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Patient Perspectives on Adherence to the New Hepatitis C Antiviral Medications: 'A New Lease on Life'

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Abstract

This study explored patients' perspectives about taking the new direct-acting antivirals (DAAs) for the treatment of Hepatitis C (i.e., sofosbuvir, simeprevir, ledipasvir/sofosbuvir, ombitasvir/paritraprevir/ritonavir and dasabuvir) to identify facilitators of medication adherence. The project was conducted using semi-structured interviews with 12 Veterans who successfully completed a treatment course on the new DAAs. The Veterans were recruited using purposive sampling. The data collected from the semi-structured interviews was analyzed using an adapted open coding method outlined by Auerbach and Silverstein (2003), with identification of relevant text sub-grouped into repeating ideas, and then creation of overarching themes and constructs. Results obtained provide insight into factors that influenced the Veterans' medication adherence during the course of treatment. Key constructs, embodying major themes supported by repeating ideas, included recognizing the "burden of HCV," the importance of the "treatment engagement process," and anticipation of "positive outcomes." Clinical implications are discussed.

Keywords

Hepatitis C, Adherence, Health Care, Health Behavior, Progressive, Quality of Life, Qualitative Research, Semi-Structured Interviews

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Patient Perspectives on Adherence to the New Hepatitis C Antiviral Medications: “A New Lease on Life”

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This study explored patients’ perspectives about taking the new direct-acting antivirals (DAAs) for the treatment of Hepatitis C (i.e., sofosbuvir, simeprevir, ledipasvir/sofosbuvir, ombitasvir/paritraprevir/ritonavir and dasabuvir) to identify facilitators of medication adherence. The project was conducted using semi-structured interviews with 12 Veterans who successfully completed a treatment course on the new DAAs. The Veterans were recruited using purposive sampling. The data collected from the semi-structured interviews was analyzed using an adapted open coding method outlined by Auerbach and Silverstein (2003), with identification of relevant text sub-grouped into repeating ideas, and then creation of overarching themes and constructs. Results obtained provide insight into factors that influenced the Veterans’ medication adherence during the course of treatment. Key constructs, embodying major themes supported by repeating ideas, included recognizing the “burden of HCV,” the importance of the “treatment engagement process,” and anticipation of “positive outcomes.” Clinical implications are discussed. Keywords: Hepatitis C, Adherence, Health Care, Health Behavior, Progressive, Quality of Life, Qualitative Research, Semi-Structured Interviews

Hepatitis C virus (HCV) is a widely recognized public health concern in the United States (Centers for Disease Control and Prevention [CDC], 1998; Edlin et al., 2001; Evon et al., 2013; Lawitz et al., 2013; Ly et al., 2012; Moyer, 2013; Sloan, Straits-Troster, Dominitz, & Kivlahan, 2004; Veterans Health Administration, 2015). It is the most common chronic blood borne infection in this country (Alter, 1999; CDC, 2011), particularly in the Veteran population. Globally, about 185 million individuals are infected with HCV, which is a seroprevalence rate of HCV of 2.8% (Hanafiah, Groeger, Flaxman, & Wiersma, 2013). While in the general US population, prevalence of HCV is estimated at 1.8% (CDC, 1998), the prevalence among Veterans enrolled in the Veterans Healthcare Administration (VHA) is much higher, ranging between 8% - 10% (CDC, 1998; Lawitz et al., 2013; Ly et al., 2012; Sloan et al., 2004; Slomski, 2014). VHA is the largest HCV care provider in the United States, serving between 174,000 and 180,000 Veterans between 2009 and 2013 (Veterans Health Administration, 2015). The consequences of chronic HCV infection are well known and mainly consist of cirrhosis and hepatocellular carcinoma that lead to increased healthcare costs

and an increased mortality. Projected medical costs for treating HCV between 2010 and 2019 could reach \$10.7 billion in direct care and a \$54.2 billion societally (Wong, McQuillan, McHutchison, & Poynard, 2000). HCV has now surpassed human immunodeficiency virus as a leading cause of death in the United States (Rustgi, 2007).

