

A QUALITATIVE STUDY EXPLORING THE BURDEN OF ULCERATIVE COLITIS AMONG CHILD, ADOLESCENT, AND ADULT PATIENTS

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BACKGROUND

- Ulcerative colitis (UC), is a chronic gastrointestinal disease characterized by colonic inflammation.¹
- To develop a comprehensive disease model across various ages, it is important to understand UC symptoms and impacts experienced by children, adolescents and adults.

OBJECTIVE

- To explore the similarities and differences in UC symptoms and impacts across various age groups (children, adolescents, and adults) and develop a disease model.

METHODS

- Children with UC aged 5–11 years and their parents/caregivers were recruited from US clinical sites.
- In-depth, face-to-face, concept elicitation (CE), and cognitive debrief (CD) interviews^{4,5,6} were conducted with children and their parents.
 - Children aged 5–7 years took part in a 45 minute CE interview.
 - Children aged 8–11 years took part in a 60 minute CE and CD interview.
 - Parents of children aged 5–7 years took part in a 90 minute CE and CD interview.
 - Parents of children aged 8–11 years old took part in a 60 minute CE and CD interview.
 - Adults and adolescents with UC took part in a 60 minute CE and CD interview.
- All interviews were conducted using a semi-structured interview guide.
- All interviews were transcribed verbatim and analyzed using thematic analysis⁷.
- The study protocol was approved by Copernicus Group Independent Review Board.

Results

- A total of 67 individuals participated in face-to-face interviews, the participants recruited were:
 - N=8 parents of 2–4-year olds;
 - N=3 5–7-year olds and their parents;
 - N=9 8–11-year olds and their parents;
 - N=14 adolescents (12–17 years);
 - N=21 adults (20–70 years).
- There was a high level of qualitative agreement between cohorts with nearly all symptoms and impacts being discussed by children, adolescents, adults and also observed by the child's parents.
- Stomach/abdominal pain was discussed by all participants.
- The most frequently discussed symptoms (discussed by ≥75%) were: blood in stool, urgent bowel movement, frequent bowel movements, diarrhea, and incomplete evacuation.
 - A few symptoms were only reported by certain cohorts there were: only parents- flu symptoms; only children and their parents - Dizziness/lightheaded; and only adults - excessive sweating.
- Impacts were less frequently discussed than symptoms, no impact was discussed by 75% of the overall sample, however they were consistently discussed across the sample.
- The most frequently discussed symptoms (discussed by >50%) were: low mood and upset (depression); worry, anxiety, fear; limitations on eating and drinking; and embarrassment.
- A few impacts were only discussed by certain cohorts.
 - Only adults and adolescents discussed: irritability, low self-esteem, relationship with others, limitations to ADL, and impact on work.
 - Whilst only children and their parents discussed an impact on physical activities and play.
 - Only adults (N=4) discussed feeling dehydrated due to their UC.
- A unified disease model was created, see figure 1.

