

Providers' Perspectives on Implementation of Low-threshold HCV Treatment in New York State: A Qualitative Study

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Background. Global study data show injection drug use is driving upwards of 79% of all new hepatitis C virus (HCV) cases in high-income countries. Low-threshold models can engage vulnerable populations in treatment to achieve HCV elimination targets. We examined the implementation of low-threshold models for HCV care in New York State, which has a robust HCV elimination program.

Methods. We conducted semi-structured interviews with 16 healthcare providers in 2022. Included providers either self-described as “low-threshold,” had a clinical focus on marginalized populations, or practiced in non-traditional settings. Interviews focused on the implementation of low-threshold HCV care. Transcripts were analyzed using thematic analysis and were categorized into themes guided by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework.

Results. Providers implemented low-threshold HCV care by facilitating access (e.g., having walk-in or telemedicine HCV services). Point-of-care testing and peer support were other important features. The inner context was driven by provider and organization values and involved providing low-threshold HCV care within health systems that were not themselves “low-threshold.” Adequate staffing was crucial for the extensive care coordination and outreach activities needed to engage persons who inject drugs (PWID). The outer context was characterized by a limited funding environment, restrictive insurance policies, and the high impact of patients' unmet social needs. Providers relied on care coordination and integrated care models to overcome these barriers.

Conclusions. Low-threshold HCV care incorporates operational flexibility and patient navigation but is challenged by patients' unmet social needs. Jurisdictions can support implementation by providing adequate funding for substantial outreach activities needed to engage vulnerable populations.

Received 08 December 2024; editorial decision 20 March 2025; accepted 24 March 2025; published online 26 March 2025

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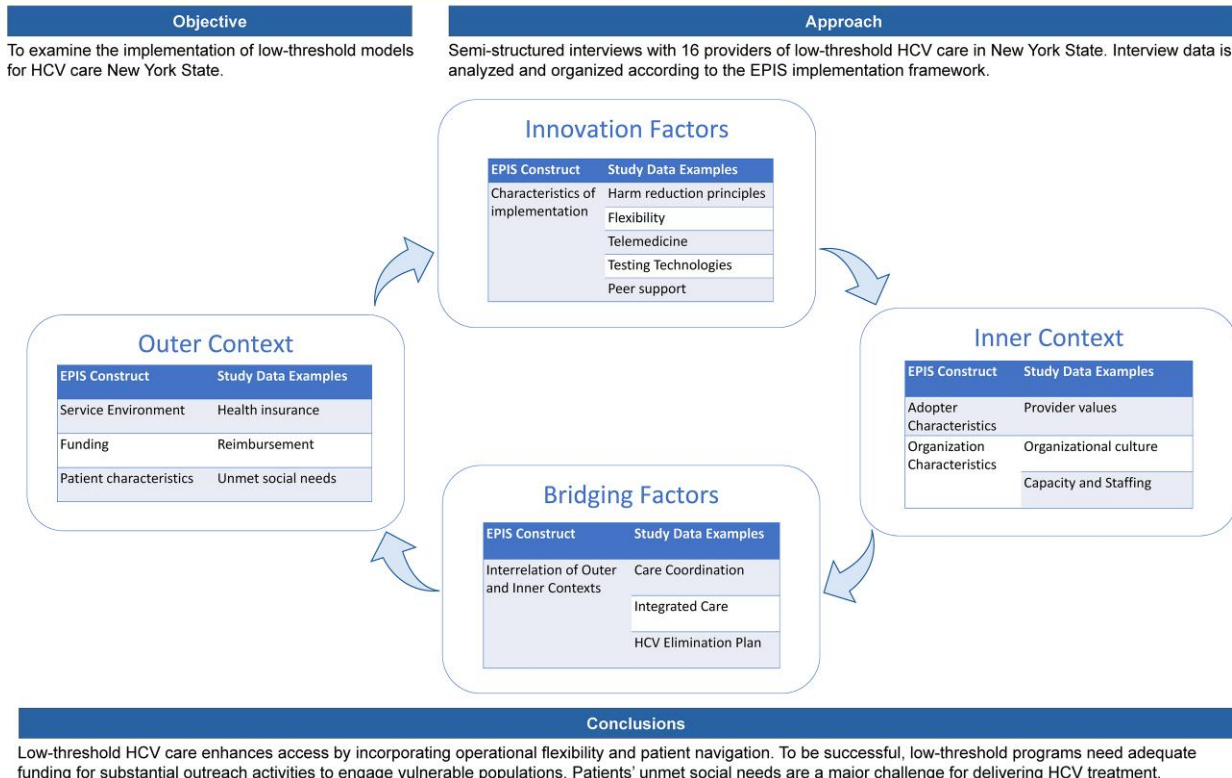
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Open Forum Infectious Diseases®

