



Contents lists available at ScienceDirect

Exploratory Research in Clinical and Social Pharmacy

journal homepage: www.elsevier.com/locate/rcsop

Pharmacist-led HIV and hepatitis C point-of-care testing and risk mitigation counseling in individuals experiencing homelessness

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ARTICLE INFO

Article history:

Received 22 December 2020

Received in revised form 30 March 2021

Accepted 30 March 2021

ABSTRACT

Introduction: Over half a million people experience homelessness on any given night in the United States. As a result of increased exposure to disease, violence, stigma, substance misuse and limited accessibility to health services, individuals experiencing homelessness are disproportionately affected by communicable diseases such as HIV and HCV with prevalence estimates as high as 21% and 36%, respectively. Pharmacists, being some of the most trusted and accessible healthcare providers, are in a unique position to have a significant impact on the nationwide initiatives in *Ending the HIV Epidemic: A Plan for America* and the *National Viral Hepatitis Plan* by offering preventative testing services and patient-centered risk mitigation counseling and education. This research looks to assess the health impacts associated with pharmacist-led HIV and HCV screening coupled with comprehensive education and risk mitigation counseling in adults experiencing homelessness.

Methods: This study was conducted in a single independent community pharmacy in Spokane, Washington which specializes in mental health services and serves a large proportion of patients who are experiencing homelessness. Study participants are walk-in patients of the pharmacy, over the age of 18, are currently experiencing homelessness, and have not received an HIV or HCV screening within the past 6 months. The study intervention includes a Risk Determination interview, administration of HIV and HCV point-of-care antibody test, comprehensive diseases state education and personalized risk mitigation counseling. Participants are then referred to a local health clinic for confirmatory testing, anonymous partner notification, and evaluation for pre-exposure prophylaxis if indicated.

Results: A total of 10 participants were included in the final data analysis. Majority of study participants were male (80%), heterosexual (90%) and over the age 30 (90%). A total of 8 participants (80%) had a reactive HCV screening and there were no reactive HIV screenings. Many of participants reported IV drug use with methamphetamine being the most used illicit substance. Half of all participants (50%) admitted to borrowing a needle for injection drug use within the past 6 months. Two participants admitted to having sexual intercourse with a partner who was known to be HCV-positive and both participants had a reactive HCV screening. All study participants reported at least one serious mental illness diagnosis and ongoing recreational drug use was cited as a coping mechanism in all participants.

Conclusion: Since efficacy of treatment is no longer the limiting factor in eradicating HCV and suppressing HIV viral load, public health efforts need to be refocused on patient engagement through preventative services in an environment that is less stigmatized than traditional testing sites, such as community pharmacies. Study participants were highly receptive to pharmacist-provided point-of-care screening services in the community pharmacy. Combining HIV and HCV point-of-care testing with comprehensive patient-centered education and risk mitigation counseling may result in lower rates of community transmission, improve linkage to care and may lead to long-term retention of marginalized populations such as those experiencing homelessness.

1. Introduction

Over half a million people experience homelessness on any given night in the United States.¹ Homelessness is defined as the condition where an individual or family does not have a physical nighttime residence and is living in areas not meant for human habitation such as outdoors, in vehicles or

abandoned buildings.² Individuals experiencing homelessness are at an increased risk for developing medical problems and treatment complications when compared to the general population.³ Increased exposure to disease, higher rates of substance misuse and psychological illness may be contributing factors to this variance.⁴ Persons at higher risk for acquiring HIV and HCV infection, including members of the LGBTQ+ community, racial

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minorities and victims of sexual assault are also disproportionately affected by homelessness.⁵ The management of chronic disease states such as HIV and HCV, require high rates of adherence and regular follow-up with a provider. These parameters are more difficult to achieve in individuals experiencing homelessness.^{3,5-7}

In 2016, there were over 1.1 million individuals living with HIV and 2.4 million people living with Hepatitis C in the United States. The CDC reports that 1 in 7 (14%) individuals are unaware of their HIV infection and it is estimated that almost half of all individuals with HCV infection are undiagnosed.^{8,9} There is significant overlap in the transmission of HIV and HCV and the prevalence of co-infection is estimated to be between 15 and 30%.¹⁰ Individuals with chronic HIV or HCV infection may present with non-specific symptoms making diagnosis difficult without routine testing. With the growing opioid epidemic, individuals experiencing homelessness are disproportionately affected by HIV and HCV with some estimated prevalence rates as high as 21% and 36% for HIV and HCV, respectively.¹¹

