Scientific Research Publishing

Health, 2025, 17(5), 594-607
https://www.scirp.org/journal/health
ISSN Online: 1949-5005
ISSN Print: 1949-4998

Hepatitis C Care among People with HIV in Puerto Rico: A Mixed-Methods Study

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How to cite this paper: Rodriguez-Diaz, C.E., Malave-Rivera, S.M., Vargas-Molina, R.L., Soler, M., Otero-Cruz, I.M., Aponte, F. and Agront, N. (2025) Hepatitis C Care among People with HIV in Puerto Rico: A Mixed-Methods Study. *Health*, **17**, 594-607.
https://doi.org/10.4236/health.2025.175038

Received: April 5, 2025
Accepted: May 27, 2025
Published: May 30, 2025

Abstract

A significant proportion of people with HIV are coinfected with the hepatitis C virus (HCV). Many of these individuals who are chronically infected with HCV will develop complications. Effective treatments are available to cure HCV infection and reduce morbidity and mortality, but most people with HCV do not receive them. The present study aimed to describe a sample of people co-infected with HIV and HCV and explore barriers and facilitators to HCV care in Puerto Rico. Using a mixed-method design, we reviewed n = 113 randomly selected medical records of people with HIV and HCV coinfection. Then, we conducted 12 qualitative interviews with a purposive sample of HCV treatment stakeholders (e.g., physicians and pharmacists). Findings indicate that coinfected individuals have been living with HIV for an average of 16.6 ± 7.7 years, 41.6% received HCV treatment, and the average time since the latest HCV treatment was 3.9 ± 4.5 years. The most common HCV genotype was 1a (26.5%; n = 30), 40.7% of the participants were treated with direct-acting antivirals, and 42 (91%) achieved a sustained virologic response. Interview findings suggest that access to HCV treatment is limited mainly due to costs, lack of insurance coverage, limited number of providers, stigma, and challenges to engagement in HIV care. A significant proportion of participants received treatment for HCV infection, and, of those, most achieved sustained virological response. Expanding coverage and increasing the number of physicians who could prescribe HCV treatment might reduce the gaps in HCV treatment accessibility and use among people coinfected with HIV and facilitate HCV elimination. Culturally appropriate interventions remain needed to address low HCV disease awareness and stigma.

Keywords

HIV, Hepatitis C, Puerto Rico, Latinos, Co-Infection

1. Introduction

HIV continues to be a global public health challenge. As of 2023, 39.9 million people worldwide are living with HIV [1]. It is estimated that of the people with HIV globally, 6.2% have been diagnosed with HCV [2]. According to the Centers for Disease Control and Prevention (CDC), of the 1.2 million people living with HIV in the United States (U.S.), 25% are coinfected with the hepatitis C virus (HCV) [3] [4]. People co-infected with HIV and HCV can have serious medical complications, including an increased risk for liver-related morbidity and mortality. Because both HIV and HCV can spread through blood, a significant risk factor for both is injection drug use. Sharing needles or other drug-injection equipment increases the probability of exposure to HIV- or HCV-infected blood. Among people who inject drugs (PWID), HCV coinfection rates increase from 50% to >90% [5].

In the U.S., the estimated prevalence of HCV is 1.0% (95% CI: 0.5% - 1.4%) [6]. Among people with HIV, the prevalence is 21%, although coinfection prevalence varies substantially according to risk group (e.g., men who have sex with men and people who inject drugs) [3]. HCV infection is a leading cause of liver-related death, cirrhosis, and hepatocellular carcinoma [7]. Individuals chronically infected with HCV require ongoing monitoring to assess for the progression of liver fibrosis. Historically, HCV treatments were used sparingly because of their toxic effects and modest efficacy [7]. Since 2013, highly effective, safe, and curative peginterferon alfa-sparing direct-acting antiviral (DAA) drugs for HCV have been available, increasing the number of eligible and willing to be treated [7].

