

# Perception of Quality of Life Among People Experiencing or Having Experienced a *Clostridium difficile* Infection in the United States: Qualitative Review of Respondents Verbatim

Lise Lurienne<sup>1</sup>, Pierre-Alain Bandinelli<sup>1</sup>, Thibaut Galvain<sup>1</sup>, Charles-Alexis Coursel<sup>1</sup>, Philippe Boutier<sup>1</sup>, Thomas Spoljar<sup>1</sup>, Caterina Oneto<sup>2</sup>, Paul Feuerstadt<sup>3</sup>  
(1) Da Volterra, Paris, France, (2) Concorde Medical Group, New York, USA, (3) Gastroenterology Center of Connecticut, Connecticut, USA

## BACKGROUND

The incidence, severity and mortality of *Clostridium difficile* infection (CDI) have been increasing during the past 10 years in the USA and in the EU, especially after 2000<sup>1,2</sup>. The number of cases of CDI, in the United States in 2011 was estimated at 453,000 resulting in approximately 29,300 deaths<sup>3</sup>.

The clinical presentation of CDI with toxigenic strains range from asymptomatic colonization, to mild or moderate diarrhea, up to fulminant and occasionally devastating toxic megacolon<sup>4</sup>. It is estimated that approximately 20-30% of patients treated with either metronidazole or vancomycin experience recurrences. Following a first recurrence, the risk of subsequent recurrence increases to 40-60%<sup>5</sup>.

Evans et al.<sup>6</sup> recently outlined that most studies of CDI focus on clinical outcomes including resolution of diarrhea, recurrence and mortality; additional patient-centered outcomes should also be explored. Patient-reported health-related quality of life (HRQOL) changes resulting from CDI have not been studied thoroughly and were derived when needed from utility data of diarrhea or hospitalization<sup>7-9</sup>.

The purpose of this study is to explore the consequences of *Clostridium difficile* infection on patients' quality of life during and after the disease. The main objective of the study is to qualitatively measure the symptomatic, psychological, behavioral, relational and productivity consequences of CDI.

## METHODS

An observational cross-sectional study involving human subjects for the collection of data through an online self-administered survey was conducted among adults living in the USA, with a self-reported diagnosis of *Clostridium difficile* infection. Participants were recruited between August 3rd and November 17th, 2017.

As there is currently no consensus towards assessment of CDI participants' quality of life<sup>10</sup>, we designed a specific qualitative questionnaire to explore the consequences of CDI on the quality of life of participants, with questions adapted from existing questionnaires and experts' opinions.

Participants responded to categorical questions about their history of CDI and the self-assessed consequences of the infection on their lives. All questions were complemented with non-compulsory open-ended fields for comments.

Based upon their responses, participants were categorized into two groups: (i) those self-reportedly experiencing an episode of CDI when participating and (ii) participants reporting a history of CDI without a currently active episode. The two groups were analyzed separately and then compared to assess differences between CDI consequences at the time of infection and the long-term consequences of CDI.

In this analysis, the non-compulsory comment fields were qualitatively reviewed independently by two members of our study team. 33 items (categorized in 5 groups: symptomatic, psychological, relational, adaptation and productivity) were screened and recorded if mentioned spontaneously by participants.

In case of disagreement on the classification of a disputed verbatim between the two reviewers, a third member of the research team decided.

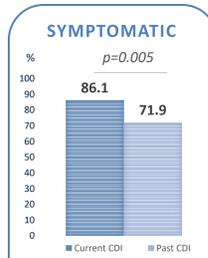
## RESULTS

### Surveyed Population

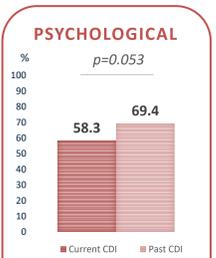
350 individuals filled the questionnaire and were analyzed: 115 subjects (33%) reported an infection at the time of the survey (Current CDI) and 235 (67%) reported an history of CDI (Past CDI).

