

Patient's Experience of Ulcerative Colitis: A Conceptual Model Based on Qualitative Interviews

Stephanie McKee¹, Greg Davis¹, Eva Brown Hajdukova², Kyran Jones³, Laurence Lucats²

¹Clarivate, London, UK; ²Sanofi, Gentilly, France; ³Sanofi, Cambridge, MA, USA

Poster Number: PCR232



Background

- Ulcerative Colitis (UC) is a chronic inflammatory bowel disease that can significantly impair patients' health-related quality of life (HRQoL)^{1,2}.
- 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

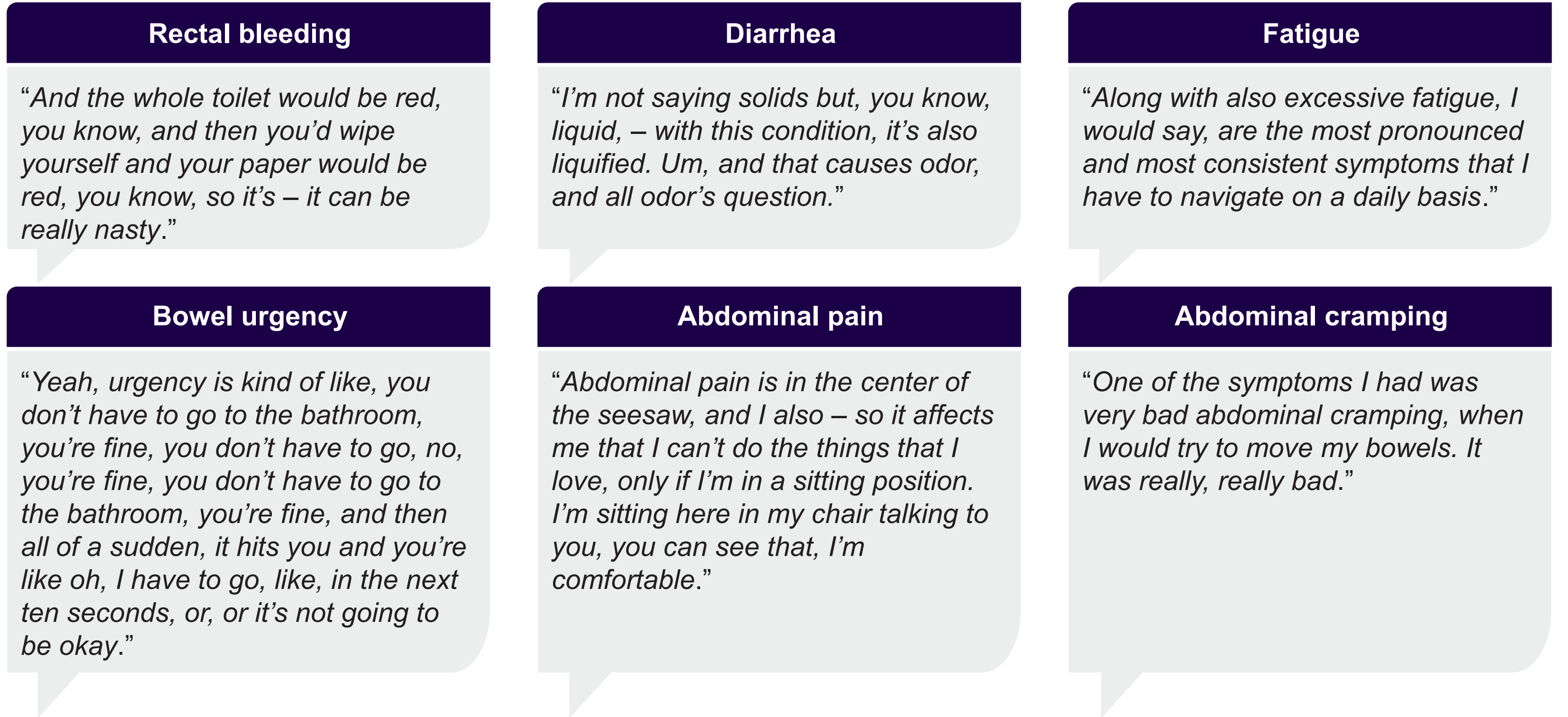
Patient characteristics		
Characteristics		Total (N = 12)
Age, years, Mean (Median) [Range]		39.5 (36) [26-69]
Gender, n		
Female		7
Race, n		
White		7
Black or African American		3
Asian		2
Ethnicity, n		
Non-Hispanic or Latino		12
Time since UC diagnosis, years, Mean (Median) [Range]		5.3 (4.2) [0.5-16.4]
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, ulcerative 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**).