Point-of-Care Testing (POCT) is performing a diagnostic test outside of a laboratory setting that produces rapid results and aids in the identification and management of chronic disease states. A positive HIV or HCV antibody POCT result is referred to as "reactive" and confirmatory testing is needed for diagnosis. While performing POCT in community pharmacies has been well established,¹² this study looks to add comprehensive education and personalized risk mitigation counseling to enhance these pharmacist-provided patient care services. Research has shown that individuals with low health literacy tend to experience more treatment failures, have lower rates of adherence, and underutilize preventative services.¹³⁻¹⁵ Pharmacist involvement in the care of individuals with HIV and HCV infection has shown to enhance adherence, reduce pill burden, and result in higher rates of viral load suppression.¹⁹⁻²² As pharmacy practice grows to expand patient care services in the community setting, pharmacists, being some of the most accessible healthcare providers, are poised to play a significant role in the care of underserved populations in a setting that is less stigmatized than traditional testing sites.

The primary objective of this study was to design and implement an enhanced point-of-care testing model for HIV and HCV screening in the community pharmacy setting. Secondary objectives were to evaluate the prevalence of HIV and HCV in adults experiencing homelessness and to identify risk factors associated with a reactive screening.

2. Materials and methods

2.1. Setting and practice description

This study was conducted in a single independent community pharmacy in Spokane, Washington which specializes in mental health services and serves a large proportion of patients who are experiencing homelessness. This site has a Clinical Laboratory Improvements Amendments of 1988 (CLIA) Certificate of Waiver, which allows them to perform simple laboratory examinations that have minimal risk of an incorrect result.²³ We used whole blood samples from a fingerstick during the administration of third-generation HIV POCT (INSTI HIV-1/2 Antibody test Kit, bioLytical Laboratories) and HCV POCT (OraQuick HCV Rapid Antibody Test, OraSure Technologies, Inc.).

The pharmacist intervention includes administration of an FDA-approved and CLIA-waived HIV and HCV point-of-care screening, a 1-on-1 risk determination interview, comprehensive disease state education and personalized risk mitigation counseling followed by referral to community partners for follow-up confirmatory testing and to establish care.

This study received full-board review by the Washington State University Institutional Review Board and was approved in December 2019 (IRB: 17925-002).

2.2. Recruitment of study participants

Eligible study participants were adult patients of First Avenue Pharmacy who are over the age of 18, are currently experiencing homelessness

(defined as having no nighttime residence, having spent the last 24 h outdoors, in an emergency shelter, or areas not meant for human habitation), who have not received an HIV or HCV screening in the last 6 months and have been determined by the investigator to accurately give informed consent. Exclusion criteria included individuals who were not experiencing homelessness, had received an HIV or Hepatitis C screening in the past 6 months, had a history of HIV or HCV diagnosis, or were unable to give informed consent.

2.3. Pharmacist intervention

The study intervention was conducted by one pharmacist (SK). The pharmacist is certified through the American Academy of HIV Medicine (AAHIVM) and received a 2-h training on post-test counseling from Spokane Regional Health District (SRHD). Once consent was received, the pharmacist began by administering the HCV POCT and the HIV POCT using blood samples obtained from a single fingerstick. The HCV POCT provided results within 20 min while the HIV POCT provided results within 5 min.

2.4. Risk determination interview

During the time the screening tests were developing, the pharmacist engaged the participant in a 1-on-1 interview focused on sexual behaviors, past and present drug use, and mental illness (Table 1). Interview questions were developed by the authors and reviewed by three HIV Clinical Pharmacists accredited through the American Academy of HIV Medicine (AAHIVM), an HIV care coordinator at the Spokane Regional Health District (SRHD), and an HIV-specialized physician at Spokane Teaching Health Clinic (STHC). The interview questionnaire was adjusted to include suggested edits from subject matter experts before implementation. Interview responses were recorded by the pharmacist and used to provide specific risk mitigation strategies for the patient during the education portion of the intervention. In addition to personalized risk mitigation counseling provided to the patient based on interview responses, the Risk Determination

Table 1
Risk determination interview questions.

