Facilitating engagement of persons with opioid use disorder in treatment for hepatitis C virus infection via telemedicine: Stories of onsite case managers


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ABSTRACT

Although hepatitis C virus (HCV) infection has high prevalence and incidence in persons with opioid use disorder (PWOD), their engagement in HCV care has been limited due to a variety of factors. In an ongoing multisite study at 12 opioid treatment programs (OTPs) throughout New York State (NYS), we have been evaluating telemedicine accompanied by onsite administration of direct acting antiviral (DAA) medications compared with usual care including offsite referral to a liver specialist for HCV management. Each site has a case manager (CM) who is responsible for all study-related activities including participant recruitment, facilitating telemedicine interactions, retention in care, and data collection. Our overall objective is to analyze CM experiences of clients' stories and events to understand how the telemedicine model facilitates HCV treatment. Hermeneutic phenomenology was used to interpret and to explicate common meanings and shared practices of the phenomena of case management, and a focus group with CMs was conducted to reinforce and expand on key themes identified from the CMs' stories. We identified three themes: (1) building trust, (2) identification of multiple competing priorities, and (3) development of personalized care approaches. Our results illustrate that trust is a fundamental pillar on which the telemedicine system can be based. Participants' experiences at the OTP can reinforce trust. Understanding the specific competing priorities and routinizing dedicated personalized approaches to overcome them are key to increasing participation in HCV care among PWOD.

1. Introduction

Hepatitis C virus (HCV) infection is the most common blood-borne infectious disease in the United States and is a leading cause of end-stage liver disease, cirrhosis, and hepatocellular carcinoma (Zeremski et al., 2013). Injection drug use (IDU) is the leading HCV transmission route.
risk factor, and persons who use drugs (PWUD) account for the vast majority of the estimated 5 million HCV-infected individuals in the United States (Chak et al., 2011; Gonzalez et al., 2017). In the past 5 years, HCV has undergone a therapeutic revolution with the development and regulatory approval of direct acting antiviral (DAA) medications. DAAs have almost universal efficacy, minimal side effects and treatment completion in two to three months in the vast majority of individuals. Three months post-treatment completion, undetectable HCV RNA in the peripheral blood signifies virologic cure. The tremendous therapeutic successes of the DAAs have led many state, federal, and international governmental bodies to declare support for HCV elimination (National Academies of Sciences et al., 2020; US Department of Health and Human Services, 2017; World Health Organization, 2016).

Linkage to HCV care remains a leading unresolved issue in HCV management, particularly in medically underserved communities that lack access to specialty care. HCV remains undiagnosed in many PWUD, and once diagnosed, many are still reluctant to pursue HCV management when referred to an HCV provider due to previous or current stigma experienced in conventional healthcare settings. In fact, when referred from substance use treatment facilities, approximately only one-third of referred individuals will adhere to the referral recommendation (Talal et al., 2017). For almost a decade, we have pursued telemedicine as a method to integrate treatment for medical and behavioral conditions (Talal, Andrews, et al., 2019; Talal, McLeod, et al., 2019). In our model, telemedicine encounters occur with patients in opioid treatment programs (OTPs), venues where persons with opioid use disorder (PWOD) receive medications for opioid use disorder (MOUD). Our premise was that telemedicine could be a modality to integrate HCV management with ongoing substance use treatment. While our early work has illustrated the effectiveness and overall PWOD preference for HCV treatment via telemedicine, in this investigation we sought to address whether a broader spectrum of the PWOD population would be amenable to telemedicine as a treatment modality (Talal, Andrews, et al., 2019; Talal, McLeod, et al., 2019). In addition, we sought to identify strategies to engage and retain PWOD into HCV treatment via telemedicine.

1.1. Description of OTPs

OTPs, including methadone treatment programs, provide a supportive multi-disciplinary environment that includes clinicians, nurses, social workers, counselors, and mental health professionals designed to enable PWOD to address or to mitigate their health and other issues. In our study, New York State (NYS) Office of Addiction Services and Supports (OASAS) regulates all study sites and stipulates frequent client attendance requirements, tightly regulated staffing ratios, and that each client has an identified OTP staff care coordinator. We found that these regulations facilitate telemedicine conduct. The frequent in-person methadone dosing requirements provide opportunities for interaction with patients who might otherwise have been lost to follow-up from the HCV treatment program. The OTP can be considered a social system that includes a “peer pipeline”, an informal communication system among OTP clients designed to disseminate information (Munoz-Plaza et al., 2008; Talal, McLeod, et al., 2019). Furthermore, PWOD generally report warm, understanding, and supportive interactions with OTP staff in comparison to interactions in general healthcare settings where stigma and disrespect are more common experiences (Earnshaw et al., 2013; Islam, 2013). PWOD frequently report their preference to congregate in accepting and familiar locations, such as OTPs, to minimize the likelihood of discrimination and stigmatization, factors that can be used to facilitate treatment for medical and behavioral conditions.

1.2. Background

We have observed that the familiar environment of the OTP can potentially be a potent factor in minimizing stigma related to substance use. The convenience of conducting telemedicine evaluations and of obtaining DAAs and MOUD simultaneously facilitates treatment adherence. In our pilot study, we found that 93% of individuals treated for HCV achieved virologic cure, and 95% preferred the HCV onsite treatment via telemedicine to offsite referral (Talal, Andrews, et al., 2019; Talal, McLeod, et al., 2019). For the past several years, we have been conducting a multi-center randomized clinical trial to compare the effectiveness of telemedicine to usual care for HCV treatment among patients on MOUD (Clinical Directors Network, 2017).