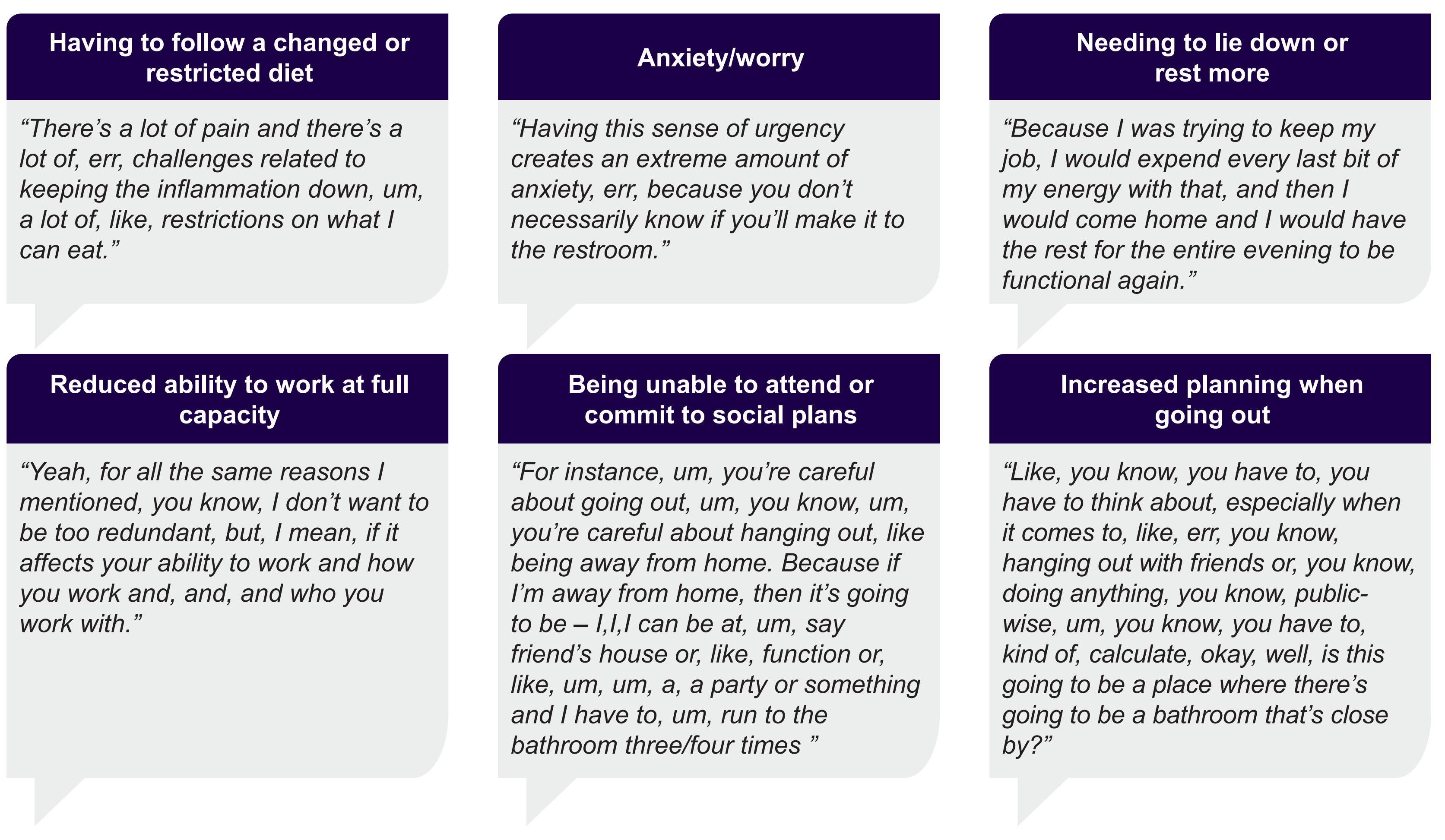
Figure 1. Symptoms of ulcerative colitis reported by patients



