

Affected ability to work at full

Missing work/taking time off ab

Physically impossible to carry

Preferring to work from home b

relationships with colleagues by

Unable to attend/commit to

Needing to cancel plans ab

Negativity/judgement from

Family and relationships

Impact on parental role ab\*

Sexual intimacy affected ab\*

Requiring hospital treatment b

Relationship with partner

**Unmet treatment needs** 

Burden of appointments b

Increased self-concealment b

Socializing impacted by

Difficulty with work travel ab

Change to part-time a

progression b

social plans ab\*

accidents ab

others ab

affected ab\*

Dating b

Social fatigue ab

Social life

Negatively affected

Negative affect on career

**Impacts** 

Work

capacity ab\*

on work a

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## Background

- Ulcerative Colitis (UC) is a chronic inflammatory bowel disease that can significantly impair patients' healthrelated quality of life (HRQoL)<sup>1,2</sup>.
- Conducting qualitative research to gather patient experiences of UC is crucial for developing drugs that improve their HRQoL.

## Objective

 To explore the symptoms and impacts of UC on adult patients in the United States (US) through qualitative interviews, aiming to develop a comprehensive conceptual model of UC.

### Methods

- This qualitative study included concept elicitation interviews with patients aged ≥18 years with a diagnosis of moderate-severe UC, as well as US clinicians experienced in the treatment and management of UC.
- Interviews were conducted online by trained interviewers using an Institutional Review Board-approved semi-structured interview guide.
- Interview transcripts were analysed using Atlas.ti software (Version 9).

### Results

### Baseline characteristics

 Twelve patients with a mean age of 39 years (range: 26-69 years) were included, along with six gastroenterologists who had an average of 23.5 years in practice (**Table 1**).

### Table 1. Demographic and clinical characteristics

Patient characteristics		
Characteristics	Total (N = 12)	
Age, years, Mean (Median) [Range]	39.5 (36) [26-69]	
Gender, n		
Female	7	
Race, n		
White	7	
Black or African American	3	
Asian	2	
Ethnicity, n		
Non-Hispanic or Latino	12	
Time since UC diagnosis, years, Mean (Median) [Range]	5.3 (4.2) [0.5-16.4]	
Number of current treatments, n		
1	10	
2	2	
Clinician characteristics		
Characteristics	Total (N = 6)	
GI specialist, n	6	
Years working as a physician, Mean (range)	23.2 (11-33)	
Years treating and managing patients with UC, Mean (range)	23.2 (11-33)	
Type of practice, n		
Private hospital	2	
Specialist Center	1	
Clinic	2	
Other (private practice)	1	
GI, gastrointestinal; N, total population; n, number of observations; UC, ulceration	ve colitis	

## Most frequent patient-reported symptoms

- The most frequently reported gastrointestinal (GI) symptoms of UC were rectal bleeding (n = 12/12), bowel urgency (n = 9/12), and diarrhea (n = 8/12).
- Additionally, many patients reported abdominal pain (n = 9/12), fatigue (n = 9/12), abdominal cramping (n = 5/12), weight loss (n = 4/12), and fever (n = 2/12) (**Figure 1**).

### Figure 1. Symptoms of ulcerative colitis reported by patients

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"And the whole toilet would be red, you know, and then you'd wipe yourself and your paper would be red, you know, so it's – it can be really nasty."

Rectal bleeding

### **Bowel urgency**

"Yeah, urgency is kind of like, you don't have to go to the bathroom, you're fine, you don't have to go, no, you're fine, you don't have to go to the bathroom, you're fine, and then all of a sudden, it hits you and you're like oh, I have to go, like, in the next ten seconds, or, or it's not going to be okay."

### Diarrhea

"I'm not saying solids but, you know, liquid, – with this condition, it's also liquified. Um, and that causes odor, and all odor's question."

### **Abdominal pain**

"Abdominal pain is in the center of the seesaw, and I also – so it affects me that I can't do the things that I love, only if I'm in a sitting position. I'm sitting here in my chair talking to you, you can see that, I'm comfortable."

