



ORIGINAL ARTICLE

# Illness Experience of Patients with Chronic Hepatitis C Participating in Clinical Trials

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**Abstract**

**Objectives:** To understand the illness experience of patients with chronic hepatitis C participating in clinical trials in the sociocultural context of Korea in an in-depth and comprehensive manner.

**Methods:** A focused ethnography approach was used to discover the pattern of illness experience of patients with chronic hepatitis C in the cultural background of Korea. Interviews were conducted with 11 patients with chronic hepatitis C participating in clinical trials and the collected data were analyzed with the domain analysis, taxonomical analysis, componential analysis, and theme analysis proposed by Spradley.

**Results:** With the cultural theme of “less-known illness, less-familiar illness,” four categories were derived: “my illness discovered by accident,” “shaken life,” “scary but inevitable treatment method,” and “precious life that can’t be wasted,” along with 12 properties.

**Conclusion:** Public campaigns or education programs are needed to meet the needs for information on the disease for patients with chronic hepatitis C participating in clinical trials and help the general public acquire knowledge or change view on this disease.

## 1. Introduction

Hepatitis C is a disease in the liver caused by hepatitis C virus (HCV), with estimates suggesting about 150 million people being infected globally (i.e., 1.6% of the population) [1]. Approximately 80% of the patients with hepatitis become chronic [2], developing complications, such as liver cirrhosis, terminal liver diseases, or hepatocellular carcinoma over a few years or decades [3]. In Korea, the prevalence of HCV representing the entire population is not yet known [4], but approximately 10–15% of cases with liver cirrhosis or hepatocellular

carcinoma are estimated to be caused by chronic hepatitis C [5].

HCV is parenterally transmitted, and its major routes of infection are transfusion of blood or blood products contaminated by HCV; organ transplant; intravenous drug abuse including narcotic drugs, unsafe injections, or medical procedures; and sexual contact with HCV carriers [6]. In particular, it is known that the reuse of contaminated needles, endoscopies, dental treatments and piercing, acupuncture or tattooing without appropriate sterilization are the risk factors of HCV infection in countries with the high prevalence of HCV [6].

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Because chronic diseases often result in social devaluation or stigma [7], they negatively affect the physical and psychosocial health of patients [8]. A previous study found that patients with chronic hepatitis C experience shame, decreased self-esteem, fear, depression, and isolation [9]. It was also revealed that patients with hepatitis C have a sense of guilt where they hide the disease or attribute it to themselves being careless due to the view that patients with chronic hepatitis C are considered illegal drug abusers [9].

Since 1989, when HCV was first discovered [10], treatments for chronic hepatitis C have been rapidly developed and many direct-acting antivirals are waiting for approval, to replace the standard combination treatment of peginterferon and ribavirin, which has shown many side effects [11]. For these direct-acting antiviral products to be approved by the Ministry of Food and Drug Safety, a clinical trial needs to be conducted on human beings to confirm the effectiveness and safety of the new drugs [12]. Therefore, those who participate in clinical trials may feel scared and anxious due to the possible side effects or uncertainties from the unknown drugs [13], and experience emotional disorders, decreased self-esteem, and powerlessness [14]. For these reasons, patients with chronic hepatitis C participating in clinical trials need to be provided with the appropriate knowledge and information on the clinical trial(s), and an understanding should be made on their experience in illness treatment to support their emotions.

In other countries, studies on the stigma, treatment experience, and illness experience of patients with chronic hepatitis C are actively underway [9,15–17]. In Korea, however, only a very few studies on the illness experience of hepatitis B, among other chronic liver diseases, have been carried out [18,19], and few studies have been conducted on patients with chronic hepatitis C [20].

The illness experience of individual patients varies depending on individuals, families, and societies; it is attributable to the social, cultural, and environmental context of the group to which they belong. A focused ethnography can be used when a researcher focuses on a special aspect rather than a general aspect and is familiar

with the study environment [21]. This study attempted to understand the illness experience of Korean patients with chronic hepatitis C participating in clinical trials in the sociocultural context in an in-depth and comprehensive manner.