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<https://doi.org/10.1093/ofid/ofaf184>

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Finbraten et al, *Open Forum Infectious Diseases* (doi:)

Keywords. hepatitis C; implementation; injection drug use; qualitative; substance use disorder.

In the United States (U.S.), approximately 2 million people live with chronic hepatitis C virus (HCV); the incidence has doubled since 2015, with about 67,000 new cases in 2022 [1]. Most new HCV cases are linked to injecting drug use, though other risk groups exist, including those with intranasal drug use or sexual risk. Nonetheless, people who inject drugs (PWID) are a priority population to achieve HCV elimination [2, 3]. The U.S. is lagging behind global elimination targets, and there is an urgent need for data on innovative and effective HCV care models tailored to marginalized populations [4].

New York State (NYS) and city have robust HCV elimination programs [5, 6]. These programs build on an infrastructure that serves PWID (e.g., widely available methadone and syringe services) and people living with human immunodeficiency virus (HIV). Among other features, the elimination programs offer a payment assistance program that covers the cost of visits, laboratory testing and testing and navigation programs in multiple settings [7]. NYS Medicaid covers first-time HCV treatment without need for prior authorization. Most importantly for this study, NYS directly funds innovative low-barrier HCV treatment programs [8].

“Low-threshold” models are increasing in popularity, though there is no consensus definition of the features of such programs. Jakubowski and Fox suggested key principles for low-threshold opioid use disorder treatment, including same-day entry, harm reduction strategies, flexibility, and availability in locations frequented by individuals with substance use disorders [9]. Low-threshold HCV programs, however, are rarely described and usually limited to single sites [10–12]. Treatment providers at low-threshold programs can offer important perspectives on program features likely to improve access and challenges unique to treating HCV. We aimed to describe the implementation of low-threshold HCV programs through interviews with treatment providers in NYS.

METHODS

Study Population

The target population was providers in NYS who: (1) self-described as “low-threshold” or “low-barrier”; (2) provided HCV care with a clinical focus on marginalized populations (e.g., people experiencing homelessness or PWID); or (3) provided HCV care outside of traditional healthcare settings (e.g.,

community-based organizations). We attempted to reach 30 providers, of which 16 agreed to be interviewed, consistent with prior systematic reviews highlighting that relatively homogenous sample sizes like our study can reach data saturation [13].

Qualitative Data Collection

We conducted semi-structured interviews between March and June 2022. We developed an interview guide focused on implementing low-threshold HCV care through team consensus. Key domains included a description of HCV care practices, participants' understanding of the term "low-threshold," barriers and success factors. Two pilot interviews were conducted, resulting in revisions to guide content and length. Interviews were conducted virtually and audio-recorded through a private meeting link. Recordings were transcribed using commercial transcription software and de-identified.

