 (8)
Ethnicity, n (%)	
Not Hispanic or Latino	9 (75)
Hispanic or Latino	3 (25)
Time since CD diagnosis, years	
Mean (Median) [Range]	10.3 (8.0) [2.5–28.8]
Number of current treatments, n	
1	11
2	1
Clinician characterist	tics
Characteristics	(N = 6)
GI specialist, n	6
Years working as a physician, Mean (range)	23.5 (11–32)
Years treating and managing patients with CD, Mean (range)	23.2 (11–33)
Type of practice, n	
Private hospital	2
Specialist center	1
Clinic	2
Other (private practice)	1
Not mutually exclusive; CD: Crohn's disease; GI: gastrointestinal; N, total population	n; n, number of observations.

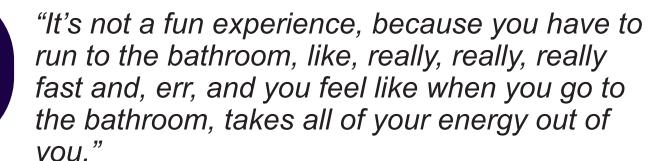
Most frequently reported symptoms by patients and clinicians

- The most frequent patient-reported gastrointestinal (GI) signs/symptoms were bowel urgency (n = 9/12), abdominal pain (n = 8/12), diarrhea (n = 7/12), frequent bowel movements (n = 6/12), and abdominal cramping (n = 6/12) (**Figure 1**).
- The most common patient-reported extraintestinal symptoms were fatigue (n = 11/12), anemia (n = 4/12), and weight loss (n = 4/12).
- Clinicians stated that diarrhea (n = 4) and abdominal pain/discomfort (n = 4) were the two core patientreported symptoms.
- Change in bowel habits or diarrhea (n = 3), weight loss (n = 1), bloating (n = 1), and gas (n = 1) were the most typical or disease-defining clinician-reported symptoms of CD reported (Figure 1).
- Clinician-reported extraintestinal manifestations of CD were skin abnormalities (n = 2), eye diseases (n = 1), and rheumatological signs (n = 1).

Figure 1: Patient and clinician description of symptoms of CD

Symptoms of CD reported by patients

Bowel urgency (n = 9)





Diarrhea (n = 7)

"My stools were all unformed... at times it was just, like, fully liquid, um, but other times it's just like, very loose.

Frequent bowel movements (n = 6)

would wake up and have to have a bowel movement, and then I would eat breakfast, and I would have to go again. And then, I would drive to work, and I would have to go right when I got there before I even went upstairs to



Abdominal pain (n = 8)

"Sometimes it would just hit me and, um, the pain would be severe."



Abdominal pain (n = 8)"It feels like cramping feeling in your stomach

and it, err, lasts for quite a bit."

CD: Crohn's Disease

Patient- and clinician-reported description of impacts of CD

- The most frequently reported impacts of CD by patients were as follows:
- Being unable to leave the house (n = 10/12), and increased planning when going out (n = 9/12).
- Depression/low mood (n = 9/12) or anxiety (n = 7/12).
- Unable to attend social events (n = 7/12) or avoid making social plans (n = 6/12).
- Feeling lack of support and understanding from others (n = 7/12) (Figure 2).
- The most common symptom-specific and general coping strategy among patients with CD were changing diet (n = 4/12) and overall attitude/mindset (n = 3/12), respectively.
- Clinicians stated that impacts on emotions, social activities, work and sleep were reported by their patients with CD (Figure 2).

Figure 2: Patient- and clinician-reported description of impacts of CD

Symptoms of CD reported by patients

Unable to leave the house (n = 10)

"I just didn't feel comfortable leaving the house or do - you know, doing anything, um, you know, it was miserable.

"I'm not able to go do activities with them [friends/family] like I'd like to... So, it makes me feel a little isolated."

Unable to attend social events (n = 7)

Avoiding making plans (n = 6)

"I was rejecting a lot of invitations at first, and also, kind of, I think I became, like, much more negative."

Depression/low mood (n = 9)

"It was, kind of, one of those, "Why me?" like, you know, things, and I did it - it, it did, it affected me negatively. I, I, I was depressed about it because I just didn't understand, like, why?"

Anxiety (n = 7)

"It makes me very anxious, worrying about it, worrying if I'm going to make it to a bathroom or knowing where a bathroom's at."

Lack of support/ understanding from others (n = 7)

"I think it's changed some of my relationships, where, like, they're supportive, especially if I'm in the hospital, but, like, most often - more often than not, they're not checking in on me to see how I'm doing."

CD: Crohn's Disease

Anxiety, depression, and worry (n = 2)

Clinician-reported impacts of CD

Impacts on patients' social lives (n = 3)

"Obviously, they're - inhibits, err, their ability to have social

relationships because, you know, you're ducking out of

a dinner or a date or something, you know, to, to run off

to the bathroom. So, it prevents normal connectivity and

interactions with other people."

Symptoms of CD reported by

err, small bowel disease."

Bloating/gas (n = 2)

Weight loss (n = 1)

bleeding, weight loss"

Abdominal discomfort (n = 4)

"Oh, diarrhea really – you know what?

