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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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SCHOLARONE™
Manuscripts

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5 2 **people with HIV who use drugs: study protocol for a mixed-methods, multisite,**
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7 3 **observational study**
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69 Abstract

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

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

90 **Ethics and dissemination.** This study was approved via expedited review by the University of
91 Pittsburgh Institutional Review Board (STUDY21090002). Study findings will be presented in

92 peer-reviewed journals and public health conferences, as well as shared with patient participants,
93 community advisory boards, and harm reduction organizations.

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

97 **Key Words:** HIV; harm reduction; substance use

98 **Word Count:** 3886

100 Article Summary

101 Strengths and limitations of this study

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

115

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Background

117 There are significant HIV health disparities between people who use drugs and people
118 who do not use drugs. Among all new HIV diagnoses in the United States (US) in 2018, one in
119 ten were among people who inject drugs (1). High rates of HIV among people who inject drugs
120 are particularly problematic given injection drug use (IDU) increases risk for HIV transmission
121 and acquisition and predicts poor retention in HIV primary care (2-5). Lack of retention in care is
122 associated with poor clinical outcomes, such as unsuppressed viral load, which contributes to
123 HIV incidence (6-9). People with HIV (PWH) who miss visits in their first year of HIV
124 treatment have more than double the mortality risk of those retained in care (10). Moreover, HIV
125 and hepatitis C (HCV) often co-occur, with an estimated 21% of PWH in the US co-infected
126 with HCV (11), and evidence that HIV viral load impacts severity of HCV infection (12, 13).

127 While social factors such as economic distress (14), trauma (15), and co-morbid mental
128 health conditions (16) all increase substance use rates and serve as barriers to care, there is strong
129 evidence that experiences of stigma in healthcare settings by people who use drugs are common
130 and contribute to poor healthcare outcomes (17-20). PWH who use drugs may experience stigma
131 related to HIV status and substance use, while PWH of color who use drugs may experience
132 additional stigma through racial discrimination (e.g., inequitable treatment based on race or
133 ethnicity) (21). Experiencing any kind of stigma in the healthcare setting is particularly
134 deleterious. We previously found that experiencing HIV stigma in healthcare settings, but not in
135 community settings, was associated with lack of viral suppression (22), while additional research
136 illuminates the negative relationship between experienced HIV stigma in the healthcare setting
137 and ART adherence (23). Experiencing substance use stigma in healthcare settings is also

1
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3 138 damaging, with people who inject drugs reporting experiences of discrimination and derogatory
4
5 139 language from their healthcare providers, contributing to decreased engagement in care (24).
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8 140 Our previous work suggests harm reduction (HR) may strengthen the patient-provider
9
10 141 relationship and mitigate the effects of stigma. HR refers to approaches aimed at reducing the
11
12 142 negative consequences of health behaviors without necessarily eliminating the problematic
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14 143 health behaviors entirely (25-28). HR stands in opposition to the traditional medical model of
15
16 144 addiction, in which any illicit drug use is labeled as abuse, and the moral model, which labels
17
18 145 substance use as simply wrong (26, 27). HR strategies such as syringe service programs (SSP),
19
20 146 naloxone distribution, and medications for opioid use disorder (MOUD) effectively engage
21
22 147 people who use drugs in care by providing services that are responsive to their needs without
23
24 148 assuming abstinence as the ideal clinical outcome, while simultaneously working to reduce
25
26 149 stigma in healthcare settings by honoring patient autonomy (27, 29-34). Though HR is typically
27
28 150 thought of as structural approaches (i.e., policies or strategies like SSPs), HR also includes
29
30 151 relational approaches to care, centered on improving the patient-provider relationship, that can be
31
32 152 implemented by healthcare teams to improve outcomes for PWH who use drugs (28, 35, 36).
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38 153 We previously defined HR principles for healthcare settings to describe ways that
39
40 154 clinicians can operationalize and provide relational HR care (i.e., humanism, pragmatism,
41
42 155 individualism, autonomy, incrementalism, and accountability without termination)(28). In our
43
44 156 mixed methods study of an HIV clinic serving PWH who use drugs, we conducted patient
45
46 157 surveys to test associations between perceptions of care related to HR (respect, user-friendly and
47
48 158 unhurried care, and clinic responsiveness) and self-reported ART adherence. After adjusting for
49
50 159 race, age, ethnicity, gender identity, sexual orientation, homelessness, and poverty status, the
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52 160 addition of the HR-related variables significantly predicted ART adherence (35, 36).
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3 161 However, there is limited research examining ways that structural and relational HR in
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5 162 HIV clinical settings reduce experiences of stigma, affect patient-provider relationships, and
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7 163 improve outcomes for PWH who use drugs. Given that integrated, coordinated HIV and
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10 164 substance use care is essential for optimizing the health outcomes of PWH who use drugs(37), an
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12 165 intervention that draws on the principles of HR to address both HIV and substance use health
13
14 166 care needs is essential. The knowledge gained from this study will enable us to develop an
15
16 167 intervention to operationalize HR care in an HIV clinic setting and, ultimately, reduce health
17
18 168 inequities for PWH who use drugs. The current manuscript provides a detailed overview of our
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20
21 169 study protocol.

24 170 **Objectives**

26 171 The study has three primary aims:

28 172 *1. Explore the relationship between healthcare providers' stigmatizing attitudes towards*
29
30
31 173 *working with PWH who use drugs and providers' acceptance and practice of structural and*
32
33 174 *relational HR to elucidate the context for intervention development.* We will survey physicians,
34
35 175 advanced practice providers, nurses, medical assistants, front-desk staff, and social workers
36
37 176 (n=125) and conduct qualitative interviews (n=40) at our study sites to develop a deeper
38
39 177 understanding of providers' attitudes towards working with PWH who use drugs, as well as the
40
41 178 ways that these attitudes are associated with the provision of structural and relational HR care.

44 179 *2. Explore the interplay between patient-perceived HR and stigma and clinical outcomes;*
46
47 180 *specifically, the degree to which (a) relational HR moderates the effect of intersectional stigma*
48
49 181 *experienced in healthcare settings (HIV- and substance use-related stigma and racial*
50
51 182 *discrimination) on patients' perceptions of their relationship with providers, (b) structural HR*
52
53 183 *moderates the relationship between the patient-provider relationship and clinical outcomes (ART*

184 *adherence, retention in care, HIV and HCV viral suppression), and (c) patient-perceived HR*
185 *care is directly associated with HIV clinical outcomes.* We will survey PWH who use drugs
186 (n=500) to assess their perceptions of providers' relational HR care, experiences of intersectional
187 stigma, and perceived quality of relationships with their providers, and to explore other potential
188 stigmatized identities and characteristics in patient focus groups (total n=36). We will also
189 psychometrically evaluate our novel scale, the Patient Assessment of Provider Harm Reduction
190 Scale (PAPHRS), to assess patients' perceptions of the degree to which their providers deliver
191 relational HR care.

192 *Using human-centered design approaches (38), develop and pre-test an intervention to*
193 *operationalize HR care for PWH who use drugs in HIV clinical settings.* Using findings from
194 Aims 1 and 2, we will meet with community member and provider collaborators (n=20)
195 including PWH who use drugs, HIV providers, and HR experts, to review results and pinpoint
196 the most valuable intervention approaches using human-centered design, ensuring the
197 intervention is responsive to end users' needs.

198 **Methods and Analysis**

199 **Study design**

200 The overarching aim of our observational study is to collect data that will inform
201 development of an intervention to be tested in a subsequent clinical trial. We will use a
202 sequential explanatory mixed-methods approach (39), following the surveys with semi-structured
203 interviews (Aim 1) and focus groups (Aim 2), in order to contextualize and gain in-depth
204 understanding of survey findings.

205 We will develop an intervention in Aim 3, in which we will meet with community
206 member and provider collaborators to review results from Aims 1 and 2 and identify the most

207 valuable intervention approaches using human-centered design, and pre-test this intervention by
208 convening small groups or one-on-one meetings with providers in Pittsburgh and Birmingham
209 (total n=12). These individuals will be different than those involved in intervention development.
210 During these meetings, we will share the mockup design (the concept poster) of the intervention
211 and explore preliminary feasibility, acceptability, and appropriateness of our prototyped
212 approach.

213 **Setting**

214 The University of Pittsburgh (Pitt) is the study coordinating center. Study sites are two
215 HIV clinics in Pittsburgh, Pennsylvania (PA) (Allegheny Health Network's Positive Health
216 Clinic [PHC], University of Pittsburgh Medical Center's HIV/AIDS Program [UPMC]) and one
217 in Birmingham, Alabama (AL) (University of Alabama at Birmingham [UAB] 1917 Clinic).
218 These are areas of the country that are disproportionately affected by both the HIV and opioid
219 epidemics and have high HCV incidence rates. Additionally, while not a study site, the study
220 involves close collaboration with a strong community partner, Birmingham AIDS Outreach
221 (BAO), an AIDS service organization providing social support services to more than 1,000 PWH
222 each year, most of whom receive HIV primary care at UAB's 1917 Clinic. BAO will lead
223 recruitment efforts and coordinate study activities in AL.

224 **Participants**

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

230 providers may, but do not have to, participate in both the survey and interview components of
231 Aim 1.

232 For both quantitative and qualitative portions of Aim 2, patient participants must be ages
233 18 or older, have a confirmed HIV diagnosis, be able to verbally consent, read, and speak
234 English, have received HIV medical care from one of the study sites for at least one year, and
235 have lifetime or recent use (past 3 months) of illicit substances (excluding marijuana) or
236 prescription drugs for non-medical reasons. As with Aim 1, eligible participants may, but do not
237 necessarily have to, complete both quantitative and qualitative portions.