Analysis

Transcripts were coded using Dedoose 9.0 and analyzed using thematic analysis [14]. We employed a mixed inductive-deductive approach, informed by the investigators' previous research on HCV care delivery [12, 15–18]. Analysis was guided by the Exploration, Preparation, Implementation, Sustainment (EPIS) framework, which we use to present the results (Figure 1) [19]. The EPIS framework was selected because of its focus on implementation and is widely used in health services research [20, 21]. Table 1 shows characteristics of the sample by setting. Providers are also described as either prescribers (e.g., physicians, advanced practice professionals), or non-prescribers (e.g., care coordinators, nurses). Quotes are attributed based on practice setting: syringe service programs (SSP), community-based organizations (CBO), opioid treatment programs (OTP), federally qualified health centers (FQHC), or hospital-based outpatient programs. Additional methodological detail is presented in the [supplemental file](#).

RESULTS

Themes are presented based on the EPIS framework, with special considerations to: innovation, inner and outer context, and bridging factors.

Innovation

Providers highlighted that innovation in providing low-threshold HCV care, although possible, requires using multiple forms of support and technology to facilitate HCV care and treatment.

Flexibility. Low-threshold care was succinctly described as "just keeping it really open and broad and flexible giving people options for how they can access care" (CBO-3). Flexibility was informed by harm reduction principles, including doing away with punitive measures such as requiring abstinence to receive care or termination of care after missed appointments.

To address patient barriers, one program detailed providing multiple approaches to receiving care, including walk-ins, community testing events, and an online portal (SSP-2). Several providers mentioned telemedicine as an innovative approach, where patients could be cured despite having "never interacted with a medical facility whatsoever" (SSP-1). Telemedicine can mitigate barriers such as lack of transportation and healthcare-associated stigma. Telemedicine can also expand program capacity to reach patients across larger geographical regions. "Before telehealth, we were in 21 counties all by word of mouth, and then since telehealth now we're in 49 counties" (CBO-2). Patients' ability to access technology and internet affects telemedicine's effectiveness: for patients "who have good signal, I think it works great" (FQHC-2).

Flexibility, while generally viewed positively, had several balancing factors. One provider worried that an overly flexible model discouraged long-term engagement: "they have to stay with you even after hep C treatment for mental health or substance use... [but] you're not engaging them long enough to make them come back" (FQHC-2). Also, although patients may prefer low-threshold settings, these settings may not always be equipped to respond to all types of medical needs:

"If a person was in like sepsis they might go to a low-threshold facility...because that's when they would feel comfortable and that would be a good thing. But it's also like that prevents them from going to a place that might actually be able to help them with a much more serious problem." (SSP-6)

HCV Testing. During the study period, point-of-care (POC) HCV antibody (RNA) testing was available. POC HCV RNA testing was not yet available in the United States, but providers were aware of its promise. Dried blood spot RNA testing was available, but results took several days. Perceptions around POC and dried blood spot testing were generally positive, but with caveats. POC testing was considered most suitable for patients "who are hesitant about doing a blood draw" (CBO-2) or having difficulties completing blood draws.

Providers indicated even with POC testing, positive cases still necessitated follow-up laboratory work:

"My job previously we did just like a point of care test, and if [the] antibody test came back reactive, then we'd do a dried blood spot...And if that came back with a viral load, then we would bring them back in or send a lab order to do all of the testing for treatment. And here at [my current job], you just come in and get your blood drawn and go from there, which I think is a way better system." (CBO-3)

Providers noted one-time POC testing "wouldn't actually change much" because HCV treatment still requires repeated