New Direct-Acting Antivirals for HCV

New US Food and Drug Administration (FDA) approved direct-acting antivirals (DAAs) (specifically, sofosbuvir, simeprevir, the combination ledipasvir/sofosbuvir, and the combination ombitasvir/paritraprevir/ritonavir and dasabuvir) became available to patients in 2014 at a cost between \$66,000 and \$84,000 per person for a 12-week course (Brennan & Shrank, 2014; Lawitz et al., 2013; Reau & Jensen, 2014; Slomski, 2014; Steinbrook & Redberg, 2014; Veterans Health Administration, 2015). Some patients who have cirrhosis need a 24-week course of these medications (American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, 2015; Veterans Health Administration, 2015). Compared to traditional interferon-based treatment regimens for Hepatitis C (HCV), these new medications have many benefits. One such benefit is that the new medications to treat HCV have a much lower side effect profile (e.g., less nausea/vomiting, dizziness, depression, sleep problems, skin reactions, headaches, fatigue, flu-like symptoms). Another advantage to taking the new medications is the reduced treatment length and better cure rates (8-24 weeks with a cure rate of 80% to over 90% instead of about 48 weeks with a 45-75% cure rate with interferon-based regimens, depending on a person's genotype [Brennan & Shrank, 2014; Lawitz et al., 2013; Reau & Jensen, 2014; Steinbrook & Redberg, 2014]). Lastly, the non-interferon based treatments are all oral (pills) administration instead of subcutaneous self-injections combined with orally administered medications. The medication prescribed and lengths of treatment are dependent on a thorough assessment of the person's HCV history (e.g., genotype, whether they have cirrhosis, prior HCV treatment, hepatocellular carcinoma [HCC], HIV co-infection). Patients are considered "cured" when the virus is undetectable in their blood three months after treatment completion.

Guidelines for Treatment

The Veterans Health Administration (VHA) has established treatment guidelines for the new HCV medications (Veterans Health Administration, 2015), that require a thorough pre-treatment assessment to identify mainly the patient's HCV genotype, viral load, stage of liver disease (presence or absence of advanced fibrosis/cirrhosis), presence of hepatocellular carcinoma, HIV co-infection, details of past HCV treatment, and mental health and substance abuse issues or cognitive limitations that could affect treatment adherence. Furthermore, the guidelines emphasize that HCV treatment must incorporate strategies to measure and support adherence to the HCV treatment regimen, given the heightened cost of treatment and Veterans' expectations for being cured (Slomski, 2014). At the VHA facility where the study took place, Veterans are required to attend an HCV Education Class (that describes, among other topics, natural history of HCV, available therapies, candidates for therapy) and an interview with a health psychologist.

Treatment guidelines for HCV in the US private sector have been somewhat different from VHA. For individuals receiving HCV treatment in the private sector, insurance companies have set up barriers for treatment, including limiting access to DAAs only to the most seriously ill patients as a result of the high cost of these medications. In contrast, most Veterans receiving HCV care through VHA are eligible for treatment with DAAs. In addition, VHA receives a 40 percent financial discount on the DAAs from pharmaceutical companies.

The DAA treatment supports within VHA (e.g., education class, health psychology assessment) are largely not required in the private sector. Outside the US, pharmaceutical companies have tiered pricing to make these medications more affordable in developing countries, where medication pricing is often negotiated with governments (e.g., 10 dollars instead of up to 1000 dollars per pill; American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, 2015; Philpott, 2014; Vann & Marcellin, 2015).

HCV Medication Adherence

The World Health Organization (2003) defines treatment adherence as “the extent to which a person’s behavior – taking medication, following a diet, or making healthy lifestyle changes – corresponds with agreed-upon recommendations from a health-care provider” (p. 17). More specifically, medication adherence is defined as the patient’s conformance with the provider’s recommendation with respect to timing, dosage, and frequency of medication-taking during the prescribed length of time in order to produce a therapeutic result (World Health Organization, 2003). Unfortunately, approximately 20-30% of all medication prescriptions are not filled consistently, and nearly 50% of medications prescribed for chronic illnesses are not taken as prescribed (Brown & Bussell, 2011; Fischer et al., 2011; World Health Organization, 2003). The direct cost of medication non-adherence to the United States health care system is estimated at \$100 billion to \$289 billion per year (Osterberg & Blaschke, 2005; World Health Organization, 2003).

Poor adherence to new HCV medications can similarly be expected to negatively impact healthcare cost and treatment outcome, given their expense and high adherence requirements for efficacy. Published research on interferon-based treatment regimens for HCV indicated that treatment response was directly affected by how closely the medication regimen was followed (Smith et al., 2007). A person is more likely to achieve a cure with at least 85% adherence to the medication regimen (DiMatteo, Giordani, Lepper, & Croghan, 2002; Evon et al., 2013; Lo Re III et al., 2009). Additionally, poor adherence to new DAAs may lead to the development of resistance to antiviral therapies.

To our knowledge, there has been no published research on factors that facilitate adherence to the new HCV medication regimens. Published literature on adherence to interferon-based treatment regimens, however, point to several facilitative factors, including: the absence of pre-existing psychiatric or substance use disorder, early detection, intervention, and at least a one month period of total abstinence from substances prior to treatment initiation, integrating the HCV medical care with mental health and substance abuse services, implementing necessary support services (e.g., case management, transportation, housing), establishing rapport in the physician-patient relationship, providing adequate education to patients on potential effects of the medications, and developing patients’ positive pre-existing beliefs about the treatment (Edlin et al., 2001; Edlin et al., 2005; Gatti, Jacobson, Gazmararian, Schmotzer, & Kripalani, 2009; Martin-Santos et al., 2008; Neame & Hammond, 2005; Sylvestre & Clements, 2007).