1.3. Structure of the parent study

The purpose of the parent study is to compare telemedicine to usual care for HCV management among HCV RNA positive PWOD in a familiar and convenient setting, the OTP. We are conducting the study in twelve OTPs located in urban areas throughout NYS as a non-blinded stepped wedge cluster randomized controlled trial with two arms: onsite HCV management through telemedicine with co-administration of DAAs and methadone versus HCV management through standard of care, referral to an offsite HCV provider. Study sites agreed voluntarily to participate in the study as they envisioned that the telemedicine model could be beneficial to their patients, and they felt comfortable participating in a research study. The primary outcome is to determine the percentage of individuals in each treatment arm who achieve a sustained virologic response (SVR), defined as undetectable HCV RNA twelve weeks post-treatment completion. We are following participants who eliminate HCV for two years post-treatment to assess for reinfection. Coverage by NYS Medicaid insurance was highly prevalent among study participants and covers methadone as MOUD as well as DAAs. The study provides each site with a case manager (CM) who is responsible for all study-related activities including participant recruitment, facilitating telemedicine interactions, retention in care, and data collection.

In the usual care arm (comparison), which occurred in the initial phase at each site, we referred patients from the OTP to an offsite HCV specialist in accordance with the sites’ standards of care. The site was the unit of randomization, and each site implemented the telemedicine intervention during one of three steps, consistent with the stepped wedge design. We assessed patients’ HCV RNA levels at screening and throughout the study. During the telemedicine visits, patients were linked with the provider via two-way videoconferencing facilitated by the CM (Fig. 1A). Indeed, the CMs act as a bridge between patients-participants and the telemedicine providers (Fig. 1B). We initiated study recruitment on March 1, 2017 and concluded on February 29, 2020.

The CMs have an important role in not only facilitating care through the telemedicine encounters but also in terms of the research study, coordinating enrollment, retention, and follow-up measurements. In our model, CMs facilitated telemedicine encounters on site at the OTP by physically placing the patient in front of the video camera and ensuring system connectivity. We incorporated interventions, such as having an OTP site clinician present at the initial telemedicine encounter who introduced the telemedicine provider as well as showing participants an introductory video (University at Buffalo, 2018), to promote PWOD comfort with the telemedicine encounter (Clinical Directors Network, 2017). What is unknown are the CMs’ experiences of working on a research study as well as facilitating clinical care via telemedicine in the setting of the OTP, their perceptions of obstacles to engaging OTP participants in care and research, and their views of and experience-based strategies in successfully engaging PWOD in telemedicine-based HCV care. We sought to understand the common meanings and shared practices of the CMs that provide insight into the challenges of simultaneously coordinating clinical care and research to guide development of sustainable interventions to promote HCV treatment among PWOD. We utilized hermeneutic phenomenology, which is a qualitative approach to interpreting texts to study a phenomenon. In this study, the texts are CMs’ stories and focus group discussion of facilitating HCV care
in PWOUD. The CMs' experiences provide unique perspectives as the CMs are the primary conduits between the participants, clinicians, and the OTP staff. While we are interested in both the telemedicine and referral models of HCV care, we emphasized CMs' stories of the facilitated telemedicine model with accompanying DAA administration. A secondary objective is to understand the ancillary benefits that accrue to PWOUD who pursue HCV treatment.

2. Methods

We used the hermeneutic phenomenological research approach to formulate the data collection questions, to interpret the CMs' experiences, and to explicate common meanings and shared practices of the phenomena of CMs engaging patients in HCV treatment. The method seeks to understand situations and interactions as they were experienced, within a context of time, place, and situational influences (Gadamer, 1998; Heidegger, 1962; Smythe et al., 2008). Understanding of a phenomenon is based on a threefold structure of understanding (Heidegger, 1962) in which the premise is that all interpretation is based on background practices that accord: 1) familiarity with the phenomenon, 2) foresight or perspective to understand the phenomenon, and 3) anticipation of what the interpretation will reveal. Life experiences form background practices that provide a horizon of understanding. In addition, our own perspectives, including history and taken-for-granted life knowledge, formulate the horizon of understanding. All of the parameters inform our interpretation of the multiplicity of meaning of our experiences. The spoken language of experiences (i.e., vignettes) reveals the interpretation of meanings; therefore, narratives of the experiences of CMs engaging patients in HCV treatment provide data for the analysis. Please see Table 1a for an overview of the steps involved in the interpretation of themes described in this work.

### Table 1a

<table>
<thead>
<tr>
<th>Steps involved in data collection and interpretation of meanings.</th>
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<tbody>
<tr>
<td>1) Case managers wrote stories of facilitating care for hepatitis C virus.</td>
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<tr>
<td>2) Interpretation of CMs narrative stories was iterative and ongoing.</td>
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<tr>
<td>• The team read each text to gain an overall understanding of the CMs' stories.</td>
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<tr>
<td>• During weekly meetings, the team shared summaries and identified themes from each text with verbatim excerpts.</td>
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<tr>
<td>• Discussions and dialogue refined the themes and interpretations. Team members discussed discrepancies and returned to the text for clarification and consensus.</td>
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<tr>
<td>• As each text was read, this refinement continued, and each text was compared to the previous texts until the team, through the ongoing dialogue with the text in a hermeneutic circular process, explicated a nuanced understanding.</td>
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<tr>
<td>3) Team members clarified and expanded on the preliminary themes during a focus group with majority of the CMs</td>
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<tr>
<td>4) Team members discussed and interpreted CMs' texts to gain consensus on the understanding of the phenomenon until a warranted interpretation was rendered as described by them and a constitutive pattern to link all themes across the texts.</td>
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| Abbreviations: CM, case manager. |

2.1. Data collection

During the conduct of the parent study, the CMs discussed a variety of instances where patients reported that the model directly or indirectly facilitated their overcoming obstacles to healthcare access and delivery related to HCV. To further explore these instances, the researchers developed an open-ended question for the CMs “to describe stories of their experiences facilitating HCV care”. After the University at Buffalo Institutional Review Board (IRB) deemed the research exempt, we recruited CMs by means of a virtual invitation during study research meetings in which they provided information. We asked CMs to write narratives of their experience of HCV treatment stories, which we
collected by email. All CMs were experienced study coordinators at the time of the request for narratives and worked in the study sites across NYS. The team (described below) performed the initial interpretation of the narratives. Subsequently, we conducted a follow-up focus group with the CMs to clarify and expand the narratives.