Interview Questions
Sexual behaviors
- How would you classify your sexual preference? (Heterosexual, Homosexual, prefer not to answer)
- Are you currently in a sexual relationship? Do you know your partners HIV/HCV status?
- Have you ever had unprotected sex? With a stranger?
- Have you ever had anal intercourse?
- Have you been diagnosed with an STD in the past 6 months?
- Have you ever had sex with a person you knew was HIV-/HCV-positive? Approximately when?
Mental health
- Have you ever been diagnosed with Depression?
- Have you ever been diagnosed with Anxiety?
- Have you ever been diagnosed with Schizophrenia?
- Have you ever been diagnosed with Bipolar Disorder?
- Have you ever been diagnosed with Insomnia?
- Have you ever been diagnosed with a psychiatric condition not mentioned above?
- Have you ever used illicit drugs as a mechanism to cope with or treat one or more of your mental health conditions?
Drug use
- Have you ever used any of the following illicit drugs? <ul style="list-style-type: none"> o Marijuana, Methamphetamine, Heroin, Cocaine, Opioids
- Have you ever injected any of the above drugs?
- Have you ever shared a needle with someone?
- Have you borrowed a needle for IVDU within the past 6 months?
- Have you borrowed a needle for IVDU from someone you knew to be HIV/HCV-positive?

Interview was also used to determine if the patient would benefit from a referral for Pre-Exposure Prophylaxis (PrEP) evaluation. A patient was referred for PrEP if they expressed willingness for referral and met the criteria set forth by the CDC.²⁴

2.5. Education

The principal design of the education provided to patients is adapted from recommendations of the CDC and the National HIV and HCV Curriculum developed by University of Washington.^{25–27} This education addresses general disease state overview, risk factors, routes of transmission, available medications for treatment and prevention, disease progression, information on available community resources and potential next steps in the setting of a reactive HIV/HCV screening. The education provided explains high level concepts in a way that is digestible for a lay person in an effort to minimize the stigma associated with a reactive HIV or HCV result. The participant is also provided information on the limitations and Window Period of the POCT which is defined as the time between acquisition of HIV or HCV and the time when the laboratory test will accurately detect the infection. The CDC recommends using a 90-day window period for all HIV and HCV antibody POCT.^{27,28} Although these POCT have high levels of sensitivity and specificity, a reactive result is still considered a preliminary positive and would require a confirmatory test for diagnosis.

During the education portion of the intervention, the pharmacist emphasizes certain topics and provides personalized risk mitigation strategies based on interview responses. For example, if the participant indicated they were an IV drug user and that they have shared needles within the past 6 months, the pharmacist would emphasize the primary routes of transmission for HIV and HCV being blood-to-blood contact and would educate the patient on specifically how sharing needles exposes the user to blood from another person. In addition to this, the pharmacist would also provide the patient with information on community resources such as needle-exchange programs at the local health district. If the participant indicated they had engaged in unprotected vaginal or anal intercourse, the pharmacist would educate the patient on exactly how blood-to-blood transmission occurs during sexual intercourse and strategies on how to mitigate risky sexual behaviors.

2.6. Test results and referral

Before the pharmacist disclosed the result of the point-of-care screening, an explanation of the limitations of the screening test was given to the study participant to include information on the window-period of the point-of-care tests, the need for a confirmatory test for diagnosis, and emotional reassurance. Individuals that had a reactive screening for HIV and HCV were referred to local partnering providers with a “warm handoff” where the pharmacist and patient would jointly call to make an appointment for follow-up testing and to establish care if the patient did not have a primary care provider. If the patient was determined to be high risk for acquiring HIV through the Risk Determination interview, a referral to be evaluated for PrEP was also made. The intervention, from patient contact to referral, took between 30 and 45 min depending on engagement of the patient during the interview and education process as well as need for post-test counseling.

3. Results

This study took place from February 2020 to May 2020 and a total of 10 participants were included in the data analysis since the study was stopped prematurely as a result of the COVID-19 pandemic. The majority of participants were male (80%), heterosexual (90%) and over the age of 30 (90%). Demographics of the study participants are included in Table 2.

When evaluating the secondary outcomes, a total of 8 (80%) participants had a reactive HCV screening and were referred for follow-up confirmatory testing and to establish care. Although none of the participants included in this study had a reactive HIV screening, five participants

Table 2
Patient demographics.

