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Impact of harm reduction care in HIV clinical settings on stigma and health outcomes for people with HIV who use drugs: study protocol for a mixed-methods, multisite, observational study

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ABSTRACT

Introduction Our previous pilot work suggests relational harm reduction strengthens relationships between people with HIV (PWH) who use drugs and their healthcare providers and improves HIV health outcomes. However, there is limited research examining ways that structural (eg, strategies like syringe service programmes) and/or relational (patient-provider relationship) harm reduction approaches in HIV clinical settings can mitigate experiences of stigma, affect patient-provider relationships and improve outcomes for PWH who use drugs. Our mixed methods, multisite, observational study aims to fill this knowledge gap and develop an intervention to operationalise harm reduction care for PWH who use drugs in HIV clinical settings.

Methods and analysis Aim 1 will explore the relationship between healthcare providers' stigmatising attitudes towards working with PWH who use drugs and providers' acceptance and practice of structural and relational harm reduction through surveys (n=125) and interviews (n=20) with providers. Aim 2 will explore the interplay between patient-perceived harm reduction, intersectional stigma and clinical outcomes related to HIV, hepatitis C (if applicable) and substance use-related outcomes through surveys (n=500) and focus groups (k=6, total n=36) with PWH who use drugs. We will also psychometrically evaluate a 25-item scale we previously developed to assess relational harm reduction, the Patient Assessment of Provider Harm Reduction Scale. Aim 3 will use human-centred design approaches to develop and pretest an intervention to operationalise harm reduction care for PWH who use drugs in HIV clinical settings.

Ethics and dissemination This study was approved via expedited review by the University of Pittsburgh Institutional Review Board (STUDY21090002). Study findings will be presented in peer-reviewed journals and public health conferences as well as shared with patient participants, community advisory boards and harm reduction organisations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ We are the first, to our knowledge, to examine intersectional stigma in people with HIV who use drugs through the multiple lenses of HIV, substance use and race.
⇒ Our study will also be the first to examine harm reduction for people with HIV who use drugs from a relational perspective (ie, the patient–provider relationship) in additional to the traditional structural approach (eg, syringe service programmes, naloxone distribution).
⇒ We will survey multiple health provider types who interface with people with HIV who use drugs, including those traditionally not included in research (eg, front desk and administrative staff, pharmacists, dieticians, etc).
⇒ A primary limitation is that our study sites explicitly provide HIV primary services to PWH, and there may be less variability among provider attitudes and patient experiences than would be found outside of this specialist setting. However, extant literature suggests that HIV providers often feel unprepared to care for and carry negative attitudes towards patients who use drugs.

Trial registration number NCT05404750.

BACKGROUND

There are significant HIV health disparities between people who use drugs and people who do not use drugs. Among all new HIV diagnoses in the USA in 2018, one in 10 were among people who inject drugs.[1] High rates of HIV among people who inject drugs are particularly problematic given injection drug use increases risk for HIV transmission and acquisition and predicts poor retention in HIV primary care.[2–5] Lack of retention in care is associated with poor clinical outcomes, such as unsuppressed viral load, which contributes

to HIV incidence.[6–9] People with HIV (PWH) who miss visits in their first year of HIV treatment have more than double the mortality risk of those retained in care.[10] Moreover, HIV and hepatitis C (HCV) often co-occur, with an estimated 21% of PWH in the USA coinfected with HCV,[11] and evidence that HIV viral load impacts severity of HCV infection.[12 13]

While social factors such as economic distress,[14] trauma[15] and comorbid mental health conditions[16] all increase substance use rates and serve as barriers to care, there is strong evidence that experiences of stigma in healthcare settings by people who use drugs are common and contribute to poor healthcare outcomes.[17–20] PWH who use drugs may experience stigma related to HIV status and substance use, while PWH of colour who use drugs may experience additional stigma through racial discrimination (eg, inequitable treatment based on race or ethnicity).[21] Experiencing any kind of stigma in the healthcare setting is particularly deleterious. We previously found that experiencing HIV stigma in healthcare settings, but not in community settings, was associated with lack of viral suppression,[20] while additional research illuminates the negative relationship between experienced HIV stigma in the healthcare setting and antiretroviral therapy (ART) adherence.[22] Experiencing substance use stigma in healthcare settings is also damaging, with people who inject drugs reporting experiences of discrimination and derogatory language from their healthcare providers, contributing to decreased engagement in care.[23]