We targeted focus group questions to each of the three themes identified from the narratives (building trust, identification of multiple competing priorities, and development of personalized care approaches) (Table 1b). We focused each question on the preliminary themes from the written stories seeking clarification and examples that provided additional data for interpretation. Probes or additional questions were asked to summarize or expand focus. The moderator sought input from each person in attendance to obtain a balanced discussion (Krueger, 1997). The forum enabled members to share and to compare similar experiences for each person in attendance to obtain a balanced discussion (Krueger, 1997). The narratives and focus group (as below) generated 60 pages of text for analysis.

We held a focus group with the CMs from each of the sites, and a member of the interpretative team (SSD) directed the focus group. Also, in attendance were investigators (AHT and UJ) as well as a nurse practitioner affiliated with the study (KD). We invited all CMs to the focus group, and all, except two, attended. We conducted the focus group virtually utilizing a HIPAA-compliant videoconferencing program zoom© (Zoom Video Communications, Inc., US). The zoom© program recorded and transcribed the focus group. The moderator and another team member edited and verified the transcripts.

2.2. Analysis

We used the CMs' email narratives and transcribed text of the focus group for interpretation or a rendering of the “fusion of horizons” (Gadamer, 1998) of the CMs’ depiction of participants' experiences and the team’s interpretation of the phenomenon. The three-member analysis team included the study principal investigator (AHT), a hepatologist with over a decade of research experience in PWoud; an expert in hermeneutic qualitative analysis (SSD) with experience in technology in patients with chronic illness; and the overall project manager who is experienced (Heidegger, 1962; Smythe et al., 2008). Reflection of the CMs’ depiction of participants' experiences and perceptions (Krueger, 1997). The narratives and focus group (as below) generated 60 pages of text for analysis.

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We interpreted the text in an iterative, circular, reflective, and reflexive manner that dynamically engaged in thinking to arrive at a temporal understanding of being-in-the-world (Heidegger, 1962), which revealed and extended the understanding of human situations as they are experienced (Heidegger, 1962; Smythe et al., 2008). Reflection involved making explicit the interpreters’ presuppositions, creating an engaged openness and closeness with the text to understand the human situation as lived (Gadamer, 1998). This preunderstanding or Gadamer's concept of “prejudice” (Gadamer, 1998) involved reflections by all members of the interpretive team.

We maintained rigor throughout the study through the use of DeWitt and Ploeg's framework of balanced integration, openness, concreteness, resonance, and actualization (De Witt & Ploeg, 2006). We achieved balanced integration in the study findings by striking an equilibrium between the voice of the participants and the researchers' philosophical interpretations. Study results, as explicated in themes and a constitutive pattern, use both verbatim excerpts and philosophical explanations, such as Heidegger's notion of the danger of a technological society where science replaces, rather than complements, thinking and the need to be aware of what matters instead of just focusing on the technology of telemedicine. Thus, the CM humanizes the caring interaction with telemedicine. We achieved openness by a systematic process of auditing the interpretive decisions as recorded in reflexive journaling. We reached concreteness in the findings by providing context to situate the reader in the phenomenon through the use of examples that resonate with life experiences. We realized resonance when the reader obtained an intuitive grasp of the meaning of the study through reading the findings and verbatim examples. Actualization addresses future resonance of study findings in future research.

3. Results

Interpretations of CMs’ experiences engaging PWoud into HCV treatment through telemedicine resulted in three related themes: Building trust, managing competing priorities, and personalizing care. The constitutive pattern that links the three themes together is “Engaging the community of trust.” Together the pattern and themes reflect the experience and perceptions of the CMs in the parent study as they recruited and facilitated the telemedicine encounters.

3.1. Theme one: building trust

Building trust to facilitate communication among the patients-participants and the research team and telemedicine provider for treatment of HCV emerged as a major theme in CMs’ perceptions in attempting to describe the engagement of PWoud in treatment of HCV via telemedicine. Three subthemes that help form and characterize the main theme of building trust also emerged: the OTP as a community with a pre-existing level of trust, building trust to engage that community, and extending that trust to HCV care and telemedicine as a novel modality for treatment delivery.

3.1.1. Recognizing the OTP setting as a community

CMs described the OTPs’ multidisciplinary teams of counselors, social workers, nurses, mental health professionals, and medical providers, all of whom support PWoud’s care in a setting that promotes caring and trusting relationships. PWouds often harbor feelings of mistrust and discomfort when interacting with healthcare personnel outside of the OTP. The perception of the CMs is that the supportive environment provided by the OTP can be utilized to help assuage these feelings. Further, CMs report feeling that this supportive environment stems from PWouds forming their own social networks with peers (e.g., the peer pipeline) as well as developing rapport with the clinic staff. Demonstrating respect to foster trust among PWouds is part of the clinic culture as one CM reiterated the importance of this setting:

They [PWoud] don’t know you, they’re very sort of tentative about you. And having the trust that’s already existing, sort of, in the clinic level and with some of the liaisons, is very important.

3.1.2. Building trust within the OTP community

An important step in engaging the OTP community is capitalizing on

| Table 1b |
| Topics included for focus group discussion. |

- Building trust with the study participants is important in creating a sense of community in the OTP to facilitate HCV treatment.
- Identifying competing priorities (medical, mental, or social determinants of health) among study participants that obstruct or interfere with pursuit of HCV treatment is essential.
- Developing strategies for personalized care approaches by CMs to address competing priorities that thwart proceeding with HCV treatment is important.

Abbreviations: OTP, opioid treatment program; HCV, hepatitis C virus; CM, case manager.
the pre-existing culture of community and trust that is characteristic of our participating OTPs. One of the challenges that CMs faced was to establish rapport in communicating with patients whose life experiences led them to mistrust others: “They don’t trust anyone. They’re super hyper vigilant... they’ve learned this [behavior] as their way of life.”

Engaging the clinic staff to communicate, educate, and coordinate with the CM in order to earn PWOUDs’ trust in non-OTP-based providers is a critical pillar for establishing a working relationship among outside providers, OTP clinic staff, and OTP patients, to enable telemedicine conduct in an OTP. While the trust is perhaps more readily established within the OTP, extending the relationships to outsiders requires more resources and liaising with the existing OTP personnel.

