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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 (e.g., strategies like syringe service programs) 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 operationalize harm reduction care for PWH who use drugs in HIV clinical settings.

Methods and analysis. Aim 1 will explore the relationship between healthcare providers' stigmatizing 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 (PAPHRS). Aim 3 will use human-centered design approaches to develop and pre-test an intervention to operationalize 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 organizations.

Trial Registration. This protocol has been voluntarily registered on ClinicalTrials.gov: NCT05404750.

Key Words: HIV; harm reduction; substance use

Word Count: 3886

Article Summary

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 (i.e., the patient-provider relationship) in additional to the traditional structural approach (e.g., syringe service programs, 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 (e.g., 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

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 United States (US) in 2018, one in ten were among people who inject drugs (1). High rates of HIV among people who inject drugs are particularly problematic given injection drug use (IDU) 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 US co-infected 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 co-morbid 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 color who use drugs may experience additional stigma through racial discrimination (e.g., 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 (22), while additional research illuminates the negative relationship between experienced HIV stigma in the healthcare setting and ART adherence (23). 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 (24).

Our previous work suggests 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 behaviors without necessarily eliminating the problematic health behaviors entirely (25-28). HR stands in opposition to the traditional medical model of addiction, in which any illicit drug use is labeled as abuse, and the moral model, which labels substance use as simply wrong (26, 27). HR strategies such as syringe service programs (SSP), naloxone distribution, and medications for opioid use disorder (MOUD) 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 honoring patient autonomy (27, 29-34). Though HR is typically thought of as structural approaches (i.e., policies or strategies like SSPs), HR also includes relational approaches to care, centered on improving the patient-provider relationship, that can be implemented by healthcare teams to improve outcomes for PWH who use drugs (28, 35, 36).

We previously defined HR principles for healthcare settings to describe ways that clinicians can operationalize and provide relational HR care (i.e., humanism, pragmatism, individualism, autonomy, incrementalism, and accountability without termination)(28). 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 (35, 36).

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 optimizing the health outcomes of PWH who use drugs(37), an intervention that draws on the principles of HR to address both HIV and substance use health care needs is essential. The knowledge gained from this study will enable us to develop an intervention to operationalize 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' stigmatizing 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.

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- 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 stigmatized 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.

Using human-centered design approaches (38), develop and pre-test an intervention to operationalize 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-centered design, ensuring 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 (39), following the surveys with semi-structured interviews (Aim 1) and focus groups (Aim 2), in order to contextualize and gain in-depth understanding of survey findings.

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-centered design, and pre-test 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 center. Study sites are two HIV clinics in Pittsburgh, Pennsylvania (PA) (Allegheny Health Network's Positive Health Clinic [PHC], University of Pittsburgh Medical Center's HIV/AIDS Program [UPMC]) 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 organization providing social support services to more than 1,000 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 one 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 one 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 (40)]; HIV primary care appointment attendance [as measured by (1) visits at least 90 days apart within one year=retained in HIV primary care (41) and (2) proportion of missed to scheduled visits (range 0-100%) (42)]; HCV viral load, for those who have hepatitis C; and retention in opioid treatment care for those with opioid use disorder (proportion of kept to scheduled visits (range 0-100%).

We will measure antiretroviral therapy (ART) adherence via self-report through the validated CASE index (43). 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- and substance use-related stigma and racial discrimination).

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.

Table 1. Aims 1 & 2 Constructs and Measurement Tools

Aim 1. Provider-reported	
Quantitative	
Provider attitudes	• Drug Problems Perceptions Questionnaire(44) • Health Care Provider HIV/AIDS Stigma Scale(45) • Racism in Healthcare Index(46)
Acceptance of HR	• Harm Reduction Acceptability Scale(47, 48)
Structural HR	• Organizational Survey of Structural HR
Structural HR	• Provider Survey of Structural HR
Qualitative	
Interviews	• Contextualize 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, 49) • Substance Use Stigma Mechanisms Scale (Enacted Stigma from Healthcare Workers subscale)(50) •Interpersonal Processes of Care Survey (Discrimination Due to Race/Ethnicity subscale)(51)
Patient-Provider Relationship	• Attitudes Toward HIV Health Care Providers Scale(52) • Single-item from Beach et al., 2006: "My provider knows me as a person."(53)
Receipt of Structural HR Care	• Patient Survey of Structural HR(54)
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 (2 visits at least 90 days apart within one year; proportion of missed to scheduled visits) • Self-reported ART adherence – CASE Index • HCV viral load • Retention in MOUD and/or in behavioral health treatment for diagnosis of Substance Use Disorder (proportion of kept to scheduled visits)
Qualitative	
Focus groups	• Assess experiences of intersectional stigma (n=36)

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 analyze 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 organizational and individual practice of structural HR, since HR policy and structures might be in place at the organizational 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(55).

In Aim 2, we will construct a generalized SEM (gSEM) to assess associations between patient-reported 1) intersectional stigma **(**HIV- 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- 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 (56), 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 longstanding 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(57). A sample size of 500 also confers sufficient power for the psychometric evaluation of PAPHRS. Suggested minimums of sample size for factor analysis includes from 3 to 20 times the number of variables and absolute ranges from 100 to over 1,000(58). The sample size of 500, which will be split into 250 for EFA and 250 for CFA, will give us ten times the number of

PAPHRS items, right in the middle of the suggested sample size range. Reise and Yu(59) recommend that the unidimensional GRM be estimated with 500 cases. For convergent validity analyses, a sample of 200 participants is sufficient to provide power of .90 for correlations larger than .80 at alpha level of .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 .30 with alpha level of .05 and a two-tailed test.

Qualitative Analysis

We will analyze interview and focus group data in NVivo 12 (60) using thematic analysis (61, 62). 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 contextualize 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 10-25% of transcripts (63). 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 (64, 65).

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 (66) 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 utilize a multi-modal 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

Because this study has minimal risks to 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 records 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 de-identified 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 utilizes 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 (HRPO) approved this study via expedited review on November 1, 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 organization representatives, and PWH; as well as a local harm reduction organization that provides services to people who use drugs.

Patient and Public Involvement

Aim 3 of this study will be devoted to designing a harm reduction intervention via community collaborator meetings with PWH who use drugs, HIV providers, and harm reduction

experts using human–centered 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 (67), 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 hypothesize 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.

[insert Figure 1 about here] Title: Figure 1. Modified Conceptual Framework

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, including the full range of treatment team members (i.e., reception, social workers, nurses, pharmacists, etc.) in our methods is particularly novel. 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 PIs 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.

Declarations

Ethics Approval and Consent to Participate: To be a part of the study, each participant will provide written informed consent (for surveys) or verbal informed consent (for qualitative interviews and focus groups) prior to any data collection activities, as approved by the ethics committee. This study was approved via expedited review by the University of Pittsburgh Institutional Review Board (STUDY21090002).

Data Availability Statement: Not applicable.

Competing Interests: The authors declare that they have no competing interests.

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Author Contributions: MH and ESK developed the study and study protocol in collaboration with DSB and JT of the University of Alabama at Birmingham; RWSC, STC, JEE, MRF, SK, and LY of the University of Pittsburgh; SF and VN of the Allegheny Health Network Center for Inclusion Health; and SK and BT, consultants to the study. The manuscript was written by ESK and MH with input and review from all authors. All authors read and approved the final manuscript.