	Current CDI N (%)	Past CDI N (%)	Total N (%)
<b>Subjects</b>	115 (32.9%)	235 (67.1%)	350 (100%)
<b>Gender</b>			
Female	99 (86.1%)	204 (86.8%)	303 (86.6%)
<b>Age Group</b>			
< 31	13 (11.3%)	15 (6.4%)	28 (8.0%)
31-40	15 (13.0%)	41 (17.4%)	56 (16.0%)
41-50	26 (22.6%)	45 (19.1%)	71 (20.3%)
51-60	29 (25.2%)	49 (20.9%)	78 (22.3%)
61-70	23 (20.0%)	58 (24.7%)	81 (23.1%)
71-80	5 (4.3%)	17 (7.2%)	22 (6.3%)
81-89	3 (2.6%)	7 (3.0%)	10 (2.9%)
>89	1 (0.9%)	3 (1.3%)	4 (1.1%)

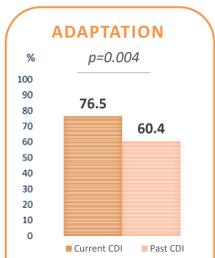
### Consequences by category (at least 1 item spontaneously mentioned)



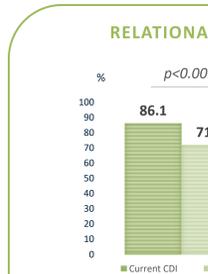
- 9 Items recorded:**
- Diarrhea
  - Physical Pain
  - Fatigue/Weakness
  - IBS
  - Weight/Appetite Loss
  - Hair Loss
  - Brain fog/Dizziness
  - Nausea/Vomiting
  - Hydration issues



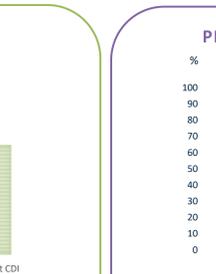
- 8 Items recorded:**
- Anxiety/Stress
  - PTSD
  - Depression
  - Lower self-esteem
  - Fear of recurrence
  - Fear to take antibiotics
  - Suicidal dispositions
  - Fear of death/Thinking they could die



- 8 Items recorded:**
- Wearing diapers
  - Eating habits changes
  - Lactose intolerance
  - Need to be near bathrooms
  - Limited displacement
  - Limited recreational activities
  - Limited contact with others
  - Germaphobia



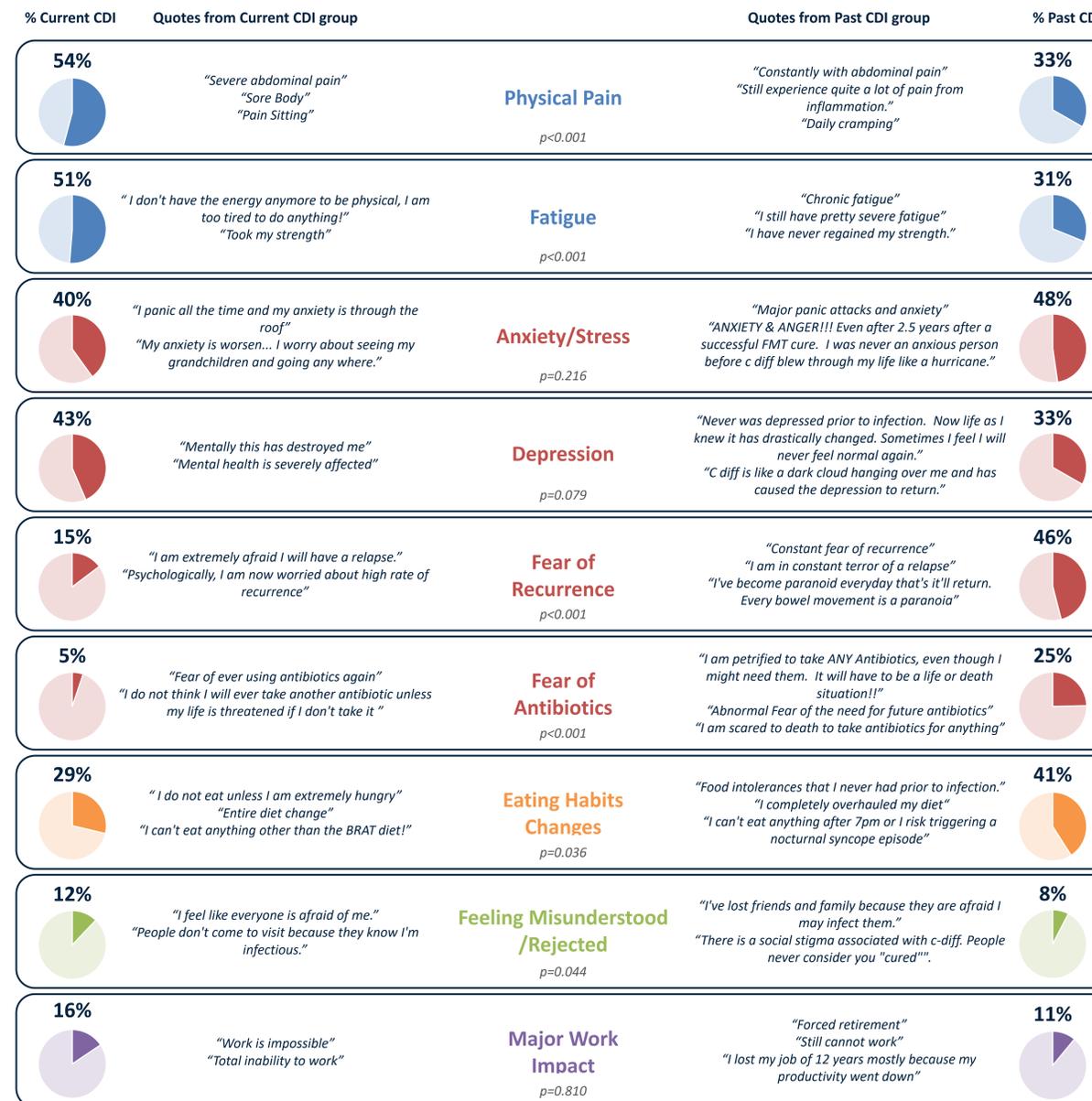
- 4 Items recorded:**
- Fear of an accident/incontinence
  - Feeling misunderstood/rejected
  - Fear to transmit the disease to others
  - Felling lonely/isolated