The purpose of this study was to identify factors that promote adherence to the new non-interferon based HCV medications among Veterans. The study originated when the VHA Chief of the Digestive Diseases Service (third author) contacted the Chief of the Psychology Service (fourth author) to form a team with her to better understand factors that would support Veterans’ HCV medication adherence to achieve cure and improve health outcomes. The first author, who worked as a health psychology fellow in the Digestive Diseases Service, and the second author, who had qualitative research and integrated primary care/mental health clinical expertise, joined the team for this project. Currently, all four authors work at VHA in various

clinical, administrative, and research capacities to support health-related behavior change among patients who receive medical services in primary care and specialty medical settings.

Methods

This study involved the use of a semi-structured interview and qualitative analysis of the experiences of Veterans living with HCV who successfully completed their prescribed non-interferon based DAAs. The study was conducted between January and October 2015. No prior published research had identified factors that facilitate adherence to the new HCV medication regimens. Thus, the authors took a naïve perspective and used a grounded theory qualitative approach in order to better understand the Veterans personal experiences taking these medications. This approach allows for a more open-ended exploration of the participants' perspectives. Moreover, grounded theory allows for the construction of a theoretical explanation for the findings that could set the foundation for future research on HCV medication adherence (Strauss & Corbin, 2000).

Recruitment

Following review and approval by the local Veterans Administration Institutional Review Board, Liver Clinic medical staff at a local VHA in the Northeast United States examined the Veterans' VHA electronic health records and identified 29 HCV-positive Veterans who had completed a workup to assess candidacy for DAA therapy (including an HCV Education Class and appointment with a health psychologist), had completed a DAA treatment regimen for HCV, and were actively engaged in outpatient treatment services within the Liver Clinic. These Veterans were mailed an opt-out letter, which requested that they call the research team to indicate if they did not want to participate in the study. If they did not respond within 10 days, the research team contacted them by telephone to describe the study and invite them to participate. One opted out. Attempts were made to reach the all remaining 28 Veterans by telephone, including leaving voicemail messages when unavailable. Twelve Veterans agreed to participate in the study, two Veterans declined participation, and 14 were not reached. The 12 participants subsequently attended an individual session with research personnel to complete the verbal informed consent process involving a review of an information form that outlined the study's purpose, voluntary nature of participation, and potential risks/benefits.

Study Participants

Participants in this study were 12 male Veterans. They were mostly Caucasian (92%), on average about 64 years old, single or divorced (75%), retired or disabled (75%), and from a variety of military backgrounds during the Vietnam era (75%). Course of prescribed DAA therapy completed by the participants were as follows: 12-week course = 9 (75%); 16-week course = 1 (8%); 24-week course = 2 (17%). All participants had undetectable HCV viral loads at the time of semi-structured interviews. They all had multiple medical and mental health comorbidities. Two-thirds of the sample had a history of high adherence to prescribed medications and one-third of the sample had a history of medium to low adherence to prescribed medications (see Table 1).

Table 1. Demographic Characteristics.

<u>Variable</u>	
<u>Male, <i>n</i> (%)</u>	12 (100%)
<u>Ethnicity, <i>n</i> (%)</u>	
Caucasian	11 (92%)
Hispanic	1 (8%)
<u>Age, <i>m</i> (SD)</u>	63.9 (5.5)
<u>Education, <i>n</i> (%)</u>	
High School	4 (33%)
Some College	4 (33%)
BA	2 (17%)
Unspecified	2 (17%)
<u>Marital Status, <i>n</i> (%)</u>	
Single	4 (33%)
Married	3 (25%)
Divorced	5 (42%)
<u>Household Composition, <i>n</i> (%)</u>	
No other residents	5 (42%)
One person	4 (33%)
Two people	3 (25%)
<u>Residence in Miles from VHA, <i>m</i> (SD)</u>	34.9 (29.37)
<u>Employment Status, <i>n</i> (%)</u>	
Employed	1 (8%)
Unemployed	2 (17%)
Retired	5 (42%)
Disabled	4 (33%)
<u>Branch of Military, <i>n</i> (%)</u>	
Army	4 (33%)
Marine Corps	2 (17%)
Navy	4 (33%)

Air Force	1 (8%)
Marine Corps and Army	1 (8%)
<u>Service Connection, n (%)</u>	6 (50%)
<u>Era of Service, n (%)</u>	
Vietnam	9 (75%)
Post-Vietnam	3 (25%)
<u>Combat Exposure, n (%)</u>	5 (42%)
<u>Military Sexual Trauma, n (%)</u>	0 (0%)
<u>Current Medical Diagnoses, n (%)</u>	4 (33.3%)
Diabetes	3 (25%)
Obesity (BMI>30)	7 (58.3%)
Hypertension	4 (33.3%)
Cirrhosis	2 (16.7%)
Varices	1 (8.3%)
Encephalopathy	1 (8.3%)
Hepatocellular Carcinoma	2 (16.7%)
Other Cancers	
<u>HIV Infection, n (%)</u>	1 (8.3%)
<u>Detectable HCV Viral Load, n (%)</u>	0 (0%)
<u>Active Mental Health Diagnosis, n (%)</u>	5 (42%)
Depression	3 (25%)
PTSD	1 (8.3%)
Bipolar	
<u>Current Mental Health Treatment, n (%)</u>	5 (42%)
<u>Active Substance Use Disorder, n (%)</u>	1 (8.3%)
<u>Current Substance Abuse Treatment, n (%)</u>	2 (16.7%)