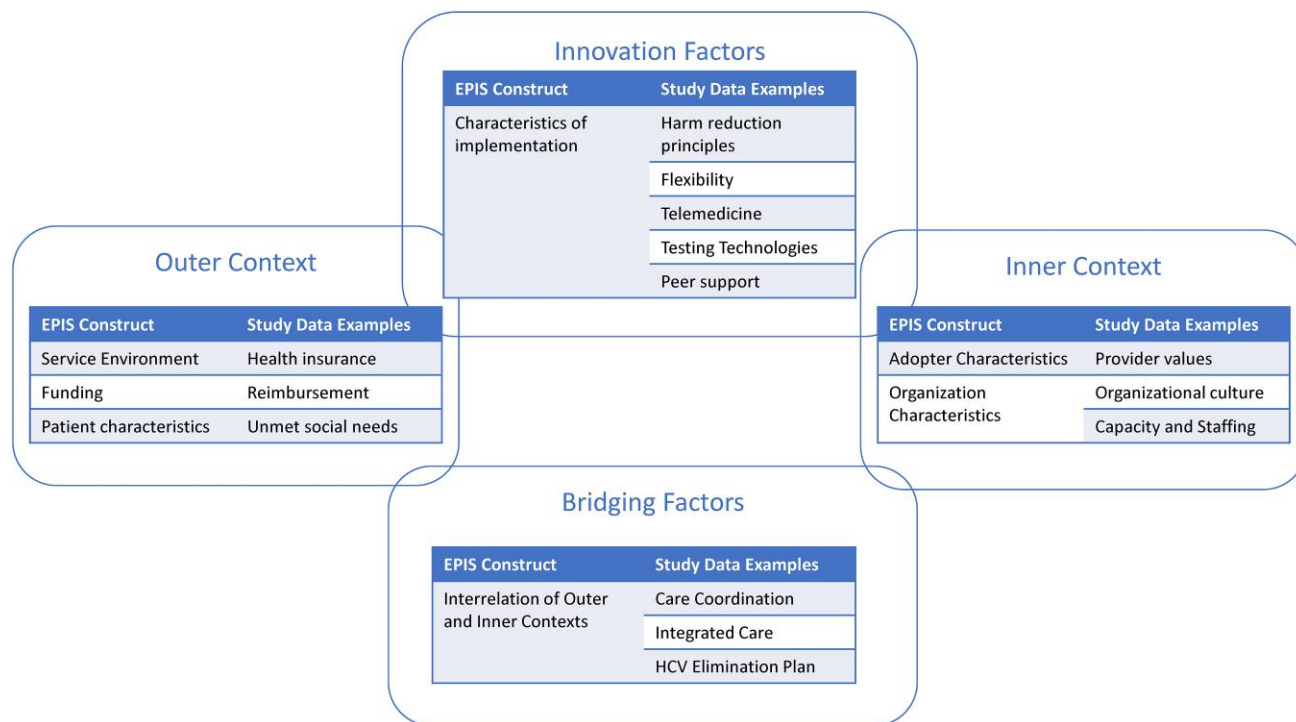


Figure 1. EPIS framework for low-threshold HCV care programs. Abbreviations: EPIS, Exploration, Preparation, Implementation, Sustainment; HCV, hepatitis C virus.

Table 1. N = 16 Qualitative Interview Participants' Role and HCV Care Setting

HCV Care Setting	Interview Participant Role	
	Prescribers	Non-prescribers
Syringe service program	N = 3 MD, NP	N = 3 Manager/Director/Coordinator
Hospital	N = 1 MD	N = 1 Director
Federally qualified health center	N = 1 MD	N = 2 Manager/Director
Community-based organization	N = 2 MD	N = 1 Phlebotomist
Opioid treatment program clinic	N = 2 MD	0

Prescribers refer to providers who can prescribe treatment, such as physicians (MD) and advanced practice professionals such as nurse practitioners (NP). Non-prescribers refer to other provider types, such as nurses, care coordinators, phlebotomists, and patient navigators.

visits for medication pickup and confirmation of cure, although a faster diagnosis “may incentivize them to come back” (CBO-1).

Integrated Peer Support. Peers with lived experience are often hired (or volunteer) to assist with building rapport, conducting outreach, providing education, connecting to resources, and/or conducting HCV testing. One participant stated that “...a lot of the city and state funding streams really support peers” (SSP-2). Peer support relies on “people interested in giving back” (SSP-4) and the organization’s ability to hire them. Low-threshold care programs are often situated in larger organizations that do not typically hire people with lived experience of drug use, which requires organizational innovation to overcome these barriers:

“For hospital programs that do hire funded peer support positions, they’ve identified creative ways for “low barrier” hiring of people with lived experience... We do everything as subcontracted because going through human resources at the medical center is a minefield for someone who might give a positive urine [drug test] or have a felony record or something.” (SSP-3)

This provider also mentioned ensuring adequate training for peers, “many of [whom] have never worked in a professional setting before” (SSP-3) as being an important component of a peer program, as well as considering whether their employment would disrupt eligibility for government benefits.