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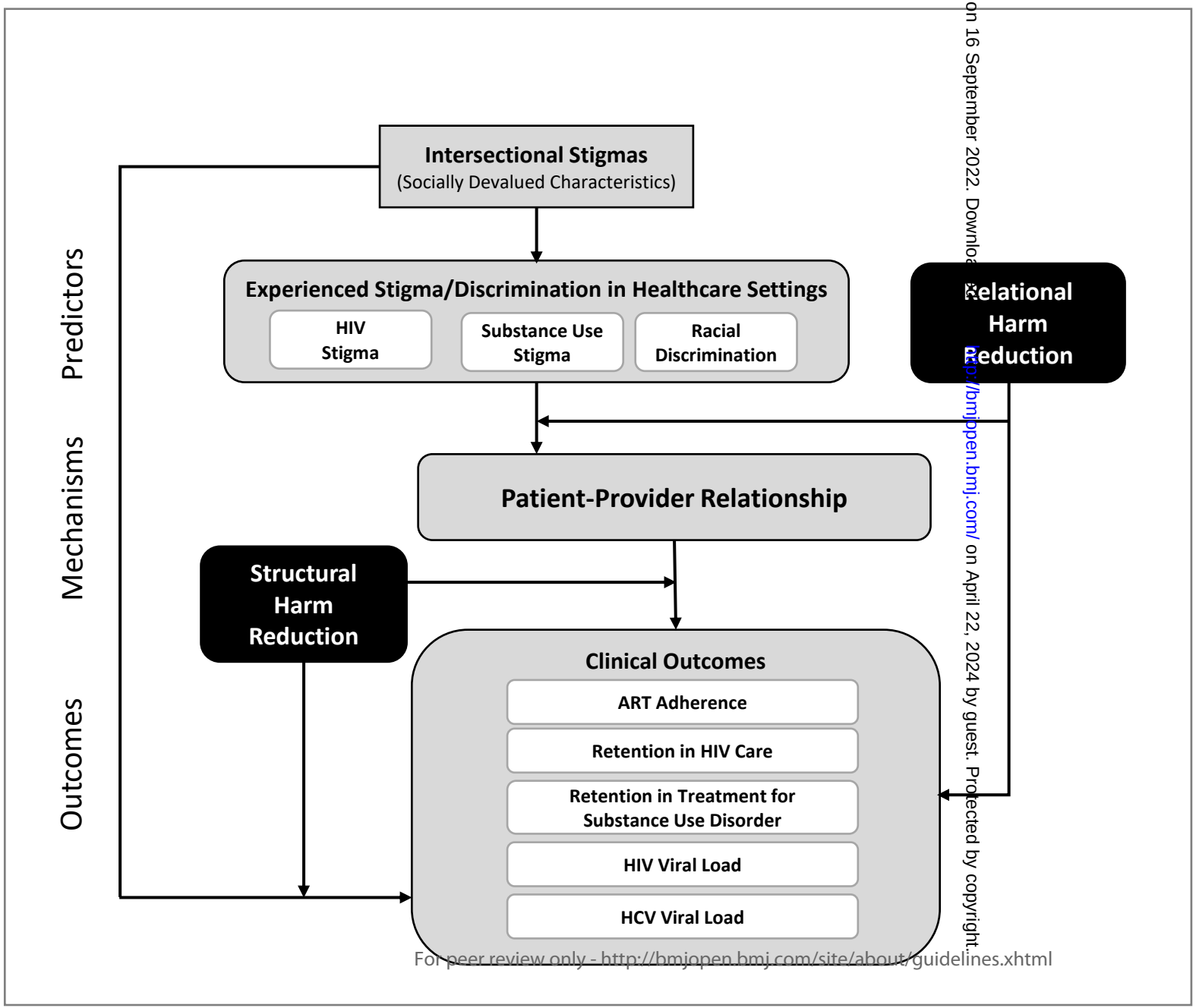
Figure Legends

Figure 1: Modified Conceptual Framework



Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2-3

Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	5-7
Objectives	#3	State specific objectives, including any prespecified hypotheses	7-8
Methods			
Study design	#4	Present key elements of study design early in the paper	8-9
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	9-10
Variables	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	11-12

Bias	#9	Describe any efforts to address potential sources of bias	11
Study size	#10	Explain how the study size was arrived at	11-13
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	n/a
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	11-13 *Note—proposed methods stated only, as analysis has not yet started*
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a—analysis has not yet started
Statistical methods	#12c	Explain how missing data were addressed	n/a—analysis has not yet started
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a—analysis has not yet started
Statistical methods	#12e	Describe any sensitivity analyses	n/a—analysis has not yet started

Results

Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	n/a—analysis has not yet started
Participants	#13b	Give reasons for non-participation at each stage	n/a—analysis has not yet started n/a—analysis has not yet started
Participants	#13c	Consider use of a flow diagram	n/a—analysis has not yet started
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	n/a—analysis has not yet started
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a—analysis has not yet started
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	n/a—analysis has not yet started

Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a—analysis has not yet started
Main results	#16b	Report category boundaries when continuous variables were categorized	n/a—analysis has not yet started
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a—analysis has not yet started
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	n/a—analysis has not yet started
Discussion			
Key results	#18	Summarise key results with reference to study objectives	n/a—analysis has not yet started
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	n/a—analysis has not yet started
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	n/a—analysis has not yet started
Generalisability	#21	Discuss the generalisability (external validity) of the study results	n/a—analysis has not yet started

Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20

BMJ Open

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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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 (e.g., strategies like syringe service programs) 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 operationalize harm reduction care for PWH who use drugs in HIV clinical settings.

Methods and analysis. Aim 1 will explore the relationship between healthcare providers' stigmatizing 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 (PAPHRS). Aim 3 will use human-centered design approaches to develop and pre-test an intervention to operationalize 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 organizations.

Trial Registration. This protocol has been voluntarily registered on ClinicalTrials.gov: NCT05404750.

Key Words: HIV; harm reduction; substance use

Word Count: 3932

Article Summary

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 (i.e., the patient-provider relationship) in additional to the traditional structural approach (e.g., syringe service programs, 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 (e.g., 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

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 United States (US) in 2018, one in ten were among people who inject drugs (1). High rates of HIV among people who inject drugs are particularly problematic given injection drug use (IDU) 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 US co-infected 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 co-morbid 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 color who use drugs may experience additional stigma through racial discrimination (e.g., 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 (22), while additional research illuminates the negative relationship between experienced HIV stigma in the healthcare setting and ART adherence (23). 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 (24).

Our previous work suggests 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 behaviors without necessarily eliminating the problematic health behaviors entirely (25-28). HR stands in opposition to the traditional medical model of addiction, in which any illicit drug use is labeled as abuse, and the moral model, which labels substance use as simply wrong (26, 27). HR strategies such as syringe service programs (SSP), naloxone distribution, and medications for opioid use disorder (MOUD) 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 honoring patient autonomy (27, 29-34). Though HR is typically thought of as structural approaches (i.e., policies or strategies like SSPs), HR also includes relational approaches to care, centered on improving the patient-provider relationship, that can be implemented by healthcare teams to improve outcomes for PWH who use drugs (28, 35, 36).

We previously defined HR principles for healthcare settings to describe ways that clinicians can operationalize and provide relational HR care (i.e., humanism, pragmatism, individualism, autonomy, incrementalism, and accountability without termination)(28). 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 (35, 36).

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 optimizing the health outcomes of PWH who use drugs(37), an intervention that draws on the principles of HR to address both HIV and substance use health care needs is essential. The knowledge gained from this study will enable us to develop an intervention to operationalize 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' stigmatizing 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 supplementary files 1 and 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- 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 stigmatized 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 supplementary files 3 and 4 for copies of the survey and focus group guide, respectively.