Our previous work suggests that harm reduction (HR) may strengthen the patient–provider relationship and mitigate the effects of stigma. HR refers to approaches aimed at reducing the negative consequences of health behaviours without necessarily eliminating the problematic health behaviours entirely.[24–27] HR stands in opposition to the traditional medical model of addiction, in which any illicit drug use is labelled as abuse, and the moral model, which labels substance use as simply wrong.[25 26] HR strategies such as syringe service programmes (SSP), naloxone distribution and medications for opioid use disorder effectively engage people who use drugs in care by providing services that are responsive to their needs without assuming abstinence as the ideal clinical outcome, while simultaneously working to reduce stigma in healthcare settings by honouring patient autonomy.[26 28–33] Though HR is typically thought of as structural approaches (ie, policies or strategies like SSPs), HR also includes relational approaches to care, centred on improving the patient–provider relationship, which can be implemented by healthcare teams to improve outcomes for PWH who use drugs.[27 34 35]

We previously defined HR principles for healthcare settings to describe ways that clinicians can operationalise and provide relational HR care (ie, humanism, pragmatism, individualism, autonomy, incrementalism and accountability without termination).[27] In our mixed methods study of an HIV clinic serving PWH who use drugs, we conducted patient surveys to test associations between perceptions of care related to HR (respect, user-friendly and unhurried care and clinic responsiveness) and self-reported ART adherence. After adjusting for race, age, ethnicity, gender identity, sexual orientation, homelessness and poverty status, the addition of the HR-related variables significantly predicted ART adherence.[34 35]

However, there is limited research examining ways that structural and relational HR in HIV clinical settings reduce experiences of stigma, affect patient–provider relationships and improve outcomes for PWH who use drugs. Given that integrated, coordinated HIV and substance use care is essential for optimising the health outcomes of PWH who use drugs,[36] an intervention that draws on the principles of HR to address both HIV and substance use healthcare needs is essential. The knowledge gained from this study will enable us to develop an intervention to operationalise HR care in an HIV clinic setting and, ultimately, reduce health inequities for PWH who use drugs. The current manuscript provides a detailed overview of our study protocol.

Objectives

The study has three primary aims:

1. *Explore the relationship between healthcare providers' stigmatising attitudes towards working with PWH who use drugs and providers' acceptance and practice of structural and relational HR to elucidate the context for intervention development.* We will survey physicians, advanced practice providers, nurses, medical assistants, front-desk staff and social workers (n=125) and conduct qualitative interviews (n=40) at our study sites to develop a deeper understanding of providers' attitudes towards working with PWH who use drugs as well as the ways that these attitudes are associated with the provision of structural and relational HR care. See online supplemental files 1,2 for copies of the survey and interview guide, respectively.

2. *Explore the interplay between patient-perceived HR and stigma and clinical outcomes; specifically, the degree to which (a) relational HR moderates the effect of intersectional stigma experienced in healthcare settings (HIV-related and substance use-related stigma and racial discrimination) on patients' perceptions of their relationship with providers, (b) structural HR moderates the relationship between the patient-provider relationship and clinical outcomes (ART adherence, retention in care, HIV and HCV viral suppression) and (c) patient-perceived HR care is directly associated with HIV clinical outcomes.* We will survey PWH who use drugs (n=500) to assess their perceptions of providers' relational HR care, experiences of intersectional stigma and perceived quality of relationships with their providers, and to explore other potential stigmatised identities and characteristics in patient focus groups (total n=36). We will also psychometrically evaluate our novel scale, the Patient Assessment of Provider Harm Reduction Scale (PAPHRS), to assess patients' perceptions of the degree to which their providers deliver relational HR care. See online supplemental files 3,4 for copies of the survey and focus group guide, respectively.