238 **Variables and Data Sources and Measurement**

239 **Outcomes.** There are five outcomes of interest in our study, all relating to the clinical
240 health of PWH who use drugs. Four of these are collected as standards of care at our study sites
241 and will be abstracted via patient electronic medical health record: HIV viral load [<200
242 copies/mL, virally suppressed (40)]; HIV primary care appointment attendance [as measured by
243 (1) visits at least 90 days apart within one year=retained in HIV primary care (41) and (2)
244 proportion of missed to scheduled visits (range 0-100%) (42)]; HCV viral load, for those who
245 have hepatitis C; and retention in opioid treatment care for those with opioid use disorder
246 (proportion of kept to scheduled visits (range 0-100%).

247 We will measure antiretroviral therapy (ART) adherence via self-report through the
248 validated CASE index (43). All study outcomes will be measured cross-sectionally, collecting all
249 HIV primary care and opioid treatment care visits within a 12-month observation window and
250 the HIV and HCV viral load data closest to the end of the observation window. Clinical data will
251 be linked to survey data by study staff at the participating clinical sites. Analysis of these
252 outcomes will enable us to explore: the relationship between patient-perceived HR care and

253 clinical outcomes, relational HR as a potential moderator of the path between intersectional
 254 stigma and the patient-provider relationship, and structural HR as a potential moderator of the
 255 path between intersectional stigma and the patient-provider relationship, in which stigma is
 256 explored as HIV- and substance use-related stigma and racial discrimination).

257 **Other Variables.** Table 1 includes a complete list of all data elements included in Aims
 258 1 through 2 of the study, including sources of data and methods of assessment, along with
 259 corresponding citations.

Table 1. Aims 1 & 2 Constructs and Measurement Tools

Aim 1. Provider-reported	
Quantitative	
Provider attitudes	<ul style="list-style-type: none"> • Drug Problems Perceptions Questionnaire(44) • Health Care Provider HIV/AIDS Stigma Scale(45) • Racism in Healthcare Index(46)
Acceptance of HR	<ul style="list-style-type: none"> • Harm Reduction Acceptability Scale(47, 48)
Structural HR	<ul style="list-style-type: none"> • Organizational Survey of Structural HR
Structural HR	<ul style="list-style-type: none"> • Provider Survey of Structural HR
Qualitative	
Interviews	<ul style="list-style-type: none"> • Contextualize survey results (n=40)
Aim 2. Provider-reported	
Qualitative	
Interviews	<ul style="list-style-type: none"> • Evaluate PAPHRS (n= 20)
Aim 2. Patient-reported (PWH who use drugs)	
Qualitative	
Focus groups	<ul style="list-style-type: none"> • Evaluate PAPHRS (n=36)
Quantitative	
Experiences of Stigma and Discrimination in Healthcare Settings	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Patient Survey of Structural HR(54)
Receipt of Relational HR care	<ul style="list-style-type: none"> • 25-item PAPHRS

Patient clinical outcomes (EHR data)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Assess experiences of intersectional stigma (n=36)

260

261 **Bias**

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

264

265 **Statistical Methods**

266 **Quantitative Analysis and Sample Sizes**

267 To analyze survey data from Aim 1, we will stratify by site and use descriptive statistics
268 and bivariate associations to explore how providers feel about HR care, as well as to determine
269 both organizational and individual practice of structural HR, since HR policy and structures
270 might be in place at the organizational level, yet not practiced by individual providers. At an
271 estimated sample size of n=125, we anticipate sufficient sample size at power=0.80. Recent
272 simulation research on SEM factor analysis suggests appropriate sample sizes with moderate
273 factor loading between n=90-120 across a range of solutions(55).

274 In Aim 2, we will construct a generalized SEM (gSEM) to assess associations between
275 patient-reported 1) intersectional stigma (HIV- and substance use- related stigma and racial
276 discrimination) in healthcare settings and patient-provider relationships and 2) patient-provider
277 relationships and clinical outcomes (ART adherence, retention in HIV and substance use care,

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3 278 and suppression of HCV and HIV). This gSEM will be constructed using a mediation approach
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5 279 wherein we will assess whether the patient-provider relationship mediates the relationship
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8 280 between intersectional stigma and clinical outcomes. Mediation will be examined by assessing
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10 281 total, direct, and indirect effects. This approach will test the degree to which the relationship
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12 282 between intersectional stigma (HIV- and substance use-related stigma and racial discrimination)
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14 283 in healthcare settings and clinical outcomes is explained by the qualities of the patient-provider
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16 284 relationship. With an estimated sample size of $n=500$ and expected reasonable ratio of sample
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18 285 size to number of parameter estimates as 5:1 (56), we anticipate sufficient sample size with eight
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20 286 covariates (age, gender, sexual and gender minority status, income, race, ethnicity, substance
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22 287 use, and study site).

26 288 We will also evaluate the novel relational HR instrument using both classical and modern
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28 289 psychometric techniques. Classical item analysis including item frequencies, item-total
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30 290 correlations, item frequency distributions, and tests of monotonicity will be examined first. The
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32 291 underlying factor structure of PAPHRS items will be explored using factor analysis. The sample
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34 292 will be randomly split into two half samples, one for exploratory factor analysis (EFA) and the
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36 293 other for confirmatory factor analysis (CFA) using Mplus.

40 294 Our Aim 2 sample size of 500 patients is based on longstanding practice for estimating
41
42 295 sample size for SEMs with latent variables. Fritz and MacKinnon have posited that $n=500$
43
44 296 confers sufficient power (at 80%) to detect small mediation effects with a cross-sectional
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46 297 study(57). A sample size of 500 also confers sufficient power for the psychometric evaluation of
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48 298 PAPHRS. Suggested minimums of sample size for factor analysis includes from 3 to 20 times
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50 299 the number of variables and absolute ranges from 100 to over 1,000(58). The sample size of 500,
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52 300 which will be split into 250 for EFA and 250 for CFA, will give us ten times the number of
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3 301 PAPHRS items, right in the middle of the suggested sample size range. Reise and Yu(59)
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5 302 recommend that the unidimensional GRM be estimated with 500 cases. For convergent validity
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7 303 analyses, a sample of 200 participants is sufficient to provide power of .90 for correlations larger
8
9 304 than .80 at alpha level of .05 with a two-tailed test. For comparisons between groups with
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11 305 expected differences, a sample size of 191 per group is needed to provide power of 0.90 for an
12
13 306 effect size of .30 with alpha level of .05 and a two-tailed test.
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19 308 **Qualitative Analysis**

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21
22 309 We will analyze interview and focus group data in NVivo 12 (60) using thematic analysis
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24 310 (61, 62). All five members of our qualitative team will participate in analysis and development of
25
26 311 the coding framework by reading through transcripts, identifying major themes to contextualize
27
28 312 the data, and supplementing with field notes and corresponding analytic memos. We will code
29
30 313 interviews and focus groups based on the initial coding framework, using processes of
31
32 314 adjudication after each interview, and iteratively modifying the codebook. This method of co-
33
34 315 coding will continue until agreement on application of the codes is achieved. All interviews and
35
36 316 focus groups will be coded, and at least 20% will be double-coded by two researchers and
37
38 317 compared for consistency, in keeping with scholars' recommendation to double-code between
39
40 318 10-25% of transcripts (63). To assess the extent to which the qualitative findings help explain the
41
42 319 quantitative results, we will integrate quantitative and qualitative findings in a joint display to
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44 320 illustrate quantitative results with their corresponding qualitative themes (64, 65).
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49 321 **Recruitment**

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52 322 **Provider recruitment.** We will recruit providers by visiting sites' staff meetings and via
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54 323 electronic messaging used by each study site for internal communications and will have a
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3 324 Research Coordinator at each of our sites to assist with these methods and serve as site-specific
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5 325 project champions. Surveys will be deployed via REDCap (66) using confidential links. We will
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8 326 continually monitor response rates by provider type and site to ensure that each provider group is
9
10 327 represented in the data. We will continue with monthly targeted electronic messages until our
11
12 328 recruitment targets are met.

13
14 329 **Patient recruitment.** We will recruit 500 patients in total from our three study sites to
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16 330 complete a one-time survey on REDCap and 36 patients from our three study sites in total to
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18 331 participate in focus groups; patients may, but do not have to, participate in both data collection
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20 332 activities. We will utilize a multi-modal recruitment plan, including word-of-mouth, flyers in
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22 333 provider waiting areas and patient rooms, messages sent through internal clinic systems for
23
24 334 patients who receive electronic messages, and in-person information during clinic visits.
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26 335 Recruitment messages will inform potential participants of eligibility requirements, the voluntary
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28 336 nature of participation, data to be collected including clinical records data, confidentiality of
29
30 337 data, and incentives.

338 **Data Collection**

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

341 **Data Management and Confidentiality**

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

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3 346 All study survey data will be collected electronically via REDCap using individual,
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5 347 confidential links and stored on Pitt servers. Participant identifiers will only be collected for
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7 348 purposes of linking survey data to medical records for subsequent analysis. This information, as
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10 349 well as consent forms, will be stored separately from the study materials. Electronic medical
11
12 350 records data from each study site will be securely transferred to Pitt for analysis using Sharefile,
13
14 351 a secure file sharing transfer service. The Pitt data team will immediately delete participant
15
16 352 identifiers once assigning a study ID to each participant linking survey and clinical data. This
17
18 353 clinical data, in addition to de-identified survey data abstracted from REDCap, will be stored on
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21 354 OneDrive.

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24 355 For qualitative methods, identifiable data will be gathered to schedule interviews or focus
25
26 356 groups, but these will not be linked to data for analysis. Because interviews and focus groups
27
28 357 could potentially include identifiable data, these will be recorded on an audio recorder with 256-
29
30 358 bit file encryption and device PIN locking to ensure data security. Once interviews are complete,
31
32 359 any identifying information will be deleted from these files, and the audio tapes will be
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34 360 transferred to a Pitt desktop and subsequently submitted to a professional transcription service.
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37 361 No identifiable data will be transcribed, and once analysis is complete the audio recording will
38
39
40 362 be deleted.

41 42 363 **Ethics and Dissemination**

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44 364 Per NIH guidelines for multisite research, the study utilizes a single IRB, wherein the
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46 365 University of Pittsburgh serves as the IRB of record for UAB, BAO, and PHC. The University of
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48 366 Pittsburgh Human Research Protection Office (HRPO) approved this study via expedited review
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51 367 on November 1, 2021.

