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Permalink

<https://escholarship.org/uc/item/73k565vx>

Journal

Journal of Public Health, 41(4)

ISSN

1741-3842

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Publication Date

2019-12-20

DOI

10.1093/pubmed/fdz045

Peer reviewed

Short Report

HCV treatment barriers among HIV/HCV co-infected patients in the US: a qualitative study to understand low uptake among marginalized populations in the DAA era

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ABSTRACT

Background Well-tolerated, highly effective HCV treatment, known as direct-acting antivirals (DAAs), is now recommended for all people living with HCV, providing the tools for HCV elimination. We sought to understand treatment barriers among low-income HIV/HCV coinfecting patients and providers with the goal of increasing uptake.

Methods In 2014, we conducted 26 interviews with HIV/HCV co-infected patients and providers from a San Francisco clinic serving underinsured and publically-insured persons to explore barriers impacting treatment engagement and completion. Interview transcripts were coded, and a thematic analysis was conducted to identify emerging patterns.

Results Conditions of poverty—specifically, meeting basic needs for food, shelter, and safety—undermined patient perceptions of self-efficacy to successfully complete HCV treatment programs. While patient participants expressed interest in HCV treatment, the perceived burden of taking daily medications without strong social support was an added challenge. This need for support contradicted provider assumptions that, due to the shorter-course regimens, support is unnecessary in the DAA era.

Conclusions Interferon-free treatments alone are not sufficient to overcome social-structural barriers to HCV treatment and care among low-income HIV/HCV co-infected patients. Support for patients with unmet social needs may facilitate treatment initiation and completion, particularly among those in challenging socioeconomic situations.

Keywords comorbidity, direct-acting antiviral treatment, HIV/HCV coinfecting, poverty, safety net, substance use

Introduction

Hepatitis C virus (HCV) is a major public health issue in the United States (US).¹ There are at least 5.2 million Americans living with HCV,² and approximately a quarter of people living with HIV (PLHIV) are coinfecting with HCV.³ Although effective antiretroviral therapy (ART) has extended the life

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expectancy of PLHIV, liver disease remains the leading cause of non-AIDS-related death among coinfecting persons.³

Chronic HCV infection disproportionately affects individuals who are black, low-income, uninsured, homeless, incarcerated, less educated and people who use drugs (PWUD).^{2,4-7} Notably, 80% of HIV-positive Americans who inject drugs (PWID) are co-infected with HCV.⁸ Given that structural and socioeconomic conditions constrain individual behavior and increase vulnerability to infection,⁹⁻¹³ consideration of such conditions has special relevance for achieving the WHO HCV targets by 2030.^{14,15}

The advent of direct-acting HCV antivirals (DAAs) has led to highly tolerable, interferon-free, often single daily dosing oral regimens with 8–12 weeks of therapy.¹⁶ Recent studies show that people who were traditionally less likely to receive older interferon-based treatments (e.g. people living with HIV/HCV coinfection, decompensated cirrhosis, PWUD, unstably housed) are now increasingly prescribed DAAs.¹⁷ Various studies have demonstrated high efficacy and adherence to DAAs among previously excluded groups¹⁷⁻¹⁹ as well as fewer DAA reimbursement restrictions.^{20,21} Although these findings indicate a shift in the prescription of DAA regimens, where those previously deemed ‘unstable’ have become prioritized for treatment,²² HCV treatment gaps still exist among socioeconomically marginalized populations.²³⁻²⁵ Specifically, treatment-eligible persons who are unstably housed or using substances remain less engaged in care,²³ resulting in treatment rates that are unlikely to achieve significant population-level reductions.^{24,25} In addition, while the global medical discourse celebrates a new era of therapy, qualitative studies have shown that discursive constructions of HCV (e.g. HCV as a stigmatized disease)—which have adversely impacted prevention, treatment and engagement²⁶⁻²⁹—endure and may pose potential barriers to DAA therapy from reaching its full potential.³⁰

We sought an understanding of the barriers to treatment in the era of DAA therapy from the perspectives of HIV/HCV coinfecting low-income patients and their providers with the goal of increasing HCV treatment uptake.

Methods

During data collection (April to June of 2014), DAA treatment was FDA-approved and sold in the US, albeit with accompanying restrictions including fibrosis and sobriety requirements.³¹ Several campaigns—both pharmaceutical company advertising and in-clinic patient counseling—ensured that many study participants were aware of DAA therapies.