### **Fatigue**

"Along with also excessive fatigue, I would say, are the most pronounced and most consistent symptoms that I have to navigate on a daily basis."

### Abdominal cramping

"One of the symptoms I had was very bad abdominal cramping, when I would try to move my bowels. It was really, really bad."

### Most frequent patient-reported impacts

- The most frequently reported impacts were as follows (Figure 2): - Having to follow a changed or restricted diet (n = 12/12)
- Anxiety/worry (n = 10/12)
- Needing to lie down or rest more (n = 9/12)
- Being unable to attend or commit to social plans (n = 9/12)
- Reduced ability to work at full capacity and missing work or taking time off (both n = 7/12)
- Increased planning/concerns when going out and spending more time at home (both n = 7/12) - Feeling stressed and experiencing embarrassment (each n = 6/12)
- Needing to cancel plans that had already been arranged (n = 6/12)

### Figure 2. Impacts of ulcerative colitis reported by patients

### Having to follow a changed or restricted diet

"There's a lot of pain and there's a lot of, err, challenges related to keeping the inflammation down, um, a lot of, like, restrictions on what I

### Reduced ability to work at full capacity

"Yeah. for all the same reasons I mentioned, you know, I don't want to be too redundant, but, I mean, if it affects your ability to work and how you work and, and, and who you work with.

## **Anxiety/worry**

"Having this sense of urgency creates an extreme amount of anxiety, err, because you don't necessarily know if you'll make it to the restroom."

### Being unable to attend or commit to social plans

"For instance, um, you're careful about going out, um, you know, um, you're careful about hanging out, like being away from home. Because if I'm away from home, then it's going to be - I,I,I can be at, um, say friend's house or, like, function or, like, um, um, a, a party or something and I have to, um, run to the

bathroom three/four times "

"Because I was trying to keep my job, I would expend every last bit of my energy with that, and then I would come home and I would have the rest for the entire evening to be functional again."

rest more

### Increased planning when going out

"Like, you know, you have to, you have to think about, especially when it comes to, like, err, you know, hanging out with friends or, you know, doing anything, you know, publicwise, um, you know, you have to, kind of, calculate, okay, well, is this going to be a place where there's going to be a bathroom that's close

## Most frequent clinician-reported symptoms and impacts

- Four out of six gastroenterologists debriefed on UC in the interviews.
- Each of these clinicians reported that UC patients can experience GI symptoms, including rectal bleeding, diarrhea, and abdominal pain (each n = 4/4) (Figure 3).
- In addition to GI symptoms, clinicians described anemia and fever (each n = 3/4).
- Clinicians described aspects of daily activities that are impacted in patients with UC (n = 4/4), including patients' ability to go to work (n = 3/4) and a need to be near a bathroom (n = 2/4) (**Figure 3**).

### Figure 3. Symptoms and impacts of ulcerative colitis reported by clinicians

### **SYMPTOMS**

Rectal bleeding



"Bleeding's very alarming to everybody, anybody. So, the GI guys, we see a lot of it, so it doesn't - it's not that alarming to me anymore, but for a patient to see a spot of blood on the toilet paper, or the - in a commode, it's - it freaks them out."

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"And the, err, probably the, the change in bowel habit. Err, the shift from normal bowel habit to, um, to frequent loose bowel movements, err, is, is the most common thing you find."



### "The more severe presentation is where they'd

have, have abdominal pain"



Conceptual model

### Anemia and fever

**Abdominal pain** 

"From our standpoint, [...] we just can't stop the bleeding and they become severely anemic, um, requiring transfusion" "They might have fever, chills"

and receiving support from family and friends (n = 7/12) (Figure 4).

### **Activities of daily living**

"Oh, it could be very detrimental, um [sighs], to the point where they're just home, they're bound to their homes and not wanting to do anything. Not go to work, not, err, spend time with friends or family."