Using human-centered design approaches (38), develop and pre-test an intervention to operationalize 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-centered design, ensuring 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 (39), following the surveys with semi-structured interviews (Aim 1) and focus groups (Aim 2), in order to contextualize 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-centered design, and pre-test 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 center. Study sites are two HIV clinics in Pittsburgh, Pennsylvania (PA) (Allegheny Health Network's Positive Health Clinic [PHC], University of Pittsburgh Medical Center's HIV/AIDS Program [UPMC]) 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 organization providing social support services to more than 1,000 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 one 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 one 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 (40)]; HIV primary care appointment attendance [as measured by (1) visits at least 90 days apart within one year=retained in HIV primary care (41) and (2) proportion of missed to scheduled visits (range 0-100%) (42)]; HCV viral load, for those who have hepatitis C; and retention in opioid treatment care for those with opioid use disorder (proportion of kept to scheduled visits (range 0-100%).

We will measure antiretroviral therapy (ART) adherence via self-report through the validated CASE index (43). 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- and substance use-related stigma and racial discrimination).

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.

Table 1. Aims 1 & 2 Constructs and Measurement Tools

Aim 1. Provider-reported	
Quantitative	
Provider attitudes	• Drug Problems Perceptions Questionnaire(44) • Health Care Provider HIV/AIDS Stigma Scale(45) • Racism in Healthcare Index(46)
Acceptance of HR	• Harm Reduction Acceptability Scale(47, 48)
Structural HR	• Organizational Survey of Structural HR
Structural HR	• Provider Survey of Structural HR
Qualitative	
Interviews	• Contextualize 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, 49) • Substance Use Stigma Mechanisms Scale (Enacted Stigma from Healthcare Workers subscale)(50) •Interpersonal Processes of Care Survey (Discrimination Due to Race/Ethnicity subscale)(51)
Patient-Provider Relationship	• Attitudes Toward HIV Health Care Providers Scale(52) • Single-item from Beach et al., 2006: "My provider knows me as a person."(53)
Receipt of Structural HR Care	• Patient Survey of Structural HR(54)
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 (2 visits at least 90 days apart within one year; proportion of missed to scheduled visits) • Self-reported ART adherence – CASE Index • HCV viral load • Retention in MOUD and/or in behavioral health treatment for diagnosis of Substance Use Disorder (proportion of kept to scheduled visits)
Qualitative	
Focus groups	• Assess experiences of intersectional stigma (n=36)

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 analyze 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 organizational and individual practice of structural HR, since HR policy and structures might be in place at the organizational 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(55).

In Aim 2, we will construct a generalized SEM (gSEM) to assess associations between patient-reported 1) intersectional stigma **(**HIV- 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- 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 (56), 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 longstanding 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(57). A sample size of 500 also confers sufficient power for the psychometric evaluation of PAPHRS. Suggested minimums of sample size for factor analysis includes from 3 to 20 times the number of variables and absolute ranges from 100 to over 1,000(58). The sample size of 500, which will be split into 250 for EFA and 250 for CFA, will give us ten times the number of PAPHRS items, right in the middle of the suggested sample size range. Reise and Yu(59) recommend that the unidimensional GRM be estimated with 500 cases. For convergent validity analyses, a sample of 200 participants is sufficient to provide power of .90 for correlations larger than .80 at alpha level of .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 .30 with alpha level of .05 and a two-tailed test.

Qualitative Analysis

We will analyze interview and focus group data in NVivo 12 (60) using thematic analysis (61, 62). 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 contextualize 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 10-25% of transcripts (63). 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 (64, 65).

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 (66) 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 utilize a multi-modal 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

Because this study has minimal risks to 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 records 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 de-identified 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 utilizes 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 (HRPO) approved this study via expedited review on November 1, 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 organization representatives, and PWH; as well as a local harm reduction organization that provides services to people who use drugs.

Patient and Public Involvement

Aim 3 of this study will be devoted to designing a harm reduction intervention via community collaborator meetings with PWH who use drugs, HIV providers, and harm reduction experts using human–centered 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 (67), 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 hypothesize 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.

[insert Figure 1 about here] Title: Figure 1. Modified Conceptual Framework

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, including the full range of treatment team members (i.e., reception, social workers, nurses, pharmacists, etc.) in our methods is particularly novel. 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 PIs 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.

Declarations

Ethics Approval and Consent to Participate: To be a part of the study, each participant will provide written informed consent (for surveys) or verbal informed consent (for qualitative interviews and focus groups) prior to any data collection activities, as approved by the ethics committee. This study was approved via expedited review by the University of Pittsburgh Institutional Review Board (STUDY21090002).

Data Availability Statement: Not applicable.

Competing Interests: The authors declare that they have no competing interests.

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Author Contributions: MH and ESK developed the study and study protocol in collaboration with DSB and JT of the University of Alabama at Birmingham; RWSC, STC, JEE, MRF, SK, and LY of the University of Pittsburgh; SF and VN of the Allegheny Health Network Center for Inclusion Health; and SK and BT, consultants to the study. The manuscript was written by ESK and MH with input and review from all authors. All authors read and approved the final manuscript.

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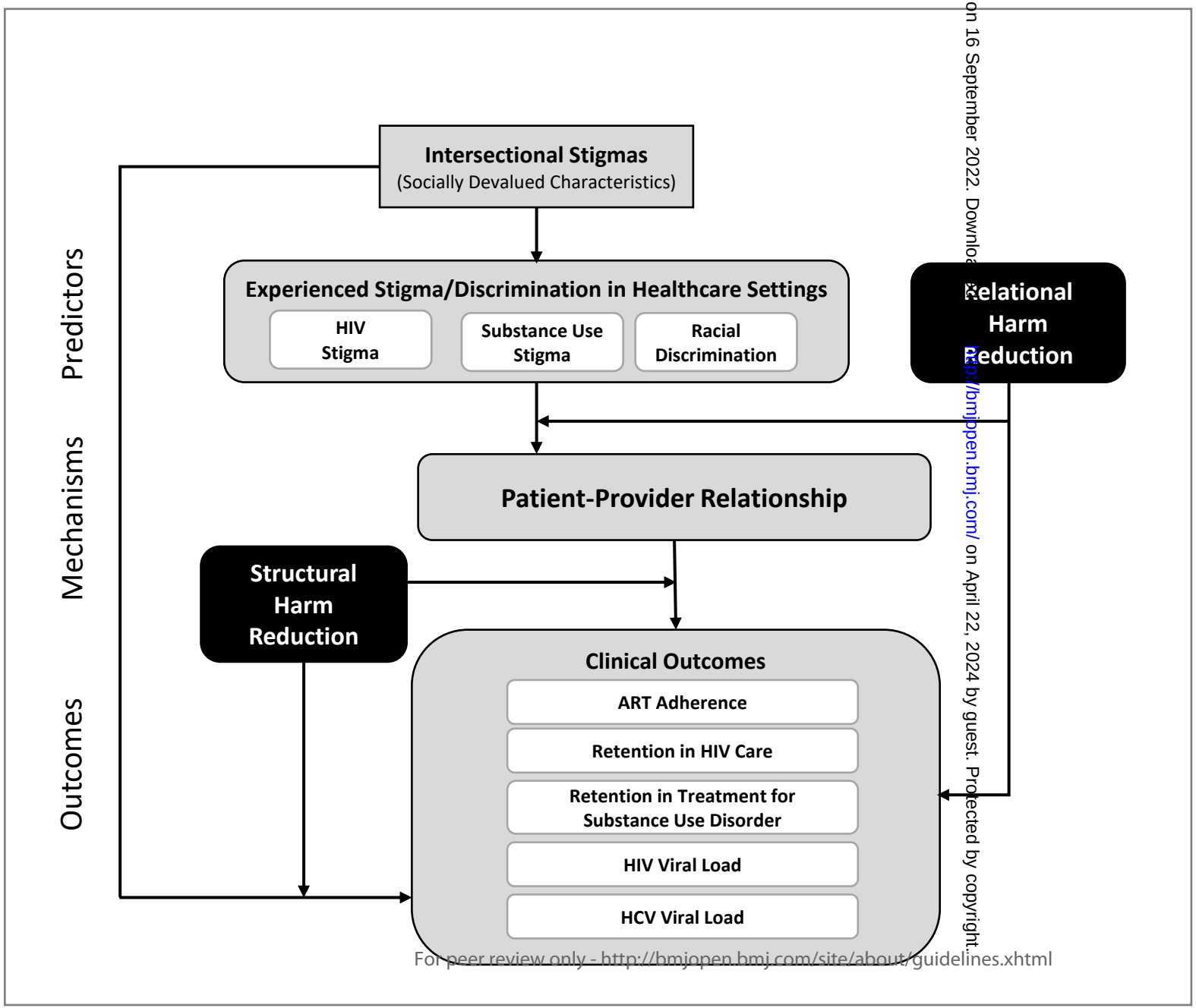
Figure Legends