A CM focused on the importance of building trust to facilitate communication between the patients-participants and the research team and telemedicine provider for treatment of HCV utilizing a meticulous strategy:

When I first came to the clinic, with the study, I met with every single counselor. It took a long time, I spent probably 20 to 30 minutes with every counselor... And when we identified people who might be appropriate subjects and we did a warm handoff as we call it, they introduced the person to me. And it makes a big difference.

In building trust with the participants, CMs indicated that it takes repeated engagement with the patients and the clinic staff, ensuring that they understand the study and the HCV treatment information, confirming that the myths and misconceptions about HCV treatment are dispelled, and that they are aware of both potential risks and likely health benefits of HCV treatment. As one case manager related:

The case managers met with her several times a month to reiterate the benefits of the PCORI study...The patient was also skeptical about the effectiveness of HCV medication... and she was unaware of the current HCV medication regimen. After five months of continuously engaging the patient using motivational interviewing skills, she consented and enrolled in the study.

Another case manager added:

I think that helped build the trust and also just having an open door so whenever she would walk by, she would see me and know that she can come and talk.

3.1.3. Building trust in telemedicine as an effective treatment modality

CMs benefited from the pre-existing trust we encountered in the participating OTPs. Once CMs established trust with OTP clients, trust was extended to the offsite telemedicine provider, which facilitated onsite telemedicine conduct. While most patients had no major apprehensions about telemedicine, at least one person “preferred to obtain HCV treatment from the community physician with whom he was already connected”. In most cases, however, CMs reported that patients’ initial fears due to the unfamiliarity with telemedicine were dispelled through education and engagement of peers who had undergone HCV treatment via telemedicine. Peers promoted messages of convenience and effectiveness of telemedicine for HCV treatment.

A CM reported that if it were not for telemedicine, the patients would not have sought HCV treatment. As the CM stated: “Many patients have indicated that this study, the treatment, and having access to a doctor via telemedicine has saved their life!” Another CM summed up the value of telemedicine:

I haven’t had any patients feel apprehensive about telemedicine. It felt like finally people were meeting them where they were already going every day. And this [telemedicine] is just so much easier [when] the CM, we set up the camera and all they [have to] do really is just walk in and then talk to the provider.

Regarding trust in the modality, another CM noted: “Once they see it work, fears were dispelled.”

3.2. Theme two: managing competing priorities and complex challenges of obtaining HCV care in PWOUD

The CMs related stories of the competing priorities and complex challenges of supporting care for this patient population that were interrelated with the patients’ competing priorities. Patients often had multiple social issues and/or medical comorbidities that obstructed or interfered with the pursuit of HCV treatment. In many cases, these complex issues presented special challenges; understanding the intricacies of these frequently interrelated problems lay the foundation for tailoring a personalized approach to HCV care for the PWOUD population, as explained in Theme 3 (see below). Three subthemes emerged as the most important for recognition of competing priorities: health literacy needs, which can breed mistrust; family and environmental concerns; and managing complicated treatment plans.

3.2.1. Understanding mistrust as a barrier to HCV treatment in conventional community settings

CMs described how, in the usual care arm of the parent study, their patients did not feel comfortable in conventional healthcare settings where they mistrusted the providers, experienced insurance barriers in the healthcare system, and felt that the healthcare system was not set up to facilitate their medical treatment. Consequently, CMs needed to advocate for the patients in these traditional healthcare settings by providing problem-solving and consistent support. In one example, the CM described the challenges facilitating care for her patients and the need for advocating for the patients when they were seeking HCV care in the community as part of the usual care study arm:

One medical office delayed faxing requests for insurance authorization for two subjects’ HCV medication for weeks until the CM called to question the delay in their treatment start dates. The office provided the explanation that both subjects’ documents had been “lost in the shuffle” of their “busy” practice.

Navigating the healthcare system can be particularly complex especially for individuals with health literacy needs. Extensive delays in obtaining a provider consultation or in filling prescriptions can breed mistrust. A CM provided an example of a situation in which patient advocacy was crucial to moving the process forward:

The specialty pharmacy, in processing the prescription, indicated that patient’s insurance was limited to another specialty pharmacy. Five months after initial transmission of treatment [information] to that specialty pharmacy and with numerous telephone calls resulted in no medication. After several consultations, the medication was finally authenticated and shipped to the clinic to be dispensed.

CMs described that another common priority of the patients was concern for confidentiality and fear of disclosure of risks related to potential incarceration from outstanding warrants as well as stigma associated with HCV infection. CMs also related patient concerns about not wanting others to know of their HCV diagnosis even in the clinic setting. The CMs were creative in the OTP setting, partnering with OTP nursing staff for dispensing DAAs with methadone as one described:

Patients that were more concerned [about] getting discovered [at the clinic], so we have to try different methods for the patient who would prefer to take the medication away from the dispensing window. I needed to reassure them that they (others) weren’t going to find out.

CMs described the delicate situations that required honoring the patients’ wishes to maintain confidentiality, which required a clear understanding of their social situations and the factors that promote mistrust:
She wanted treatment... but she had not disclosed to her partner that she had hepatitis C, and I got the sense that her partner was very controlling. She could go to the methadone clinic because her partner knew that she was receiving methadone treatment... But if she had gone to an outside clinic, her partner would have wanted to know about it.

CM also had situations where patients had disclosed their risks of outstanding warrants and their fear of incarceration as a barrier to HCV care, as one CM related:

One patient, for whom there was an active legal warrant in the community based on a crime committed while previously using drugs, declined to participate in the study based on fear that any inclusion of his name or identifying data, even in a medical context, could result in his immediate arrest and incarceration.

3.2.3. Managing complicated treatment plans with multiple comorbidities

CMs prioritized care with patients who needed to balance family and life concerns, such as work schedules and child care, as one CM explained:

Both husband and wife being involved in the project... they had the young kids at home. So, it was always an issue. Who's going to come and who's going to stay with the kids? It was actually much easier for them to do it in the methadone clinic, rather than going and seeing a doctor elsewhere.