## 2. Materials and methods

### 2.1. Research design

This is a focused ethnography to explore the illness experience of Korean patients with chronic hepatitis C who participate in clinical trials in the sociocultural context. The first author of this study was in constant contact with patients with chronic hepatitis C in the Department of Gastroenterology. The gastroenterology outpatient clinic is a place reflecting the culture that can affect the experience of patients and is of help for exploring the culture related to the illness experience of patients with chronic hepatitis C participating in clinical trials. The gastroenterology outpatient clinic for this study is located at a tertiary hospital in a metropolitan city in Korea.

### 2.2. Participants

We included 11 adults who intended to participate in the study after reading the notice for recruiting with regard to the illness experience of patients with chronic hepatitis C participating in clinical trials (Table 1).

### 2.3. Data collection

Data were collected through in-depth interviews and participatory observations. During the interviews, the responses and attitudes of participants and the emotion and feeling of the interviewer were recorded in detail. In-depth interviews were conducted two to three times per participant with each interview taking 1–1.5 hours in a meeting room of the gastroenterology department or a tea house, depending on the preference of participants. Participatory observations were made at the level of observation as participants. The observations as participants were performed in such a way that the author as a medical professional collected data while providing

**Table 1.** General characteristics of participants.

No.	Sex	Age (y)	Educational level	Route of infection	Detection time (years ago)	Occupation
1	Female	69	Elementary school	Acupuncture, Transfusion	26	Full-time worker
2	Female	60	High school	Acupuncture	20	House wife
3	Male	45	High school	Drug, Tattoo	11	Self employment
4	Male	59	High school	Acupuncture	10	Religious man
5	Female	60	Middle school	Piercing, Dental treatment	2	House wife
6	Male	57	High school	Drugs	15	Self employment
7	Male	49	High school	Drug, Tattoo	4	Crewman
8	Female	63	Elementary school	Acupuncture	3	House wife
9	Male	56	High school	Acupuncture, Tattoo	12	Self employment
10	Female	64	Elementary school	Tattoo	3	House wife
11	Male	59	High school	Drug	15	Self employment

consultations and treatment processes by responding to the demands made by participants.

**2.4. Ethical issue**

The study was approved by the Institutional Review Board (IRB No. 1041386-20150826-HR-008-03), and was conducted in accordance with the principles of the Declaration of Helsinki. Before data collection, the participants provided signed informed consent. Their rights and privacy were protected throughout the study.

**2.5. Data analysis**

Data were analyzed with the domain analysis, taxonomical analysis, componential analysis, and theme analysis proposed by Spradley [22]. In the first step, the recorded interviews by participants were transcribed. An overall picture for the treatment of patients with chronic hepatitis C was drawn through this step. In the second step, a categorization was made by planning the questions for the next steps or the focuses of observations and considering the semantic relations of the explored data based on the domain analysis. In the third step, a componential analysis was performed, in which the properties of the categories were systematically derived by classifying the data into similar meanings. In the fourth step, the process of the theme analysis was carried out, where the culture theme that reappeared both implicitly and explicitly in the treatment processes for patients with chronic hepatitis C and repeatedly appeared in the culture was discovered.

**3. Results**

The results of the analysis using a focused ethnography showed that four categories and 12 properties

were derived with the cultural theme of “less-known illness, less-familiar illness” (Table 2). The properties in each category are as follows:

**3.1. My illness discovered by accident**

**3.1.1. Uncertainty over the incurable disease**

*I heard that there would be no cure at all, and I need to sleep well, try not to gain weight and not to be picky about food. [Participant 1]*

*I was scared because there was no medication for the disease. I seemed to get more addicted to drugs because there is no medication for the disease. [Participant 6]*

**3.1.2. Regret over the reckless life in the past**

*I had led a reckless life until my late thirties. I couldn't take care of my health at the time. [Participant 3]*

*I had repeatedly made up my mind to quit drugs, but I kept failing. Even after I was arrested, I couldn't stop it. I was completely crazy. I was a psycho ... really insane. [Participant 6]*

**3.1.3. Unexpected responses from and ignorance of people around me**

*A majority of people don't know about hepatitis C and hepatitis B. They might have heard about liver cirrhosis, but hepatitis C. [Participant 6]*