Figure 1: Modified Conceptual Framework



Provider Survey

This first section asks you some basic demographic information and information related to your experience working in HIV and/or substance use healthcare settings.

With respect to your gender, how do you currently identify? Please check all that apply.	☐ Woman ☐ Man ☐ Transgender woman or transfeminine ☐ Transgender man or transmasculine ☐ Non-binary ☐ Genderqueer ☐ Two-spirit ☐ Something else
Please specify your gender.	_____
What sex were you labelled with at birth?	◯ Male ◯ Female ◯ Intersex
With respect to your sexual orientation, how do you currently identify? Please check all that apply.	☐ Heterosexual/straight ☐ Lesbian ☐ Gay ☐ Bisexual ☐ Pansexual ☐ Asexual ☐ Questioning ☐ Queer ☐ Something else
Please specify your sexual orientation.	_____
What is your racial identity? Please choose all that apply.	☐ Black or African American ☐ White ☐ Asian ☐ Native American or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Something else
Please specify your race.	_____
Are you Hispanic or Latino/Latina/Latinx?	◯ Yes ◯ No
How long have you provided services to people with HIV?	◯ 1-5 years ◯ 6-10 years ◯ 11-20 years ◯ More than 20 years
How long have you provided services to people who use drugs?	◯ 1-5 years ◯ 6-10 years ◯ 11-20 years ◯ More than 20 years

What best describes your job title?	◯ Front desk, reception, or greeter ◯ Social Worker, Medical Social Worker, or Case Manager ◯ Peer Navigator or Community Health Worker ◯ Medical Assistant ◯ Nurse ◯ Certified Nurse Practitioner ◯ Physician Assistant ◯ Physician ◯ Pharmacist ◯ Mental health provider ◯ Something else
Please specify your job title.	_____
Have you ever used illegal drugs (NOT including marijuana) or prescription drugs for non-medical reasons?	◯ Yes ◯ No ◯ Prefer not to answer
Do you have personal experience with friends or family members using illegal drugs (NOT including marijuana) or prescription drugs for non-medical reasons?	◯ Yes ◯ No ◯ Prefer not to answer
Are you living with HIV?	◯ Yes ◯ No ◯ Prefer not to answer
How long ago were you diagnosed with HIV?	◯ Less than 1 year ◯ 1-5 years ◯ 6-10 years ◯ 11-20 years ◯ More than 20 years ◯ Prefer not to answer
How old are you?	◯ 18-23 ◯ 24-29 ◯ 30-35 ◯ 36-41 ◯ 42-47 ◯ 48-53 ◯ 54-59 ◯ 60-65 ◯ 66-71 ◯ 72+ ◯ Prefer not to answer

This set of questions asks you about your experience working with people who use drugs. Please answer as honestly as possible.

	Strongly agree	Agree	Somewhat agree	Neutral	Somewhat disagree	Disagree	Strongly disagree
I feel I have a working knowledge of drugs and drug related problems.	○	○	○	○	○	○	○
I feel I know enough about the causes of drug problems to carry out my role when working with drug users.	○	○	○	○	○	○	○
I feel I know enough about the physical effects of drug use to carry out my role when working with drug users.	○	○	○	○	○	○	○
I feel I know enough about the psychological effects of drugs to carry out my role when working with drug users.	○	○	○	○	○	○	○
Even if their drug use is stable, parents who use illicit drugs cannot be good parents to infants and young children.	○	○	○	○	○	○	○
I feel I know enough about the factors which put people at risk of developing drug problems to carry out my role when working with drug users.	○	○	○	○	○	○	○
I feel I have the right to ask patients/clients questions about their drug use when necessary.	○	○	○	○	○	○	○
I feel I have the right to ask a patient for any information that is relevant to their drug problems.	○	○	○	○	○	○	○
If I felt the need when working with drug users I could easily find someone who would help me clarify my professional responsibilities.	○	○	○	○	○	○	○
If I felt the need when working with drug users I could easily find someone with whom I could discuss any personal difficulties that I might encounter.	○	○	○	○	○	○	○

	Strongly agree	Agree	Somewhat agree	Neutral	Somewhat disagree	Disagree	Strongly disagree	N/A--I do not provide medical or support services
If I felt the need I could easily find someone who would be able to help me formulate the best approach to working with a drug user.	○	○	○	○	○	○	○	
I feel that there is little I can do to help drug users.	○	○	○	○	○	○	○	
I feel I am able to work with drug users as well as I can with other client groups.	○	○	○	○	○	○	○	
All in all, I am inclined to feel I am a failure with drug users.	○	○	○	○	○	○	○	
In general, I have less respect for drug users than for most other patients/clients I work with.	○	○	○	○	○	○	○	
I often feel uncomfortable when working with drug users.	○	○	○	○	○	○	○	
In general, one can get satisfaction from working with drug users.	○	○	○	○	○	○	○	
In general, it is rewarding to work with drug users.	○	○	○	○	○	○	○	
In general, I feel I can understand drug users.	○	○	○	○	○	○	○	
I feel I know how to counsel drug users over the long term.	○	○	○	○	○	○	○	○
I feel I can appropriately advise my patients/clients about drugs and their effects.	○	○	○	○	○	○	○	○

This next set of questions asks you about your attitudes towards people who use drugs. Please answer as honestly as possible.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
People who use drugs who will not accept abstinence as their treatment goal are in denial.	○	○	○	○	○
It is not acceptable to teach injecting drug users how to use bleach to sterilize their injecting equipment.	○	○	○	○	○
A choice of treatment outcome goals (for example, abstinence, reduced use of drugs or safer use of drugs) should be discussed with all people seeking help for drug problems.	○	○	○	○	○
People who live in government-funded housing must be drug free.	○	○	○	○	○
Doctors should be permitted to prescribe heroin and similar drugs to treat drug addiction as long as doing so reduces problems such as crime and health risks.	○	○	○	○	○
Even if their drug use is stable, women who use illicit drugs cannot be good mothers to infants and young children.	○	○	○	○	○
Drug users should be given honest information about how illicit drugs may be used more safely (for example, how overdose or related health hazards may be avoided).	○	○	○	○	○
People who use drugs who are not willing to accept abstinence as their treatment outcome goal should be offered treatment that aims to reduce the harm associated with their continued drug use.	○	○	○	○	○