52 53 54 368 **Consent**

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3 369 For patient surveys associated with Aim 2 (n=500), informed consent will be obtained
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5 370 electronically in REDCap. Consent will include the voluntary nature of participation, data to be
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7 371 collected including access to clinical records data, confidentiality of data, and information about
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10 372 incentives. We have received a waiver to document consent for provider surveys (n=125) and
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12 373 interviews (n=40) associated with Aim 1, and for patient focus groups associated with Aim 2
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14 374 (n=36). Provider survey consent will be obtained via a “click to consent” function in REDCap,
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16 375 and, for patient and provider qualitative methods, verbal consent will be obtained by the research
17
18 376 team immediately before data collection. Participants will be informed of the study aims and
19
20 377 approach, voluntary nature of participation, right to exit the study with no penalty or risk of
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22 378 penalty, confidentiality of data, and incentives. No human subjects data will be collected as part
23
24 379 of Aim 3 so consent for these methods will not be obtained. However, given the sensitive
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26 380 inclusion criteria for patients, expectations for confidentiality related to participation will occur
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28 381 at the start of each patient focus group or stakeholders meeting.
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33 382 **Dissemination Plan**

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35 383 Study findings will be presented in peer-reviewed journals and public health conferences.
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37 384 Findings will also be shared with patient participants online or in in-person community forums
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39 385 held at study sites and with providers during regularly scheduled staff meetings. We will also
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41 386 share findings with the members of BAO’s and PHC’s community advisory boards, which is
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43 387 composed of researchers, community organization representatives, and PWH; as well as a local
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45 388 harm reduction organization that provides services to people who use drugs.
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49 389 **Patient and Public Involvement**

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51 390 Aim 3 of this study will be devoted to designing a harm reduction intervention via
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53 391 community collaborator meetings with PWH who use drugs, HIV providers, and harm reduction
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3 392 experts using human-centered design. Members of our community advisory boards will inform
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5 393 and direct dissemination of results.
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8 394 **Discussion**

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10 395 Ultimately this mixed methods observational study, taking place in two culturally-distinct
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12 396 regions with similarly high HIV and HCV incidence rates, aims to discover whether HR
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14 397 approaches have the potential to improve HIV, HCV, and substance use outcomes for PWH who
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16 398 use drugs. Given persistent racial health disparities, exploring racial discrimination experienced
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18 399 in healthcare settings is also critical. Our work builds on the Conceptual Framework for HIV-
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20 400 Related Stigma, Engagement in Care and Health Outcomes (67), which posits that multiple
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22 401 dimensions of stigma create different pathways to and effects on clinical outcomes for PWH. We
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24 402 are innovatively adapting this model (Figure 1) to focus specifically on experienced HIV stigma
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26 403 in healthcare settings, to incorporate substance use stigma and racial discrimination in an
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28 404 exploration of intersectional stigma, and to include our premise that the provision of HR can
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30 405 reduce and mitigate patients' experiences of stigma in healthcare settings. We hypothesize that
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32 406 the effect of intersectional stigma on the patient-provider relationship is reduced in the presence
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34 407 of higher degrees of relational HR care, structural HR attenuates the effect of poor patient-
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36 408 provider relationships on clinical outcomes, and higher degrees of HR care are associated with
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38 409 better clinical outcomes. Understanding the contributions of both structural and relational HR
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40 410 can help us determine which practices must be in place to improve patient outcomes.
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47 411 *[insert Figure 1 about here] Title: Figure 1. Modified Conceptual Framework*
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49 412 A primary strength of our study is that we will collect data from a range of participants,
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51 413 including both patients and providers, and we will integrate both qualitative and quantitative
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53 414 methods to elicit rich data. Study results have the potential to contribute to changing standards of
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3 415 care for providers who work with PWH who use drugs and improve care for this population;
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5 416 therefore, it is paramount that both sets of stakeholders' voices are included in all phases of the
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7 417 study. While many studies explore the effects of patient-provider relationships on clinical
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9 418 outcomes, including the full range of treatment team members (i.e., reception, social workers,
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11 419 nurses, pharmacists, etc.) in our methods is particularly novel. However, these strengths also add
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13 420 complexity to the protocol, as there are multiple stages of recruitment, data collection, and
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15 421 analysis across two states and three HIV clinics.
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19 422 Another potential challenge of this study, as with all research conducted during this time,
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21 423 is the ongoing challenges posed by the COVID-19 pandemic. For this reason, we have planned
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23 424 study activities so that all phases of data collection may occur online as needed. Both PIs have
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25 425 experience conducting virtual interviews and focus groups, should this be necessary. Indeed,
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27 426 improving care for PWH who use drugs becomes even more critical as people with multiple
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29 427 vulnerabilities have increased risk for COVID-19, and rising rates of unemployment and poverty
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31 428 drive people further into survival economies, increasing risk for HIV and HCV.
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35 429 **Declarations**

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38 430 *Ethics Approval and Consent to Participate:* To be a part of the study, each participant will
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40 431 provide written informed consent (for surveys) or verbal informed consent (for qualitative
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42 432 interviews and focus groups) prior to any data collection activities, as approved by the ethics
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44 433 committee. This study was approved via expedited review by the University of Pittsburgh
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46 434 Institutional Review Board (STUDY21090002).
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49 435 *Data Availability Statement:* Not applicable.

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51 436 *Competing Interests:* The authors declare that they have no competing interests.
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3 437 *Funding:* Funding for this study was provided by the US National Institutes of Health, National
4
5 438 Institute on Drug Abuse (1R01DA054832-01). The funder had no role in the design of the study,
6
7 439 data collection, data analyses, interpretation of data, or preparation of this manuscript.
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9

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11
12 441 with DSB and JT of the University of Alabama at Birmingham; RWSC, STC, JEE, MRF, SK,
13
14 442 and LY of the University of Pittsburgh; SF and VN of the Allegheny Health Network Center for
15
16 443 Inclusion Health; and SK and BT, consultants to the study. The manuscript was written by ESK
17
18 444 and MH with input and review from all authors. All authors read and approved the final
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20 445 manuscript.
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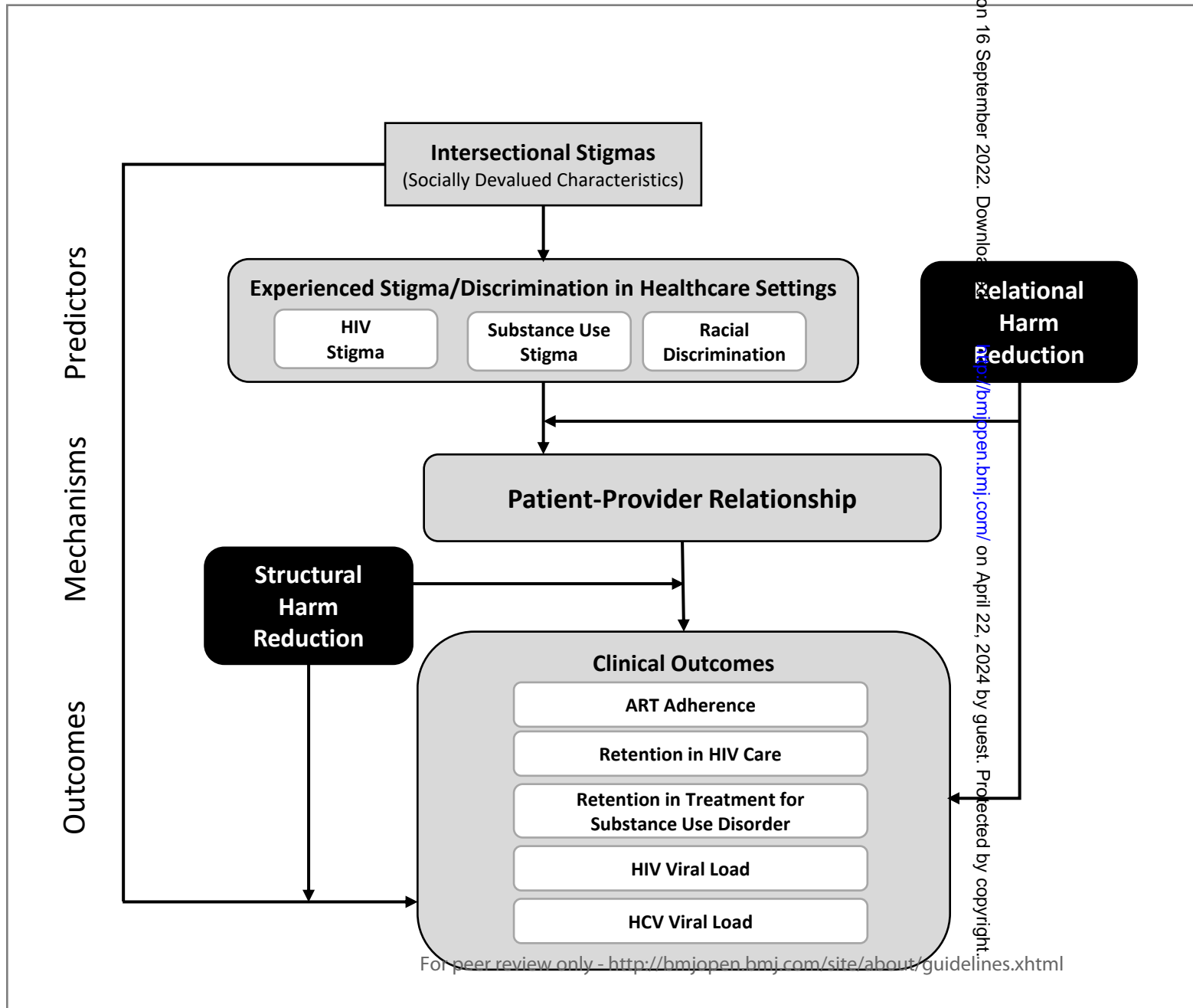
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Figure Legends