Using human-centred design approaches,[37] *develop and pretest an intervention to operationalise HR care for PWH who use drugs in HIV clinical settings.* Using findings from aims 1 and 2, we will meet with community member and provider collaborators (n=20), including PWH who use drugs, HIV providers and HR experts, to review results and pinpoint the most valuable intervention approaches using human-centred design, ensuring that the intervention is responsive to end users' needs.

METHODS AND ANALYSIS

Study design

The overarching aim of our observational study is to collect data that will inform development of an intervention to be tested in a subsequent clinical trial. We will use a sequential explanatory mixed-methods approach,[38] following the surveys with semistructured interviews (aim 1) and focus groups (aim 2), in order to contextualise and gain in-depth understanding of survey findings. The study is funded from September 2021 through June 2026. Recruitment for the provider survey (aim 1) began in April 2022.

We will develop an intervention in aim 3, in which we will meet with community member and provider collaborators to review results from aims 1 and 2 and identify the most valuable intervention approaches using human-centred design and pretest this intervention by convening small groups or one-on-one meetings with providers in Pittsburgh and Birmingham (total n=12). These individuals will be different than those involved in intervention development. During these meetings, we will share the mockup design (the concept poster) of the intervention and explore preliminary feasibility, acceptability and appropriateness of our prototyped approach.

Setting

The University of Pittsburgh (Pitt) is the study coordinating centre. Study sites are two HIV clinics in Pittsburgh, Pennsylvania (PA) (Allegheny Health Network's Positive Health Clinic (PHC), University of Pittsburgh Medical Centre's HIV/AIDS Programme and one in Birmingham, Alabama (AL) (University of Alabama at Birmingham (UAB) 1917 Clinic). These are areas of the country that are disproportionately affected by both the HIV and opioid epidemics and have high HCV incidence rates. Additionally, while not a study site, the study involves close collaboration with a strong community partner, Birmingham AIDS Outreach (BAO), an AIDS service organisation providing social support services to more than 1000 PWH each year, most of whom receive HIV primary care at UAB's 1917 Clinic. BAO will lead recruitment efforts and coordinate study activities in AL.

Participants

For both quantitative and qualitative portions of aim 1, providers are eligible if they have worked at one of the study sites for least 1 year; provide service or care to PWH or people who use drugs at high risk for HIV acquisition and are able to verbally consent, read and speak English. Providers may include any employee who directly interfaces with patients, including, but not limited to, physicians, nurses, social workers, pharmacists and front desk staff. Eligible providers may, but do not have to, participate in both the survey and interview components of Aim 1.

For both quantitative and qualitative portions of aim 2, patient participants must be ages 18 or older, have a confirmed HIV diagnosis, be able to verbally consent, read and speak English, have received HIV medical care from one of the study sites for at least 1 year and have lifetime or recent use (past 3 months) of illicit substances (excluding marijuana) or prescription drugs for non-medical reasons. As with aim 1, eligible participants may, but do not necessarily have to, complete both quantitative and qualitative portions.

VARIABLES AND DATA SOURCES AND MEASUREMENT

Outcomes

There are five outcomes of interest in our study, all relating to the clinical health of PWH who use drugs. Four of these are collected as standards of care at our study sites and will be abstracted via patient electronic medical health record: HIV viral load (<200 copies/mL, virally suppressed[39]); HIV primary care appointment attendance (as measured by[1] visits at least 90 days apart within 1 year=retained in HIV primary care[40] and[2] proportion of missed to scheduled visits (range 0–100%)[41]); HCV viral load, for those who have HCV and retention in opioid treatment care for those with opioid use disorder (proportion of kept to scheduled visits (range 0–100%)).