<u>History of IV Drug Use, n (%)</u>	7 (58%)
<u>Past 30 Days Outpatient Clinic Attendance, m (SD)</u>	1.9 (1.4)
Medical	0.5 (0.7)
Mental Health	0.2 (0.4)
Substance Use	
<u>Morisky Adherence Category, n (%)</u>	8 (66.7%)
High Adherence	1 (8.3%)
Medium Adherence	3 (25%)
Low Adherence	

Note. For the Current Medical Disorders category, the percentages exceed 100% because patients could have multiple medical comorbidities. For Morisky prescribed medication adherence scores, interpretation is as follows: 0 = high adherence; 1-2 = medium adherence; and 3 or more = low adherence.

The Semi-Structured Interview

All authors developed a semi-structured interview to obtain information about factors that influenced Veterans' adherence to the new HCV medications. Questions were open-ended and designed to elicit perspectives on the experience of living with HCV, being on the new medications to treat HCV, managing challenges throughout their treatment, and completing a course of treatment for HCV (see Table 2). The interview was developed successively: (1) the first author initially drafted questions based on a literature review of issues affecting medication adherence and in consultation with the Liver Clinic staff; (2) co-authors reviewed and edited questions to target areas of interest for this study, while minimizing suggestion in questioning; and (3) the first author conducted mock interviews with Liver Clinic staff to eliminate redundant items and finalize wording.

Table 2. Semi-structured Interview.

-
- 1) What has it been like for you to have Hepatitis C?
 - 2) Why did you choose to receive the new treatment for your Hepatitis C?
 - 3) What has been your experience being on the new medications for Hepatitis C?
 - 4) Why did you choose to stay on the medication and complete treatment?
 - 5) What were some challenges you experienced along the way while you were on the medication?
 - a. What, if any, side effects did you experience that you attribute to the Hepatitis C medication?
 - b. How did you overcome them?
 - 6) What helped you with your decision to stay on the medication?
 - 7) What does it mean for you to have completed this course of treatment?
 - 8) What do you think we can do to help patients increase their likelihood of completing treatment?
 - 9) What else would be important for me to know in order to get the best understanding of why you completed Hepatitis C treatment?
-

Morisky Medication Adherence Questionnaire

This 8-item, self-report measure of patient adherence to prescribed medications (Morisky, Ang, Krousel-Wood, & Ward, 2008) was administered to participants following their completion of the semi-structured interview. It has been applied to a broad range of medications used to treat chronic illnesses and to various cultures (Al-Qazaz et al., 2010; Korb-Savoldelli et al., 2012; Morisky, Ang, Krousel-Wood, & Ward, 2008) and has been shown to be a reliable ($\alpha=.83$) measure with good concurrent and predictive validity (Bailey et al., 2012; Morisky, Ang, Krousel-Wood, & Ward, 2008; Reynolds et al., 2012). A total score is interpreted as follows: 0 = high adherence; 1-2 = medium adherence; and 3 or more = low adherence.

Semi-Structured Interviewing

After providing consent, Veterans completed the semi-structured interview about their experiences with taking the new HCV medications. The first author conducted the interviews using a semi-structured format to guide the line of inquiry (see Table 2). The interviewer adopted a non-leading style and used open-ended questions to probe for elaboration about factors influencing the participants' medication adherence. During the interview process, the first author took brief manual notes while the participants responded as a means to highlight words of interest for further inquiry. Information about the participants' demographic background, medical issues, and mental health /substance use history was extracted from the electronic health record following the semi-structured interview. All interviews were audio

recorded and took about one hour to complete. The first author transcribed all of the recorded interviews. These interviews were conducted until there was a saturation of data.

Qualitative Data Analysis

All interviews were coded using an adapted coding method outlined by Auerbach and Silverstein (2003), rooted in grounded theory as described by Strauss and Corbin (2000). The first and second authors coded and thematically analyzed the interview transcripts. First, each author independently identified relevant text (i.e., Veterans' reasons for adherence to the new HCV medications, factors that facilitated their adherence, and how they successfully managed barriers that arose during their trial), subgrouped the relevant text into repeating ideas (i.e., participants' use of similar words or sentences to convey the same idea), and coded them within the transcripts. The authors conducted this open coding line-by-line for all transcripts. Afterward, the authors compared their coding, resolved discrepancies, and identified overarching themes from the repeating ideas that describe the Veterans' subjective experiences. Next, they categorized themes into theoretical constructs, which function to tie qualitative data to overarching frameworks through which to understand results. The last author reviewed the identified repeating ideas, themes, and constructs across four transcripts he randomly selected from the complete set of 12 and confirmed their presence. Finally, the first author calculated the percentage of participant interviews in which each theme and repeating idea was present.