While treatment for HCV for mono- and coinfected patients is available, several barriers continue to challenge the feasibility of providing care and achieving HCV elimination. Although new DAAs have become available and costs continue to decline, the initial retail costs of $83,000 to $153,000 per treatment prompted health plans and payers to institute restrictive policies and pre-authorization procedures for treatment [8]-[10]. Further, restrictive policies on access to new, curative HCV treatments have been documented to challenge access [11]. These policies vary but often include restrictions based on liver fibrosis stage, documented alcohol and drug abstinence, and the practitioner's clinical specialty [8].

In Puerto Rico (PR), a territory of the U.S., HCV remains a significant public health issue. The prevalence of HCV in the general adult population is relatively high at 2.3% (95% CI: 1.3% - 4.2%) when compared to the US, and it is prevalent among 5.2% of people with HIV [12]. Moreover, the overall prevalence of HCV among persons who inject drugs is 76.5% (95% CI: 70.8% - 81.4% [13]. PR experiences a syndemic of unsafe injecting drug use, overdoses with opiates, HIV, and HCV [14] [15], and, overall, policies to curb the HCV epidemic in the archipelago are lacking [16]-[19]. For example, there is no reliable HCV surveillance system. Hence, the ability to accurately estimate incidence, prevalence, risk factors, and the characteristics of those getting infected (e.g., age and risky behaviors) is limited. In clinic-based samples of people with HIV, it has been documented that

13.2% have also received a diagnosis of chronic Hepatitis C [20]. Further, while treatment and cure for HCV are available, the knowledge about access to, retention in, and success of care for people with HIV and HCV coinfection is limited [21]. People with HIV and HCV coinfection may have a faster disease progression that requires better-articulated interventions [22]. Providers of HCV care and other stakeholders supporting the implementation of treatment have the ability and power to improve access to the services needed by those affected by HCV and HIV.

Considering the limited available data informing strategies to eliminate HIV/HCV coinfection in PR, this study aimed to explore the clinical characteristics of people coinfected with HIV and HCV engaged in HIV care in PR and to identify barriers and facilitators for HCV treatment.

2. Methods

We conducted an explanatory sequential mixed-methods study [23]. We collected and analyzed quantitative data, followed by qualitative data collection and analysis. This approach provided an opportunity to describe the clinical characteristics of people with HIV and HCV co-infection and explore stakeholders' perspectives on access to HCV care in PR. After the data were collected and analyzed, we comprehensively interpreted the findings. For the quantitative component of our study, we reviewed medical records from six clinics that have experience providing HCV and HIV treatment in PR. The medical records review was guided by a previously developed and validated instrument created by our research team and used for similar purposes [20]. The data collection instrument included indicators of sociodemographic characteristics (sex, age, etc.), date of HIV and HCV diagnoses, history of antiretroviral therapy (ART), indicators of HIV disease progression (CD4, Viral Load), HCV RNA, HCV Genotype, GFR, APRI, FIB-4, history of treatment for HCV infection, history of methadone use, among others. Medical records included in our sample were randomly selected from all active records of patients who met the inclusion criteria. Data from the medical records were logged on a paper and pen chart review document. Data were digitalized using Quality Data Services (QDS) for management and analysis. Data extracted from the medical records were analyzed using the Statistical Package for Social Sciences (SPSS), version 26. Descriptive analyses were conducted to illustrate the characteristics and clinical outcomes of people with HIV and HCV in PR.

For the qualitative component of the study, we designed a semi-structured interview guide covering the main areas to discuss with key informants. This data collection instrument was developed and reviewed by members of the research team and experts in the HIV/HCV field in PR. All interviews were conducted in Spanish by one member of the research team, who contacted potential participants via phone or email and provided information about the study. Once interest in the interview was confirmed, the interviewer shared the consent form and coordinated a time and place to meet. All interviews were audio-recorded, and par-

ticipants received $100 USD as a token of appreciation for their collaboration in the study. A content analysis [24] was conducted with the assistance of Dedoose. This approach served to identify commonalities and differences in the data and then to focus on relationships between different data sources. Members of the research team developed a codebook with a scheme to guide the analytic process. As transcripts were prepared, we identified patterns and relationships related to the research domains. New codes were added during data collection as new emergent categories were identified. During the analysis, we looked for patterns in and between the data to identify differences and commonalities across respondents. Quotes from the interviews were translated into English for dissemination purposes.