**Table 2.** Cultural theme, categories, and properties.

Cultural theme (1)	Categories (4)	Properties (16)
Less known illness, less-familiar illness	My illness discovered by accident	Uncertainty over the incurable disease
		Regret over the reckless life in the past
		Disappointment to medical staff who did not explain properly
		Fear for the development of the disease
	Unexpected responses from & ignorance of people around me	Alert against indiscreet supplementary & alternative therapies
		Scary but inevitable treatment method
		Frustration from the side effects of the existing standard treatments
		Encouragement from people around me
	Shaken life	A slowly developing hope in difficult time
		Precious life that can't be wasted
		Thorough medication compliance
		Expectation for the removal of stigma
	My intention to be totally changed	

*People called me a junkie behind me. Now they can't call me a junkie in front of me because of my human right. I carry a law book with me because I want to sue them. Now, it is not acceptable to call someone a junkie. [Participant 6]*

### 3.2. Shaken life

#### 3.2.1. Disappointment to medical staff who did not explain properly

*To be honest, I was responsible for not doing my own research, but the physicians who treated me did not explain properly. If they explained the process and development of my disease, I could know how serious my disease was. They just showed me the chart in English, and when I asked something, they only said it would be OK. I thought I was OK because the physicians told me that I would be OK. [Participant 9]*

#### 3.2.2. Fear for the development of the disease

*Whenever I felt tired, even while washing dishes, I thought I felt sick because of my hepatitis. I thought it might be due to the elevated values from my test. After the exam in March, I went for another exam every month in May, June and July, because I was concerned. [Participant 2]*

#### 3.2.3. Alert against indiscreet supplementary and alternative therapies

*I have never tried something that people say is good for the liver. I have never taken Korean herbal medicine. Someone suggested me take oriental raisin tree tea, but I didn't feel like taking it. If it were that effective, why would not other people take it? [Participant 1]*

*I found from the Internet that I must not take Korean herb tea or raw food in particular. Since then, I stopped eating raw fish due to the possible infection from parasites, although I used to enjoy eating raw fish. [Participant 7]*

### 3.3. Scary but inevitable method

#### 3.3.1. Frustration from the side effects of the existing standard treatments

*When I first got the injection, I thought I would die. I couldn't do my work because I felt like my body was burning. I was totally exhausted and almost dead because of the terrible fever overnight. The next morning, pain was gone, but I didn't have appetite. I lost 8 kg within a month. [Participant 7]*

*In the beginning, I was treated with the Interferon and Ribavirin combination. It was a 48-week treatment course for 1 year, and I still clearly remember that time. I had fever, body ache, including my four limbs, headache, shortness of breath, which made my walking hard, thinned hairs, lost weight, retching, insomnia and depression. I endured all of those for my treatment. [Participant 9]*

#### 3.3.2. Encouragement from people around me

*My friend told me not to drink alcohol and just get treatment. He was worried about the possibility of my getting cirrhosis and ending up dead. He told that he cared for me a lot next to his family and cried. [Participant 1]*

*I learned from the TV that medication for hepatitis is more effective than that for hepatitis B from a year before. [Participant 8]*

#### 3.3.3. A slowly developing hope in difficult time

*I haven't been in the society for over 10 years because I was in jail. I was insane. I can now focus a little on my disease as there is treatment medication available. I am not distracted now because I have a job in a small company. Now, I think narcotic drugs are not better than salt. They are useless. [Participant 6]*

*About three of my friends died of liver diseases. I was scared and thought I needed to get treatment now. I was also encouraged by the news that the new medication is very effective. [Participant 11]*

### 3.4. Precious life that can't be wasted

#### 3.4.1. Thorough medication compliance

*I think I am really lucky because I can get this treatment after a long wait. It is like winning a lottery. [Participant 11]*

*I don't find the treatment process difficult. There is no problem, but I skipped taking medication twice by mistake. I am a little concerned that missing medication can result in a bad treatment result. Is it possible to get two more pills for me? [Participant 2]*

#### 3.4.2. Expectation for the removal of stigma

*Once I am cured, I can proudly say that I have been suffering from hepatitis C and finally overcome all the difficulties from the disease. [Participant 9]*

*It doesn't have to be badly recognized. Although it is only infected through blood, people are a little hesitant about being near me. I want to be a leader in changing such recognition.* [Participant 9]

### 3.4.3. My intention to be totally changed

*I can't express it in words. There is no way to do that. I want to spend the rest of my life for contributing to something good. How can I waste this blessed life? I am going to do something that can make people happy.* [Participant 8]

## 4. Discussion

This study employed a focused ethnography approach to derive psychological change and cultural significance experienced by patients with hepatitis C, which is not well-known in the sociocultural background of Korea, while they were participating in clinical trials.