In most cases, nothing can be done to motivate clients in denial except to wait for them to "hit bottom."	○	○	○	○	○
It is acceptable to prescribe substitute drugs (such as methadone, buprenorphine, or medications for opioid use disorder) in order to reduce crime and other social problems associated with illicit drug use.	○	○	○	○	○
Prisons should not provide sterilizing tablets or bleach in order for inmates to clean their drug injecting equipment.	○	○	○	○	○
As long as clients are making progress towards their treatment goals, methadone maintenance programs should not kick clients out of treatment for using street drugs.	○	○	○	○	○
Measures designed to reduce the harm associated with drug use are acceptable only if they eventually lead clients to pursue abstinence.	○	○	○	○	○
People who use drugs may be more likely to seek professional help if they are offered at least some treatment options that do not focus on abstinence.	○	○	○	○	○
The prescription of substitute drugs such as methadone should be forbidden.	○	○	○	○	○
People whose drug use is stable should be trained to teach other drug users how to use drugs more safely (for example, how to inject more safely).	○	○	○	○	○
Making clean injecting equipment available to injecting drug users is likely to reduce the rate of HIV infection.	○	○	○	○	○

It is possible to use drugs (not including marijuana) without necessarily misusing or abusing drugs.	○	○	○	○	○
Information educating drug users about their safe drug use and safer sex should be detailed and explicit, even if this information would be offensive to some people.	○	○	○	○	○
Opiate users should only be prescribed methadone for a limited period of time.	○	○	○	○	○
Drug injectors who are not willing to accept abstinence as a treatment goal at the beginning of treatment should be given easy access to clean injecting equipment to reduce the spread of HIV and other blood-borne diseases.	○	○	○	○	○
Women who use illicit drugs during pregnancy should automatically lose custody of their babies.	○	○	○	○	○
People who use drugs should be praised for making changes such as switching from injection drugs to other routes of administration such as snorting, smoking, or ingesting.	○	○	○	○	○
Abstinence is the only acceptable treatment goal for people who use illicit drugs.	○	○	○	○	○

Keep going; you are over halfway done with the survey! We greatly appreciate your time.

This next section asks about working with patients with HIV.

Below is a list of ideas about patients with HIV. Some of the ideas may be true for you, and some of them may not. People hold a wide range of ideas about patients with HIV, and we are interested in your particular ideas. Again, please answer the questions honestly--your responses are completely confidential.

	Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree
I believe most HIV+ patients acquired the virus through risky behavior.	○	○	○	○	○	○
I think HIV+ patients have engaged in risky activities despite knowing these risks.	○	○	○	○	○	○
I think people would not get HIV if they had sex with fewer people.	○	○	○	○	○	○
HIV+ patients present a threat to my health.	○	○	○	○	○	○
HIV+ patients present a threat to the health of other patients.	○	○	○	○	○	○
I think if people act responsibly they will not contract HIV.	○	○	○	○	○	○
HIV+ patients tend to have numerous sexual partners.	○	○	○	○	○	○
I enjoy working with HIV+ patients.	○	○	○	○	○	○
I would rather not come into physical contact with HIV+ patients.	○	○	○	○	○	○
I would want to wear two sets of gloves when examining HIV+ patients.	○	○	○	○	○	○
I would be comfortable working alongside another health care provider who has HIV.	○	○	○	○	○	○
I think many HIV+ patients likely have substance use problems.	○	○	○	○	○	○
I would rather see an HIV-negative patient than see an HIV+ patient with non-HIV-related concerns.	○	○	○	○	○	○

I have learned a lot by working with HIV+ patients.	○	○	○	○	○	○
HIV+ patients should accept responsibility for acquiring the virus.	○	○	○	○	○	○
I worry about contracting HIV from HIV+ patients.	○	○	○	○	○	○
I often think HIV+ patients have caused their own health problems.	○	○	○	○	○	○
HIV+ patients make me uncomfortable.	○	○	○	○	○	○
I would be hesitant to send HIV+ patients to get blood work done due to my fear of others' safety.	○	○	○	○	○	○
It is a little scary to think I have touched HIV+ patients.	○	○	○	○	○	○
I worry that universal precautions are not good enough to protect me from HIV+ patients.	○	○	○	○	○	○
I would feel uncomfortable knowing one of my colleagues is HIV+.	○	○	○	○	○	○
HIV+ patients who have acquired HIV through injection drug use are more at fault for contracting HIV than HIV+ patients who have acquired HIV through a blood transfusion.	○	○	○	○	○	○
I tend to think that HIV+ patients do not share the same values as me.	○	○	○	○	○	○
HIV+ patients who have acquired HIV through sex are more at fault for contracting HIV than HIV+ patients who have acquired HIV through a blood transfusion.	○	○	○	○	○	○
It would be hard to react calmly if a patient tells me they are HIV+.	○	○	○	○	○	○

	Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree	N/A--I do not provide medical or support services
I believe I have the right to refuse to treat HIV+ patients for the safety of other patients.	○	○	○	○	○	○	○
I believe I have the right to refuse to treat HIV+ patients if other staff members are concerned about safety.	○	○	○	○	○	○	○
I would avoid conducting certain procedures on HIV+ patients.	○	○	○	○	○	○	○
I believe I have the right to refuse to treat HIV+ patients if I feel uncomfortable.	○	○	○	○	○	○	○
I believe I have the right to refuse to treat HIV+ patients to protect myself.	○	○	○	○	○	○	○
I believe I have the right to refuse to treat HIV+ patients if I am concerned about legal liability.	○	○	○	○	○	○	○

This section asks about treatment services to patients of different races at your organization.

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Providers treat African American and White people the same.	○	○	○	○	○
Racial discrimination at [el5] is common.	○	○	○	○	○
At [el5], African American and White people receive the same kind of care.	○	○	○	○	○
African Americans can receive the care they want as equally as White people can at [el5].	○	○	○	○	○

Finally, we have just a few more questions about services offered at [el5].

Staff at this site are trained to offer a range of recovery options for people who use drugs.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
At [el5], abstinence is assumed by most staff members to be the treatment goal for all patients who use drugs.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
There are materials and information at [el5] that would make it clear to people who use drugs that they are welcome here.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
Narcan is distributed to all patients at [el5].	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
Narcan is distributed to all patients at [el5] who have a history of opioid use.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
At [el5], harm reduction is part of our everyday language.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
Medications for opioid use disorder are easily accessible at [el5].	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
Medications for opioid use disorder are easily accessible through a close referral agreement with a partner site.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree
Sterile syringes are legal in my location.	◯ Yes ◯ No
Sterile syringes are easily accessible at this site.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree

Sterile syringes are easily accessible through a close referral agreement with a partner site.	◯ Strongly agree ◯ Agree ◯ Neither agree nor disagree ◯ Disagree ◯ Strongly disagree

Thank you so much for your time taking this survey! Your answers will help us learn how to better provide harm reduction services to people with HIV who use drugs.

You are eligible to receive a $25 gift card as a thank you for your time. The following page will ask you information needed to receive this incentive; this information will not be linked to your survey answers. Would you like to receive the $25 gift card?	◯ Yes ◯ No

Please hit the submit button to submit your answers.

Impact of harm reduction care in HIV clinical settings on stigma and health outcomes for PLWH who use drugs

Provider Qualitative Interview Guide

1. Describe your role at [Clinic]. Also tell me a bit about the patient population you see.
    - How are your patients at [Clinic] the same or different from other places you've worked?
    - What's unique about working with PLWH who use drugs?
    - Probe for research positions as applicable
        i. How is this different from other clinical care; what does patient interaction look like?
        ii. How often in contact/amount of time spent with patients in a typical week/ how often do you see patients? How much time do you spend with them at visits?
        iii. Empanelment?