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)

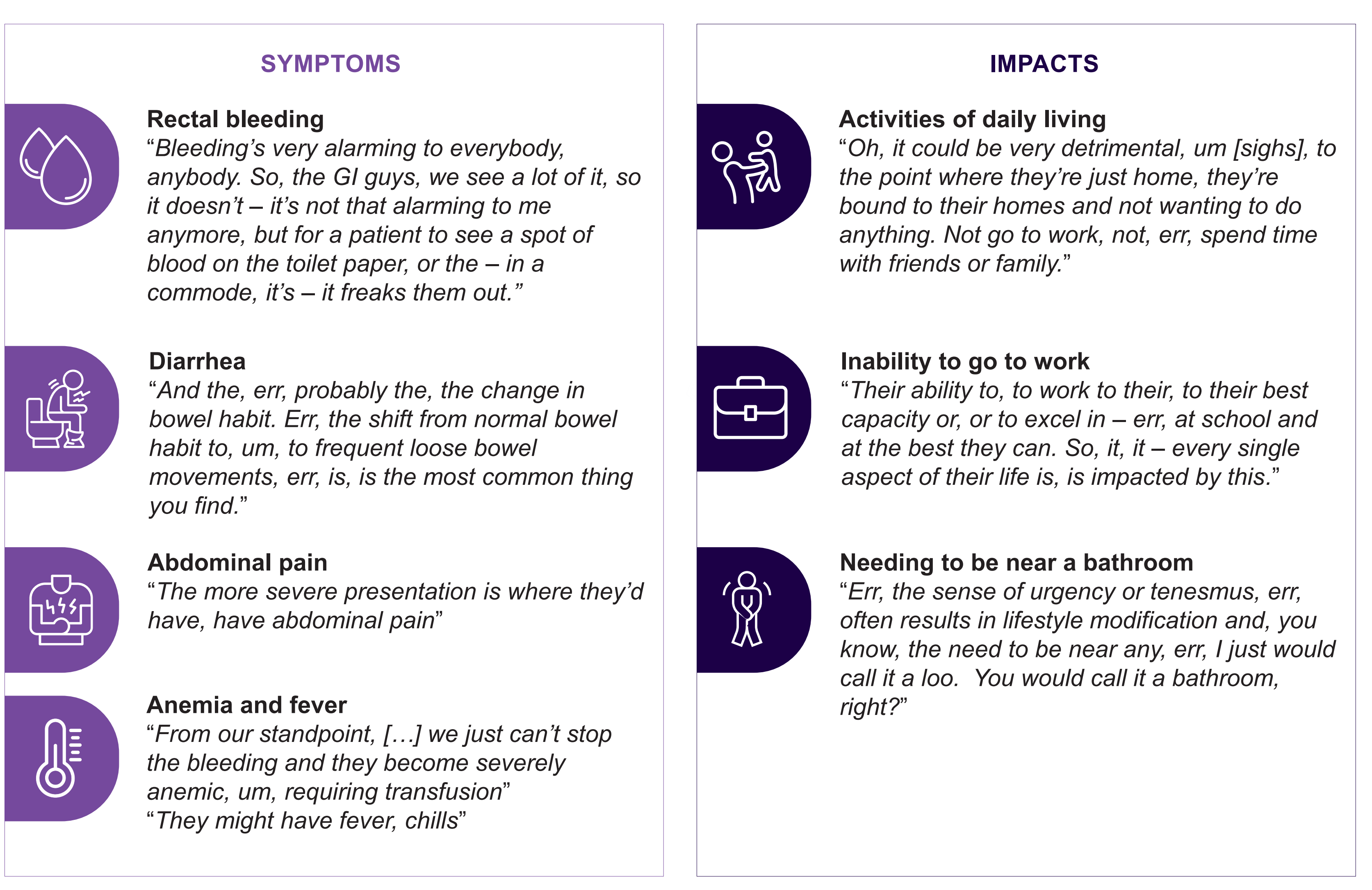
Figure 2. Impacts of ulcerative colitis reported by patients



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**).