**IMPACTS** 



### Inability to go to work "Their ability to, to work to their, to their best

capacity or, or to excel in - err, at school and at the best they can. So, it, it – every single aspect of their life is, is impacted by this."



A comprehensive conceptual model was developed based on qualitative interview results (Figure 4).

• Patients reported various coping strategies including diet changes to avoid triggering symptoms (n = 6/12)

### Needing to be near a bathroom

"Err, the sense of urgency or tenesmus, err, often results in lifestyle modification and, you know, the need to be near any, err, I just would call it a loo. You would call it a bathroom.

### 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** SM and GD are employees of Clarivate. KJ and LL are employees of Sanofi and may hold stock or stock options. EBH is a consultant for Sanofi.

### **Funding**

The study was funded by Sanofi

Medical writing support was provided by Sunita Rana and Rahul Nikam from Sanofi.

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### Figure 4. Comprehensive conceptual model with concepts reported in qualitative interviews

# Updated disease conceptual model for ulcerative colitis

**Emotional wellbeing** 

Embarrassment ab

Anxiety/Worry ab\*

• Stress ab

bodies a

bodies a

• Guilt a

Sleep

Diet

diet ab

eat ab

Denial a

Confusion a

Frustration ab

Depression ab

Anger/Irritability

Unable to rely on their

Sense of giving up

control over their

Low self-esteem

Feeling isolated ab

Negative thoughts to

**Hobbies and leisure** 

sports/activities ab

Difficulty travelling a

Disrupted sleep ab

Changed/restricted

Unable/less able to

More conscious of

professionals ab

eating times b

Sleeping longer t

Unable to participate in

• Fatigue ab

Lethargy b

• Weakness ab

**Nutritional** and

Weight loss ab\*

Difficulty absorbing

Fever ab\*

Sweating a

Anemia ab\*

nutrients k

Anorexia

Skin problems/

inflammation a

Dehydration a\*

Irregular/rapid heartbeat

Pain-related symptoms

**Activities of daily living** 

Spending more time at

home due to condition a

Difficulty with chores ab

Difficulties with self-

Increased planning (when

apprehensive/cautious in

Being unable to leave the

going out) ab\*

at home) ab

care/hygiene

Increased planning (when

**Energy-related symptoms** 

extraintestinal symptoms

**Signs and Symptoms** 

- Gastrointestinal symptoms
- Rectal bleeding ab\*
- Bowel urgency ab\*
- Diarrhea ab\*
- Fecal incontinence ab
- Frequent bowel
- movements ab\*
- Nausea ab\*
- Flatulence ab
- Tenesmus ab\*
- Mucus in stool ab\*
- Bloating ab
- Constipation al
- Ulcers ab
- Acid reflux ab
- Strictures t • Fissures b
- Perianal abscess b
- Fistulas b Colon inflammation\*
- Abdominal pain ab\*
- Abdominal cramping Rectal pain or soreness Joint/back pain ab\*
- Physical functioning General physical
- functioning ab Not being able to be
- physically active ab
- Life planned around access to toilets
- Needing to lie down/rest
- Reduced activities/
- freedom
- Financial burden
- Life on hold a
- Altered cloth choice a
- Reduced mobility b

❖a = Reported in the original conceptual model by Mapi ❖b = Identified in Clarivate patient interviews \* = Identified in Clarivate clinician interviews

# Coping strategies

- Alleviating stress ab Engaging in exercise t Support from friends and family ab
- Using a heating pad b Support from medical Hot water (e.g. a bath) b

# Limitations

- Many patients had well-controlled disease during interviews, leading to reliance on recall for symptom reporting.
- This study involves only US patients with UC, so the results may not be generalizable to other geographical areas or disease sub-types/severities.

## Conclusions

- UC affects most aspects of patients' HRQoL.
- The conceptual model provides an understanding of UC, highlighting a broad range of symptoms, impacts and coping strategies.
- This model will inform healthcare providers about patients' experiences and may help guide the development of more effective, patient-centered treatments.

**Acknowledgement** 

### **Contact information**