Another example demonstrates the complexity of the patients' situations. In this case, the individual had to contend with pressing child care needs as well as imminent concerns about her personal safety:

A subject with young children, one with special needs, was living with an abusive partner. She was accountable to him for her time (no “extra” time for HCV treatment appointments or labs) as well as for money earned at her job. Inviting that patient to participate in the study led to discussion of her more immediate needs, and a referral to her primary counselor for intervention. For this subject, a multi-step path to HCV treatment began with a safe plan to remove herself and her children from their unsafe home situation. When she felt worthy and able to accept support from those able to help meet her immediate needs, she was able to begin HCV treatment.

CMs also described how having treatment through telemedicine at the clinic accommodated their transportation and job schedules, so that they did not need to take time off from work for HCV treatment.

Some patients work. It was an issue for them. So, if they start working at 8 am or 9 am, going to some other venue, which is not the methadone clinic, would be much more difficult. So, and everything has to be accommodated for them so they can come [at] six in the morning and everything [is] done around that time.

3.2.2. Family and environmental concerns

CMs also described how managing treatment through telemedicine at the clinic accommodated their transportation and job schedules, so that they did not need to take time off from work for HCV treatment.

3.2.3. Managing complicated treatment plans with multiple comorbidities

CMs skillfully advocated for patients when managing multiple physical and mental comorbidities as well as other competing priorities and barriers to HCV care throughout the study including study enrollment, ongoing HCV treatment, and treatment follow-up. Managing HCV care was especially challenging for individuals with mental health issues that frequently co-occur with addiction. Many of the eligible patients also had psychiatric conditions including anxiety, depression, agoraphobia, social anxiety, schizophrenia, and bipolar disorder. These comorbid psychiatric and psychological conditions contributed to patients' reluctance to receive treatment for HCV. For example, one patient who, "suffers from paranoid ideation... was very difficult to get her to stay on medication, continuing on the course."

Comorbid medical conditions further complicated the HCV care. Another example illustrated how information on the condition of their liver disease enabled participation in HCV treatment:

A patient with cirrhosis was not motivated to enroll initially deferring to work schedules and other priorities. However, upon evaluation, as she found out that she had cirrhosis, she became enrolled and was... engaged in the study as well as in HCV treatment. The previously unrecognized cirrhosis diagnosis was a motivating factor for the patient to engage and to persist in treatment.

In addition to comorbidities, the CMs described common financial challenges, insurance status, homelessness, and immigrant status including one example of an individual who lost insurance because he was an immigrant:

One middle-aged immigrant was experiencing homelessness. Despite dealing with financial constraints and housing instability, he was extremely eager to enroll in the study... However, due to him forgetting to recently his insurance, it was deactivated. It took him about 5 weeks to successfully reenroll his insurance, complete the initial blood draw, and become enrolled in the study.

3.3. Theme three: personalizing care among PWOUHD

CMs told stories of the complicated lives of their patients where HCV treatment was not the first priority. In order to proceed with HCV treatment, patients often required extensive accommodations and personalization to address each of their unique needs that often were related to competing priorities and complex challenges described under Theme 2 above. Mental health issues, in conjunction with addiction, often presented challenges that complicated the treatment course in the context of building trust in an environment where “mistrust [is] a way of life”. One CM described how difficult it is trying to work with a patient while they are actively using illicit substances:

I have had a patient fall asleep during the session trying to fill out the questionnaire and said ‘maybe we can try it again next week’... You kind of have to, you know, weigh the pros and cons, like do I try again tomorrow? Do I wait a week? So, those kinds of things happen in this population and they’re more of the norm than an exception.

CMs also talked about common paranoia symptoms and misunderstandings that occurred, which required constant reassurance, repeated engagement, and support. One patient thought she had to go to another city to receive HCV treatment:

The patient expressed concern during the telemedicine visit because the HCV provider indicated that he is usually in another city during the telemedicine sessions. Upon hearing this information, the patient exhibited paranoid behavior and indicated that she is not going to go to [that city]. [By] reassuring the patient... and coaching from the [facilitator], the telemedicine visit was able to continue.

When personalizing care, the CMs described a plethora of activities included in the subthemes: meeting clients where they are, managing family and life concerns, educating and coaching, advocating for clients to facilitate treatment, communication to enable supportive environments, and assessing progress toward improved health.

3.3.1. Meeting clients where they are

CMs unequivocally emphasized the importance of “personalized approaches to overcome the challenges that are associated with difficult-to-engage patients,” which includes truly listening to clients’ concerns. This personalized approach is tailored to meet the individual needs and to address the unique aspects of each patient at any given time.

Being mindful of patients’ treatment expectations and recognizing their personal challenges is part of accommodating individuals’ unique needs at any given time before or during the treatment cascade:

I think you have to have a lot of patience with them and to answer all of their questions and not push them if they’re not ready at that point in time.
And, you know, they may come back and meet with us a second time and then you know, as they get to know us again, they build trust.

Other CMs described being empathetic and mindful of the patients’ lives:

Just be open minded and a lot of the people that you’re going to speak to have gone through such hardships throughout their lives... One patient, the reason she wanted to be treated was because her daughter died from complications with HCV. So being mindful that giving the medications is changing their lives and how that may be shaping their experiences... If you have a patient that [is] sometimes rude... But you got to understand the things they’re going through... Always treat them with respect and understanding.

One CM described a method she uses to tailor to patient preferences in order to facilitate communication:

“[It] took a lot of hand holding and reassurance to get [the patient] to a new treatment. We gave her some time and went back to the [HCV provider].”

CMs’ stories reflect their awareness of patients’ unique experiences and competing priorities that might interfere with HCV care, and they will go to great lengths to facilitate continued engagement.

The patient indicated that he was homeless and was residing in a shelter where his daily stay required “winning a raffle” in order to remain in the shelter for the following day and... there was correspondence to the shelter indicating the reasons for possibly prolonging the patient’s stay at the shelter in anticipation of the possible side effects the patient might experience. The patient was granted one week of prolonged stay to facilitate managing possible side effects.