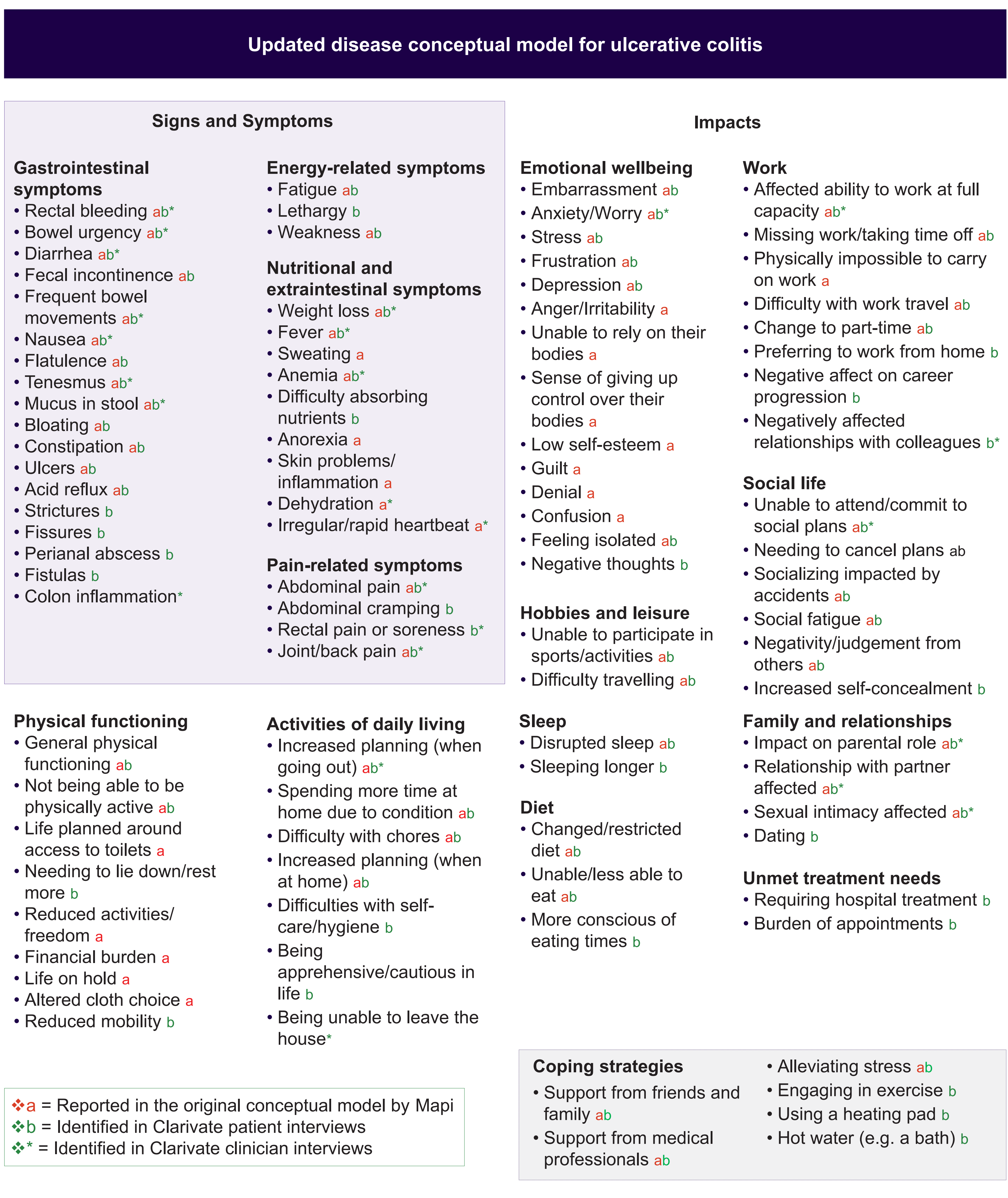
Figure 3. Symptoms and impacts of ulcerative colitis reported by clinicians



Conceptual model

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

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



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.**

References

- Knowles et al. *Inflamm Bowel Dis*. 2018; 24: 742–751.
- Mokrowiecka et al. *Adv Med Sci*. 2008; 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.

Acknowledgement

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

Contact information

Kyran Jones | kyran.jones@sanofi.com