We will measure ART adherence via self-report through the validated Center for Adherence Support Evaluation (CASE) index.[42] All study outcomes will be measured cross-sectionally, collecting all HIV primary care and opioid treatment care visits within a 12-month observation window and the HIV and HCV viral load data closest to the end of the observation window. Clinical data will be linked to survey data by study staff at the participating clinical sites. Analysis of these outcomes will enable us to explore: the relationship between patient-perceived HR care and clinical outcomes, relational HR as a potential moderator of the path between intersectional stigma and the patient-provider relationship and structural HR as a potential moderator of the path between intersectional stigma and the patient–provider relationship, in which stigma is explored as HIV-related and substance use-related stigma and racial discrimination).

Table 1 Aims 1 and 2 constructs and measurement tools

Aim 1. Provider-reported	
Quantitative	
Provider attitudes	▶ Drug Problems Perceptions Questionnaire[56] ▶ Healthcare Provider HIV/AIDS Stigma Scale[57] ▶ Racism in Healthcare Index[58]
Acceptance of HR	▶ Harm Reduction Acceptability Scale[59 60]
Structural HR	▶ Organisational Survey of Structural HR
Structural HR	▶ Provider Survey of Structural HR
Qualitative	
Interviews	▶ Contextualise survey results (n=40)
Aim 2. Provider-reported	
Qualitative	
Interviews	▶ Evaluate PAPHRS (n=20)
Aim 2. Patient-reported (PWH who use drugs)	
Qualitative	
Focus groups	▶ Evaluate PAPHRS (n=36)
Quantitative	
Experiences of stigma and discrimination in healthcare settings	▶ Enacted HIV Stigma from Health Facility Staff[20 61] ▶ Substance Use Stigma Mechanisms Scale (Enacted Stigma from Healthcare Workers subscale)[62] ▶ Interpersonal Processes of Care Survey (Discrimination Due to Race/Ethnicity subscale)[63]
Patient–provider relationship	▶ Attitudes Toward HIV Healthcare Providers Scale[64] ▶ Single-item from Beach *et al*: 'My provider knows me as a person.'[65]
Receipt of structural HR care	▶ Patient Survey of Structural HR[66]
Receipt of relational HR care	▶ 25-item PAPHRS
Patient clinical outcomes (EHR data)	▶ HIV viral load (<200 copies/mL, virally suppressed) ▶ Retention in HIV primary care (two visits at least 90 days apart within 1 year; proportion of missed to scheduled visits) ▶ Self-reported ART adherence—CASE Index ▶ HCV viral load ▶ Retention in MOUD and/or in behavioural health treatment for diagnosis of substance use disorder (proportion of kept to scheduled visits)
Qualitative	
Focus groups	▶ Assess experiences of intersectional stigma (n=36)

ART, antiretroviral therapy; HR, harm reduction; MOUD, medications for opioid use disorder; PAPHRS, Patient Assessment of Provider Harm Reduction Scale; PWH, people with HIV.

Other variables

Table 1 includes a complete list of all data elements included in aims 1 through 2 of the study, including sources of data and methods of assessment, along with corresponding citations.

Bias

While participants may experience social desirability bias, the provider confidentiality and patient anonymity of the surveys is expected to mitigate this bias.

STATISTICAL METHODS

Quantitative analysis and sample sizes

To analyse survey data from aim 1, we will stratify by site and use descriptive statistics and bivariate associations to explore how providers feel about HR care as well as to determine both organisational and individual practice of structural HR, since HR policy and structures might be in place at the organisational level, yet not practiced by individual providers. At an estimated sample size of n=125, we anticipate sufficient sample size at power=0.80. Recent simulation research on SEM factor analysis suggests appropriate sample sizes with moderate factor loading between n=90–120 across a range of solutions.[43]