2. Relational aspects of care
    - Describe a typical interaction with a patient.
        i. How much do you know about your patients' lives?
            1. How often do you talk with your patients about things outside of clinical care?
            2. Beyond clinical care, how do you learn about your patients' lives?
            3. Why did you become a(n)…. [provider position]
            4. In your mind, what is the ideal relationship between provider/patient?

3. When you talk with people outside of [Clinic] about the work that you do, how do you describe it?

4. I'd like to know more about your experience working with people with HIV who use drugs.
    - What kinds of things have helped you do this work? [e.g., clinical training, continuing education, coursework, self-taught]
    - How comfortable or uncomfortable are you working with this population?
        i. Follow-up: Has this changed over time? Did you do anything in particular that helped you feel more comfortable?
    - In some of the survey responses we got from different sites, we learned that sometime providers find it challenging to work with people who use drugs. Do you agree? What do you think drives that?
    - What about benefits of working with this population? What are some of things you like about working with this community?

Impact of harm reduction care in HIV clinical settings on stigma and health outcomes for PLWH who use drugs

5. How do you make use of the substance use resources in your Clinic? Community? Describe how referral works to your community collaborators.

6. What happens when patients who inject drugs ask you about how to use safer?
    - Probe (If they go right to referrals): What are those conversations like?

7. In your experience working at [Clinic], have you noticed any differences in the way White and Black PLWH who use drugs are treated?
    - Without using names, describe any instances of racial discrimination you have witnessed or heard about.
    - Again without using names, describe any provider or clinic staff racial biases you are aware of.

8. What are the service gaps for PLWH who use drugs in your (a) clinic or (b) community?
    - What do you think is the number one barrier to care for PLWH who use drugs?
    - What other barriers to care do PLWH who use drugs face?
    - How can we improve health outcomes for PLWH who use drugs?

9. I'd like to transition a bit and talk about harm reduction specifically. Tell me about your experience with harm reduction, or just what you know about it. [if providers do not know what harm reduction is, be ready to provide a definition.]
    - What kinds of training specific to harm reduction have you had?
    - What are your thoughts about this approach to care?
    - [If only structural HR is mentioned]: Harm reduction also has to do with the way providers interact with their patients. What are your thoughts on that?

10. Is there anything about working with PLWH who use drugs that I didn't ask about but is important for me to know?
    - Is there anyone else you think we should talk with?

Patient Survey

Thank you for filling out this survey! This survey is intended for people with HIV with either past or current substance use who receive HIV medical care at one of the following sites: The Pittsburgh AIDS Center for Treatment (PACT) at The University of Pittsburgh Medical Center's HIV/AIDS Program; Allegheny Health Network's Positive Health Clinic; or the University of Alabama at Birmingham's 1917 Clinic. All of your answers will be kept confidential and will not be shared with anyone outside of the study team.

How do you describe yourself? Please check all that apply.

- ☐ Woman
- ☐ Man
- ☐ Transgender woman or transfeminine
- ☐ Transgender man or transmasculine
- ☐ Non-binary
- ☐ Genderqueer
- ☐ Two-spirit
- ☐ Something else

Please tell us your gender.

_____

What sex were you labeled with at birth?

- ◯ Male
- ◯ Female
- ◯ Intersex

With respect to your sexual orientation, how do you currently identify? Please check all that apply.

- ☐ Heterosexual/straight
- ☐ Lesbian
- ☐ Gay
- ☐ Bisexual
- ☐ Pansexual
- ☐ Asexual
- ☐ Questioning
- ☐ Queer
- ☐ Something else

Please tell us your sexual orientation.

_____

What is your racial identity? Please choose all that apply.

- ☐ Black or African American
- ☐ White
- ☐ Asian
- ☐ Native American or Alaskan Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Something else

Please tell us your race.

_____

Are you Hispanic or Latino/Latina/Latinx?

- ◯ Yes
- ◯ No

What is the highest grade or level of school you have completed or the highest degree you have received?	◯ Never attended school ◯ 1st grade ◯ 2nd grade ◯ 3th grade ◯ 4th grade ◯ 5th grade ◯ 6th grade ◯ 7th grade ◯ 8th grade ◯ 9th grade ◯ 10th grade ◯ 11th grade ◯ Graduated high school OR received GED or equivalent ◯ Some college, no degree ◯ Bachelor's degree (example: BS, BA) ◯ Master's degree (example: MA, MS) ◯ Professional school degree (example: MD, JD) ◯ Doctoral degree (example: PhD) ◯ Don't know
How would you best describe your current employment status?	◯ Employed full-time ◯ Employed part-time ◯ Not employed: a student ◯ Not employed: receive assistance ◯ No source of income ◯ Something else
Please describe your current employment status.	_____
How much do you make in a year, before taxes (i.e., personal yearly income)?	◯ Less than $10,000/year ◯ $10,000 to $29,999 ◯ $30,000 to $49,999 ◯ $50,000 to $69,999 ◯ $70,000 or more ◯ Don't know ◯ Prefer not to answer
How many other people (NOT including you) does your income support?	_____

The next two statements are about your food situation. For each statement, please tell me whether the statement was often true, sometimes true, or never true for your household in the last 12 months.

	Often true	Sometimes true	Never true
Within the past 12 months I/we worried whether our food would run out before we got money to buy more.	○	○	○
Within the past 12 months the food I/we bought just didn't last and we didn't have money to get more.	○	○	○

The next few questions ask about where you live.

In the past 2 months, have you been living in stable housing that you own, rent, or stay in as part of a household?	◯ Yes--living in stable housing ◯ No--not living in stable housing
Are you worried or concerned that in the next 2 months you may NOT have stable housing that you own, rent, or stay in as part of a household?	◯ Yes--worried about housing in near future ◯ No--not worried about housing in near future

This section asks you questions about your HIV history and treatment.

How long ago were you diagnosed with HIV?	◯ Less than 1 year ◯ 1-5 years ◯ 6-10 years ◯ 11-20 years ◯ More than 20 years ◯ Not sure
How are you currently taking your HIV medication?	◯ Via oral medication (by mouth) ◯ Via injection
How often do you feel that you have difficulty taking your HIV medications as prescribed?	◯ Never ◯ Rarely ◯ Most of the time ◯ All of the time
On average, how many days per week would you say that you missed at least one dose of your HIV medications?	◯ Every day ◯ 4-6 days a week ◯ 2-3 days a week ◯ Once a week ◯ Less than once a week ◯ Never
When was the last time you missed at least one dose of your HIV medications?	◯ Within the past week ◯ 1-2 weeks ago ◯ 3-4 weeks ago ◯ Between 1-3 months ago ◯ More than 3 months ago ◯ Never
In general, would you say your health is:	◯ Excellent ◯ Very good ◯ Good ◯ Fair ◯ Poor
Please select the MONTH of your birthday using the drop-down list.	◯ 1 (January) ◯ 2 (February) ◯ 3 (March) ◯ 4 (April) ◯ 5 (May) ◯ 6 (June) ◯ 7 (July) ◯ 8 (August) ◯ 9 (September) ◯ 10 (October) ◯ 11 (November) ◯ 12 (December)

Please select the DAY of your birthday using the drop-down list.	◯ 1 ◯ 2 ◯ 3 ◯ 4 ◯ 5 ◯ 6 ◯ 7 ◯ 8 ◯ 9 ◯ 10 ◯ 11 ◯ 12 ◯ 13 ◯ 14 ◯ 15 ◯ 16 ◯ 17 ◯ 18 ◯ 19 ◯ 20 ◯ 21 ◯ 22 ◯ 23 ◯ 24 ◯ 25 ◯ 26 ◯ 27 ◯ 28 ◯ 29 ◯ 30 ◯ 31

Please select the YEAR of your birthday using the drop-down list.