3.3.3. Educating and coaching

Education and coaching emerged as a crucial element to patient engagement in HCV treatment. CMs described sharing knowledge of newer HCV treatment options, such as DAAs; however, common challenges were managing perceptions of HCV seriousness, expectations of treatment outcomes, and risks of non-treatment. The CMs related that they often needed to dispel myths regarding HCV treatment that was part of the lore of past interferon treatment with its negative side-effects. There was a need to convince them of the DAAs’ outstanding ability to cure the infection with minimal side effects. As one CM explained about the educational process for HCV treatment:

“It took several times for me, talking to them. And explaining to [them] what we were going to do about HCV. [They] didn’t understand that hepatitis C could destroy the liver. The minute they find that out, they really become a little anxious and scared because most of them have known someone who has died from liver cancer. It’s patient education to start to understand more.

Educating patients about HCV, telemedicine, and research while involving staff at all levels as well as using peers is paramount to creating and fostering trust across all members of the team involved in telemedicine. “Flexibility, patience and persistence. I think these are the key components.”

3.3.4. Advocating for clients to facilitate treatment

The CMs constantly worked with the patients throughout the continuum of HCV care and study follow-up by providing consistent engagement and support, at times over a 5-month period. CMs maintained sensitivity and patient-centeredness, while respecting and reinforcing the patient’s choice and clarifying that DAAs differ substantially from interferon-based therapies. CMs also reported the need to “reemphasize that enrolling is completely voluntary, and to discuss [their] personal challenges unrelated to the study.” Advocating required persistence and ongoing reinforcement of the message of a possible cure to “walk alongside him from start to finish.”

Another CM related the need to delicately balance these efforts to obviate undue participant burden:

She [the patient] was beginning to feel pressured or pushed, and we didn’t want her to feel that way and... We gave her some time and went back to talk to her again. And she said, no, absolutely... We thought we addressed all her concerns, but we still don’t know why she was saying no, but we didn’t want to push her too much, she was feeling pressured.

In the day-to-day clinic “we’re busy and you know participation takes a lot of time and a lot of hand holding.” However, CMs are unequivocal in letting the patients know that they are their advocates:

“You make it really clear in the beginning to both the participant/patient and the clinic staff that you [the CM] are there to facilitate getting them into treatment. If they do have those really serious competing priorities and they work, so they have to come into the clinic at six o’clock, and they need to be out by 6:30. You need to be there, you need to be able to accommodate that. Because otherwise, really, they would tell you, this is the only time I can do it, and if you cannot do it at that time, I'm not going to be in the study. I'm not going to get the treatment, it's as simple as that.
3.3.5. Communication to enable supportive environments

CMs have repeated engagement with counselors and other OTP staff while gaining agreement of the whole team: staff, patient, and, in some cases, the patient's family. There is a need for repeated study updates and education of the entire team – not just the patient. However challenging, facilitating and capitalizing on team communication will enable creation of a supportive environment, leading to engendering the trust requisite for successful telemedicine conduct and ultimately HCV treatment pursuit in a patient-centered manner. One CM related:

It's definitely a team approach, especially in this setting. You have to build into the setting that you need to talk to not only the counselor but also clinic staff, even security guards... and then the medical director, staff, and the dispensing nurses. It takes that kind of team approach to manage difficult cases.

CMs also consider the patients' peers as part of the team community:

A lot of people came to me, having been referred by someone who was already [in the] study... They can dispel a lot of the myths around hepatitis C treatments, especially those patients who are concerned about interferon and the side effects. Patients can tell them, 'No, I did it. It wasn't bad, went quickly, maybe a couple of side effects. Nothing that bad. You can do it'.

3.3.6. Assessing progress toward improved health

Overall, the CMs felt that the telemedicine approach to HCV care in this setting assisted in personalizing HCV care in conjunction with addiction treatment and was an overall positive experience for the patients. As evidenced by the description below, in a number of cases, achieving HCV cure was a gateway to health stability, i.e., HCV cure and education of the entire team.

SVR as indicated by the fact that they do not receive incentives for cases, the patient's family. There is a need for repeated study updates while gaining agreement of the whole team: staff, patient, and, in some cases, the patient's family. There is a need for repeated study updates while gaining agreement of the whole team: staff, patient, and, in some

During the course of HCV treatment, patients usually demonstrate increased methadone compliance, less missed visits, and improved toxicology reports... However, substance abuse relapse is very common, and we are highly understanding of this feature. We refrain from patient judgment and instead focus on recommending “clean drug use”, meaning avoid sharing of drug apparatus. Almost all patients have gone on to complete HCV treatment and polysubstance abuse recovery. This dual nature management plan allows patients to focus on other aspects of their lives, such as mental illness, family care, employment, and education.

CMs often reflected that their patients' treatment progress and HCV cure were accomplishments, relating that “medical professionals understanding and facilitating treatment while clients focus on their lives.” In other words, HCV treatment and cure were permissive for subsequently affording patients the opportunity to address their identified competing priorities and other challenges - as another CM related thoughtfully:

He shared that while incarcerated and thinking about his future, he thought about what he’d learned about HCV, his liver, and treatment from his earlier study participation, and he had set HCV treatment as a priority goal for his return to the community.

CMs also reflected on the concerns of HCV reinfection:

If you have a couple, you want to treat them at the same time to get them through the study and treatment at the same time... I’ve had several re-infections over the time... She said, I want to get treated right away, but I know there’s no point... if he [the person she lives with] is positive and I used with him. And that’s how I got it back. So, she said, I have to convince him to get treatment this time. We spend some time brainstorming. And she, on her own, made it happen.

According to CMs, patients value their own recovery after achieving SVR as indicated by the fact that they do not receive incentives for participating in the two-year post-treatment follow-up to assess for reinfection. As one CM commented, the patients demonstrated their dedication to the study by the fact that after they achieved HCV cure ...

… there’s no incentive, other than just getting the blood drawn, there is no monetary payment. There’s nothing after the SVR visit. But they come for blood draws for 18 months, after 24 months, and they do it. And you know, when you call them up that, six months after whenever the last time was, they are like, oh really, has it already been a year? And they kind of reflect on that. Wow, You know, I’ve been here now for a year already in. It’s always kind of a nice recognition of, you know, you built this trust, they got cured, and it was an experience for them that they can appreciate, for sure.