In aim 2, we will construct a generalised SEM (gSEM) to assess associations between patient-reported (1) intersectional stigma (HIV-related and substance use-related stigma and racial discrimination) in healthcare settings and patient–provider relationships and (2) patient-provider relationships and clinical outcomes (ART adherence, retention in HIV and substance use care and suppression of HCV and HIV). This gSEM will be constructed using a mediation approach, wherein we will assess whether the patient–provider relationship mediates the relationship between intersectional stigma and clinical outcomes. Mediation will be examined by assessing total, direct and indirect effects. This approach will test the degree to which the relationship between intersectional stigma (HIV-related and substance use-related stigma and racial discrimination) in healthcare settings and clinical outcomes is explained by the qualities of the patient–provider relationship. With an estimated sample size of n=500 and expected reasonable ratio of sample size to number of parameter estimates as 5:1,[44] we anticipate sufficient sample size with eight covariates (age, gender, sexual and gender minority status, income, race, ethnicity, substance use and study site).

We will also evaluate the novel relational HR instrument using both classical and modern psychometric techniques. Classical item analysis including item frequencies, item-total correlations, item frequency distributions and tests of monotonicity will be examined first. The underlying factor structure of PAPHRS items will be explored using factor analysis. The sample will be randomly split into two half samples, one for exploratory factor analysis (EFA) and the other for confirmatory factor analysis (CFA) using Mplus.

Our aim 2 sample size of 500 patients is based on long-standing practice for estimating sample size for SEMs with latent variables. Fritz and MacKinnon have posited that n=500 confers sufficient power (at 80%) to detect small mediation effects with a cross-sectional study.[45] A sample size of 500 also confers sufficient power for the

psychometric evaluation of PAPHRS. Suggested minimums of sample size for factor analysis include from 3 to 20 times the number of variables and absolute ranges from 100 to over 1000.[46] The sample size of 500, which will be split into 250 for EFA and 250 for CFA, will give us 10 times the number of PAPHRS items, right in the middle of the suggested sample size range. Reise and Yu[47] recommend that the unidimensional graded response model (GRM) be estimated with 500 cases. For convergent validity analyses, a sample of 200 participants is sufficient to provide power of 0.90 for correlations larger than 0.80 at alpha level of 0.05 with a two-tailed test. For comparisons between groups with expected differences, a sample size of 191 per group is needed to provide power of 0.90 for an effect size of 0.30 with alpha level of 0.05 and a two-tailed test.

Qualitative analysis

We will analyse interview and focus group data in NVivo V.12[48] using thematic analysis.[49 50] All five members of our qualitative team will participate in analysis and development of the coding framework by reading through transcripts, identifying major themes to contextualise the data and supplementing with field notes and corresponding analytic memos. We will code interviews and focus groups based on the initial coding framework, using processes of adjudication after each interview and iteratively modifying the codebook. This method of co-coding will continue until agreement on application of the codes is achieved. All interviews and focus groups will be coded, and at least 20% will be double-coded by two researchers and compared for consistency, in keeping with scholars' recommendation to double-code between 10% and 25% of transcripts.[51] To assess the extent to which the qualitative findings help explain the quantitative results, we will integrate quantitative and qualitative findings in a joint display to illustrate quantitative results with their corresponding qualitative themes.[52 53]

Recruitment

Provider recruitment

We will recruit providers by visiting sites' staff meetings and via electronic messaging used by each study site for internal communications and will have a Research Coordinator at each of our sites to assist with these methods and serve as site-specific project champions. Surveys will be deployed via REDCap[54] using confidential links. We will continually monitor response rates by provider type and site to ensure that each provider group is represented in the data. We will continue with monthly targeted electronic messages until our recruitment targets are met.

Patient recruitment

We will recruit 500 patients in total from our three study sites to complete a one-time survey on REDCap and 36 patients from our three study sites in total to participate in focus groups; patients may, but do not have to, participate in both data collection activities. We will use a multimodal recruitment plan, including word-of-mouth, flyers in provider waiting areas and patient rooms, messages sent through internal clinic systems for patients who receive electronic messages and in-person information during clinic visits. Recruitment messages will inform potential participants of eligibility requirements, the voluntary nature of participation, data to be collected including clinical records data, confidentiality of data and incentives.

Data collection

Data will be collected through a combination of surveys, focus groups or individual interviews, and electronic medical records, as previously described.