636 Figure 1: Modified Conceptual Framework

For peer review only



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 sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche 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

1	Introduction		
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4	Background /	#2	Explain the scientific background and rationale for
5			5-7
6	rationale		the investigation being reported
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8			
9	Objectives	#3	State specific objectives, including any prespecified
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11			hypotheses
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15	Methods		
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18	Study design	#4	Present key elements of study design early in the
19			8-9
20			paper
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23	Setting	#5	Describe the setting, locations, and relevant dates,
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25			including periods of recruitment, exposure, follow-up,
26			and data collection
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31	Participants	#6a	Give the eligibility criteria, and the sources and
32			9-10
33			methods of selection of participants.
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36	Variables	#7	Clearly define all outcomes, exposures, predictors,
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38			potential confounders, and effect modifiers. Give
39			diagnostic criteria, if applicable
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44	Data sources /	#8	For each variable of interest give sources of data
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46	measurement		and details of methods of assessment
47			(measurement). Describe comparability of
48			assessment methods if there is more than one
49			group. Give information separately for for exposed
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1	Bias	#9	Describe any efforts to address potential sources of	11
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6	Study size	#10	Explain how the study size was arrived at	11-13
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9	Quantitative	#11	Explain how quantitative variables were handled in	n/a
10	variables		the analyses. If applicable, describe which groupings	
11			were chosen, and why	
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16	Statistical	#12a	Describe all statistical methods, including those used	11-13
17	methods		to control for confounding	
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24				<i>Note—proposed</i>
25				<i>methods stated</i>
26				<i>only, as analysis</i>
27				<i>has not yet</i>
28				<i>started</i>
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35	Statistical	#12b	Describe any methods used to examine subgroups	n/a—analysis has
36	methods		and interactions	not yet started
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41	Statistical	#12c	Explain how missing data were addressed	n/a—analysis has
42	methods			not yet started
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46	Statistical	#12d	If applicable, describe analytical methods taking	n/a—analysis has
47	methods		account of sampling strategy	not yet started
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51	Statistical	#12e	Describe any sensitivity analyses	n/a—analysis has
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1 2 3 4 5 6 7 8 9 10 11 12 13 14	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
15 16 17 18 19 20 21 22 23 24	Participants	#13b	Give reasons for non-participation at each stage	n/a—analysis has not yet started n/a—analysis has not yet started
25 26 27 28 29 30	Participants	#13c	Consider use of a flow diagram	n/a—analysis has not yet started
31 32 33 34 35 36 37 38 39 40 41 42	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
43 44 45 46 47	Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	n/a—analysis has not yet started
48 49 50 51 52 53 54 55 56 57 58 59 60	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

1	Main results	#16a	Give unadjusted estimates and, if applicable,	n/a—analysis has
2			confounder-adjusted estimates and their precision	not yet started
3			(eg, 95% confidence interval). Make clear which	
4			confounders were adjusted for and why they were	
5			included	
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12			Main results	#16b
13	variables were categorized	not yet started		
14	Main results	#16c	If relevant, consider translating estimates of relative	n/a—analysis has
15			risk into absolute risk for a meaningful time period	not yet started
16				
17	Other analyses	#17	Report other analyses done—e.g., analyses of	n/a—analysis has
18			subgroups and interactions, and sensitivity analyses	not yet started
19	Discussion			
20	Key results	#18	Summarise key results with reference to study	n/a—analysis has
21			objectives	not yet started
22	Limitations	#19	Discuss limitations of the study, taking into account	n/a—analysis has
23			sources of potential bias or imprecision. Discuss	not yet started
24			both direction and magnitude of any potential bias.	
25				
26	Interpretation	#20	Give a cautious overall interpretation considering	n/a—analysis has
27			objectives, limitations, multiplicity of analyses,	not yet started
28			results from similar studies, and other relevant	
29			evidence.	
30				
31	Generalisability	#21	Discuss the generalisability (external validity) of the	n/a—analysis has
32			study results	not yet started

1 Other

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3 Information

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5
6 Funding [#22](#) Give the source of funding and the role of the 20
7 funders for the present study and, if applicable, for
8 the original study on which the present article is
9 based
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16 None The STROBE checklist is distributed under the terms of the Creative Commons Attribution
17 License CC-BY. This checklist can be completed online using <https://www.goodreports.org/>, a tool
18 made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)
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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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Manuscripts

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3 1 **Impact of harm reduction care in HIV clinical settings on stigma and health outcomes for**
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5 2 **people with HIV who use drugs: study protocol for a mixed-methods, multisite,**
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7 3 **observational study**
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69 Abstract

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

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

90 **Ethics and dissemination.** This study was approved via expedited review by the University of
91 Pittsburgh Institutional Review Board (STUDY21090002). Study findings will be presented in

92 peer-reviewed journals and public health conferences, as well as shared with patient participants,
93 community advisory boards, and harm reduction organizations.

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

97 **Key Words:** HIV; harm reduction; substance use

98 **Word Count:** 3932

100 Article Summary

101 Strengths and limitations of this study

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

115

116

Background

117 There are significant HIV health disparities between people who use drugs and people
118 who do not use drugs. Among all new HIV diagnoses in the United States (US) in 2018, one in
119 ten were among people who inject drugs (1). High rates of HIV among people who inject drugs
120 are particularly problematic given injection drug use (IDU) increases risk for HIV transmission
121 and acquisition and predicts poor retention in HIV primary care (2-5). Lack of retention in care is
122 associated with poor clinical outcomes, such as unsuppressed viral load, which contributes to
123 HIV incidence (6-9). People with HIV (PWH) who miss visits in their first year of HIV
124 treatment have more than double the mortality risk of those retained in care (10). Moreover, HIV
125 and hepatitis C (HCV) often co-occur, with an estimated 21% of PWH in the US co-infected
126 with HCV (11), and evidence that HIV viral load impacts severity of HCV infection (12, 13).

127 While social factors such as economic distress (14), trauma (15), and co-morbid mental
128 health conditions (16) all increase substance use rates and serve as barriers to care, there is strong
129 evidence that experiences of stigma in healthcare settings by people who use drugs are common
130 and contribute to poor healthcare outcomes (17-20). PWH who use drugs may experience stigma
131 related to HIV status and substance use, while PWH of color who use drugs may experience
132 additional stigma through racial discrimination (e.g., inequitable treatment based on race or
133 ethnicity) (21). Experiencing any kind of stigma in the healthcare setting is particularly
134 deleterious. We previously found that experiencing HIV stigma in healthcare settings, but not in
135 community settings, was associated with lack of viral suppression (22), while additional research
136 illuminates the negative relationship between experienced HIV stigma in the healthcare setting
137 and ART adherence (23). Experiencing substance use stigma in healthcare settings is also

1
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3 138 damaging, with people who inject drugs reporting experiences of discrimination and derogatory
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5 139 language from their healthcare providers, contributing to decreased engagement in care (24).
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8 140 Our previous work suggests harm reduction (HR) may strengthen the patient-provider
9
10 141 relationship and mitigate the effects of stigma. HR refers to approaches aimed at reducing the
11
12 142 negative consequences of health behaviors without necessarily eliminating the problematic
13
14 143 health behaviors entirely (25-28). HR stands in opposition to the traditional medical model of
15
16 144 addiction, in which any illicit drug use is labeled as abuse, and the moral model, which labels
17
18 145 substance use as simply wrong (26, 27). HR strategies such as syringe service programs (SSP),
19
20 146 naloxone distribution, and medications for opioid use disorder (MOUD) effectively engage
21
22 147 people who use drugs in care by providing services that are responsive to their needs without
23
24 148 assuming abstinence as the ideal clinical outcome, while simultaneously working to reduce
25
26 149 stigma in healthcare settings by honoring patient autonomy (27, 29-34). Though HR is typically
27
28 150 thought of as structural approaches (i.e., policies or strategies like SSPs), HR also includes
29
30 151 relational approaches to care, centered on improving the patient-provider relationship, that can be
31
32 152 implemented by healthcare teams to improve outcomes for PWH who use drugs (28, 35, 36).
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38 153 We previously defined HR principles for healthcare settings to describe ways that
39
40 154 clinicians can operationalize and provide relational HR care (i.e., humanism, pragmatism,
41
42 155 individualism, autonomy, incrementalism, and accountability without termination)(28). In our
43
44 156 mixed methods study of an HIV clinic serving PWH who use drugs, we conducted patient
45
46 157 surveys to test associations between perceptions of care related to HR (respect, user-friendly and
47
48 158 unhurried care, and clinic responsiveness) and self-reported ART adherence. After adjusting for
49
50 159 race, age, ethnicity, gender identity, sexual orientation, homelessness, and poverty status, the
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52 160 addition of the HR-related variables significantly predicted ART adherence (35, 36).
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3 161 However, there is limited research examining ways that structural and relational HR in
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5 162 HIV clinical settings reduce experiences of stigma, affect patient-provider relationships, and
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7 163 improve outcomes for PWH who use drugs. Given that integrated, coordinated HIV and
8
9 164 substance use care is essential for optimizing the health outcomes of PWH who use drugs(37), an
10
11 165 intervention that draws on the principles of HR to address both HIV and substance use health
12
13 166 care needs is essential. The knowledge gained from this study will enable us to develop an
14
15 167 intervention to operationalize HR care in an HIV clinic setting and, ultimately, reduce health
16
17 168 inequities for PWH who use drugs. The current manuscript provides a detailed overview of our
18
19 169 study protocol.

20 21 22 23 24 170 **Objectives**

25
26 171 The study has three primary aims:

27
28 172 1. *Explore the relationship between healthcare providers' stigmatizing attitudes towards*
29
30 173 *working with PWH who use drugs and providers' acceptance and practice of structural and*
31
32 174 *relational HR to elucidate the context for intervention development.* We will survey physicians,
33
34 175 advanced practice providers, nurses, medical assistants, front-desk staff, and social workers
35
36 176 (n=125) and conduct qualitative interviews (n=40) at our study sites to develop a deeper
37
38 177 understanding of providers' attitudes towards working with PWH who use drugs, as well as the
39
40 178 ways that these attitudes are associated with the provision of structural and relational HR care.
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42 179 See supplementary files 1 and 2 for copies of the survey and interview guide, respectively.