Participants

The clinics for data collection were purposively selected to be inclusive [25] of sites with different models of care, funding sources, geographical locations, and years of experience providing HIV/HCV care. The study sample in each clinic was randomly selected using a web-based random number generator. Included medical records were from adult women and men (inclusive of transgender people) who received HIV-related services in the selected clinics. The inclusion criteria included having a history of HCV coinfection, being 21 years of age or older, and having active medical records for at least 6 months, as evidenced in the chart history. Data collection was conducted by a trained clinician from May to August 2019.

Key informants for the qualitative interviews were purposively selected [25] based on their different roles, experiences, and knowledge about HIV and HCV treatment in PR. Those invited to participate in the interviews included physicians (e.g., family physicians, infectious diseases specialists), HIV care providers, management personnel from the health insurance industry, medical-management personnel at publicly funded clinics, pharmacists, and researchers. Interviews were conducted from September to December 2019. All research activities were approved by the Human Research Subjects Protection Office at Medical Sciences Campus of the University of Puerto Rico.

3. Results

3.1. Characteristics of a Sample of People Co-Infected with HIV and HCV in Puerto Rico

A total of n = 113 medical records were reviewed. As illustrated in **Table 1**, most participants were male (n = 95; 84.1%) and virally suppressed (n = 83; 73.5%). The mean age was 52.3 ± 9.2 years, and the Body Mass Index (BMI) averaged 27.5 ± 6.2 kg/m^2. The average time since HIV diagnosis was 16.6 ± 7.7 years. In terms of HIV health indicators, participants had a mean CD4 count of 636.6 ± 333.6 cell/mm^3 and a mean of 5.3 ± 4.9 years since they started ART. Among those with HCV treatment experience (41.6%), the average time since the latest treatment was 3.9 ± 4.5 years.

Table 1. Characteristics of a sample of people co-infected with HIV and HCV in PR.

Characteristics	Total (n = 113)	
	n	%
Sex		
Male	95	84.1
Female	18	15.9
Virally suppressed	83	73.5
	mean	**SD**
Age	52.3	9.2
Weight (lbs.)	174.8	40.9
Height (in)	66.9	3.6
Body mass index	27.5	6.2
Years with HIV	16.6	7.7
Years since HIV treatment started (n = 112)	5.3	4.9
Years since latest HCV treatment (n = 47)	3.9	4.5
CD4 count (cell/mm^3)	636.6	333.6
CD4 percentage	31.5	11.1

3.2. HCV Disease Indicators

The most common HCV genotype identified in the study sample was 1a (26.5%; n = 30), followed by 1b (13.3%; n = 15) and 1c (8.85; n = 10). However, 24.8% of the records reviewed did not have evidence of being tested for HCV genotype. Also, most records (91.2%; n = 103) showed no RAS testing evidence. The mean eGFR was 59.1 ± 8.1 mL/min/1.73m^2. Only seven participants had a documented APRI score with a mean of 0.7 ± 0.2, and 22 participants had a Fibrosis score mean of 0.5 ± 0.3. The most common Fibrosis stage was F4 (8.9%), although most records (75.6%) did not include information on testing for fibrosis scores. Other clinical indicators documented among coinfected patients included total cholesterol level (164 ± 38.3), hemoglobin of 6.3% ± 1.3 g/dL, systolic pressure of 124.8 ± 15.,9mmHg and a diastolic pressure of 77.7 ± 9.2 mmHg.

As shown in Table 2, most records included documentation of the patient's history of tobacco use (68.1%), substance use (61.1%), and depression (57.5%). Half of the sample (50.4%) had a history of injecting drugs, and 10.6% had had a Hepatitis B infection. Among the women in the sample, 77.8% had evidence of ever being pregnant in their lifetime.

Table 2. Prevalence of comorbidities in a sample of people with HIV and HCV co-infection.