◯ 2005	◯ 2004	◯ 2003
◯ 2002	◯ 2001	◯ 2000
◯ 1999	◯ 1998	◯ 1997
◯ 1996	◯ 1995	◯ 1994
◯ 1993	◯ 1992	◯ 1991
◯ 1990	◯ 1989	◯ 1988
◯ 1987	◯ 1986	◯ 1985
◯ 1984	◯ 1983	◯ 1982
◯ 1981	◯ 1980	◯ 1979
◯ 1978	◯ 1977	◯ 1976
◯ 1975	◯ 1974	◯ 1973
◯ 1972	◯ 1971	◯ 1970
◯ 1969	◯ 1968	◯ 1967
◯ 1966	◯ 1965	◯ 1964
◯ 1963	◯ 1962	◯ 1961
◯ 1960	◯ 1959	◯ 1958
◯ 1957	◯ 1956	◯ 1955
◯ 1954	◯ 1953	◯ 1952
◯ 1951	◯ 1950	◯ 1949
◯ 1948	◯ 1947	◯ 1946
◯ 1945	◯ 1944	◯ 1943
◯ 1942	◯ 1941	◯ 1940
◯ 1939	◯ 1938	◯ 1937
◯ 1936	◯ 1935	◯ 1934
◯ 1933	◯ 1932	◯ 1931
◯ 1930	◯ 1929	◯ 1928
◯ 1927	◯ 1926	◯ 1925
◯ 1924	◯ 1923	◯ 1922
◯ 1921	◯ 1920	◯ 1919
◯ 1918	◯ 1917	◯ 1916
◯ 1915	◯ 1914	◯ 1913
◯ 1912	◯ 1911	◯ 1910
◯ 1909	◯ 1908	◯ 1907
◯ 1906	◯ 1905	◯ 1904
◯ 1903	◯ 1902	◯ 1901
◯ 1900		

This section about your use of substances over your LIFETIME.	
In your lifetime, have you ever used cocaine (coke, crack, etc.)?	◯ Yes ◯ No
In your lifetime, have you used prescription stimulants for non-medical reasons (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)? (By "non-medical reasons," we mean that you used a prescription stimulant in a way that was NOT prescribed to you by your doctor.)	◯ Yes ◯ No
In your lifetime, have you ever used methamphetamine (speed, crystal meth, ice, etc.)?	◯ Yes ◯ No
In your lifetime, have you ever used inhalants (nitrous oxide, glue, gas, paint thinner, etc.)?	◯ Yes ◯ No
In your lifetime, have you ever used sedatives or sleeping pills in a way that was not prescribed by a doctor (Valium, Serepax, Ativan, Xanax, Librium, Rohypnol, GHB, etc.)?	◯ Yes ◯ No
In your lifetime, have you ever used hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)?	◯ Yes ◯ No
In your lifetime, have you ever used street opioids (heroin, opium, etc.)?	◯ Yes ◯ No
In your lifetime, have you ever used prescription opioids for non-medical reasons (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.) ?	◯ Yes ◯ No
In your lifetime, has there been any other illegal substance you have used OR prescription medication you used in a way that was not prescribed to you by your doctor?	◯ Yes, please specify ◯ No
Please tell us the other other illegal substance OR prescription medication you used for non-medical reasons. (Note: if there is more than one substance that fits this description, please list the substance you have used most recently.)	_____

The second set of questions asks you about your use of substances over the PAST 3 MONTHS only.	
Have you used any illegal substance OR prescription medication for non-medical reasons over the PAST 3 MONTHS? (Please note that we are NOT asking about marijuana/weed.)	◯ Yes ◯ No
In the past 3 months, how often have you used cocaine (coke, crack, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used prescription stimulants for non-medical reasons (Ritalin, Concerta, Dexedrine, Adderall, diet pills, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used methamphetamine (speed, crystal meth, ice, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used inhalants (nitrous oxide, glue, gas, paint thinner, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used sedatives or sleeping pills in a way that was not prescribed by a doctor (Valium, Serepax, Ativan, Librium, Xanax, Rohypnol, GHB, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used hallucinogens (LSD, acid, mushrooms, PCP, Special K, ecstasy, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used street opioids (heroin, opium, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
In the past 3 months, how often have you used prescription opioids for non-medical reasons (fentanyl, oxycodone [OxyContin, Percocet], hydrocodone [Vicodin], methadone, buprenorphine, etc.)?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily

In the past 3 months, how often have you used [nida9_other]?	◯ Never ◯ Once or twice monthly ◯ Monthly ◯ Weekly ◯ Daily or almost daily
Have you ever used any drug by injection that was NOT prescribed to you by a doctor?	◯ No, never ◯ Yes, but not in the past 3 months ◯ Yes, in the past 3 months

This section asks you about your experiences with HIV medical care over the past 12 months. How often have you experienced the following at [eli4]?

Healthcare workers were unwilling to care for me because I am living with HIV.	◯ Never ◯ Rarely ◯ A lot of the time ◯ Most of the time
Healthcare workers provided poorer quality of care to me than to other patients because I am living with HIV.	◯ Never ◯ Rarely ◯ A lot of the time ◯ Most of the time
Healthcare workers talked badly about people living with HIV.	◯ Never ◯ Rarely ◯ A lot of the time ◯ Most of the time
Healthcare workers confronted or educated someone who was mistreating a patient living with HIV.	◯ Never ◯ Rarely ◯ Most of the time ◯ All of the time
Healthcare workers disclosed or told my HIV status to others without my permission.	◯ Never ◯ Rarely ◯ A lot of the time ◯ Most of the time
Healthcare workers provided extra support or care to me because I am living with HIV or they think that I am living with HIV.	◯ Never ◯ Rarely ◯ A lot of the time ◯ Most of the time
Healthcare workers sent or referred me to another health facility because the workers do not want to treat me at [eli4].	◯ Never ◯ Rarely ◯ A lot of the time ◯ Most of the time
Healthcare workers used extra infection control precautions (like wearing extra gloves) when caring for me because I am a person living with HIV.	◯ Never ◯ Rarely ◯ Most of the time ◯ All of the time

This section asks you about your beliefs about your medical team at [eli4].

By "medical team," we are referring to the people at [eli4] that provide you with health care services, such as doctors, nurses, social workers/case managers, etc.

I believe that my medical team is knowledgeable about HIV/AIDS.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team puts an effort into my treatment.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
I believe my medical team is motivated to help me.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team cares about my health.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
I believe that my medical team knows a lot about HIV treatment drugs.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
I believe I receive the best available health care.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team is lazy.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree

My medical team is knowledgeable about new HIV treatments.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
I believe that my medical team cares about me.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team supports me.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team encourages me.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team is helpful.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team makes me feel comfortable.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team spends enough time with me.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team is sensitive to how I feel.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree

My medical team thinks I am a bad person because I have HIV.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team cares about my opinion.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
I believe that my medical team sees me as stupid.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree
My medical team negatively judges me.	◯ Strongly disagree ◯ Disagree ◯ Somewhat disagree ◯ Somewhat agree ◯ Agree ◯ Strongly agree

Think about your past experiences using drugs. In the questions below, please share how often healthcare workers at [eli4] have treated you in these ways because of your drug use.