Results

Three theoretical constructs, nine themes, and 28 repeating ideas (italicized in text below) were identified within the transcripts and coded. Table 3 lists the percentage of participant interviews in which each theme and repeating idea was present.

Table 3. Theoretical Constructs, Themes, and Repeating Ideas.

TC 1: Burden of HCV
T 1: Chronic Illness with Chronic Negative Impact (100%)
RI 1: "I'm Not Healthy" (100%)
RI 2: "It's Always in the Back of Your Mind" (83.3%)
RI 3: Stigma (50%)
RI 4: Interactions Between Mental Health and Substance Use Disorders (25%)
T 2: Knowledge is Power (100%)
RI 5: Course of HCV and Its Consequences (91.7%)
RI 6: Pros/Cons to New Non-Interferon Versus Interferon-Based Treatments (75%)
TC 2: Treatment Engagement Process
T 3: Treatment as "No Brainer" (100%)
RI 7: Realistic Hope for Cure (100%)

RI 8: “I Want to be Healthy” (100%)

RI 9: Improved Quality of Life (83.3%)

T 4: Easy Treatment (91.7%)

RI 10: Simplicity of Regimen (91.7%)

RI 11: Clear End to Treatment (41.7%)

RI 12: Manageability of Side Effects (83.3%)

RI 13: Availability of Medications (83.3%)

RI 14: Aversion to Interferon (83.3%)

T 5: Provider Facilitation of Treatment (83.3%)

RI 15: Clear and Honest Communication (58.3%)

RI 16: Rapport with Providers (50%)

RI 17: Trust for Provider Expertise (83.3%)

T 6: Patient Facilitation of Treatment (100%)

RI 18: Routine for Medication Adherence (75%)

RI 19: Commitment to Behavioral Strategies for Managing Side Effects (91.7%)

RI 20: Self-encouragement (75%)

RI 21: Determination to Complete Treatment (100%)

T 7: Social/Economic Facilitation of Treatment (58.3%)

RI 22: Supports are Key (50%)

RI 23: Cost is Important

TC 3: Positive Outcomes

T 8: “I’m Free” (75%)

RI 24: “I Don’t Have to Worry Anymore” (58.3%)

RI 25: “A New Lease on Life” (58.3%)

T 9: System Variables in New HCV Treatment (83.3%)

RI 26: Satisfaction with the VHA System (50%)

RI 27: “The VA Saved My Life” (58.3%)

RI 28: Areas in Need of Improvement (66.7%)

Note. TC = Theoretical Constructs; T = Themes; RI = Repeating Ideas.

Theoretical Construct 1: Burden of HCV

Theme 1: Chronic Illness with Chronic Negative Impact (100%). All Veterans discussed their concerns about how HCV progressively impaired their health and would be fatal without treatment. (“*I’m not healthy*” [100%]). Veteran’s spoke in detail about how their

poor health negatively affected their lives physically, emotionally, and socially (e.g., “I wanted to get rid of the virus. I want to have a healthy, normal life.”).

Most Veterans noted how “[HCV is] *always in the back of your mind*” (83.3%). They emphasized the psychological distress of HCV, even in the absence of physical symptoms (e.g., “It’s a burden in itself... you know you’re sick you’re always waiting for the other foot to come down”).

The *stigma* of living with HCV emerged as a prevalent theme (50%). Participants discussed how HCV impaired their social functioning and relationships (e.g., “Stigmatized... they think that they’re going to catch it if they come in contact with me, like AIDS or something”).

Some participants (25%) talked about the negative *interactions between mental health and substance use disorders* and how having HCV worsened these conditions (e.g., “[HCV] affected me in all ways...mentally, physically... it was just very stressful...it was wearing on my whole body”).

Theme 2: Knowledge is Power (100%). Veterans identified knowing about *the course of HCV and its consequences* (91.7%) as an important consideration for taking the new non-interferon based HCV medications. They identified the deleterious progression of HCV, its specific effects on the liver, and what might happen without treatment (e.g., “Knowing it’s [HCV]...destroying and scarring up my liver...it’s unhealthy, it carries a death sentence”).

Knowledge about the *pros/cons of the new non-interferon versus interferon-based treatments* factored into the participants’ decision to adhere to their medication regimens (75%). Veterans recognized the advantages of the new HCV medications compared to the drawbacks of the interferon-based treatments, such as length of treatment, flu-like side effects, and self-injections (e.g., “The liver specialist...advised that ‘if it was me, I wouldn’t take [interferon], because I believe that there are some medications in the system that would treat you better’... he said ‘your Hepatitis C ain’t that bad, I would wait until something better comes in the pipeline’”).

