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

Symptoms associated with UC

Stool symptoms

- Blood in stools
- Diarrhea/loose stools
- Sudden need for bowel movement
- Incomplete evacuation
- Frequent bowel movements
- Constipation
- Mucus in stools
- Incontinence/leaking
- BM tenesmus

Abdominal symptoms Abdominal/stomach pain

- Stomach cramping
- Feeling gassy/passing gas Stomach bloating

Vomiting/Nausea

Other symptoms

- Dizziness/lightheaded#
- Flu symptoms*
- Sweating+

*Discussed by parents only; # Discussed by children/parents only; +Discussed by adults and adolescents only; ~Discussed by adults only

Impacts due to UC symptoms

Emotional/Psychological

- Low mood and upset (depression) Worry, anxiety, fear
- **Embarrassment**
- Frustration
- Anger Irritability+
- Low self-esteem+

Social

- Having to plan around UC
- Impact on social life
- Relationships with others+

Physical

- Fatigue and tiredness
- Impact on physical activities and play#
- Limitations to ADL+ Limitations on eating/drinking
- Impact on sleep

Feeling dehydrated~

- Weight loss/changing weight*
- Other
- Impact on school
- Impact on work+

"Yeah, typically the biggest symptom is blood in my stool." SL-005-A-M [24 Y/O]

"She just holds her stomach tells me 'My stomach's hurting feels like somethings moving around in my stomach." CH-001-F-P [9 Y/O]

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

"[Describing a collage] I'm laying in a bed and I'm crying. And I'm using the bathroom, I'm crying." CH-016-M-C [8 Y/O]

like, beef-ish. Like, I ate Italian beef and I was running to the bathroom-... like, right after | ate it." CH-010-a-F [17 Y/O]

"if I eat anything greasy or

mom, I think there was blood in my poop. There was some blood." NO-001-F-P [11 Y/O]

"Um, she'll just say, 'Hey

"yeah, it's a lot **of planning** involved, planning medications, planning on ... I have to get up and prepare, and just plan just to go to the bathroom." BM-002-A-F [44 Y/O]

HRQOL

'It feels like someone's, like, hitting your stomach. And it's, like, burning pain. Like your stomach is, like, burning." CH-015-F-C [11 Y/O]

"in the first year when these symptoms was occurring more and more, I was real worried." BM-005-A-M [45 Y/O]

"You know, he-he'll be very agitated if [the stomach pain is] worse, because it scares him" RP-013-F-P [5 Y/O].

"It's kind of like a sharp, sharp pain. ..and just .. It's pain .. right here on my abdomen .. That area." CH-01-a-M [12 Y/O]

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.

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