43
44
45 180 2. *Explore the interplay between patient-perceived HR and stigma and clinical outcomes;*
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47 181 *specifically, the degree to which (a) relational HR moderates the effect of intersectional stigma*
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49 182 *experienced in healthcare settings (HIV- and substance use-related stigma and racial*
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51 183 *discrimination) on patients' perceptions of their relationship with providers, (b) structural HR*
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3 184 *moderates the relationship between the patient-provider relationship and clinical outcomes (ART*
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5 185 *adherence, retention in care, HIV and HCV viral suppression), and (c) patient-perceived HR*
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7 186 *care is directly associated with HIV clinical outcomes.* We will survey PWH who use drugs
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10 187 (n=500) to assess their perceptions of providers' relational HR care, experiences of intersectional
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12 188 stigma, and perceived quality of relationships with their providers, and to explore other potential
13
14 189 stigmatized identities and characteristics in patient focus groups (total n=36). We will also
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16 190 psychometrically evaluate our novel scale, the Patient Assessment of Provider Harm Reduction
17
18 191 Scale (PAPHRS), to assess patients' perceptions of the degree to which their providers deliver
19
20 192 relational HR care. See supplementary files 3 and 4 for copies of the survey and focus group
21
22 193 guide, respectively.

26 194 *Using human-centered design approaches (38), develop and pre-test an intervention to*
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28 195 *operationalize HR care for PWH who use drugs in HIV clinical settings.* Using findings from
29
30 196 Aims 1 and 2, we will meet with community member and provider collaborators (n=20)
31
32 197 including PWH who use drugs, HIV providers, and HR experts, to review results and pinpoint
33
34 198 the most valuable intervention approaches using human-centered design, ensuring the
35
36 199 intervention is responsive to end users' needs.

40 200 **Methods and Analysis**

41 201 **Study design**

42 202 The overarching aim of our observational study is to collect data that will inform
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44 203 development of an intervention to be tested in a subsequent clinical trial. We will use a
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46 204 sequential explanatory mixed-methods approach (39), following the surveys with semi-structured
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48 205 interviews (Aim 1) and focus groups (Aim 2), in order to contextualize and gain in-depth
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206 understanding of survey findings. The study is funded from September 2021 through June 2026.

207 Recruitment for the provider survey (Aim 1) began in April 2022.

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

216 **Setting**

217 The University of Pittsburgh (Pitt) is the study coordinating center. Study sites are two
218 HIV clinics in Pittsburgh, Pennsylvania (PA) (Allegheny Health Network's Positive Health
219 Clinic [PHC], University of Pittsburgh Medical Center's HIV/AIDS Program [UPMC]) and one
220 in Birmingham, Alabama (AL) (University of Alabama at Birmingham [UAB] 1917 Clinic).
221 These are areas of the country that are disproportionately affected by both the HIV and opioid
222 epidemics and have high HCV incidence rates. Additionally, while not a study site, the study
223 involves close collaboration with a strong community partner, Birmingham AIDS Outreach
224 (BAO), an AIDS service organization providing social support services to more than 1,000 PWH
225 each year, most of whom receive HIV primary care at UAB's 1917 Clinic. BAO will lead
226 recruitment efforts and coordinate study activities in AL.

227 **Participants**

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

235 For both quantitative and qualitative portions of Aim 2, patient participants must be ages
236 18 or older, have a confirmed HIV diagnosis, be able to verbally consent, read, and speak
237 English, have received HIV medical care from one of the study sites for at least one year, and
238 have lifetime or recent use (past 3 months) of illicit substances (excluding marijuana) or
239 prescription drugs for non-medical reasons. As with Aim 1, eligible participants may, but do not
240 necessarily have to, complete both quantitative and qualitative portions.

241 **Variables and Data Sources and Measurement**

242 **Outcomes.** There are five outcomes of interest in our study, all relating to the clinical
243 health of PWH who use drugs. Four of these are collected as standards of care at our study sites
244 and will be abstracted via patient electronic medical health record: HIV viral load [<200
245 copies/mL, virally suppressed (40)]; HIV primary care appointment attendance [as measured by
246 (1) visits at least 90 days apart within one year=retained in HIV primary care (41) and (2)
247 proportion of missed to scheduled visits (range 0-100%) (42)]; HCV viral load, for those who
248 have hepatitis C; and retention in opioid treatment care for those with opioid use disorder
249 (proportion of kept to scheduled visits (range 0-100%).

250 We will measure antiretroviral therapy (ART) adherence via self-report through the
 251 validated CASE index (43). All study outcomes will be measured cross-sectionally, collecting all
 252 HIV primary care and opioid treatment care visits within a 12-month observation window and
 253 the HIV and HCV viral load data closest to the end of the observation window. Clinical data will
 254 be linked to survey data by study staff at the participating clinical sites. Analysis of these
 255 outcomes will enable us to explore: the relationship between patient-perceived HR care and
 256 clinical outcomes, relational HR as a potential moderator of the path between intersectional
 257 stigma and the patient-provider relationship, and structural HR as a potential moderator of the
 258 path between intersectional stigma and the patient-provider relationship, in which stigma is
 259 explored as HIV- and substance use-related stigma and racial discrimination).

260 **Other Variables.** Table 1 includes a complete list of all data elements included in Aims
 261 1 through 2 of the study, including sources of data and methods of assessment, along with
 262 corresponding citations.

Table 1. Aims 1 & 2 Constructs and Measurement Tools

Aim 1. Provider-reported	
Quantitative	
Provider attitudes	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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

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3 275 simulation research on SEM factor analysis suggests appropriate sample sizes with moderate
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5 276 factor loading between n=90-120 across a range of solutions(55).
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8 277 In Aim 2, we will construct a generalized SEM (gSEM) to assess associations between
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10 278 patient-reported 1) intersectional stigma (HIV- and substance use- related stigma and racial
11
12 279 discrimination) in healthcare settings and patient-provider relationships and 2) patient-provider
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14 280 relationships and clinical outcomes (ART adherence, retention in HIV and substance use care,
15
16 281 and suppression of HCV and HIV). This gSEM will be constructed using a mediation approach
17
18 282 wherein we will assess whether the patient-provider relationship mediates the relationship
19
20 283 between intersectional stigma and clinical outcomes. Mediation will be examined by assessing
21
22 284 total, direct, and indirect effects. This approach will test the degree to which the relationship
23
24 285 between intersectional stigma (HIV- and substance use-related stigma and racial discrimination)
25
26 286 in healthcare settings and clinical outcomes is explained by the qualities of the patient-provider
27
28 287 relationship. With an estimated sample size of n=500 and expected reasonable ratio of sample
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30 288 size to number of parameter estimates as 5:1 (56), we anticipate sufficient sample size with eight
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32 289 covariates (age, gender, sexual and gender minority status, income, race, ethnicity, substance
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34 290 use, and study site).
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40 291 We will also evaluate the novel relational HR instrument using both classical and modern
41
42 292 psychometric techniques. Classical item analysis including item frequencies, item-total
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44 293 correlations, item frequency distributions, and tests of monotonicity will be examined first. The
45
46 294 underlying factor structure of PAPHRS items will be explored using factor analysis. The sample
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48 295 will be randomly split into two half samples, one for exploratory factor analysis (EFA) and the
49
50 296 other for confirmatory factor analysis (CFA) using Mplus.
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297 Our Aim 2 sample size of 500 patients is based on longstanding practice for estimating
298 sample size for SEMs with latent variables. Fritz and MacKinnon have posited that n=500
299 confers sufficient power (at 80%) to detect small mediation effects with a cross-sectional
300 study(57). A sample size of 500 also confers sufficient power for the psychometric evaluation of
301 PAPHRS. Suggested minimums of sample size for factor analysis includes from 3 to 20 times
302 the number of variables and absolute ranges from 100 to over 1,000(58). The sample size of 500,
303 which will be split into 250 for EFA and 250 for CFA, will give us ten times the number of
304 PAPHRS items, right in the middle of the suggested sample size range. Reise and Yu(59)
305 recommend that the unidimensional GRM be estimated with 500 cases. For convergent validity
306 analyses, a sample of 200 participants is sufficient to provide power of .90 for correlations larger
307 than .80 at alpha level of .05 with a two-tailed test. For comparisons between groups with
308 expected differences, a sample size of 191 per group is needed to provide power of 0.90 for an
309 effect size of .30 with alpha level of .05 and a two-tailed test.

310

311 **Qualitative Analysis**

312 We will analyze interview and focus group data in NVivo 12 (60) using thematic analysis
313 (61, 62). All five members of our qualitative team will participate in analysis and development of
314 the coding framework by reading through transcripts, identifying major themes to contextualize
315 the data, and supplementing with field notes and corresponding analytic memos. We will code
316 interviews and focus groups based on the initial coding framework, using processes of
317 adjudication after each interview, and iteratively modifying the codebook. This method of co-
318 coding will continue until agreement on application of the codes is achieved. All interviews and
319 focus groups will be coded, and at least 20% will be double-coded by two researchers and

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3 320 compared for consistency, in keeping with scholars' recommendation to double-code between
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5 321 10-25% of transcripts (63). To assess the extent to which the qualitative findings help explain the
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7
8 322 quantitative results, we will integrate quantitative and qualitative findings in a joint display to
9
10 323 illustrate quantitative results with their corresponding qualitative themes (64, 65).

11 12 13 324 **Recruitment**

14
15 325 **Provider recruitment.** We will recruit providers by visiting sites' staff meetings and via
16
17 326 electronic messaging used by each study site for internal communications and will have a
18
19 327 Research Coordinator at each of our sites to assist with these methods and serve as site-specific
20
21 328 project champions. Surveys will be deployed via REDCap (66) using confidential links. We will
22
23 329 continually monitor response rates by provider type and site to ensure that each provider group is
24
25 330 represented in the data. We will continue with monthly targeted electronic messages until our
26
27 331 recruitment targets are met.