Figure 1. Unified disease model of UC

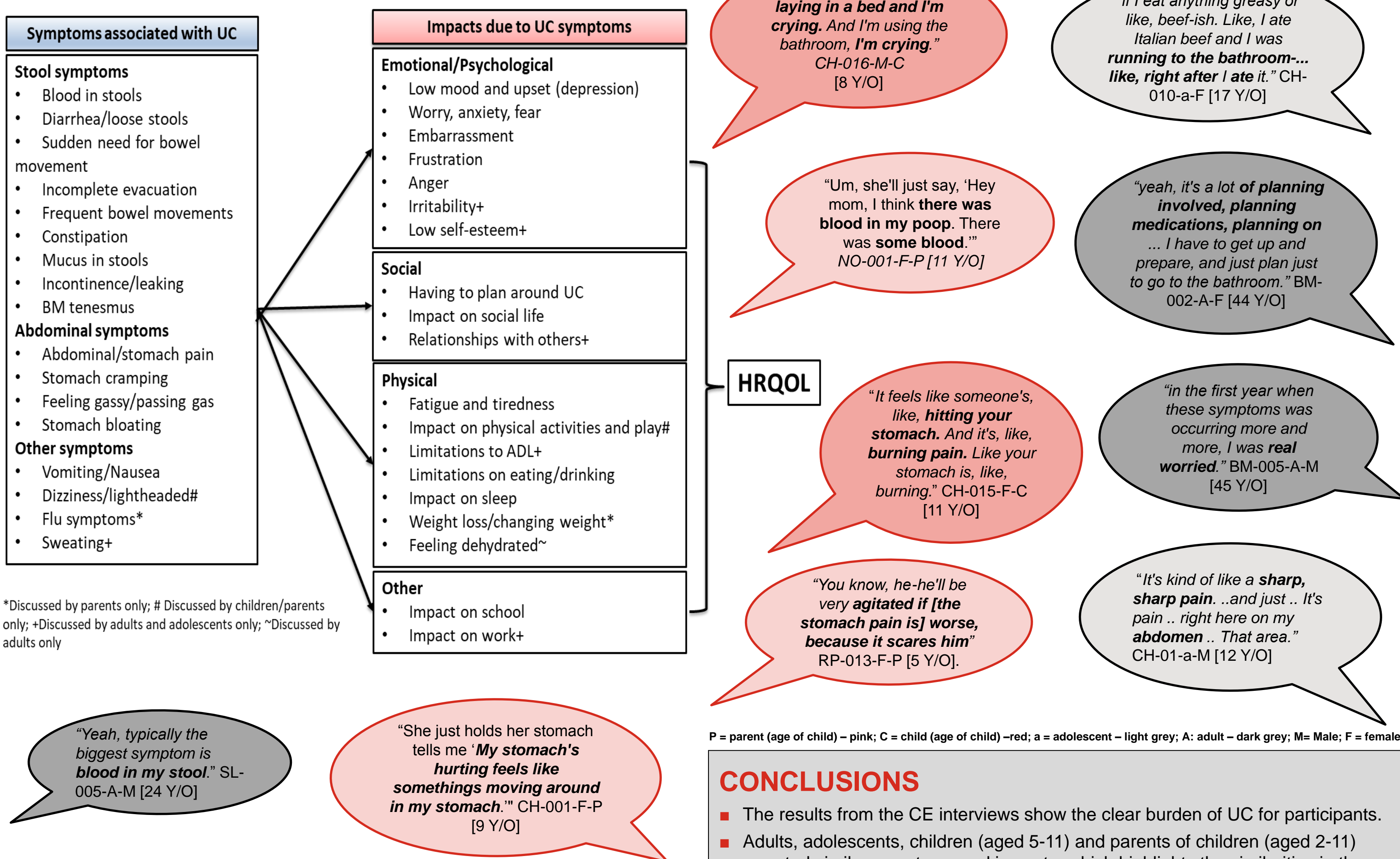


Table 1. Demographics and UC Characteristics

	Child's Age 2-4 years (n = 8)	Child's Age 5-7 years (n=3)	Child's Age 8-11 years (n=9)	Adult (N=21)	Adol (N=14)
Gender – Female	2 (25.00%)	0	5 (55.56%)	11 (53%)	7 (50%)
Race – White	5 (62.50%)	1 (33.33%)	6 (66.67%)	14 (66%)	10 (71%)
Clinician reported severity					
Mild	6 (75.00%)	1 (33.33%)	4 (44.44%)	5 (24%)	9 (64%)
Moderate	1 (12.50%)	1 (33.33%)	5 (55.56%)	8 (38%)	4 (29%)
Severe	1 (12.50%)	1 (33.33%)	0	8 (38%)	1 (7%)
Mean months since UC diagnosis	16.3 (6.88)	21.0 (8.19)	41.7 (20.87)	9.3 (16.00)	3.0 (3.12)
Mean hospitalizations due to UC over past 6 months	0	0	1 (11.11%)	1.5 (1.0 SD)	0
Parent/caregiver data					
Gender – Female	7 (87.50%)	3 (100.00%)	9 (100.00%)	N/A	N/A
Race – White	5 (62.50%)	1 (33.33%)	6 (66.67%)	N/A	N/A
Ethnicity –non-Hispanic	8 (100.00%)	3 (100.00%)	8 (88.89%)	N/A	N/A

CONCLUSIONS

- The results from the CE interviews show the clear burden of UC for participants.
- Adults, adolescents, children (aged 5-11) and parents of children (aged 2-11) reported similar symptoms and impacts, which highlights the similarities in the symptoms and impacts experienced by participants with UC.
- A unified disease model was developed based of the similarities in the concepts discussed, figure 1.
- A few impacts were only discussed in certain age groups, due to them not being applicable to other age groups i.e., impact on work not discussed by children, impact on play not discussed by adults.

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DISCLOSURES

- AN, LD and THG are employees and stock holders at Eli Lilly and Company.
- Clinical Outcomes Solutions is a health research consultancy paid to conduct this research by Eli Lilly and Company.