In summary, living with progressive HCV is burdensome to Veterans physical, psychological, and social well-being. Reflecting Veterans’ specific burdens in juxtaposition with information about the many benefits of DAAs (e.g., high cure rates, ease of administration, low side-effect profile) could promote greater HCV medication adherence

Theoretical Construct 2: Treatment Engagement Process

Theme 3: Treatment as “No Brainer” (100%). All participants wanted effective treatment for their HCV. They spoke about the new medication giving them a *realistic hope for cure* (100%). Through their own investigation and in discussions with providers, Veterans decided the new treatment’s high cure rate made adherence an obvious choice (e.g., “I was optimistic that I would be cured... that helped a lot”). In addition, all Veterans reported “*I want to be healthy*” and saw adherence to the new HCV medications as critical to that goal. A large portion of Veterans also talked about how treating their HCV could give them an *improved quality of life* (83.3%).

Theme 4: Easy Treatment (91.7%). The majority of the Veterans commented on the relative *simplicity of the regimen* (91.7%) for the new HCV medications, which promoted their treatment adherence. Participants liked the pill form and having clear instructions (e.g., “The protocol is so simple... it’s effortless”).

Some participants liked having a *clear end to treatment* (41.7%). They discussed how the clear and specific timeframe for the treatment allowed them to count down their days of treatment (e.g., “When you’re on this medicine, you have to understand that there’s an end to

it eventually...it's only a temporary treatment for a longer lasting result"), and this bolstered their adherence.

Several Veterans commented how the *manageability of side effects* (83.3%) helped them adhere to the new HCV medications. None of the participants reported any significant side effects that hampered their ability to complete treatment. Some reported mild physical side effects, which they managed independently or with the help of providers (e.g., "It's not that bad at all, this new medication... side effects were manageable").

Most Veterans appreciated the *availability of medications* (83.3%). They discussed how VHA made the new medications easily available to them, and this availability promoted their desire to begin and complete the treatment protocol (e.g., "It [new HCV treatment] was available... they [the VHA] said 'would you... be interested in trying it?' so of course I am...who wants to continue being sick?").

Many participants commented how their own or others' past negative treatment experiences with interferon-based regimens gave them an *aversion to interferon* (83.3%). Veterans said these experiences made waiting for the new medications worthwhile and motivated adherence (e.g., "After the interferon...this [new HCV treatment] was...sweet sailing... this is like taking aspirin...I kept wondering, is this going to do any good...I don't feel anything").

Theme 5: Provider Facilitation of Treatment (83.3%). Veterans highlighted the importance of provider facilitation of treatment. Veterans noted that *clear and honest communication* (58.3%) helped their medication adherence (e.g., "Conversations...were straight forward, professional, to the point, answered all my questions, and I felt very comfortable and that's what led me to proceed with the medication"). Having *rapport with providers* (50%) also mattered to Veterans, particularly in the context of a preexisting positive patient-provider relationship (e.g., "I had a pretty good relationship with my doctor...I had been seeing him a little while...we had a little rapport").

Veterans talked about having *trust for provider expertise* (83.3%). They respected their providers as knowledgeable medical professionals and followed their HCV treatment advice (e.g., "I believe that it's important for me to work with my providers to ensure the best possible results in maintaining a good state of health. I do my part; I can't do the medical part with limited knowledge and limited access to whatever's necessary, so I trust the system").

Theme 6: Patient Facilitation of Treatment (100%). Patient's also engaged in behaviors that supported their medication adherence. Three-fourths of the sample reported that establishing a *routine for medication adherence* was helpful. Participants described integrating the HCV medication regimen into their preexisting daily routines (e.g., "I arranged it so I take a thyroid medication first thing in the morning ...every day and then I would take the medication...at the same time").

Moreover, most Veterans made a *commitment to behavioral strategies for managing side effects* (91.7%). Veterans spoke about how they attempted to cope with medication side effects by trying strategies recommended by providers or other patients (e.g., "I'm a very impatient person to begin with, but that...multiplied...when I was on that stuff [new HCV medication]. I really had to count to 10 a lot...I've got calendars...I got a pad on my desk and I write down everything.").

Veterans typically used *self-encouragement* to promote adherence (75%) (e.g., "I can do this." or "It was only the last two weeks of the program and I kept saying to myself, you only got two more weeks on it, just do it... I had a countdown... all of a sudden... I was right at the end of it"). Veterans reported that this self-encouragement gave them *determination to complete treatment* using all available resources during treatment (e.g., "I was determined to do it.").

Theme 7: Social/Economic Facilitation of Treatment (58.3%). Veterans reported that *supports are key* (58.3%) to success. Veterans talked about how outside support from family and friends helped them to begin the regimen, cope, adhere, and complete the regimen (e.g., “[My wife’s] always been there to push...my wife handles most of the medication.”). In addition, some Veterans spoke about how *cost is important* (25%) and that knowledge of how costly the new medications are made them more motivated for adherence (e.g., “I think the VA hospital has been more than kind in asking me to do this...I know how expensive it is and I appreciate it and I just wanted to go along with their program.”).