28
29 332 **Patient recruitment.** We will recruit 500 patients in total from our three study sites to
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31 333 complete a one-time survey on REDCap and 36 patients from our three study sites in total to
32
33 334 participate in focus groups; patients may, but do not have to, participate in both data collection
34
35 335 activities. We will utilize a multi-modal recruitment plan, including word-of-mouth, flyers in
36
37 336 provider waiting areas and patient rooms, messages sent through internal clinic systems for
38
39 337 patients who receive electronic messages, and in-person information during clinic visits.
40
41 338 Recruitment messages will inform potential participants of eligibility requirements, the voluntary
42
43 339 nature of participation, data to be collected including clinical records data, confidentiality of
44
45 340 data, and incentives.

46 47 48 49 50 341 **Data Collection**

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3 342 Data will be collected through a combination of surveys, focus groups, or individual
4
5 343 interviews, and electronic medical records, as previously described.
6
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8 344 **Data Management and Confidentiality**

9
10 345 Because this study has minimal risks to participants, does not assign participants to study
11
12 346 arms, does not perform an intervention, and is not a clinical trial, all data and safety monitoring
13
14 347 will be conducted by the Project Director. Since this research does not qualify as a clinical trial, a
15
16 348 Data and Safety Monitoring Plan is not required.
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19 349 All study survey data will be collected electronically via REDCap using individual,
20
21 350 confidential links and stored on Pitt servers. Participant identifiers will only be collected for
22
23 351 purposes of linking survey data to medical records for subsequent analysis. This information, as
24
25 352 well as consent forms, will be stored separately from the study materials. Electronic medical
26
27 353 records data from each study site will be securely transferred to Pitt for analysis using Sharefile,
28
29 354 a secure file sharing transfer service. The Pitt data team will immediately delete participant
30
31 355 identifiers once assigning a study ID to each participant linking survey and clinical data. This
32
33 356 clinical data, in addition to de-identified survey data abstracted from REDCap, will be stored on
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35 357 OneDrive.
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40 358 For qualitative methods, identifiable data will be gathered to schedule interviews or focus
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42 359 groups, but these will not be linked to data for analysis. Because interviews and focus groups
43
44 360 could potentially include identifiable data, these will be recorded on an audio recorder with 256-
45
46 361 bit file encryption and device PIN locking to ensure data security. Once interviews are complete,
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48 362 any identifying information will be deleted from these files, and the audio tapes will be
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50 363 transferred to a Pitt desktop and subsequently submitted to a professional transcription service.
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364 No identifiable data will be transcribed, and once analysis is complete the audio recording will
365 be deleted.

366 **Ethics and Dissemination**

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

371 **Consent**

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

385 **Dissemination Plan**

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3 386 Study findings will be presented in peer-reviewed journals and public health conferences.
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5 387 Findings will also be shared with patient participants online or in in-person community forums
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8 388 held at study sites and with providers during regularly scheduled staff meetings. We will also
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10 389 share findings with the members of BAO's and PHC's community advisory boards, which is
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12 390 composed of researchers, community organization representatives, and PWH; as well as a local
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14 391 harm reduction organization that provides services to people who use drugs.
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17 392 **Patient and Public Involvement**

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19 393 Aim 3 of this study will be devoted to designing a harm reduction intervention via
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21 394 community collaborator meetings with PWH who use drugs, HIV providers, and harm reduction
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23 395 experts using human-centered design. Members of our community advisory boards will inform
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25 396 and direct dissemination of results.
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28 397 **Discussion**

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30 398 Ultimately this mixed methods observational study, taking place in two culturally-distinct
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32 399 regions with similarly high HIV and HCV incidence rates, aims to discover whether HR
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34 400 approaches have the potential to improve HIV, HCV, and substance use outcomes for PWH who
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36 401 use drugs. Given persistent racial health disparities, exploring racial discrimination experienced
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38 402 in healthcare settings is also critical. Our work builds on the Conceptual Framework for HIV-
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40 403 Related Stigma, Engagement in Care and Health Outcomes (67), which posits that multiple
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42 404 dimensions of stigma create different pathways to and effects on clinical outcomes for PWH. We
43
44 405 are innovatively adapting this model (Figure 1) to focus specifically on experienced HIV stigma
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46 406 in healthcare settings, to incorporate substance use stigma and racial discrimination in an
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48 407 exploration of intersectional stigma, and to include our premise that the provision of HR can
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50 408 reduce and mitigate patients' experiences of stigma in healthcare settings. We hypothesize that
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3 409 the effect of intersectional stigma on the patient-provider relationship is reduced in the presence
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5 410 of higher degrees of relational HR care, structural HR attenuates the effect of poor patient-
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7 411 provider relationships on clinical outcomes, and higher degrees of HR care are associated with
8
9 412 better clinical outcomes. Understanding the contributions of both structural and relational HR
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11 413 can help us determine which practices must be in place to improve patient outcomes.
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15 414 *[insert Figure 1 about here] Title: Figure 1. Modified Conceptual Framework*
16

17 415 A primary strength of our study is that we will collect data from a range of participants,
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19 416 including both patients and providers, and we will integrate both qualitative and quantitative
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21 417 methods to elicit rich data. Study results have the potential to contribute to changing standards of
22
23 418 care for providers who work with PWH who use drugs and improve care for this population;
24
25 419 therefore, it is paramount that both sets of stakeholders' voices are included in all phases of the
26
27 420 study. While many studies explore the effects of patient-provider relationships on clinical
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29 421 outcomes, including the full range of treatment team members (i.e., reception, social workers,
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31 422 nurses, pharmacists, etc.) in our methods is particularly novel. However, these strengths also add
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33 423 complexity to the protocol, as there are multiple stages of recruitment, data collection, and
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35 424 analysis across two states and three HIV clinics.
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40 425 Another potential challenge of this study, as with all research conducted during this time,
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42 426 is the ongoing challenges posed by the COVID-19 pandemic. For this reason, we have planned
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44 427 study activities so that all phases of data collection may occur online as needed. Both PIs have
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46 428 experience conducting virtual interviews and focus groups, should this be necessary. Indeed,
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48 429 improving care for PWH who use drugs becomes even more critical as people with multiple
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50 430 vulnerabilities have increased risk for COVID-19, and rising rates of unemployment and poverty
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52 431 drive people further into survival economies, increasing risk for HIV and HCV.
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Declarations

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433 *Ethics Approval and Consent to Participate:* To be a part of the study, each participant will

434 provide written informed consent (for surveys) or verbal informed consent (for qualitative

435 interviews and focus groups) prior to any data collection activities, as approved by the ethics

436 committee. This study was approved via expedited review by the University of Pittsburgh

437 Institutional Review Board (STUDY21090002).

438 *Data Availability Statement:* Not applicable.

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

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441 Institute on Drug Abuse (1R01DA054832-01). The funder had no role in the design of the study,

442 data collection, data analyses, interpretation of data, or preparation of this manuscript.

443 *Author Contributions:* MH and ESK developed the study and study protocol in collaboration

444 with DSB and JT of the University of Alabama at Birmingham; RWSC, STC, JEE, MRF, SK,

445 and LY of the University of Pittsburgh; SF and VN of the Allegheny Health Network Center for

446 Inclusion Health; and SK and BT, consultants to the study. The manuscript was written by ESK

447 and MH with input and review from all authors. All authors read and approved the final

448 manuscript.

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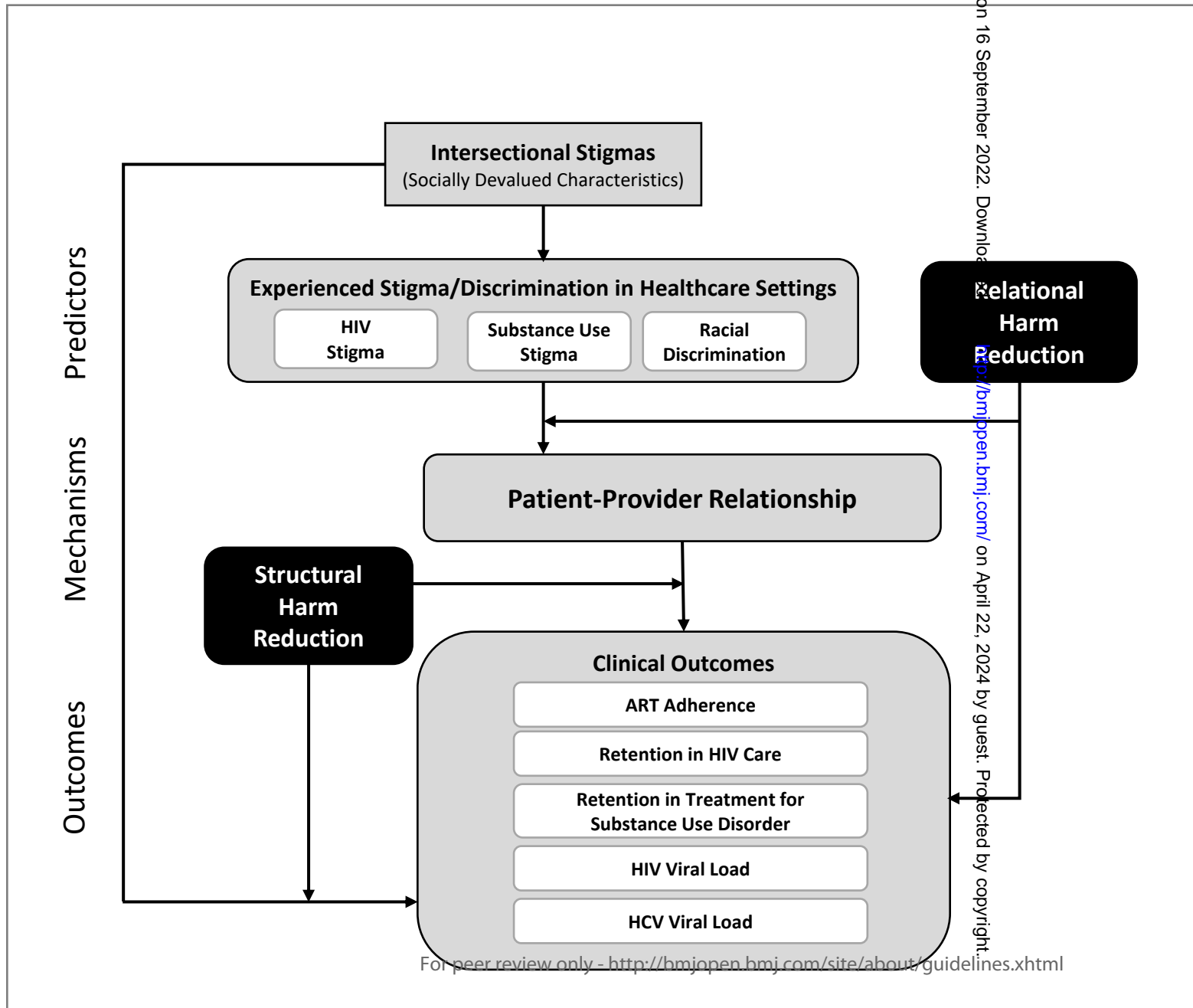
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Figure Legends