3.4. Constitutive pattern (construct): enacting teledicine HCV treatment in a community of trust

To widen the community of trust among substance users in an OTP, the CM represents a critical component of a multilayered endeavor (Fig. 2). OTPs can represent a “community for substance users” with their own internal culture, norms, and trust: an environment with reduced stigma toward substance users compared to that encountered in conventional healthcare settings. Researchers and healthcare providers have traditionally viewed this population as “difficult-to-engage”, not only in HCV treatment offsite, but also in research. That perception, however, partially stems from an under-recognition of the potency of competing priorities, multilevel barriers, and prior stigmatizing experiences. In attempting to engage substance users at an OTP in research, the first hurdle to overcome is to engender trust. Researchers may encounter distrust (e.g., “you want me to be your guinea pig.”), especially in settings and with individuals without significant research experience. Upon gaining substance users' trust to consider research participation, researchers need to convey the importance and value of HCV treatment and dispel PWOD misconception about HCV. The trust existent in the OTP facilitates trust in teledicine and the teledicine provider. The community of trust initiates from the foundation of trust in the OTP, then moves to research, then to teledicine encounters, and finally to commencing safe and effective HCV treatment. Building trust, minimizing stigma, and managing competing priorities and complex challenges during the above process require utilizing various engagement strategies and advocating on behalf of clients.
4. Discussion

We sought to understand the CMs’ point of view on telemedicine as a therapeutic modality for delivery of HCV treatment onsite in OTPs as well as ancillary benefits that might accrue from HCV treatment. Using a qualitative approach, we found that the CMs’ perceptions of the issues involved in successfully implementing HCV treatment via telemedicine in the OTP community focused on three themes: the need for building trust, understanding the competing priorities that challenge PWOUd pursuit of HCV care, and how to deliver personalized care to the PWOUd population.

In this study, the first theme that emerged was the need to build trust. It appears that PWOUd trust in OTP staff and others who are assuming care for them is foundational to establishing a therapeutic alliance. Trust within OTPs can be considered a spectrum. Although not universally encountered in OTPs, OTPs have been shown to be able to provide a trusting, warm, and welcoming environment with a sense of community and security for PWOUds (Earnshaw et al., 2013; Islam, 2013; Munoz-Plaza et al., 2008; Woo et al., 2017). Perhaps because of a self-selection process, study participants readily identified our study sites and their staff members as trusted venues. Trust and, more specifically, building trust to facilitate communication between the patients-participants, the

### Table 2

<table>
<thead>
<tr>
<th>Themes</th>
<th>Subthemes</th>
<th>Specific challenges of telemedicine model</th>
<th>Study observations and practical advice</th>
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<td>Utilizing pre-existing culture and trust in OTPs to enable research and telemedicine</td>
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<td></td>
<td>Building trust within the OTP community</td>
<td>Overcoming mistrust and discomfort of external providers</td>
<td>Ensuring awareness of patient benevolence, regulatory compliance</td>
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<td>Adding telemedicine as part of OTP community</td>
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<td>Building trust in telemedicine as an effective treatment modality</td>
<td>PWOUd trust of telemedicine provider</td>
<td>Facilitating communication between participants, research team, and telemedicine provider</td>
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<td>Confidentiality and security concerns with telemedicine</td>
<td>Education about research, HCV treatment, and telemedicine</td>
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<td>PWOUd mistrust and stigma of healthcare system</td>
<td>Educating and ensuring transparency</td>
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<tr>
<td></td>
<td></td>
<td>Asymptomatic nature of HCV</td>
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<td>Low HCV knowledge</td>
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<td>Difficulty navigating healthcare system</td>
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<td>Unstable housing</td>
<td>Awareness of telemedicine's convenience in managing schedules, transportation, childcare, etc.</td>
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<td>Domestic violence</td>
<td>Enacting cultural sensitivity in managing social strata, ethnic and linguistic barriers, literacy and education levels</td>
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<td>Scheduling conflicts</td>
<td>Educating about HCV, e.g., potential for cirrhosis, cancer</td>
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<td>Transportation difficulties</td>
<td>Educating about relative ease of treatment, e.g., interferon versus DAAs, minimal side-effects, high efficacy</td>
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<td>Managing complex treatment plans with multiple comorbidities</td>
<td>Managing addictions, physical and mental comorbidities</td>
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<td>Prioritizing medical, social conditions over addressing HCV treatment</td>
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<td>Accommodating patient needs in external community</td>
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<td>Personalizing individual's unique needs and timing interventions for optimal effects</td>
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<td>Dispelling HCV treatment myths</td>
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<td>Individual involvement in care process</td>
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<td>Schedule adjustment to permit telemedicine and SUD care in OTP</td>
<td>Reinforcing the importance of treatment while respecting individual's autonomy</td>
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<td>Communication to enable supportive environments</td>
<td>Engaging the team to understand each person's views</td>
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<td>Assessing progress toward improved health</td>
<td>Monitoring treatment outcomes</td>
<td>Engaging entire OTP and research team</td>
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Abbreviations: OTP, opioid treatment program; PAC, patient advisory committee; PWOUd, persons with opioid use disorder; HCV, hepatitis C virus; CM, case manager; SUD, substance use disorder; PCP, primary care provider; DAA, direct acting antiviral.
research team, and the telemedicine provider, emerged as a major theme in CMs’ descriptions of participant engagement in HCV treatment via telemedicine. Trust also extended to the telemedicine provider through repeated engagement via telemedicine encounters.

We identified that health literacy needs, medical and social-structural determinants of health, and a complex treatment plan can be important barriers to care for HCV infection. These conditions and issues, such as mental health diagnoses, including depression and anxiety, may be directly or indirectly related to substance use. Consistent with the findings of others, we found that the asymptomatic nature of HCV infection can result in a low perceived need among PWOUD to pursue HCV treatment compared to competing medical and mental health conditions (Earnshaw et al., 2013; Munoz-Plaza et al., 2008). Increases in PWOUD knowledge of HCV and exposure to peers with HCV telemedicine experience facilitate pursuit of HCV treatment (Munoz-Plaza et al., 2008). In our study, we found that social and structural issues that affected PWOUD can include lack of insurance, unstable housing, domestic violence, immigration status, schedule conflicts with employment and child care, and transportation difficulties. Potential stigma associated with substance use and difficulties navigating the complex healthcare system may engender feelings of mistrust and discomfort in conventional healthcare settings (Zeremski et al., 2013).

