## Original Research Reports

## Mental and Emotional Impairment in Patients With Hepatitis C is Related to Lower Work Productivity

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**Background:** Patients with Hepatitis C virus (HCV) have a higher risk of developing mental and emotional health (MEH) issues compared with the general population. Objective: Our aim was to assess the relationship between MEH and work productivity (WP) in patients with HCV. Methods: Patients with HCV enrolled in multinational clinical trials completed 4 questionnaires (Short Form 36 [SF-36], the Functional Assessment of Chronic Illness Therapy-Fatigue [FACIT-F], Chronic Liver Disease Questionnaire-Hepatitis C Virus [CLDQ-HCV], and the WP and Activity-Specific Health Problem [WPAI:SHP]) while they were not under treatment. The emotional domain (EM) of CLDQ-HCV, the role emotional, mental health, and the mental summary score of the SF-36 were used as the MEH indicators. We compared patients with an EM score of less than 4.66 (range: 1-7), which is the lowest quartile of emotional health, and those with an EM score of more than 6.33, which is

the topmost quartile. Results: A total of 4333 patients were enrolled. Of those, 3,888 had MEH issues and WP data available. Patients were  $52.3 \pm 9.9$  years old, 65.8% of them were male, 63.7% were treatment naïve, 19.7% were cirrhotic, 29.0% reported having a history of depression, and 18.7% had a history of anxiety. Patients at the top quartile of the EM were older, were more likely to be men, had less anxiety and depression, and were less likely to be cirrhotic and fatigued, but they were more likely to be employed as compared with the patients at the lowest quartile of the EM domain (all p < 0.0001). Furthermore, these patients had less WP impairment (0.023  $\pm$  0.101 vs. 0.310  $\pm$  0.288, p < 0.05). Multivariate regression analysis revealed that RE and EM were both predictive of WP scores (all p <0.0001), presenteeism, and absenteeism (all p < 0.003). Conclusion: In patients with HCV, impairment in MEH is predictive of lower WP.

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#### INTRODUCTION

Chronic hepatitis C is a major cause of mortality and morbidity. Although Hepatitis C virus (HCV) is known to cause liver disease (cirrhosis and hepatocellular carcinoma), it also affects patients' well-being and health-related quality of life, which is a major component of patient-reported outcomes (PROs). These PRO aspects of HCV infection can have a profound effect on these patients' everyday life, including work productivity (WP).

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WP is defined as the economic productivity that is directly affected by an illness and is potentially amendable to treatment.<sup>4</sup> Furthermore, WP is composed of 2 components, which are absenteeism, or hours of work completely missed due to an illness, and presenteeism, or impaired productivity while working.<sup>4</sup> Previous studies have shown that patients with HCV have significant WP impairment.<sup>5,6</sup> Historical treatment of HCV with interferon and ribavirin additionally worsened WP during treatment and for at least some time after treatment cessation.<sup>6–8</sup> On the contrary, achieving sustained virologic response, which is equivalent to HCV cure, has been associated with improvement in WP.<sup>6–11</sup>

It is possible that WP impairment is influenced by clinical factors including psychiatric diseases and sociodemographic factors, as well as by patients' experience-related factors captured by PROs. Given the high burden of psychiatric diseases in patients with HCV (such as depression and anxiety) and mental/emotional health (MEH)-related PRO impairments, these factors could influence and drive WP impairment in patients who are infected with HCV. <sup>12,13</sup>

Finally, it is important to note that WP impairment in HCV has direct influence on patients and their families as well as the society. In fact, WP losses due to HCV infection in the United States have been estimated to be more than \$7 billion, and curing HCV can lead to substantial savings. <sup>14,15</sup> In this context, identifying psychiatric and mental health (MH) factors associated with WP impairment in HCV has important implications for the management of these patients. Therefore, the aim of this study was to use a large database of patients with HCV infection to identify psychiatric and MH PRO predictors of WP.

#### **METHODS**

#### Study Population

This study is a retrospective analysis of the data collected in 2012–2015 during 11 multicenter multinational phase 3 clinical trials of anti-HCV treatment regimens. All study participants had chronic HCV infection; patients with compensated cirrhosis, history of failing a previous anti-HCV treatment, or coinfection with HIV were eligible. Inclusion and exclusion criteria for the trials used in this study have been published. <sup>1–23</sup> Age; sex; ethnicity; and extensive

medical history, including self-reported history of anxiety or panic disorders, depression or mood disorders, type 2 diabetes, and illegal drug use and alcohol abuse, were collected for all study participants at screening.

### Emotional Health and Work Productivity

All patients completed 4 standard questionnaires: the Chronic Liver Disease Questionnaire-Hepatitis C Virus (CLDQ-HCV),<sup>24</sup> Short Form 36 (SF-36),<sup>25</sup> the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F),<sup>26</sup> and the WP and Activity-Specific Health Problem (WPAI:SHP)<sup>27</sup> in their native language before receiving any treatment. From the SF-36, CLDQ-HCV, and FACIT-F questionnaires, mental and EH (MEH) domains were selected.

From SF-36,<sup>25</sup> the role emotional (RE), MH, and mental component summary were used as generic mental PROs. There were 3 questions included in the assessment of RE that asked about frequency of having problems, such as cutting down the amount of time doing activities, accomplishing less than desired, or doing activities less carefully than usual, which would be "a result of any emotional problems (such as feeling depressed or anxious)." In the MH questionnaire, 5 questions asked about a proportion of time a patient has been/felt "nervous," "so down in the dumps that nothing could cheer you up," "calm and peaceful," "downhearted and depressed," or "happy." A 4-week recall period was used. The mental component summary score is a linear combination of these 2 items adjusted for their correlation with other healthrelated quality of life-related items of SF-36. The RE and MH scores were transformed to range from 0–100, with greater values indicating better emotional and MH. The mental component summarywas transformed to have a mean of 50 and a standard deviation of 10 in the general U.S. population.

The emotional well-being component of FACIT-F<sup>26</sup> was also used. Its 6 statements, which a patient is supposed to confirm on a scale of 0 ("not at all") to 4 ("very much"), include "I feel sad," "I am satisfied with how I am coping with my illness," "I am losing hope in the fight against my illness," "I feel nervous," "I worry about dying," and "I worry that my condition will get worse." A 7-day recall period was presumed. The emotional well-being score is designed to range from 0–24, with greater scores indicating better health.

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