Figure 1: Modified Conceptual Framework

For Peer review only



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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

1 What best describes your job title?
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- 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

13
14 Please specify your job title.
15 _____
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17 Have you ever used illegal drugs (NOT including
18 marijuana) or prescription drugs for non-medical
19 reasons?
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- Yes
 No
 Prefer not to answer

21
22 Do you have personal experience with friends or family
23 members using illegal drugs (NOT including marijuana)
24 or prescription drugs for non-medical reasons?
25

- Yes
 No
 Prefer not to answer

26 Are you living with HIV?
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- Yes
 No
 Prefer not to answer

30 How long ago were you diagnosed with HIV?
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- Less than 1 year
 1-5 years
 6-10 years
 11-20 years
 More than 20 years
 Prefer not to answer

37 How old are you?
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 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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel I know enough about the causes of drug problems to carry out my role when working with drug users.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel I know enough about the physical effects of drug use to carry out my role when working with drug users.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel I know enough about the psychological effects of drugs to carry out my role when working with drug users.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Even if their drug use is stable, parents who use illicit drugs cannot be good parents to infants and young children.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel I have the right to ask patients/clients questions about their drug use when necessary.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I feel I have the right to ask a patient for any information that is relevant to their drug problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
If I felt the need when working with drug users I could easily find someone who would help me clarify my professional responsibilities.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

1	If I felt the need I could easily	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2	find someone who would be able								
3	to help me formulate the best								
4	approach to working with a drug								
5	user.								
6									
7	I feel that there is little I can do	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8	to help drug users.								
9									
10	I feel I am able to work with drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
11	users as well as I can with other								
12	client groups.								
13									
14	All in all, I am inclined to feel I	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
15	am a failure with drug users.								
16									
17	In general, I have less respect	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
18	for drug users than for most								
19	other patients/clients I work								
20	with.								
21	I often feel uncomfortable when	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
22	working with drug users.								
23									
24	In general, one can get	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
25	satisfaction from working with								
26	drug users.								
27									
28	In general, it is rewarding to	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
29	work with drug users.								
30									
31	In general, I feel I can	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
32	understand drug users.								
33		Strongly	Agree	Somewha	Neutral	Somewha	Disagree	Strongly	N/A--I do
34		agree		t agree		t disagree		disagree	not
35									provide
36									medical
37									or support
38									services
39									
40	I feel I know how to counsel drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41	users over the long term.								
42									
43	I feel I can appropriately advise	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44	my patients/clients about drugs								
45	and their effects.								
46									
47									
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60									

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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is not acceptable to teach injecting drug users how to use bleach to sterilize their injecting equipment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
People who live in government-funded housing must be drug free.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Even if their drug use is stable, women who use illicit drugs cannot be good mothers to infants and young children.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

1	In most cases, nothing can be	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2	done to motivate clients in					
3	denial except to wait for them to					
4	"hit bottom."					
5						
6	It is acceptable to prescribe	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7	substitute drugs (such as					
8	methadone, buprenorphine, or					
9	medications for opioid use					
10	disorder) in order to reduce					
11	crime and other social problems					
12	associated with illicit drug use.					
13						
14						
15	Prisons should not provide	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16	sterilizing tablets or bleach in					
17	order for inmates to clean their					
18	drug injecting equipment.					
19						
20	As long as clients are making	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21	progress towards their treatment					
22	goals, methadone maintenance					
23	programs should not kick clients					
24	out of treatment for using street					
25	drugs.					
26						
27	Measures designed to reduce	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28	the harm associated with drug					
29	use are acceptable only if they					
30	eventually lead clients to pursue					
31	abstinence.					
32						
33						
34	People who use drugs may be	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
35	more likely to seek professional					
36	help if they are offered at least					
37	some treatment options that do					
38	not focus on abstinence.					
39						
40	The prescription of substitute	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41	drugs such as methadone should					
42	be forbidden.					
43						
44	People whose drug use is stable	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45	should be trained to teach other					
46	drug users how to use drugs					
47	more safely (for example, how					
48	to inject more safely).					
49						
50	Making clean injecting	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
51	equipment available to injecting					
52	drug users is likely to reduce the					
53	rate of HIV infection.					
54						
55						
56						
57						
58						
59						
60						

For peer review only

- 1 It is possible to use drugs (not
2 including marijuana) without
3 necessarily misusing or abusing
4 drugs.
- 5
6 Information educating drug
7 users about their safe drug use
8 and safer sex should be detailed
9 and explicit, even if this
10 information would be offensive
11 to some people.
- 12
13 Opiate users should only be
14 prescribed methadone for a
15 limited period of time.
- 16
17 Drug injectors who are not
18 willing to accept abstinence as a
19 treatment goal at the beginning
20 of treatment should be given
21 easy access to clean injecting
22 equipment to reduce the spread
23 of HIV and other blood-borne
24 diseases.
- 25
26
27 Women who use illicit drugs
28 during pregnancy should
29 automatically lose custody of
30 their babies.
- 31
32 People who use drugs should be
33 praised for making changes such
34 as switching from injection drugs
35 to other routes of administration
36 such as snorting, smoking, or
37 ingesting.
- 38
39
40 Abstinence is the only
41 acceptable treatment goal for
42 people who use illicit drugs.
- 43
44

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

46
47
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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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think HIV+ patients have engaged in risky activities despite knowing these risks.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think people would not get HIV if they had sex with fewer people.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
HIV+ patients present a threat to my health.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
HIV+ patients present a threat to the health of other patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think if people act responsibly they will not contract HIV.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
HIV+ patients tend to have numerous sexual partners.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I enjoy working with HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would rather not come into physical contact with HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would want to wear two sets of gloves when examining HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would be comfortable working alongside another health care provider who has HIV.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think many HIV+ patients likely have substance use problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would rather see an HIV-negative patient than see an HIV+ patient with non-HIV-related concerns.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

1	I have learned a lot by working with HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2							
3	HIV+ patients should accept responsibility for acquiring the virus.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4							
5							
6							
7	I worry about contracting HIV from HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8							
9							
10	I often think HIV+ patients have caused their own health problems.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11							
12							
13							
14	HIV+ patients make me uncomfortable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15							
16	I would be hesitant to send HIV+ patients to get blood work done due to my fear of others' safety.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17							
18							
19							
20	It is a little scary to think I have touched HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21							
22							
23	I worry that universal precautions are not good enough to protect me from HIV+ patients.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24							
25							
26							
27	I would feel uncomfortable knowing one of my colleagues is HIV+.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28							
29							
30							
31	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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32							
33							
34							
35							
36							
37							
38	I tend to think that HIV+ patients do not share the same values as me.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39							
40							
41							
42	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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43							
44							
45							
46							
47							
48	It would be hard to react calmly if a patient tells me they are HIV+.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
49							
50							
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54							
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57							
58							
59							
60							

	Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree	N/A--I do not provide medical or support services
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
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For peer review only

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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Racial discrimination at [e15] is common.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
At [e15], African American and White people receive the same kind of care.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
African Americans can receive the care they want as equally as White people can at [e15].	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For peer review only

Finally, we have just a few more questions about services offered at [e15].

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 [e15], 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 [e15] 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 [e15].

- Strongly agree
 Agree
 Neither agree nor disagree
 Disagree
 Strongly disagree

Narcan is distributed to all patients at [e15] who have a history of opioid use.

- Strongly agree
 Agree
 Neither agree nor disagree
 Disagree
 Strongly disagree

At [e15], 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 [e15].

- 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

1 Sterile syringes are easily accessible through a close
2 referral agreement with a partner site.

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

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

11 You are eligible to receive a \$25 gift card as a thank
12 you for your time. The following page will ask you
13 information needed to receive this incentive; this
14 information will not be linked to your survey answers.

- Yes
- No

16 Would you like to receive the \$25 gift card?

19 Please hit the submit button to submit your answers.

For peer review only

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

1 What is the highest grade or level of school you have
2 completed or the highest degree you have received?

- 3 Never attended school
4 1st grade
5 2nd grade
6 3rd grade
7 4th grade
8 5th grade
9 6th grade
10 7th grade
11 8th grade
12 9th grade
13 10th grade
14 11th grade
15 Graduated high school OR received GED or equivalent
16 Some college, no degree
17 Bachelor's degree (example: BS, BA)
18 Master's degree (example: MA, MS)
19 Professional school degree (example: MD, JD)
20 Doctoral degree (example: PhD)
21 Don't know

22 How would you best describe your current employment
23 status?

- 24 Employed full-time
25 Employed part-time
26 Not employed: a student
27 Not employed: receive assistance
28 No source of income
29 Something else

30 Please describe your current employment status.
31 _____

32 How much do you make in a year, before taxes (i.e.,
33 personal yearly income)?

- 34 Less than \$10,000/year
35 \$10,000 to \$29,999
36 \$30,000 to \$49,999
37 \$50,000 to \$69,999
38 \$70,000 or more
39 Don't know
40 Prefer not to answer

41 How many other people (NOT including you) does your
42 income support?
43 _____
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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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Within the past 12 months the food I/we bought just didn't last and we didn't have money to get more.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For peer review only

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

For peer review only

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)

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

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For peer review only

1 Please select the YEAR of your birthday using the
2 drop-down list.
3

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- 38 1903 1902 1901
- 39 1900

For peer review only

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.)? Yes
 No

(By "non-medical reasons," we mean that you used a prescription stimulant in a way that was NOT prescribed to you by your doctor.)