In order to successfully engage OTP patients in well-tolerated, highly curative HCV treatment via telemedicine, a modality to which most of them were unaccustomed, CMs developed personalized approaches to build trust. CMs play vital roles as recruiters, educators, facilitators, and motivators while simultaneously expressing empathy utilizing a patient-centered approach. CMs became part of the OTP community with seamless interactions with the entire OTP staff permitting them to be patient advocates, educators, and liaisons between providers, patients, and OTP staff. The idea of “meeting people where they are” appears a critical prerequisite to engage PWOUD in HCV treatment via telemedicine. This concept is consistent with theories of behavioral change, such as the transtheoretical model, in that interventions designed to change behavior need to concern issues most important to the patient (Prochaska & DiClemente, 1982). Our findings align with models of access to healthcare for vulnerable populations that conceptualize access to care as a recursive, dynamic, interactive, and experiential process (Hjøt et al., 2019). Building upon previous theories of access to care, these integrated frameworks stress the importance of individuals’ prior service experiences and the role of health professionals as mediators of their service trajectories (Dixon-Woods et al., 2006). The models stress the importance of positive therapeutic relationships and patient-centeredness in that individuals’ values, preferences, and needs are prioritized in coordinating their care. In the telemedicine integrated care model, the CM is the patient advocate. Furthermore, in our study, CMs reported that being mindful of these contingencies helped to obviate exerting undue participant burden and enhanced building the rapport necessary for effective communication and effecting change (Prochaska et al., 2015). CMs, collaborating with the rest of the health system, helped to empower and enable the individual to negotiate change at any given stage of the HCV treatment cascade (Hjøt et al., 2019). CMs reassured participants that they were available to participants whenever and wherever needed. Ongoing education and coaching, particularly around HCV infection, were important attributes to effect change, which frequently required participation of the entire OTP staff, healthcare providers, and peers. The study required measurement of progress, specifically cure, which was also important to ensure the sustainability of telemedicine. We and others have found that HCV cure provides an opportunity to address issues in other dimensions, such as treatment of addiction and improving living situations (Batchelder et al., 2015; Marinbo & Barreira, 2013).

Hermeneutic phenomenology utilizes narratives to derive unique meanings from a situation in order to develop practical knowledge or wisdom. Heidegger's reflections on technology are particularly relevant to telemedicine. Thus, in order for technology to be most effective, evaluating the users’ experiences and reactions can provide relevant insights. Prior investigation utilized hermeneutic phenomenology to study the experience of addictions (Vandermause, 2007, 2012). In our study, the CMs facilitated the telemedicine encounters, and we included several specific interventions, such as having the site clinician at the initial telemedicine encounter, to maximize the likelihood that patient’s trust in the OTP is extended to the telemedicine provider (Talal, McLeod, et al., 2019). Through these interventions, we are beginning to understand how telemedicine encounters can be facilitated to be effective in vulnerable, difficult-to-engage populations such as PWOUD (Table 2). Heidegger wrote, “the bridge swings over the stream... [and] gathers around and leads in many ways” (Heidegger, 1971, p. 152). With the facilitation by individuals, such as CMs, virtual technologies, such as telemedicine, can be a bridge to connect vulnerable populations to specialty providers in a secure manner (Heath et al., 2013; Rheingold, 2000; Wilkes et al., 2014). Experts recognize that telemedicine effectively integrates healthcare, such as medical and behavioral treatments (National Academies of Sciences et al., 2020; SAMHSA-HRSA Center for Integrated Health Solutions, 2017; The Addiction Technology Transfer Center Network Coordinating Office, 2019).

Prior investigation utilized qualitative approaches to study patient and staff experiences in integration of HIV and OUD care (Oldfield et al., 2019). In our study, we utilized qualitative approaches to derive unique meanings from telemedicine encounters with a vulnerable population. We analyzed the narrative texts to identify themes that we clarified and expanded through a focus group. CMs supplied vignettes based upon their experiences with patients. As such, the themes emerging from the analysis represent the CMs' perceptions managing patients’ care and not the patients’ actual experiences of HCV care. Researchers and providers should address the identified themes (e.g., Theme 2) to facilitate engagement of and virtual healthcare delivery to vulnerable populations. The knowledge gained from these approaches is most applicable to the OTP sites participating in this study and, as such, requires further investigation of the transferability of the identified themes in engaging and integrating telemedicine use with vulnerable populations to other types of substance use treatment facilities. We have identified several states that have regulations related to MOUD that parallel those in NYS that should facilitate expansion of the telemedicine model. Another important consideration is the integration of the CMs’ themes with the patient perspective, which is particularly important in the development of patient-centered telemedicine interventions.

4.1. Conclusions

Through this investigation, we have identified the importance of sustained engagement, demonstration of respect, and the value of developing trust with a vulnerable patient population in order to achieve therapeutic successes. CMs viewed our study sites as trusted venues, which facilitated PWOUD engagement in HCV treatment. CMs were able to utilize a variety of different tactics to enable study participants to achieve the goal of HCV elimination. Further investigation of these themes in other populations and settings is important to enable HCV elimination among vulnerable populations.

CRediT authorship contribution statement

Andrew H. Talal: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Writing - original draft, Writing - review & editing. Urmo Jaanimagi: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing - original draft, Writing - review & editing. Kathleen Davis: Investigation, Data curation, Writing - review & editing. Jordan Bailey: Investigation, Data curation, Writing - review & editing. Barbara M. Bauer: Investigation, Data curation, Writing - review & editing. Arpan Dharia: Investigation, Data curation, Writing - review & editing. Saliyah George: Investigation, Data curation, Writing -
Declaration of competing interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jsat.2021.108421.

References