Healthcare workers have not listened to my concerns.	◯ Never ◯ Not often ◯ Somewhat often ◯ Often ◯ Very often
Healthcare workers have thought that I'm pill shopping, or trying to con them into giving me prescription medications to get high or sell.	◯ Never ◯ Not often ◯ Somewhat often ◯ Often ◯ Very often
Healthcare workers have given me poor care.	◯ Never ◯ Not often ◯ Somewhat often ◯ Often ◯ Very often

This section asks you about your treatment at [eli4] due to your race or ethnicity.

How often did doctors at [eli4] pay less attention to you because of your race or ethnicity?	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
How often did you feel discriminated against by doctors at [eli4] because of your race or ethnicity?	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always

In this section, we want to know a bit more about your relationship with your healthcare provider at [eli4]. For this set of questions, think about the main person who provides your HIV care, that is, the person who writes your prescriptions for HIV medications.

My provider helps me identify health goals that work for me.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider expects that my health behaviors will improve every time I see them.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider expects me to achieve perfect health behaviors.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider cares about why I make the health decisions I make.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider understands that sometimes I make decisions based on quality of life rather than strict health outcomes.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider helps me understand that sometimes my health behaviors will level off or go backwards.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider supports the idea that I have the final say in decisions about my health.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider negatively judges the choices I make.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider will drop me from care if I miss too many appointments.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always

My provider respects me even if I have harmful health behaviors.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider makes me feel comfortable telling them anything.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider gives me information that is specific to my needs.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
I believe my provider will drop me from care if I don't reach my goals.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider celebrates when I make positive health changes even if they are small changes.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
I often feel my provider wants me to do things that are unrealistic for me.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
I have an equal voice with my provider in making decisions about my care.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider helps me understand how my harmful behaviors might impact my health.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider is better at making decisions for my own health than I am.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
I do not feel my provider is able to give me different options even though my needs change from time to time.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always

My provider has talked to me about whether or not I use substances.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider has talked to me about substance use treatment options.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider has talked to me about how to avoid infections related to substance use.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always ◯ Not applicable
My provider has talked to me about how to use Naloxone/Narcan to reverse overdose.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider has talked to me about how to be careful when I'm not sure what's in my drugs.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always
My provider has given me information that I have used in my daily life to use substances safely.	◯ Never ◯ Rarely ◯ Sometimes ◯ Usually ◯ Always

In this final section, we want to know a bit more about your relationship with your healthcare team at [eli4], including front desk staff, social workers/case managers, and medical care team members (like doctors, nurses, nurse practitioners, fellows, etc.).

For each type of healthcare worker at [eli4] listed below that you currently see, think about the extent to which they know you as a person.

If there is more than one healthcare worker in a category (example: you have more than one nurse you see at [eli4]), please answer based on how much you feel these multiple people know you as a person.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
My medical provider(s) (the person or people who prescribe my medications) knows me as a person.	○	○	○	○	○
My social worker(s)/case manager(s) knows me as a person.	○	○	○	○	○
My nurse(s) knows me as a person.	○	○	○	○	○
The person (or people) who works at the front desk knows me as person.	○	○	○	○	○
My pharmacist(s) knows me as a person.	○	○	○	○	○

How often have you felt stigmatized by each of the following types of healthcare workers at [eli4]?

	Never	Not often	Somewhat often	Often	Very often
Medical providers (the person or people who prescribe my medications)	○	○	○	○	○
Social workers/case managers	○	○	○	○	○
Nurses	○	○	○	○	○
Front desk staff	○	○	○	○	○
Pharmacists	○	○	○	○	○

Please click "submit" to submit your answers.

Thank you so much for your time taking this survey! You may receive a $35 incentive as a thank-you for your time. The following page will collect additional information needed to process the payment; this information will not be linked to your survey answers.

Would you like to receive the incentive?

◯ Yes
◯ No

Please click "next page."

Impact of harm reduction care in HIV clinical settings on stigma and health outcomes for PLWH who use drugs

Thank you for joining our focus group today. The aim of this study is to understand things that influence health and clinical outcomes for people living with HIV who use drugs. We are especially interested in your healthcare experiences at [Clinic], so when we ask you questions about your healthcare experiences, please make sure to think about your experiences as they relate to [Clinic].

Focus Group Questions

1. **Please tell me about your experiences getting medical care at [Clinic].**
    a. How do people feel about the services here?
    b. To what extent do you think your experiences have affected your health?

2. **Overall, what is important to you in an HIV healthcare provider?** When I say providers, I'm talking about everybody who works there: front desk or receptionist staff, social workers, pharmacists, nurses, and people that provide your clinical care.

    a. What are the kinds of things providers have done that have made you feel you could talk to them about anything related to your health?
    b. Are there certain types of providers you tend to feel most comfortable talking to? By what types, I mean are there certain positions at your HIV care center you are most likely to talk to? What about any types of providers that you don't feel comfortable talking to about this?

3. **As we all know, people experience stigma and discrimination based on many things in their lives. Can you describe any experiences at [Clinic] you have with discrimination based on parts of who you are?**
    a. Probes: substance use, HIV, race, HCV, age, sexual identity, gender identity, disability
    b. Have these experiences changed over time?
    c. How do these experiences compare to other places where you've gotten HIV care?

4. **You may also have witnessed other people experiencing stigma or discrimination at [Clinic]. Can you tell me about what you saw?**

5. **Please describe any resources or sources of support you are aware of that are available for people with HIV who use drugs in your (a) clinic and (b) community.**
    a. Probes: accessibility/barriers to care; quality of available services; gaps in available services

b. Have you ever heard about "harm reduction"? What does that mean to you? What do you think about it?

6. **Think about your own experiences accessing healthcare? What can be done to make sure people with similar experiences receive good health care?**
   a. Probes: Policy changes; more medical training; expand health insurance access; more people working in healthcare with characteristics that reflect their patient population

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2-3

Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	5-7
Objectives	#3	State specific objectives, including any prespecified hypotheses	7-8
Methods			
Study design	#4	Present key elements of study design early in the paper	8-9
Setting	#5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	9
Participants	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	9-10
Variables	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	11-12

Bias	#9	Describe any efforts to address potential sources of bias	11
Study size	#10	Explain how the study size was arrived at	11-13
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	n/a
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	11-13 *Note—proposed methods stated only, as analysis has not yet started*
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	n/a—analysis has not yet started
Statistical methods	#12c	Explain how missing data were addressed	n/a—analysis has not yet started
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	n/a—analysis has not yet started
Statistical methods	#12e	Describe any sensitivity analyses	n/a—analysis has not yet started
Results			

Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	n/a—analysis has not yet started
Participants	#13b	Give reasons for non-participation at each stage	n/a—analysis has not yet started n/a—analysis has not yet started
Participants	#13c	Consider use of a flow diagram	n/a—analysis has not yet started
Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	n/a—analysis has not yet started
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a—analysis has not yet started
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	n/a—analysis has not yet started

Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a—analysis has not yet started
Main results	#16b	Report category boundaries when continuous variables were categorized	n/a—analysis has not yet started
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a—analysis has not yet started
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	n/a—analysis has not yet started
Discussion			
Key results	#18	Summarise key results with reference to study objectives	n/a—analysis has not yet started
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	n/a—analysis has not yet started
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	n/a—analysis has not yet started
Generalisability	#21	Discuss the generalisability (external validity) of the study results	n/a—analysis has not yet started

Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	20