Data management and confidentiality

Since this study has minimal risks for participants, does not assign participants to study arms, does not perform an intervention, and is not a clinical trial, all data and safety monitoring will be conducted by the Project Director. Since this research does not qualify as a clinical trial, a Data and Safety Monitoring Plan is not required.

All study survey data will be collected electronically via REDCap using individual, confidential links and stored on Pitt servers. Participant identifiers will only be collected for purposes of linking survey data to medical records for subsequent analysis. This information, as well as consent forms, will be stored separately from the study materials. Electronic medical record data from each study site will be securely transferred to Pitt for analysis using Sharefile, a secure file sharing transfer service. The Pitt data team will immediately delete participant identifiers once assigning a study ID to each participant linking survey and clinical data. This clinical data, in addition to deidentified survey data abstracted from REDCap, will be stored on OneDrive.

For qualitative methods, identifiable data will be gathered to schedule interviews or focus groups, but these will not be linked to data for analysis. Because interviews and focus groups could potentially include identifiable data, these will be recorded on an audio recorder with 256-bit file encryption and device PIN locking to ensure data security. Once interviews are complete, any identifying information will be deleted from these files, and the audio tapes will be transferred to a Pitt desktop and subsequently submitted to a professional transcription service. No identifiable data will be transcribed, and once analysis is complete, the audio recording will be deleted.

Ethics and dissemination

Per NIH guidelines for multisite research, the study uses a single IRB, wherein the University of Pittsburgh serves as the IRB of record for UAB, BAO and PHC. The University of Pittsburgh Human Research Protection Office approved this study via expedited review on 1 November 2021.

Consent

For patient surveys associated with aim 2 (n=500), informed consent will be obtained electronically in REDCap. Consent will include the voluntary nature of participation, data to be collected including access to clinical records data, confidentiality of data and information about incentives. We have received a waiver to document consent for provider surveys (n=125) and interviews (n=40) associated with aim 1, and for patient focus groups associated with aim 2 (n=36). Provider survey consent will be obtained via a 'click to consent' function in REDCap, and, for patient and provider qualitative methods, verbal consent will be obtained by the research team immediately before data collection. Participants will be informed of the study aims and approach, voluntary nature of participation, right to exit the study with no penalty or risk of penalty, confidentiality of data and incentives. No human subjects' data will be collected as part of aim 3, so consent for these methods will not be obtained. However, given the sensitive inclusion criteria for patients, expectations for confidentiality related to participation will occur at the start of each patient focus group or stakeholders meeting.

Dissemination plan

Study findings will be presented in peer-reviewed journals and public health conferences. Findings will also be shared with patient participants online or in in-person community forums held at study sites and with providers during regularly scheduled staff meetings. We will also share findings with the members of BAO's and PHC's community advisory boards, which is composed of researchers, community organisation representatives and PWH as well as a local HR organisation that provides services to people who use drugs.

Patient and public involvement

Aim 3 of this study will be devoted to designing a HR intervention via community collaborator meetings with PWH who use drugs, HIV providers and HR experts using human-centred design. Members of our community advisory boards will inform and direct dissemination of results.

DISCUSSION

Ultimately this mixed methods observational study, taking place in two culturally distinct regions with similarly high HIV and HCV incidence rates, aims to discover whether HR approaches have the potential to improve HIV, HCV and substance use outcomes for PWH who use drugs. Given persistent racial health disparities, exploring racial discrimination experienced in healthcare settings is also critical. Our work builds on the Conceptual Framework for HIV-Related Stigma, Engagement in Care and Health Outcomes,[55] which posits that multiple dimensions of stigma create different pathways to and effects on clinical outcomes for PWH. We are innovatively adapting this model (figure 1) to focus specifically on experienced HIV stigma in healthcare settings, to incorporate substance use stigma and racial discrimination in an exploration of intersectional stigma and to include our premise that the provision of HR can reduce and mitigate patients' experiences of stigma in healthcare settings. We hypothesise