Demographics and interview responses	Value (N = 10)
Age	
18–30	10%
30–40	40%
40–50	20%
50 +	30%
Sexual Orientation	
Male	80%
Female	20%
Sexual preference	
Homosexual	10%
Heterosexual	90%
Current Living Situation	
Outdoors	30%
Motel/Single room occupancy	10%
Homeless shelter	50%
Staying with friends/ “Couch surfing”	10%
Prior knowledge about HIV/HCV	
No knowledge	10%
Very little knowledge	40%
Some knowledge	30%
Good understanding	20%

Our primary outcome was to describe the implementation of the comprehensive HIV and HCV POC screening and education services in a community pharmacy setting.

(50%) were determined to be high risk for acquiring HIV by the pharmacist and were referred to be evaluated for Pre-exposure prophylaxis (PrEP).

3.1. Sexual behaviors

Only two (20%) patients indicated they were currently in a sexual relationship and both did not know the HIV or HCV status of their sexual partners. Two participants (20%) admitted to having sex with an individual that they knew was HCV positive and both participants had a reactive HCV screening. Table 3

3.2. Drug use

All participants (100%) reported actively using at least one illicit drug with the majority of participants admitting to injection drug use (90%) with the most popular drug for injection being Methamphetamine.

Table 3
Sexual behavior interview responses.

Interview questions	Value (N = 10)
Currently in a sexual relationship	
Yes	20%
No	80%
Ever engaged in unprotected sex	
Yes	100%
No	0%
Ever engaged in unprotected sex with a stranger	
Yes	80%
No	20%
Ever engaged in unprotected anal intercourse	
Yes	70%
No	30%
STD diagnosis within the previous 6 months*	
Yes	20%
No	80%
Sex with partner known to be HIV/HCV-positive	
Yes	20%**
No	80%

* Both participants were female.

** Partner was Known to be HCV +, both participants also reported injection drug use.

Table 4
Drug use interview responses.

Interview questions	Value (N = 10)
Marijuana use	90%
Methamphetamine use	80%
Heroin use	60%
Cocaine use	40%
Opioids	50%
IV Drug Use (IVDU)	90%
Ever shared a needle IVDU	80%
Shared a needle for IVDU within last 6 months	50%
Shared needle for IVDU with someone who is known to be HIV/HCV-positive	0%

Table 5
Mental health interview responses.

Interview questions	Value (N = 10)
Depression	70%
Anxiety	70%
Schizophrenia	60%
Bipolar Disorder	50%
Insomnia	70%
Other*	70%
More than 1 mental illness diagnosis	90%
Reported illicit drug use as a means of coping with mental illness	100%

* PTSD (60%); ADHD (10%).

Eight (80%) participants indicated they had ever shared a needle with another person while five (50%) participants admitted to borrowing a needle for injection drug use within the past 6 months and all five were referred for evaluation for PrEP [Table 4](#).

3.3. Mental health

All participants reported they were diagnosed with at least one mental illness, with a majority of participants reporting multiple (2 or more) co-occurring mental illnesses (90%), and all participants indicated that mental illness was contributing factor to their ongoing illicit drug use [Table 5](#)

4. Discussion

Pharmacists are poised to play a significant role in US Department of Health and Human Services (DHHS) nationwide initiatives in *Ending the HIV Epidemic: A Plan for America* (EHE) which looks to end the HIV epidemic in the US by 2030, and the National Viral Hepatitis Plan which looks to eliminate new viral Hepatitis transmission and to connect those with chronic Hepatitis B and C with quality care and curative treatments.^{29,30}

The primary mode of transmission for HIV is through sexual contact with anal intercourse posing the highest risk and men who have sex with men (MSM) being the largest cohort of HIV-positive individuals (69% of all new infections in 2018).⁸ Although most participants identified as heterosexual (90%), the results of the risk determination interview across study participants showed a high level of unprotected sexual encounters with strangers as well as anal intercourse (80% and 70%). Participants were educated on the level of risk these acts pose and were offered a safe sex take-home package which included both male and female condoms as well as lubrication and information on PrEP. Two participants reported having sex with an individual known to be positive for Hepatitis C and both had a positive HCV POCT. The rate of HCV transmission through sexual exposure overall is about 15% in the United States but injection drug use is often an involved risk factor.²⁶