Inner Context

Individual Adopter Characteristics: Providers’ Values. Most participants described stigma and discrimination toward PWID as pervasive factors that can be mitigated by low-threshold models:

“A low-threshold model, I think it just dignifies the patient in that we have life-saving medications and no matter who you are, you deserve them.” (SSP-2)

Providers saw their programs as being a place “that people can access care with people that they are comfortable with...a place where they are able to speak freely and not worry about how they’re going to be perceived” (SSP-6).

Provider values sometimes worked against low-threshold care. Providers referred to varying “comfort” with low-threshold practices resulting from fear about wasted resources or improper prescribing. One provider stated: “A lot of patients would be sent off with 8 or 12 weeks of treatment and you would never see them again... Maybe they took all the medication and got cured, but we’ll never know” (Hospital-1). Another spoke about being “too low-threshold...using up the resources of the organization” to engage heavily with a few patients, rather than “the public health model of how many people you can treat” (CBO-2).

Organizational Characteristics. Organizational culture was highlighted as a facilitator.

“A culturally competent organization or team helps with this sort of low-threshold model... I think the understanding of the population that we’re servicing... And you also have as an organization a policy on stigma, a free plan that we’ve put in place for us staff as well.” (FQHC-3)

Employing a culture that is driven by de-stigmatization of drug use is seen as a major factor for low-threshold models. However, participants again noted disparity between provider and organizational priorities: “it’s a low-threshold model, but we’re still in a system that has a ton of barriers, and we have to work within that system” (CBO-3). This could be due to interpretation of law/regulation around low-threshold treatment:

“Even though we believe that low-threshold might help the person, but there’s a legal barrier there and...like you can’t get the organization or the individual provider in trouble. There’s a threshold for the org and there’s a threshold for the provider, and you have to find what that threshold is.” (CBO-2)

One participant, who was in a position of organizational leadership, detailed the complexities of implementing low-threshold programs in larger organizations:

“When you’re just a doctor sitting with somebody...that’s easy. What’s harder is managing large programs of staff and nurses and doctors and stuff, and trying to, manage all the different situations that come up and developing policy balances all the different priorities... For example, if you run a crisis program where people...are trying to get away from the streets and stop using, and then someone’s using on the unit, and they’re upset about it... What’s the right response for the program? You don’t want the person that’s using on the unit to feel like they’re a bad person, but they also can’t be using on the unit because other people in the unit don’t want to be around

active use. And what are you, how do you like attend to all the different needs in those situations? That’s where I think that the work is most difficult.” (CBO-1)

Staffing was also an organizational consideration. The “constant scramble” to meet demand without adequate staff was “exhausting,” contributing to provider and staff burnout (CBO-3), and limiting the degree of service provision:

“Having minimal staff is a barrier because we’re not able to do as much outreach. We’re not able to go into the communities where people can see us some more and build that trust with them to get them connected, to testing and treatment.” (SSP-4)

Additionally, flexibility in appointment times and late arrivals can run up against the fixed staffing model that is common in healthcare practice:

“We have one provider who sees 20–30 people a day...so then one person misses an appointment or comes late, that has a ripple effect on the rest of the roster for the day.” (SSP-4)

Outer Context

Health Insurance and Pharmacy Access. Prior authorization by insurers delays the delivery of HCV treatment. Insurers may require specific lab testing, such that “obtaining the medication ordered can take anywhere from a week to a month...and then we have no idea where the patient] is” (Hospital-1). Insurers often specify that HCV medications can only be dispensed through only specific specialty pharmacies, which limits care access.