Comorbidity	Total (N = 113)	
	n	%
Tobacco use	77	68.1
Substance use	69	61.1
Depression	65	57.5
Dyslipidemia	57	50.4
Injecting drug use	57	50.4
Hypertension	52	46.0
Obesity	39	34.5
Overweight	33	29.2
Alcohol abuse	25	22.1

3.3. Insurance-Related Challenges

Most participants identified the costs as the most significant barrier to accessing HCV treatment, particularly for mono-infected patients who benefit from PR publicly funded health care services (Known as *Vital* at the time of the study). In addition, participants highlighted the absence of total cost coverage by most insurance companies.

> "*The treatment is really very expensive*. […] *The therapy for the patient's cure, not accounting for laboratories and follow-up care, maybe around $28,000 to $30,000*."

Participants also mentioned the time-consuming procedures for approval and their impact on delaying treatment initiation. They referenced how the existing criteria for treatment (*i.e.*, complicated HCV status, F3 - F4 fibrosis, cirrhosis, hepatic or liver cancer, and transplant candidate) limit access to treatment. Additionally, for active drug-using patients, the required negative test for illicit drug use within 6 months delays treatment initiation and allows for potential HCV transmission. Stakeholders also expressed extreme oversight of eligibility criteria from private health insurance companies, limiting access to patients with justifiable needs.

> "…*In Puerto Rico, the protocol to provide HCV is insane, and right now, there are only funds to treat patients who are coinfected with HIV*."

Some participants indicated that limited strategies from the public health authorities for HCV treatment awareness, outreach, and detection of new cases delay diagnosis and treatment efforts. Similarly, they pointed out the limited up-to-date

studies that provide epidemiological data—specifically incidence and prevalence—to inform a national plan to eliminate HCV in PR. Lastly, they recognized that the limited number of specialists and certified centers providing HCV treatment makes it difficult to access treatment.

"[…] *in Puerto Rico, we are behind in treating those already diagnosed. We have experienced limited access to treatment, and we have really struggled in scaling up testing and diagnosis.*"
Interviewer—"*How many people are authorized to provide* [*HCV*] *treatment in PR?*" *Participant*—"*I will look it up for you now.* [*short pause*] *Roughly, like…it must be about ten, I think.*"

3.4. Individual Challenges

Interviewees perceived that patients perceive seeking treatment is difficult and time-consuming, resulting in frustration and discouragement. Similarly, participants shared how the anticipated stigma associated with HCV and HIV might prevent potential candidates from accessing treatment at specific clinics.

"*Treatment for hepatitis is through a referral process; sometimes* [*the challenge is*] *having to go to another clinic, disclose their HIV status again, say again that they have Hepatitis C, and having to share their* [*clinical and behavioral*] *history again. Often, we have patients who know that we treat HIV and infectious diseases, and they do not want to come to this clinic because they can be singled out. That happens with HIV, but it happens with hepatitis as well because the patients who come here know that they are coinfected or have an infectious disease. Perhaps these ideas of who comes to the clinics affect the patients* [*engagement in care*]. *Some patients think that 'I am not going to receive treatment until there is treatment* [*for HCV available*] *in my primary clinic.'*"

3.5. Facilitators for HCV Treatment

Participants shared that although a significant portion of people with HIV/HCV co-infection have healthcare coverage, most private health insurance plans in PR include some coverage for HCV care. However, it varies by the kind of coverage chosen by the patient. Ryan White Part B/ADAP Program was identified as an essential resource for coinfected patients as it helps them cover their treatment expenses. Clinical trials were also identified as opportunities to access HCV treatment.

"*Some patients benefit through the Ryan White Program, but that is only to coinfected patients. They benefit from the grant for hepatitis medication* [AIDS Drug Assistance Program]."
"[*In centers where they conduct clinical trials*] *they provide services if the patient meets the criteria for inclusion in the study. Those are research studies, so* [*the patient*] *enters the study for free treatment but is limited to the*

drug being studied."

The establishment of the *Advisory Committee in the PR Department of Health* (composed of healthcare providers, researchers, and academics) was considered an advocacy resource to improve treatment access for patients insured by the government's health insurance. Participants also documented that establishing case evaluation committees at HIV-specialized clinics was a resource to facilitate treatment and procedures for coverage.