Injection drug use remains the most common risk factor for HCV transmission, with over 60% of all HCV diagnoses in the United States being attributed to people who inject drugs (PWID).³¹ An overwhelming majority of participants reported injection drug use (90%) with an alarming rate reporting shared needles (80%). These findings may explain the high rates of reactive HCV POCT (8 out of 10 participants). Study participants were referred to the local health districts needle exchange program and were educated on the risks of re-using needles as well as re-infection after treatment for HCV. Many individuals who are experiencing homelessness suffer from substance misuse and mental health disorders which often poses a reciprocal relationship which was reinforced by the results of this study.³² All participants reported at least one diagnosis of a mental health disorder and admitted to using substances as a coping mechanism. A meta-analysis conducted by Sin et al. showed that non-adherence was 35% greater among people who did not receive treatment for underlying depression. The authors also discovered that the odds of adhering to HIV care were 83% higher for people receiving treatment for depression.³³ Springer et al. saw similar results evaluating the impact of extended-release naltrexone in incarcerated individuals living with HIV and Opioid Use Disorder transitioning to the community. The authors concluded that extended-release naltrexone was associated with improvement or maintenance of viral load suppression when compared to placebo.³⁴ The findings of this study further highlight the priority of treating substance misuse and mental illness to effectively control communicable infections such as HIV and Hepatitis C.

Given the high rates of injection drug use, mental health diagnoses and risky sexual behaviors, the findings of this study support existing literature about the significant risk of acquiring HIV and HCV in individuals experiencing homelessness. Pharmacist-led disease state education may reduce the likelihood of acquiring HIV and HCV infection, and has been shown to significantly improve adherence to treatment.^{19–22,35} Improvement in treatment outcomes can also be seen with increased health literacy. Yang et al. found that Hepatitis C education significantly improved acceptance of antiviral treatment in rural China.¹⁸ Similarly, in Pakistan, Mushtaq et al. reported education status as a strong predictor of sustained virologic response (SVR) in patients being treated for chronic Hepatitis C.³⁶ Many of the behaviors that contribute to this elevated risk for infection in the homeless population, can be attributed to low health literacy and modified through education and counseling by a healthcare provider.

Although the COVID-19 pandemic halted data collection prematurely, our small sample size still shows a high level of detection for Hepatitis C (8 out of 10 participants with a reactive HCV POCT) and prevalence of high-risk individuals that were referred for Pre-Exposure Prophylaxis in the prevention of HIV (5 out of 10 participants referred). Since efficacy of treatment is no longer the limiting factor in eradicating Hepatitis C and suppressing HIV viral load, our efforts need to be refocused on patient engagement. Accompanying point-of-care screening with comprehensive education and personalized risk mitigation counseling looks to reduce transmission, combat stigma, and remove barriers to clinical engagement in the community pharmacy setting.

4.1. Limitations

Implementation of this service and the benefits it provides must be analyzed in the context of its limitations. The sample size of this study included 10 participants. Spokane Regional Health District (SRHD) provides routine testing services for individuals experiencing homelessness and as a result, many interested participants did not meet the inclusion criteria of this study. In addition, the COVID-19 pandemic halted data collection due to institutional limitations on face-to-face research. The small sample size significantly limits the generalizability of the results. Historically, pharmacists have indicated infrastructure, availability, staffing and adequate training to be constraints in providing these comprehensive clinical services in the community setting. In addition to these logistical concerns, the lack of a model for reimbursement and bureaucratic limitations further complicates the expanding role of pharmacists providing clinical services in the

community setting. This study was conducted in an independent community pharmacy that specializes in mental health care, offering administration of long acting injectables and other services which would lead to an expectation of a high level of mental illness diagnoses. Despite this confounding factor, using substances to cope with mental illness in the homeless population highlights the importance of treating the underlying mental health condition to better control the transmission of communicable infections such as HIV and Hepatitis C. Future research should focus on addressing existing barriers to reimbursement, pharmacist availability and infrastructure.

5. Conclusion

This research sought to design and implement an HIV and HCV screening and education model targeted towards individuals experiencing homelessness. Study participants were highly receptive to pharmacist-provided point-of-care screening services in the community pharmacy. Combining HIV and HCV point-of-care screening with comprehensive patient-centered education and risk mitigation counseling may result in lower rates of community transmission, improve linkage to care and lead to long-term retention of marginalized and difficult to reach populations such as those experiencing homelessness.

Acknowledgements

The authors would like to acknowledge Easton Stoner, PharmD and Andy Moore, PharmD for their work in assisting with data collection. The authors would also like to acknowledge Kathy Ton, PharmD, AAHIVP and Rustin Crutchley, PharmD, AAHIVP for their expertise.

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