“I can’t choose which specialty pharmacy to work with. So when I work with these inferior specialty pharmacies,... I can spend hours on the phone trying to get the prescription understood. I’ve had to explain to a pharmacist why a second month of Mavyret is necessary. Things that like, the ridiculous things.” (SSP-1)

Specialty pharmacies may not have widespread retail locations and rely on delivering to patients directly. This, in turn, requires patients to have a phone to coordinate delivery, and an address to deliver to.

Funding. Many providers stated that increased funding will enhance access to services:

“More funding creates more opportunities, which creates more staff, which creates a wider reach... We can get people in quicker and get them through the treatment process

quicker. We will see those [case] numbers decrease quicker.” (SSP-4)

However, insurance reimbursement often did not cover low-threshold activities such as care coordination, or restricted the environment in which services could be provided:

“All of the staff time, like faxing the stuff to the specialty pharmacy... we just don’t get paid more than we would for a 10-minute methadone [visit]. From my perspective that is the ultimate barrier to care.” (OTP-1)

Many programs relied on grant funding to pay for expenses such as patient incentives and care coordination. Grant funding, while essential, had drawbacks in terms of being time-limited. One provider said: “the only negative to being grant funded is if the grant ends” (FQHC-1). Grants can also be overly restrictive or complex:

“It was not sustainable...I was thankful when the funding wasn’t renewed, to be honest, because it was becoming too much.” (SSP-3)

Unmet Social Needs. Having adequate access to transportation, phones, and housing were commonly cited as unmet patient needs preventing engagement with HCV treatment:

“They have many things that are much more important in their lives right now than hepatitis C treatment. They have nowhere to live. They have no phone, they have no social support... And it’s like sometimes it’s almost feels, I’m not sure what word to use, but inappropriate to try to engage someone around Hep C treatment when they’re literally standing in front of you, almost naked, hungry.” (Hospital-1)

Implementing a low-threshold model requires, from the provider, a balance between “being aware of the fact that there are social determinants that they’re working on but not holding treatment until there’s a perfect situation” (FQHC-2). Unmet social needs of patients were exacerbated throughout the COVID-19 pandemic, during which many programs relied on telehealth for continuity of care.

Programs attempt to overcome social barriers through various methods, including adapting medication delivery to patient’s needs, or providing referrals to social services:

“Occasionally I’ll have them if somebody is truly homeless and is concerned about the stuff getting stolen and nowhere safe to store anything. I’ll get their medicine, give them like a week’s worth at a time. I have had clients that I gave them months’ worth of medicine and they’ll come in and be like, it’s gone.” (SSP-5)

Nevertheless, several providers highlighted that the impact of social determinants and the lack of structures to meet basic need threaten the effort to eliminate HCV:

“I’m skeptical that elimination or anything close to it will be achieved. And it’s in part because of all the, it’s and it’s a symptom of all the structural problems where we don’t believe that people have a right to basic health care. We don’t believe that people have a right to basic housing. We don’t believe that people have a right to basic mental health care. We don’t have universal health care and we, probably at least in the short term, never will.” (SSP-3)

Bridging Factors

As bridging factors, we highlight factors that facilitate low-threshold HCV care implementation by operating across the inner and outer contexts.

Care Coordination. Care coordination enabled patients with complex social and economic needs to engage with health systems that did not necessarily consider those needs. Outreach and navigation activities were particularly important to ensure medication adherence and follow-up:

“A lot of doctors, I think still, they prefer not to have anything to do with Hep C treatment because of the follow-up and keeping track of the client. They just don’t have the staff to do that.” (SSP-5)

Care coordination activities were performed by a variety of staff, including “care coordinators,” “navigators,” “case management,” “linkage specialists,” and peers. Providers mentioned a diverse array of roles that primarily focus on providing outreach to patients; being a trusted and accessible point of contact; and helping arrange referrals to services such as insurance or housing support.

Integrated Care. One provider emphasized the need to address other care needs after HCV cure, such as care for ongoing liver disease.