Sampling and recruitment

Given that (1) HCV treatment delivery necessitates a series of joint decisions by providers and patients regarding issues including patient readiness and costs,³² and (2) current DAA treatments differ markedly from previous HCV treatments, formally assessing both patient and provider preferences is a valuable first step toward new treatment paradigms in the age of DAA treatment.

Patients

US ‘safety net hospitals’ treat individuals who are low-income, publicly insured or uninsured, and are critical in reducing health disparities among socially marginalized persons living with HCV.^{33,34} We recruited patients from the Zuckerberg San Francisco General Hospital and Trauma Center (ZSFG) HIV/AIDS clinic (‘Ward 86’), an urban safety net hospital clinic.³⁴ Providers (including author AFL) presented study information to patients during routine care appointments and referred interested persons to a study interviewer (LM) for more details and potential enrollment. Eligible patients were HIV/HCV coinfecting, ≥ 18 years of age, receiving HIV care, and English-speaking. Persons who had received treatment (interferon-based or interferon-free) were not excluded from the study.

Providers

Hepatologists, HIV primary care providers, and non-HIV primary care providers who had the authority to provide HCV treatment, were identified by HCV care program directors in clinics affiliated with the ZSFG HCV care program and invited to participate via e-mail. Provider recruitment efforts ceased after approximately five e-mail attempts.

Data collection

Using prior qualitative and quantitative HCV research as a starting point,^{32,35-38} both interview guides were developed by author EDR and edited by authors TMN and LM with contributing input from all authors. In-person patient interviews were conducted in a private room by a trained interviewer (LM). Interviews began with a brief overview of DAA regimens, including regimen length, mode of administration, side effects and effectiveness. The patient interview guide posed questions about DAA therapy including concerns and perceived barriers impacting treatment engagement and completion. Interviews took 35 min on average to conduct. Provider interviews were conducted both in-person and on the phone by a trained interviewer (TMN). The provider interview guide included questions about facilitators and barriers of HCV therapy that could impact both the

provider's recommendation for a patient to be treated including mental health, substance abuse and housing status.

Both patients and providers were administered a short demographic survey prior to the interview. All participants were paid \$25 for their time. Interviews were audio-recorded and transcribed verbatim.

Data analysis

From 2015 to 2016, transcripts were coded and analyzed according to Braun & Clarke's steps of qualitative thematic analysis.³⁹ A team of six researchers developed a list of codes and sub-codes after data collection, drawing from the interview guide and an initial review of the data. One researcher (AL) coded all transcripts using Dedoose© software, version 7.5.9 (2016). In accordance with prior research conducted with similar populations, ~20% ($n = 5$) of the transcripts were then double-coded by a second researcher to determine coding discrepancies (TMN).⁴⁰ We did not identify substantial discrepancies between the primary- and double-coding; therefore, the coding and codebook were deemed reliable. Documents summarizing emerging concepts and patterns across patient and provider transcripts were shared among five members of the research team (TMN, AWB, AL, LM and EDR) and discussed in eight two-person meetings (TMN and EDR) and three all-team meetings. Recruitment stopped when patient interviews suggested saturation.

All study procedures were conducted with the approval of the University of California, San Francisco Institutional Review Board. Written informed consent from all providers and written and oral information consent from all patients was obtained.

Results

Participant characteristics

Patients

Among 18 individuals interviewed, 12 were male, 10 identified as non-White, 15 had an average monthly income below \$1000 (median monthly income in the City of San Francisco was \$7287⁴¹), and the mean age was 51 years ($SD = 7$). On average, participants had been HIV-infected for 19 years and HCV-infected for 13 years. A history of homelessness was reported by 15 participants, with three reporting homelessness in the prior 6 months. (The US Department of Housing and Urban Development (HUD) definition of homelessness was used in the construction of the interview guide; however, participants used their own definition and understanding based on their lived experiences during study

interviews.) A lifetime history of injection drug use was reported by 14 participants and four PWID reported injecting in the prior six months. All but one participant was currently taking HIV medications and six people had received previous treatment for HCV.

Providers

Out of eight healthcare practitioners interviewed, four were hepatologists, two were HIV primary care providers, one was a non-HIV primary care provider, and one was a hepatologist nurse practitioner. The provider sample included seven women and three non-White individuals. A history of prescribing interferon-based and/or interferon-free HCV medication was reported by all but one provider.

Study themes

Distinct concepts and categories regarding HCV treatment preferences were identified across interviews as themes. The most prominent themes included (1) comorbidity, (2) treatment challenges in the context of competing needs and (3) perceptions of needs for engaging in DAA therapy.

