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

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**RESULTS**

**Surveyed Population**

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

**Consequences and Verbatim by Item**

<table>
<thead>
<tr>
<th>Category</th>
<th>Current CDI (%)</th>
<th>Past CDI (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Pain</td>
<td>51%</td>
<td>43%</td>
<td>15%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>40%</td>
<td>33%</td>
<td>16%</td>
</tr>
<tr>
<td>Anxiety/Stress</td>
<td>48%</td>
<td>33%</td>
<td>11%</td>
</tr>
<tr>
<td>Depression</td>
<td>43%</td>
<td>33%</td>
<td>10%</td>
</tr>
<tr>
<td>Fear of Recurrence</td>
<td>46%</td>
<td>33%</td>
<td>10%</td>
</tr>
<tr>
<td>Fear of Antibiotics</td>
<td>29%</td>
<td>25%</td>
<td>7%</td>
</tr>
<tr>
<td>Eating Habits Changes</td>
<td>41%</td>
<td>33%</td>
<td>8%</td>
</tr>
<tr>
<td>Feeling Misunderstood/Rejected</td>
<td>41%</td>
<td>29%</td>
<td>8%</td>
</tr>
<tr>
<td>Major Work Impact</td>
<td>12%</td>
<td>11%</td>
<td>4%</td>
</tr>
</tbody>
</table>

**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, 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 patients’ quality of life (QoL), we designed a specific questionnaire to explore and capture the consequences of CDI on the quality of life of participants, with questions adapted from existing questionnaires, guidelines and expert 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-reported 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. Each item (categorized in 5 groups: somatic, 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.

**ACKNOWLEDGMENTS**

We are extremely grateful to Nancy Corral and the Giff Foundation, the *Clostridium difficile* infection support group as well as the Foggy Hill Foundation who helped us disseminate the survey to the population of CDI patients and survivors. We also thank Marie David for her valuable advice when analyzing the data.

This survey was determined to be exempt from an Institutional Review Board review under Category 2 (45 CFR 46.101(b)(2) by Harvard IRB, Independent IRB, on August 5, 2017.

**REFERENCES**


**DISCUSSION**

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

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

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=.058). Some items are also mentioned more frequently by participants after clearance of the infection, including PTD (p=.001), fear of recurrence (p=.001) and the fear of taking antibiotics ever again (p=.001).

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

**CONCLUSIONS**

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 2010. The number of cases of CDI in the United States in 2011 was estimated at 235,000 resulting in approximately 29,300 deaths.

The clinical presentation of CDI with toxigenic strains range from asymptomatic colonization, to mild or moderate diarrhea, up to septic shock and occasionally devastating toxic megacolon; i.e. an 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 60-80%.

Even et al. recently outlined that most studies of CDI focus on clinical outcomes including resolution of diarrhea, recurrence and mortality, hence the patient-centered aspects should 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. 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 somatic, psychological, behavioral, relational and productivity consequences of CDI.

**BACKGROUND**

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