“I had someone I treated last year [for HCV] and he had diabetes too...and he’s ‘I’m ready whenever you want to take me [for primary care],’ but he’s discharged from our program... It’s frustrating because if we had another aftercare program that could then work with these people that have been cured, then maybe we could actually prevent death from cirrhosis.” (SSP-1)

Another suggestion was integration with primary care practices to properly address a patients’ health holistically: “So of course, like having an embedded primary care program would

lead to better outcomes for people that can actually get to that place” (OTP-1). Another explained that low-threshold HCV care can be another entry way for patients to be engaged in other types of care: “It opens the door to them, like trusting some type of healthcare worker getting some blood work somewhere. I do think that is a priority side effect to treating hep C” (SSP-2).

HCV Elimination Plan. Awareness and communication of HCV plans were highlighted as important for getting providers onboard with eliminating HCV. Through a 5-year state grant, several programs are receiving funding to drive down HCV infection rates. With this, providers saw a relationship between low-threshold models and HCV elimination: “You need to be able to have a wide-reaching net and not have barriers to providing the treatment. Otherwise, you wouldn’t be able to eliminate” (Hospital-2). However, several providers were skeptical that the existence of elimination planning was sufficient to overcome the significant underfunding, particularly of social services, that underlies low-threshold models. As one interview participant stated, “you can’t eliminate hep C by itself because it doesn’t exist by itself” (FQHC-2).

DISCUSSION

Our findings add to literature describing the perspectives of U.S. providers on HCV treatment [22–24]. Our study focuses specifically on the challenges and successes of low-threshold programs, adding to our understanding of implementing HCV treatment in these settings. These lessons are particularly salient for other jurisdictions with HCV elimination plans, including other states and a national plan.

Specifically, jurisdictions can “build-in” funding for strategies that promote low-threshold care, such as care coordination. Several studies have highlighted the effectiveness of care coordination to enable HCV treatment [15, 25]. Despite robust evidence, our participants described how care coordination is a major challenge in the current payment model. Sustainability is particularly limited when dependent on grant funding, which suggests the need for other revenue mechanisms that allow programs to provide these high-touch services. Insurance-based solutions such as recently implemented Medicare revenue codes for care coordination may provide an alternative solution, particularly if Medicaid programs follow suit. However, further research is needed to understand if this mechanism would be accessible to low-threshold programs and/or provides sufficient funding.

Other opportunities include supporting adoption of telemedicine-based HCV management and of POC HCV RNA tests that have recently been approved in the U.S. Recent clinical trial evidence confirms the effectiveness of telemedicine, but there are limitations in real-world application,

most notably the need for patients to have access to technology and a private place to receive care [26–28]. International data from HCV care models already using POC tests report high linkage to care and cure rates, although our participants cautioned that efforts to ensure follow-up are still required [29].

Despite the promise of low-threshold strategies, our participants emphasized the difficulty of providing care in their social and fiscal environments. Elimination was seen as an uphill battle; motivated providers, patients, and communities are innovating around a failing social safety net, but with the recognition that a disease-specific program alone cannot fully overcome the substantial barriers to well-being experienced by this population [30].

As a qualitative study of a geographically restricted and selected sample, our results are not generalizable but do reflect experiences in a jurisdiction with robust HCV elimination efforts. Low-threshold programs take many forms, and it is unlikely that we identified all of them. Technology and practice are constantly changing, but many of factors reported here are still prevalent. Our study describes low-threshold HCV care implementation considerations and strategies that can play an important role in developing future HCV elimination programming.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Acknowledgments. We acknowledge the study participants for sharing their time and expertise.

Financial support. This work was supported by the National Institute on Drug Abuse (K01 DA048172 to S. N. K., P30 DA030500 to B. R. S.), and by the Harkness Fellowship in Healthcare Policy and Practice at the Commonwealth Fund (to A. F.). The opinions expressed in this work are those of the authors, and do not necessarily reflect the views of the funding agencies or the U.S. Government.

Potential conflicts of interest. Dr Kapadia and Dr Eckhardt report grants to their institutions from Gilead Sciences, Inc. unrelated to the current study. All other authors report no potential conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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