Comorbidity

Within this safety net clinic environment, HIV/HCV coinfecting participants struggled with the impact of additional health problems, including chronic health conditions and mental health comorbidity. The cumulative burden made addressing each one overwhelming.

You know, it gets confusing when you're being treated for HIV, depression and eventually Hep C. Like, you don't know where one problem ends, as far as symptoms, and where the next one begins. (Patient participant #15)

At times, more serious or complex comorbid conditions eclipsed the management and self-care of other health problems, such as HCV. As a result, both patients and providers frequently subscribed to coping techniques of tackling a single problem at a time. In particular, the idea of getting HIV 'under control' first was a common theme.

No [I have never been recommended Hep C treatment]. My doctor...wants to get my HIV controlled before I go and take the treatment for Hep C just because my HIV could affect or the Hep C could affect my HIV...I think it's a good choice just because, you know any number of things could go wrong where people were dual diagnosis. (Patient participant #10)

This was echoed by an HIV primary care provider who suggested that focusing on the clinically-dominant comorbid

condition—which was often HIV—is a function of medical training and the result of competing health and social needs in this safety net population.

I think the teaching has always been, with regard to coinfection is, you know, treat the HIV first, get that stabilized. And then treat the Hep C. So, if I have a patient who is not engaged in care and not getting their HIV under control, it's really hard for me to recommend getting their Hep C treatment. (HIV primary care provider #2)

Treatment challenges in the context of competing needs

Alongside complex and multiple medical demands, competing priorities of daily living were challenging in this vulnerable patient population. Situations relating to obtaining and maintaining basic needs such as food, housing, and safety exacerbated health conditions by interfering with self-care, disease management, and access to care. Clinicians were aware of, and often attempting to intervene on behalf of, patient social challenges while simultaneously addressing a multitude of related clinic-specific challenges such as drug–drug interactions, drug costs, and high patient volume. While the challenges were described as complicated, frustrating and time consuming, providers still expressed enthusiasm for DAA therapy, particularly in vulnerable populations, and recognized the importance of their continued role as gatekeepers to treatment. One provider noted that the people standing to benefit most from DAA may not be aware of the treatment due in part to competing priorities, making the role of pro-active education by clinicians crucial.

My patients are not asking for Hep C treatment. And it's more like I'm telling them the news, 'Hey, have you heard that there's a new and different way to do this now?' And they're like, 'Oh, okay. I'll think about it. I'll add it to my list of many other things to do.' (HIV primary care provider #2)

As a central component of daily living challenges, many patient participants discussed food insecurity—the limited or uncertain availability of nutritionally adequate foods⁴²—as a barrier to HIV treatment adherence and reflected on how it might also be a barrier to DAA therapy. One participant described how food insecurity constrained ART adherence—and could potentially affect DAA adherence—through the side effects that resulted from taking medication on an empty stomach.

Now, how are [individuals who are homeless] supposed to get food so that they can take their pills? Because...it's very hard to take on an empty stomach...it would be hard because they can't, you know,

they're not guaranteed to eat...You get sick...I have to take food with my pills because they come right up if I don't. (Patient participant #6)

Many participants indicated that the precarity associated with homelessness and unstable housing made planning and prioritizing medication adherence difficult, even if it was just one pill a day.

Well, it'd be hard if you're homeless...Well, for one, you don't know where you're going to be at, and you don't know when you're going to be sleeping. So, right there, it's hard, the same time every day with their pills, right off the bat. (Patient participant #5)

In this safety net setting, histories of violence, trauma, mental health conditions, and substance use were often linked, which made treatment readiness and adherence uniquely challenging.

I don't want to think I have to take pills for the rest of my life... I've been through some traumatic experiences in my life, and taking pills hurts. It hurts my throat...I was choked with a dog chain. So...I go through this traumatic thing every time that I take my pills. (Patient participant #6)

When asked if he had ever tried to get HCV treatment, one participant described how he prioritized abstinence from drug use over treatment:

Well, actually, no, because I wasn't really concerned about Hep C in my life, because I was dealing with just getting myself clean, getting myself...together so Hep C was really not one of my major things. (Patient participant #11)

Providers also discussed the importance of provider support as patients confronted with competing demands and limited resources may be compelled to contend with those demands over medication adherence and engagement in care.