Diarrhea is, um, is relatively ubiquitous with

Crohn's, especially with a flare, almost by

definition, and it's a small bowel disease,

primarily. Err, diarrhea is, um, sort of, an

"Some patients can present as abdominal

where the terminal ileum bottom, the small

"It could be, it could be as, as mild as

unexplained abdominal pain, bloating"

"Um, usually abdominal pain, change in their

bowel habits, sometimes nausea, um, rectal

pain. Often, err, right lower quadrant, which is

intestine is, which is a common site of Crohn's

overwhelmingly common problem because of,

Diarrhea (n = 4)

"There are – there is, there is – tend to be increased risk of depression, anxiety, and other psychological diagnoses in people with Crohn's disease....so, they have more psychological problems 'cause they - before they had Crohn's disease, or they're just more depressed and anxious 'cause they have to go to the bathroom all the time?...But psychological issues, kind of, go into the Crohn's disease, err, personality, if you will. So, yeah, it's a significant impact on, on quality of life, no question."

Attendance at work and/or school (n = 2)

"If you have somebody who has eight to ten loose bowel movements for a day, obviously, that, that inhibits their ability to work.

Affected sleep (n = 1)

"It could severely impact their life. I-it may interrupt their sleep, um, really their whole day."

Conceptual model

 A comprehensive CM was developed based on the qualitative interviews and a prior literature review (Figure 3).

Figure 3: Updated conceptual model of CD

Updated conceptual model of Crohn's disease Signs and Symptoms Impacts GI symptoms Emotional wellbeing Social life **Nutritional/extraintestinal** manifestations Bowel urgency at Depression/low mood Unable to attend social events ^a Fatigue/tiredness/low Diarrhea ab* Anxiety/worry ab Avoiding making plans ^{ab} energy ^{al} Embarrassment ^a Interrupted by bathroom breaks Frequent bowel Anemia ^{ab} movements ab Increased self-concealment ^b Frustration ^{ab} Weight loss ^{ab*} Rectal bleeding at Fear ^{ab} Experiencing negativity/ Dizziness ^{ab} judgement from others ab Nausea/vomiting ab Self-consciousness ^a Feeling cold Fecal incontinence al Decreased enjoyment of Feeling burdensome Difficulty absorbing Constipation ab Irritability nutrients | Bloating ab Feeling isolated a Increased frequency of Family and relationships Bowel obstruction b infections Feeling traumatized Clostridium difficile Lack of support/understanding Dehydration Hopelessness from others b Fever ^{ab*} Feeling stressed at Fistulas b Reduced romance/intimacy ab

 Infertility ^a Uncertainty ^a Loss of appetite at Malaise ^b Low self-esteem Strictures ^t Skin abnormalities Anger ^a Abscesses Eye diseases Denial ^a Mucus in stool Rheumatological signs Obsessive thoughts ^a

Activities of daily living

Difficulty with chores ^{ab}

Avoiding driving

Increased planning (when going out)

Increased planning (when at home)

Difficulty with self-care/hygiene

- Flatulence a* Headache Heartburn/indigestion Night sweats
- Food cravings ^e Gurgling/noises **Pain-associated symptoms**

Bodily aches and pains ^t

Abdominal pain ab* Abdominal cramping a

- Rectal pain/soreness Joint pain ^b
- Changed/restricted diet
- Conscious of eating/ drinking times b
- Unable to eat at all

- General coping strategies Change in attitude towards life at Maintaining a positive outlook ^{ab}
- Strengthened bonds with friends / family ^a Increased spirituality, sense of being fortunate
- Engaging in exercise ^{ab}
- Choosing rest and relaxation b Self-training / self-limiting behavior a

Work and education Unable to leave the house

Disrupted sleep

Needing to nap ^b

Needing to rest b

Reduced mobility

Loss of strength

Changing diet ^{all}

Pain relief

Staying hydrated ^{ab}

Massaging joints

• Heat

Consuming caffeine/sugar

Physical functioning

- Interrupted workdays
- Taking time off ^{ab}
- Unable to attend work/school at all all Decreased productivity

Diminished parenting ability

Hobbies and leisure

Difficulty travelling ab

Appointment burden

Surgery burden ^{ab}

Medication burden ^b

Hospitalization burden

Treatment uncertainty

Drug interaction risks

Treatment and healthcare

Relying on a partner for support

Unable to do sports/activities ab

- Reduced working hours
- Changed job/career at
- **Symptom-specific coping strategies**
 - a = Reported in the original conceptual
 - model by Mapi • b = Identified in
 - patient interviews • * = Identified in clinician interviews

Limitations

- Some participants had well controlled disease at the time of the interview, leading to reliance on recall for symptom reporting.
- Generalizability of the study results should be considered because the study included patients only from the US

Conclusions

- CD impacts most aspects of patients' HRQoL.
- The CM provides insight into CD and outlines a wide spectrum of symptoms, effects, and coping mechanisms.
- The CM will serve as the foundation for more efficient patient-centered care strategies and options, as well as for the development of targeted future treatments.

1. Knowles et al. Inflamm Bowel Dis. 2018; 24: 742-751.

2. Mokrowiecka et al. Adv Med Sci. 2006; 51: 142-147.

Conflicts of interest

CC and SK are employees of Clarivate and were paid a fixed fee by Sanofi to undertake this research project, they may hold stock or stock options. KJ and LL are employees of Sanofi and may hold stock or stock options. EBH is a consultant for Sanofi. **Funding**

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