From this study, the cultural theme of “less-known illness, less-familiar illness” was derived in the cultural domain of the illness experience of Korean patients with chronic hepatitis C. With this theme, four categories were derived: “my illness discovered by accident,” “shaken life,” “scary but inevitable treatment method,” and “precious life that can't be wasted,” along with the semantic structure of 12 properties. Each category is discussed in the following sections.

In the first category of “my illness discovered by accident,” the major experience related to the diagnosis of patients was found to include “uncertainty” and “regret.” In addition, they experienced “a sense of stigma” from people around them due to the lack of awareness of hepatitis C. Hepatitis C is more chronic than hepatitis B (5% vs. 50–80%) [23] and has a long process of development without specific symptoms [24]. Therefore, the diagnosis of hepatitis C often causes frustration to the patients, because they usually are diagnosed during their regular check-ups without any symptoms for a long time. In Korea, the combination treatment of peginterferon and ribavirin had been a standard treatment for hepatitis C until the revision of the treatment guideline by the Korean Association for the Study of the Liver in 2015 [25]. However, the combination treatment had many side effects and required a longer treatment period with a lower cure rate. As a result, those who were diagnosed with chronic hepatitis C felt uncertain due to the recognition that it is not easy to be treated, and regretted for their behaviors in the past. In addition, a social stigma was created because of the lack of knowledge on the transmission routes of hepatitis C by the general public. Therefore, an education program needs to be developed for patients or

the general public on the causes, transmission routes, and treatment methods of hepatitis C.

In the second category of “shaken life,” patients are unhappy with the medical staff who did not properly explain how to manage the disease after the diagnosis of chronic hepatitis C, and afraid that the disease may rapidly develop into cirrhosis or liver cancer. While they are tempted to take the food that people say is beneficial for the liver, they are also cautious of the food because it can reduce the detoxicating function of the liver. The fact that the participants of this study were not satisfied with the explanation from the medical staff contrasts with the results reported by Sun and Ju [20], who noted that participants considered physicians and nurses their information sources for chronic hepatitis C by 72.6% and 7.1%, respectively. This indicates that although physicians explain patients about chronic hepatitis C, they could not explain enough for patients to be satisfied. Frazer et al [26] also revealed that the level of knowledge on hepatitis C of nurses is lower than that on other infectious diseases. Therefore, education for hepatitis C customized to nurses needs to be provided to the nurses who are in contact with patients with hepatitis C by developing a program based on the knowledge level of nurses on hepatitis C.

In the third category of “scary but inevitable treatment method,” patients were afraid of participating in clinical trials in many aspects and felt frustrated due to the side effect of the existing standard treatments, but they became hopeful with the encouragement by people around them and the results of clinical trials. Although the treatment guideline for chronic hepatitis C was revised in 2015 and took effect partly from 2016, patients are still concerned about the side effects because the new guideline has not been proved on a long-term basis. They, however, made their mind to participate because they did not have other options. Therefore, a program that can reduce the uneasiness of patients by understanding their psychological mechanism needs to be run before they participate in clinical trials.

In the fourth category of “precious life that can't be wasted,” they wanted to be reborn by thoroughly ensuring medication compliance and to change the recognition on the stigma in which people link the cause of hepatitis C with the abuse of narcotic injection. Considering the previous studies suggesting that medication compliance in chronic diseases is better when the level of knowledge of patients is higher [27–28], an effort needs to be made to enhance their knowledge on chronic hepatitis C. To this end, the need of patients for the domain they want to know should be first identified and then a systematic education program should be developed to address such need.

The results of this study will be the basic data to develop an education program to improve the knowledge of the general public or patients with chronic hepatitis C on hepatitis C and prevent the transmission of the disease.

## Conflicts of interest

All authors have no conflicts of interest to declare.

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