The access piece...I think it's a bigger piece than we talked about because, for instance, ...women with HIV, they don't get treatment because they tend to have lower socioeconomic status, lower financial status, they've got children, so they can't get to the clinic because they don't have bus fare, cab fare, food, child care. So, this is an unmet need... I think it's really, really important...So, we can do better. (Hepatologist #4)

Perceptions of needs for initiating and engaging in DAA

While patient participants expressed interest in trying an all-oral, interferon-free regimen, the perceived burden of

undergoing HCV treatment and taking daily medications without social support was an added challenge. Provider responses regarding the need for support was mixed. One provider noted:

...certainly having someone like a behaviorist who can...be supportive of patients emotionally if they go to treatment I think is important...a lot of our patients don't like going to groups. So, they want to have that individual support...who that might be, is it a professional or is it a peer? [Some clinics] have a lot of really great peer support. (HIV primary care physician #2)

Most provider participants stressed that 'nowadays [with DAA], you don't even need support.'

Because Peginterferon for 48 weeks was really, really hard on patients, and now it's a little bit less in the forefront, the social support. I mean, we can probably get them - a person through [DAA] treatments for three months without a lot of social support. (Hepatology nurse practitioner #1)

While provider perspectives were mixed on whether support was necessary, patient participants consistently mentioned the need for social support provided by family members or healthcare professionals to initiate DAA therapy and encourage medication adherence.

Maybe [I would take the DAA pills] if I had somebody to take it and give it to me, but it's too much. I already take enough pills. (Patient participant #16)

Very challenging...I think that [people starting DAA] would need, like, some sort of support system...somebody that helps them daily with their medication on a regular basis...I guess there's some that, like, would be able to focus and do it on their own, but it's just - not everybody can do that. (Patient participant #1)

Discussion

Main findings of this study

Findings demonstrate that poverty and comorbidity pose significant barriers to initiating and completing DAA-based HCV treatment in clinics serving low-income patients. Results suggest that programs offering systematic, planned and structured support for treatment and unmet social needs during DAA therapy stand to improve rates of treatment completion. Our findings also highlight a clear discrepancy between the low level of support that healthcare providers think their patients need and the higher level of support patients state they need; this gap in understanding

and communication could result in compromised quality of care.

Our participants made frequent comparisons to living with HIV and receiving ART. In a study of current and former PWID seeking HCV treatment in New York City, participants also used HIV as a benchmark for understanding HCV.⁴³ While the NYC participants juxtaposed the perceived severity of HIV alongside HCV, several of our participants described the need to 'control' their HIV before even considering HCV treatment in the context of living with and managing multiple chronic health conditions. Current guidelines do not state an ordered approach to HIV and HCV therapy.⁴⁴ However, given the US Department of Health and Human Services (DHHS) recommendation to initiate ART in all people living with HIV,⁴⁵ many providers start HIV therapy first, followed by HCV treatment. While continued liver damage is a likely result of delaying HCV therapy, both providers and patients of the current study described temporary treatment delays as a bridge to eventual successful completion. All participants expressed an appreciation for the time-sensitive nature of HCV infection and no participant expressed an intention or desire to defer treatment indefinitely.

What is already known on this topic

Our results are consistent with recent literature showing low DAA therapy uptake among vulnerable populations, including people who are homeless and/or using substances.^{23,46} Simply making interferon-free treatments available is necessary but insufficient to overcome barriers to HCV treatment and care among low-income PLHIV.²³⁻²⁵

What this study adds

The focus on the high burden of co-occurring conditions and competing priorities of daily living in participant interviews may explain the low level of DAA uptake in low-income populations. While some providers assume that newer short-courses of DAA treatment may not necessitate support, patients consistently indicate otherwise. Instituting short-term treatment support, including the coordination of comprehensive multidisciplinary team-based care,⁴⁷ utilization of patient assistance programs for individuals without insurance,⁴⁷ expansion of peer support programs,⁴⁸ and implementing strategies to reduce pill burden, while addressing social and structural challenges and competing demands could bridge this health disparity gap among HIV/HCV co-infected safety net patients.

Limitations of this study

The main limitation of our findings is the use of a small convenience sample. However, consistencies were observed between findings reported here and those reported in prior studies,⁴⁷ suggesting some similar barriers to DAA treatment among HIV/HCV co-infected persons from multiple marginalized communities.

Acknowledgements

We deeply thank our research participants for sharing their experiences and time with this study. We also thank our Ward 86 collaborators, including Val Robb, and community collaborators at the Tom Waddell and Ward 93 Methadone clinics.

Funding

This work was supported by an AIDS Clinical Trials Group (ACTG) – National Institute on Drug Abuse (NIDA) supplement (UM1AI068636-09; Subaward 110080, CFDA#93.855), as well as National Institutes of Health mentoring grants, K24DA039780 and K24DA037034.

No financial disclosures were reported by the authors of this paper.

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