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

1 In the past 3 months, how often have you used
2 [nida9_other]?

- 3 Never
- 4 Once or twice monthly
- 5 Monthly
- 6 Weekly
- 7 Daily or almost daily

8 Have you ever used any drug by injection that was NOT
9 prescribed to you by a doctor?

- 10 No, never
- 11 Yes, but not in the past 3 months
- 12 Yes, in the past 3 months

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For peer review only

**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

1 My medical team is knowledgeable about new HIV
2 treatments.
3
4
5
6
7

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

8 I believe that my medical team cares about me.
9
10
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14

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

15 My medical team supports me.
16
17
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19
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21

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

22 My medical team encourages me.
23
24
25
26
27
28

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

29 My medical team is helpful.
30
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32
33
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35

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

36 My medical team makes me feel comfortable.
37
38
39
40
41
42

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

43 My medical team spends enough time with me.
44
45
46
47
48
49

- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

50 My medical team is sensitive to how I feel.
51
52
53
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- Strongly disagree
- Disagree
- Somewhat disagree
- Somewhat agree
- Agree
- Strongly agree

1 My medical team thinks I am a bad person because I
2 have HIV.

- Strongly disagree
 Disagree
 Somewhat disagree
 Somewhat agree
 Agree
 Strongly agree

8 My medical team cares about my opinion.

- Strongly disagree
 Disagree
 Somewhat disagree
 Somewhat agree
 Agree
 Strongly agree

15 I believe that my medical team sees me as stupid.

- Strongly disagree
 Disagree
 Somewhat disagree
 Somewhat agree
 Agree
 Strongly agree

22 My medical team negatively judges me.

- Strongly disagree
 Disagree
 Somewhat disagree
 Somewhat agree
 Agree
 Strongly agree

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

33 Healthcare workers have not listened to my concerns.

- Never
 Not often
 Somewhat often
 Often
 Very often

39 Healthcare workers have thought that I'm pill
40 shopping, or trying to con them into giving me
41 prescription medications to get high or sell.

- Never
 Not often
 Somewhat often
 Often
 Very often

45 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

For peer review only

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

1 My provider respects me even if I have harmful health
2 behaviors.
3
4
5
6

Never
 Rarely
 Sometimes
 Usually
 Always

7 My provider makes me feel comfortable telling them
8 anything.
9
10
11
12

Never
 Rarely
 Sometimes
 Usually
 Always

13 My provider gives me information that is specific to
14 my needs.
15
16
17
18

Never
 Rarely
 Sometimes
 Usually
 Always

19 I believe my provider will drop me from care if I
20 don't reach my goals.
21
22
23
24

Never
 Rarely
 Sometimes
 Usually
 Always

25 My provider celebrates when I make positive health
26 changes even if they are small changes.
27
28
29
30

Never
 Rarely
 Sometimes
 Usually
 Always

31 I often feel my provider wants me to do things that
32 are unrealistic for me.
33
34
35
36
37

Never
 Rarely
 Sometimes
 Usually
 Always

38 I have an equal voice with my provider in making
39 decisions about my care.
40
41
42
43

Never
 Rarely
 Sometimes
 Usually
 Always

44 My provider helps me understand how my harmful
45 behaviors might impact my health.
46
47
48
49

Never
 Rarely
 Sometimes
 Usually
 Always

50 My provider is better at making decisions for my own
51 health than I am.
52
53
54
55

Never
 Rarely
 Sometimes
 Usually
 Always

56 I do not feel my provider is able to give me different
57 options even though my needs change from time to time.
58
59
60

Never
 Rarely
 Sometimes
 Usually
 Always

1 My provider has talked to me about whether or not I
2 use substances. Never
3 Rarely
4 Sometimes
5 Usually
6 Always

7 My provider has talked to me about substance use
8 treatment options. Never
9 Rarely
10 Sometimes
11 Usually
12 Always

13 My provider has talked to me about how to avoid
14 infections related to substance use. Never
15 Rarely
16 Sometimes
17 Usually
18 Always
19 Not applicable

20 My provider has talked to me about how to use
21 Naloxone/Narcan to reverse overdose. Never
22 Rarely
23 Sometimes
24 Usually
25 Always

26 My provider has talked to me about how to be careful
27 when I'm not sure what's in my drugs. Never
28 Rarely
29 Sometimes
30 Usually
31 Always

32 My provider has given me information that I have used
33 in my daily life to use substances safely. Never
34 Rarely
35 Sometimes
36 Usually
37 Always
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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.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My social worker(s)/case manager(s) knows me as a person.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My nurse(s) knows me as a person.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The person (or people) who works at the front desk knows me as person.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My pharmacist(s) knows me as a person.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Social workers/case managers	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Nurses	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Front desk staff	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Pharmacists	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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."

For peer review only

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

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

- 1
2
3 b. Have you ever heard about “harm reduction”? What does that mean to you?
4 What do you think about it?
5
6
7 **6. Think about your own experiences accessing healthcare? What can be done to**
8 **make sure people with similar experiences receive good health care?**
9 a. Probes: Policy changes; more medical training; expand health insurance
10 access; more people working in healthcare with characteristics that reflect
11 their patient population
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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 sectional reporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche 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

1	Introduction			
2				
3				
4	Background /	#2	Explain the scientific background and rationale for	5-7
5				
6	rationale		the investigation being reported	
7				
8				
9	Objectives	#3	State specific objectives, including any prespecified	7-8
10			hypotheses	
11				
12				
13				
14				
15	Methods			
16				
17				
18	Study design	#4	Present key elements of study design early in the	8-9
19			paper	
20				
21				
22				
23	Setting	#5	Describe the setting, locations, and relevant dates,	9
24			including periods of recruitment, exposure, follow-up,	
25			and data collection	
26				
27				
28				
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31	Participants	#6a	Give the eligibility criteria, and the sources and	9-10
32			methods of selection of participants.	
33				
34				
35				
36	Variables	#7	Clearly define all outcomes, exposures, predictors,	10-12
37			potential confounders, and effect modifiers. Give	
38			diagnostic criteria, if applicable	
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43				
44	Data sources /	#8	For each variable of interest give sources of data	11-12
45				
46	measurement		and details of methods of assessment	
47			(measurement). Describe comparability of	
48			assessment methods if there is more than one	
49			group. Give information separately for for exposed	
50			and unexposed groups if applicable.	
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1	Bias	#9	Describe any efforts to address potential sources of	11
2			bias	
3				
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5				
6	Study size	#10	Explain how the study size was arrived at	11-13
7				
8				
9	Quantitative	#11	Explain how quantitative variables were handled in	n/a
10	variables		the analyses. If applicable, describe which groupings	
11			were chosen, and why	
12				
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16	Statistical	#12a	Describe all statistical methods, including those used	11-13
17	methods		to control for confounding	
18				
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22				
23				
24				<i>Note—proposed</i>
25				<i>methods stated</i>
26				<i>only, as analysis</i>
27				<i>has not yet</i>
28				<i>started</i>
29				
30				
31				
32				
33				
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35	Statistical	#12b	Describe any methods used to examine subgroups	n/a—analysis has
36	methods		and interactions	not yet started
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41	Statistical	#12c	Explain how missing data were addressed	n/a—analysis has
42	methods			not yet started
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45				
46	Statistical	#12d	If applicable, describe analytical methods taking	n/a—analysis has
47	methods		account of sampling strategy	not yet started
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51	Statistical	#12e	Describe any sensitivity analyses	n/a—analysis has
52	methods			not yet started
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57	Results			
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1	Participants	#13a	Report numbers of individuals at each stage of	n/a—analysis has
2			study—eg numbers potentially eligible, examined for	not yet started
3			eligibility, confirmed eligible, included in the study,	
4			completing follow-up, and analysed. Give	
5			information separately for for exposed and	
6			unexposed groups if applicable.	
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15	Participants	#13b	Give reasons for non-participation at each stage	n/a—analysis has
16				not yet started
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25	Participants	#13c	Consider use of a flow diagram	n/a—analysis has
26				not yet started
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31	Descriptive data	#14a	Give characteristics of study participants (eg	n/a—analysis has
32			demographic, clinical, social) and information on	not yet started
33			exposures and potential confounders. Give	
34			information separately for exposed and unexposed	
35			groups if applicable.	
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43	Descriptive data	#14b	Indicate number of participants with missing data for	n/a—analysis has
44			each variable of interest	not yet started
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48	Outcome data	#15	Report numbers of outcome events or summary	n/a—analysis has
49			measures. Give information separately for exposed	not yet started
50			and unexposed groups if applicable.	
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1	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
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13	Main results	#16b	Report category boundaries when continuous variables were categorized	n/a—analysis has not yet started
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16	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
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19	Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	n/a—analysis has not yet started
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22	Discussion			
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36	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
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39	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
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45	Generalisability	#21	Discuss the generalisability (external validity) of the study results	n/a—analysis has not yet started
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1 Other

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3 Information

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6 Funding

[#22](#)

Give the source of funding and the role of the

20

7 funders for the present study and, if applicable, for

8
9 the original study on which the present article is

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11 based

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16 None The STROBE checklist is distributed under the terms of the Creative Commons Attribution

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