3.6. Providers and Patients as Facilitators

Interviewees provided several examples of providers and patients supporting HCV care in PR. Among these facilitators, they identified the disposition of providers to go the "extra mile" facilitating procedures to negotiate coverage or accelerate treatment approval, and the "prejudice-free" approach from providers (i.e., not stigmatizing practices such as using recreational drug use). Participants also highlighted the patients' disposition and willingness to seek treatment at available certified clinics.

"*... I have always tried to find and bring* [*to PR*] *as many clinical studies as possible, both with the pharmaceutical industry and as part of the AIDS Clinical Trial Units. That's how we have participated in five or four trials and provided* [*HCV*] *care to 35 or 40 co-infected and mono-infected patients.*"

"*When a patient comes, I am not one of those [physicians*] *who say—'Oh no, you have to quit smoking, and you can't drink even once* […].' *No! I provide treatment to everyone it can be given. I offer it, and I give it to them.*"

3.7. Recommendations

Key informants shared specific recommendations to improve access to HCV treatment in PR. Those recommendations included establishing a national public-financed program to eliminate HCV and revising the national guidelines for eligibility among patients covered by the government's health insurance. Participants also recommended increasing providers' capacity and reducing geographical barriers to access treatment. This approach was also identified as a strategy to reduce anticipated stigma, allowing patients to receive services in their primary care clinic and not disclose their health status to new providers. Finally, it was recommended to certify HIV care providers and primary care providers trained in HCV care to manage coinfected patients.

"*… and what about the 'mogolla'* [*mess*] *that you must be a hepatologist or an infectious disease specialist to provide HCV care? A trained general practitioner can prescribe and provide* [*HCV*] *treatment.*"

Other recommendations shared by participants included developing partnerships for HCV testing, providing navigation services to people with HCV, and developing health advocacy initiatives for people affected by HCV.

4. Discussion

Access to care is fundamental to preventing disease progression and the inherent complications of an HIV/HCV coinfection. Knowing the population that can benefit and the context in which care is provided is necessary to improve access to HCV. This study provides general characteristics of people coinfected with HIV and HCV in PR and a description of the perceived challenges and facilitators for access to HCV care.

The study sample presents similar characteristics previously described among people with HIV in PR, including a low level of hemoglobin that has been discussed as unique and as a driver of specific clinical care (e.g., vitamins and supplements) and social services (e.g., supplemental nutrition services) [20]. While previous studies have assessed comorbidities among people with HIV in PR, to our knowledge, this is the first study to describe a clinic-based sample of people coinfected with HCV. Research conducted by Abadie and colleagues [26] documented social determinants of HIV/HCV coinfection among people who inject drugs in rural PR. They found that coinfection was correlated with older age, a more extended period of drug use, medical insurance coverage, and identifying with a sexual or gender minority group. Our study expands the knowledge about some clinical characteristics needed to understand and propose strategies for access to HCV for all people with HIV and HCV, regardless of a particular risk factor.

The random sample of people coinfected with HIV and HCV included in this study demonstrates clinical characteristics similar to other clinic-based samples of people with HIV in PR [20] [27]. The importance of providing HCV treatment to people with HIV has been widely documented; however, only 41.6% had evidence of having received HCV care in this sample. Results showed that several clinical indicators for HCV care were not recorded in the medical records reviewed, including HCV genotype RAS testing, APRI score, and Fibrosis score. The lack of this information is a barrier to providing prompt and proper care. Further, the results of these tests illustrate that many patients get tested for indicators of HCV disease progression in the late stages of the infection, which could challenge treatment outcomes.

The patients' data reviewed in this study also revealed a high prevalence of tobacco and substance use. These practices have been considered exclusionary in HCV treatment guidelines in PR [7]. Nonetheless, as shared by key informants during the semi-structured interviews, providers have been using their clinical judgment to provide treatment despite the presence of these practices in order to facilitate access to HCV care.

As part of the qualitative interviews, key informants revealed that beyond the cumbersome criteria established by the PR Department of Health for HCV care provision, the high costs of the treatment and the procedures to achieve approval to provide treatment were significant barriers. These findings are consistent with the challenges to HCV care documented in other jurisdictions [28] [29]. However, these challenges can have severe repercussions in PR, considering the higher prev-

alence of HCV, the limited clinical information available to initiate care, and the problematic procedures in place. Key informants also expressed the limited HCV disease awareness efforts in PR and the limited number of specialists or primary care providers providing HCV care. The implications of this scenario could be detrimental to the well-being of people with HIV/HCV co-infection and point to areas for public health intervention to increase HCV awareness, outreach, and detection and the need to improve and expand the healthcare workforce engaged in HCV care.