- 4 Items recorded:**
- Mentioning an economic impact
  - Lower capacities (work/home tasks)
  - Forgetful/Difficulty to concentrate
  - Major Work Impact (Lost job/forced retirement/ Forced changed job)

- A majority of Current CDI subjects (86%) spontaneously reported at least one of the symptomatic consequences, primarily physical pain (55%) and fatigue (51%). This was also seen in the Past CDI participants, albeit less frequently (72%, p=0.005) with physical pain and fatigue being mentioned by approximately one third of respondents after the infection (33% and 31%).
- The share of subjects reporting (without prompting) at least one psychological item was high during and after CDI (58% and 69% respectively, p=0.053). Anxiety/stress and depression were often stated by participants in both groups. Two consequences were seen significantly more frequently in the Past CDI cohort: Post-Traumatic Stress Disorder (11% vs. 0%, p<0.001) and fear of recurrence (46% vs. 15%, p<0.001) including the fear of taking antimicrobials again (25% vs. 5%, p<0.001).
- Lifestyle adaptation measures seemed to decrease after clearance of the infection but were high in both groups (77% Current CDI, 60% Past CDI; p=0.004); many patients reported changes in their eating habits during and after CDI (29% and 41%, respectively, p=0.036).
- Finally, 16% of Current CDI and 11% of Past CDI respondents mentioned a major impact of CDI on their professional life (e.g. lost job, forced retirement or inability to work) (p=0.810).

### Consequence and Verbatim by Item



## DISCUSSION

While the societal burden of CDI is well described in the literature, our study is one of the first aimed at understanding the major burden of CDI on patients' quality of life during and after self-reported episodes.

In our study, in both groups, a majority of patients reported spontaneously being symptomatically, psychologically and relationally affected by CDI as well as having adapted their behavior consequently to the infection.

Our results also reinforce the long-lasting nature of CDI consequences: CDI effects are not only experienced during the infection, but also in the subsequent months after clearance of the infection with similar proportions of subjects reporting psychological consequences (p=0.053). Some items are also mentioned more frequently by participants after clearance of the infection, including PTSD (p<0.001), fear of recurrences (p<0.001) and the fear of taking antibiotics ever again (p<0.001).

These results further reinforce the need for enhanced therapeutics in the prevention and treatment of this devastating infection.

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This survey was determined to be exempt from an Institutional Review Board review under Category 2 (45 CFR 46.101(b)(2)) by Schulman IRB, an independent IRB, on August 3, 2017.

Da Volterra (Paris, France)  
Tel. +33 1 58 39 32 20  
Corresponding author:  
[lise.lurienne@davolterra.com](mailto:lise.lurienne@davolterra.com)



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