These seven themes underscore factors that could better engage Veterans in their HCV treatment. Veterans’ adherence to DAAs could be maximized by emphasizing their realistic hope for cure and expectations for an improved quality of life given the effectiveness of these medications and their simple, clearly delineated regimens. Moreover, teaching Veterans strategies to improve medication adherence, facilitating collaborative patient-provider working relationships that foster trust, and leveraging extant social supports could further support Veterans’ efforts to take their HCV medication regimens as prescribed over the full course of treatment.

Theoretical Construct 3: Positive Outcomes

Theme 8: “I’m Free” (75%). Veterans said “[*they*] don’t have to worry anymore” (58.3%) about being HCV positive and reported a decrease in psychological distress and anxiety following the completion of the medication trial (e.g., “Knowing that...Hepatitis C is at a level where it’s not traceable, it can give me peace of mind...put my mind at ease, one less thing to worry about.”).

Many Veterans felt they had “*a new lease on life*” (58.3%) following treatment completion. They noted having improved relationships and social functioning and discovering new purpose and value in life (e.g., “I’ve been given a new lease on life... it helped me to be more mindful of how I attended to my day-to-day... with nutrition, exercise... supports, a refinement of my values and a sense of... purpose”).

Theme 9: System Variables in New HCV Treatment (83.3%). Participants identified how VHA had successfully established a treatment-accessible system for Veterans to receive the new HCV medication. Half of participants reported relative *satisfaction with the VHA system*. Veterans talked about how the structure implemented in the Liver Clinic helped them adhere to treatment (e.g., “I was at the hospital every two weeks and that was important because... I kept up with my medication... they... guide you... sometimes you’re on a medicine that can have an effect on your mind, you can tend to stop taking the medicine or you don’t take it properly and that can affect the outcome”).

More than half of the Veterans felt “*the VA saved my life*” (58.3%). Veterans appreciated that the VHA provided Veterans with the new HCV medication (e.g., “The VA basically saved my life.”). Nonetheless, Veterans noted *areas in need of improvement* to maximize medication adherence within the VHA system (66.7%) (e.g., “More contact from a doctor or from a professional type of person through the course of the medication... I met with the doctor every two weeks, but that was quick.”).

Successful completion of the HCV treatment regimen resulted in decreased psychological distress and ability to re-engage in productive life activities and social relationships. Bringing emphasis to these positive outcomes and experiences could promote medication adherence. More contact with treatment team members could further improve DAA adherence.

Discussion

Three qualitatively derived theoretical constructs involving the experiences of Veterans' who successfully completed the new HCV medication trials elucidated factors that likely affected their medication adherence: burden of HCV, treatment engagement process, and positive outcomes. Veterans described burdensome psychological distress, anxiety, and worry about having HCV and knowing about the progressively negative and ultimately fatal health consequences of the disease. Learning about the more efficacious and tolerable non-interferon based medications, relative to prior medication options, gave Veterans hope they could lift these burdens and solidified their commitment to medication adherence.

Veterans highlighted the importance of the treatment engagement process. To them, it was a "no brainer" when providers presented to them the high efficacy rates, treatment simplicity, decreased length of treatment with a clear end point, and manageable side effects compared to interferon-based regimens. Veterans looked forward to the ability to transform from "unhealthy" individuals to "healthy" people who had a chance to improve the quality of their lives.

Provider, patient, and social/economic factors also facilitated medication adherence. Conditions facilitating adherence included: (1) having a strong working relationship with one's provider based on trust, open communication, rapport, and respect; (2) harnessing patient-driven strategies to promote adherence, such as incorporating the new medications into preexisting routines, using strategies to cope with medication side effects, and engaging regularly in positive self-talk and encouragement; (3) enlisting support from family and friends; and (4) heightening awareness about the cost of treatment and the opportunity provided to Veterans to receive the new HCV medications. These conditions facilitating adherence support the previously published literature regarding the importance of implementing necessary support services (e.g., case management, transportation, housing), establishing rapport in the physician-patient relationship, providing adequate education to patients on potential effects of the medications, and developing patients' positive pre-existing beliefs about the treatment (Edlin et al., 2001; Edlin et al., 2005; Gatti, Jacobson, Gazmararian, Schmotzer, & Kripalani, 2009; Martin-Santos et al., 2008; Neame & Hammond, 2005; Sylvestre & Clements, 2007).

Upon treatment completion, Veterans report feeling "free," having a new chance at developing healthy relationships, an improved sense of purpose, and a desire to better their lives more broadly (e.g., eating healthier, exercising, being abstinent from substances of abuse, getting additional support for mental health or other medical issues). Most Veterans reported satisfaction with the local VHA system's structure and process for providing the new HCV treatment, and they expressed appreciation and gratitude to the VHA for giving them access to it. In short, they felt they were given "a new lease on life" and wanted VHA healthcare providers to enhance services by providing Veterans prescribed the new HCV medications more professional medical contact throughout the course of treatment.