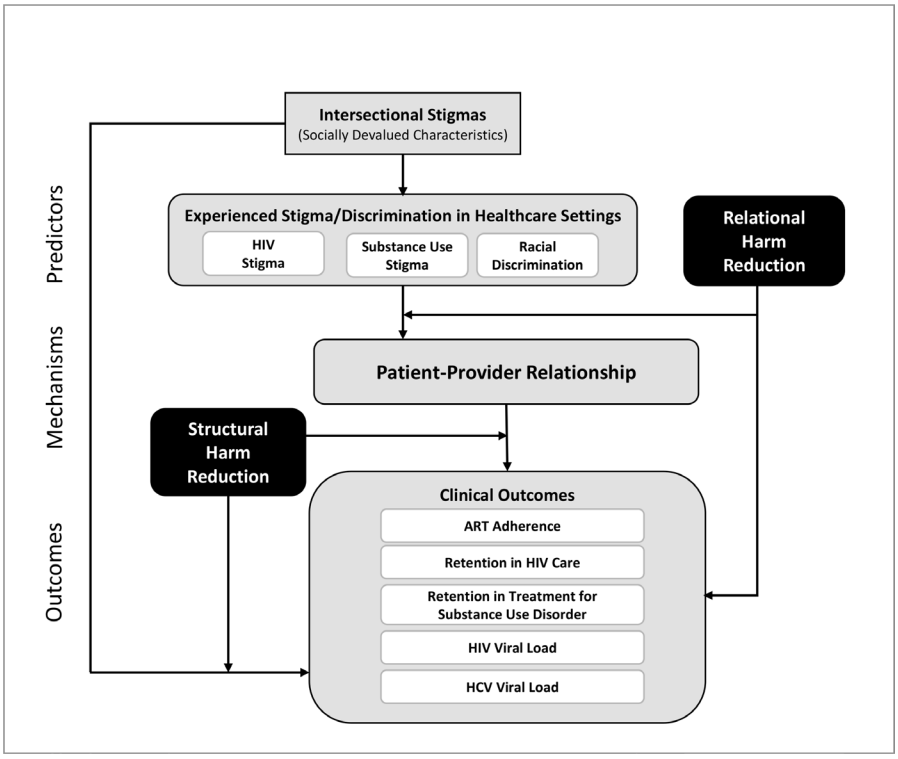

Figure 1 Modified conceptual framework. ART, antiretroviral therapy; HCV, hepatitis C virus.

that the effect of intersectional stigma on the patient–provider relationship is reduced in the presence of higher degrees of relational HR care, structural HR attenuates the effect of poor patient–provider relationships on clinical outcomes and higher degrees of HR care are associated with better clinical outcomes. Understanding the contributions of both structural and relational HR can help us determine which practices must be in place to improve patient outcomes.

A primary strength of our study is that we will collect data from a range of participants, including both patients and providers, and we will integrate both qualitative and quantitative methods to elicit rich data. Study results have the potential to contribute to changing standards of care for providers who work with PWH who use drugs and improve care for this population; therefore, it is paramount that both sets of stakeholders' voices are included in all phases of the study. While many studies explore the effects of patient–provider relationships on clinical outcomes, our study is novel in that it includes the full range of treatment team members (e.g., receptionists, social workers, nurses, pharmacists) in our methods, rather than focusing on physicians alone. However, these strengths also add complexity to the protocol, as there are multiple stages of recruitment, data collection and analysis across two states and three HIV clinics.

Another potential challenge of this study, as with all research conducted during this time, is the ongoing challenges posed by the COVID-19 pandemic. For this reason, we have planned study activities, so that all phases of data collection may occur online as needed. Both principal investigators have experience conducting virtual interviews and focus groups, should this be necessary. Indeed, improving care for PWH who use drugs becomes even more critical as people with multiple vulnerabilities have increased risk for COVID-19, and rising rates of unemployment and poverty drive people further into survival economies, increasing risk for HIV and HCV.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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