Stigma towards HCV, HIV, and sexually transmitted infections was also documented as a barrier to HCV care. The negative impact of anticipated and enacted stigma on people with HIV is well documented and still represents a significant challenge [30]. For people coinfected with HCV, it may represent a compounding harmful experience that could have an impact at the individual level by alienating people from healthcare and at the community level by increasing the number of people who don't know their HCV status or delaying care until it is too late. This has a significant impact on the populations most vulnerable to HCV infection and the healthcare systems.

The allocation of funding for HCV care for people with HIV through the AIDS Drug Assistance Program was praised among interviewees as a structural strategy to increase access to care. However, they also recognize how this is a benefit limited to people with HIV. Key informants also emphasized the lack of options to subsidize care for people with HCV infection but who are not infected with HIV. A participant expressed how clinical trials in PR are a mechanism to improve access to HCV care. This resembles the early days of the HIV epidemic when the best chance to receive treatment was by enrolling in clinical trials [31]. While it could benefit, it poses ethical and structural challenges for providing HCV care.

Lastly, the semi-structured interviews revealed that the healthcare personnel were a major contributor to access to HCV care. As shared by the participants, there is a commitment to provide the best care possible, even if it implies not following all the procedures in place that were mainly perceived as barriers. Moreover, the interviewees recommended increasing access to HCV care and improving the services in place.

Since the data for this study were collected, some changes have been made to improve access to HCV care in PR. As of March 2020, the PR Department of Health included treatment for HCV infection as a benefit for those enrolled in government health insurance (*Vital*). Further, the regulations for HCV care were changed to improve access, including allowing primary care providers to treat HCV infection. While these are significant changes, other barriers remain, including the medication cost, the lack of an HCV surveillance system, low disease awareness, and stigma.

5. Limitations

While this study provides important information, it is not without limitations. A

significant limitation is the retrospective quantitative data collection through medical record reviews. Data collection was limited to the information documented in the medical record (paper or electronic). Therefore, we may have missed important information that was unavailable in the medical records. For instance, due to the overall scarcity of information regarding HCV in the medical records reviewed, we could not capture information that could help us to provide a better profile of participants (e.g., time since HCV diagnosis). The sample of medical records included in this analysis is limited to people with HIV who are engaged in care. Therefore, it does not reflect the clinical characteristics of those with HIV who are not in care and are likely to have different clinical outcomes. We also missed the opportunity to document the total number of eligible records in each clinic, which limited our ability to demonstrate representativeness. Qualitative interviews were conducted with stakeholders in HIV and HCV care willing to participate in the study, and their experiences could be different from those who were not interested in sharing their experiences providing HCV care or those who could provide HCV care but were not doing it. Although the goal of the study was to explore the perspectives of those providing HCV care and other stakeholders in the HCV services, we acknowledge that the voices of those affected by HIV and HCV are not included in this study. They are uniquely positioned to provide more information that could help improve access to HCV care in PR.

6. Conclusion

This study explored the clinical characteristics of people coinfected with HIV and HCV engaged in HIV care in PR and elicited vital information to improve access to HCV care. The characteristics of people with HIV co-infected with HCV evidence the need to improve HCV awareness, monitor disease progression, and access to treatment. While some systemic changes have been implemented to improve access to HCV since data for this study was collected, the cost of the medication, low disease awareness, and stigma remain significant barriers. Thus, there are opportunities to implement interventions to better provide HCV care in settings already providing HIV services and to integrate HCV awareness and care in primary healthcare services. Further, culturally appropriate interventions are urgently needed to address the negative impact of stigma.

Acknowledgements

AbbVie Corp. provided financial support for this study. We are grateful to community partners who granted access to patients' medical records and to the graduate and undergraduate students from the University of Puerto Rico who supported other research activities related to this project.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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