Clinical Implications

This study suggests that older, medically compromised HCV-positive Veterans view adherence to the new non-interferon DAAs as a fortuitous opportunity to improve their health and quality of life. Veterans, their providers, and VHA policy makers are invested in achieving these life-changing positive outcomes (Veterans Health Administration, 2015). To maximize adherence to these medications, providers should consider the individual medical, psychological, and social burdens stemming from having HCV, educate Veterans about the fatal progression of the disease if left untreated, and introduce information about the acceptability, feasibility, and efficacy of the new medications as a likely pathway to cure. In

addition, given that many HCV-positive Veterans may hold negative views of HCV medication intervention based on their experiences in previous interferon-based treatment trials, distinguishing the new class of HCV medications from interferon-based treatment is particularly important. Talking with Veterans in this manner about benefits of the new vs. older HCV medication options is consistent with motivational enhancement interventions that help patients explore and resolve their ambivalence toward behavior change (Magill et al., 2014). Providers should also help patients develop specific medication adherence plans that identify when patients might take their medications, how they will manage side effects, and how they will encourage themselves to continuously adhere to their regimens. Establishing rapport, building trust, and being clear and honest with patients about their treatment plan, including addressing comorbid mental health and substance use issues, could further maximize patient medication adherence. Moreover, underscoring the positive outcomes reported by other patients who have completed HCV medication trials, perhaps through testimonials, might lend additional confidence and hope to patients who want medical relief and physical and mental rejuvenation from HCV. These various factors for promoting adherence underscore the importance of tailoring one's interventions to the Veteran. Depending on the Veterans and their presenting concerns, certain areas might be more of a focus for their purposes of maximizing their medication adherence.

Veterans in this study expressed gratitude for having access to the new and expensive DAAs and recommended even more contact with their providers during the course of treatment. Specialty medical services may be limited in the amount of additional in-person contact that can be provided (Ford et al., 2012). However, the VHA has many other clinical interventions that could support new HCV medication adherence, such as nurse case managers (Piette, Weinberger, Kraemer, & McPhee, 2001), health psychology consultations (Zeiss & Karlin, 2008), and telehealth interventions such as in-home messaging devices to monitor and prompt adherence (Darkins et al., 2008). In addition, offering Veterans support groups (Perlman, Cohen, Altieri, Brennan, Brown, & Mainka, 2010), shared medical visits (Watts et al., 2009), and increased coordinated contact with other professionals involved in treatment (e.g., mental health or substance use provider) could further promote Veterans' adherence to the new HCV medications.

Current VHA Treatment for HCV

The VHA, being the largest HCV care provider in the United States, has seen a rapid growth in the number of Veterans seeking treatment with the new DAAs (US Department of Veterans Affairs, 2015a; US Department of Veterans Affairs, 2015b; Veterans Health Administration, 2015). Initially, the VHA reported that cost would not be a factor in prescribing the new medications (Ross, 2013), and all Veterans that wanted to be treated were to be treated (Veterans Health Administration, 2015). With this recommendation, 17% of the VHA's total pharmacy budget for fiscal year 2015 was allocated to the new HCV medications, totaling \$696 million (Flynn, 2015). Nearing the end of the fiscal year 2015, the VHA faced a budget deficit of more than \$2.5 billion, largely attributable to the provision of these new medications (Daly, 2015; Oppel, 2015). In response to this deficit, VHA began using the Choice Program to refer Veterans interested in HCV treatment to community, non-VHA providers (Daly, 2015). Along with this outsourcing of treatment, only those Veterans with advanced liver disease are considered top priority for treatment (US Department of Veterans Affairs, 2015a; US Department of Veterans Affairs, 2015b; Wagner, 2015). Given that this study was conducted with Veterans who received HCV treatment within the VHA, it remains unclear what effect the Choice Program will have on Veterans' experiences being treated for HCV and their rates of adherence to the new HCV medications.

Study Limitations and Implications for Future Research

This study's generalizability is limited by its small sample size, focus on older Veterans, and implementation during the initial release of the new HCV medications. Future studies should assess how younger and less medically ill Veterans with HCV view access and adherence to the new HCV medications. Factors affecting their adherence may differ from this study's sample in that the burdens of HCV may not have accumulated to the same degree. Likewise, with the advent of the Choice Program at the VHA and evolving healthcare insurance policies in the United States, the HCV treatment experiences of patients may change, which could influence medication adherence in different ways. In addition, qualitatively examining factors that affect patients who did not complete their new HCV medication treatment trials is needed to identify new strategies to keep patients at risk for dropout in treatment. Participants in this study had completed varying lengths of HCV treatment, including 12-, 16-, and 24-weeks. Future studies should consider how the length of treatment impacts adherence. Finally, following a cohort of Veterans over a longer course of time post medication trial, identifying the accrued benefits, and conducting cost-benefit analyses could provide helpful information to Veterans and inform both healthcare policy and funding decisions as negotiated pricing and HCV treatment services continue to evolve in VHA and non-VHA care settings (American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, 2015).

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