Study Title: Development of an Online Provider Intervention to Address Intersectional Stigma and Medical Mistrust in People with HIV

ClinicalTrials.gov Identifier: NCT05803720

Document date: November, 2023

Study Protocol

Abstract

Intersectional stigma and discrimination are key contributors to health disparities, including in HIV care, in Black and Latinx communities. As a result of historical and ongoing stigma and discrimination in the U.S., medical mistrust is highly prevalent in Black and Latinx communities, including those living with HIV, and contributes to low care engagement, treatment nonadherence, and poor health outcomes. However, no evidence-based provider intervention is available for providers to gain knowledge and skills to address intersectional stigma and medical mistrust with patients. This study aims to develop an intervention for HIV care providers working with individuals who experience intersectional stigma and discrimination to help reduce the impact of intersectional stigma and strengthen the provision and utilization of HIV care services. The proposed intervention has the potential to improve providers' competence to address the impact of intersectional stigma and medical mistrust with patients, which may in turn improve patients' or clients' healthcare engagement, treatment adherence, and health outcomes. This project is a collaboration among researchers from RAND, provider trainers from California Prevention Training Center (CAPTC), and an HIV care physician-researcher at Brigham and Women's Hospital. Researchers conduct intervention and study protocol development and research assessment; provider trainers at CAPTC are involved throughout the intervention development process and are the trainers who implement the online intervention to provider participants. The study is presented regularly at the UCLA Center for HIV Identification, Prevention, and Treatment Services (CHIPTS) Community Advisory Board (CAB) to elicit feedback from community stakeholders.

There are two aims. **Aim 1 (formative stage)** involves developing an online provider intervention for HIV care providers to gain knowledge and skills to address the impact of experiencing intersectional stigma and discrimination, with a particular focus on medical mistrust, using input from key community stakeholders. We have been engaging community stakeholders via UCLA CHIPTS CAB to provide feedback on the intervention content. Based on CAB's suggestion, we conducted interviews with 21 HIV care consumers to inform the development of this intervention. In addition, we have conducted a usability test in two online groups of HIV care providers (n = 18) to pilot test the intervention protocol. We have conducted qualitative feedback interviews with the pilot usability test participants to elicit feedback and revise the intervention protocol accordingly. **Aim 2 (pilot RCT)** involves conducting a pilot randomized controlled trial (RCT) in 60 providers caring for patients/clients at risk or living with HIV to test the intervention (n = 30) against a no-treatment control group (n = 30). Similar to the usability test, the intervention will be delivered by trainers from CAPTC (including a recorded session and a live training session via Zoom). Provider training outcomes will include providers' use of skills learned in the intervention to address intersectional stigma and medical mistrust using hypothetical patient scenarios, and provider-reported HIV service delivery outcomes. Outcomes will be assessed at baseline, immediately post-intervention, and at 6-month follow-up. A mixed-method process evaluation will be conducted at post-intervention to assess the acceptability, feasibility, and appropriateness of the online intervention.

Study Setting

The intervention pilot test (Aim 2) will occur online. Participants will be randomized to receive either the online intervention or the no-intervention control condition. All participants will complete the eligibility screening and study assessment online (via the online survey, videoconferencing, and/or phone call, as appropriate). Participants who are in the intervention condition will complete the intervention via a combination of asynchronous, self-paced learning and a 2-hour live training session via Zoom.

Recruitment Procedures

Participants will be recruited through online listservs of HIV providers. We have used this method in our usability test of 18 HIV care providers (Aim 1). The study team (including PI, Co-Is, and project coordinator) will send the recruitment email and flyer to listservs of HIV providers. The recruitment email includes information about the study team, goal of the study, brief description of the intervention (e.g., estimated total time commitment, online format), incentives, study contact information, and a brief online form for potential participants to express interest and leave contact information. Similar to our recruitment procedures in the usability test, the recruitment material will be sent to listservs of organizations such as CAPTC's listserv, Pacific AIDS Education and Training Center (PAETC), and New England AIDS Education and Training Center (NEAETC). The study coordinator at RAND will then conduct an eligibility screening. Participants can complete the assessment immediately after the screening or make an appointment to do the assessment at a convenient time.

Informed Consent

Participants will provide verbal consent for study participation prior to the baseline assessment; the participant's signatures will be waived due to the online nature of the participation. Prior to the baseline assessment, the study coordinator will send the consent forms for study participation and for audio/video recording to the participants via email. Participants will be told that they can email or call the study coordinator to ask any questions about the study. At the beginning of the baseline assessment, the research staff will briefly go over the consent forms and ask for permission before turning on the recording. Participants' verbal consent to study participation and audio/video recording will be captured at the beginning of the recording.

The consent forms will include a description of the study, including the nature of the study participation, possible risks and benefits of participation, how their data will be protected, their ability to withdraw from the study at any time without consequences, and a description of the intervention (e.g., format, content) and assessment (e.g., types of assessment, time points) protocol as well as the estimated time commitment to complete each component. Participants will be told that if they agree to participate in the study, in addition to completing the assessment, they may be selected to participate in the provider training intervention and complete a feedback interview after completing the intervention. The consent procedure will inform participants that they do not have to answer any questions that make them upset or uncomfortable, during the assessment, that they can terminate participation at any time without penalty, and that they will still receive monetary compensation if they do not answer all the questions at each assessment point. During both recruitment and informed consent, participants will be told that all data will be kept confidential and that their responses will in no way negatively affect them. Participants will also be informed about the incentives for completing the assessment as well as the provider training and feedback interview (if they are randomized to the intervention group).

Intervention Description

Participants who are randomized to receive the provider training will complete three modules. The provider training protocol described below was tested in the pilot usability test with 18 providers and they were generally satisfactory in terms of the content and format of the training. Minor revisions to the training material will be made to improve the process (e.g., allocating more time for the role plays in the breakout room, minor edits of selected slides) prior to the beginning of provider training groups for the pilot RCT. Module 1 will be a recorded presentation (45 min) covering background information; the participants can view on their own time prior to the live session or attend an optional live session to view the module 1 material. Module 2 will be a 2-hour live training session focusing on skill building. Module 3 will be a workbook focusing on review, reflection, and making an action plan; the participant will complete and submit within one week of completing the live session (up to 30 min) or attend an optional 30-min live-session that will be facilitated by the trainers to complete this.

We will record the attendance of the optional sessions for module 1 and 3 and elicit participant's feedback on their feasibility and usefulness, which will help planning for future studies of this intervention.

The total time for completing the training is approximately 3.5 hours. Intervention participants will receive an additional $200 for completing the training and the qualitative feedback interview at post-training. The provider training will occur online, and the participants will receive intervention material via email and participate in a 2-hour live training session via Zoom. They will submit workbook (module 3) via email to the study coordinator. The training will be delivered by three experienced provider trainers from CAPTC. The lead trainer is identified as a Black gay man, and all trainers will include their self-identification in the self-introduction at the beginning of module 1 and 2. All trainers have over 20 years of experience with provider training on a range of topics covering HIV/STD, stigma, and motivational interviewing. The feedback from the pilot usability test was positive on the trainers.

A brief description of the three modules is presented in the Appendix. Module 1 (background) aims to increase knowledge about intersectional stigma, discrimination, and medical mistrust, and how these experiences impact adherence, care engagement, and health outcomes in people living with HIV. Module 1 also includes HIV care consumers' recommendations and quotes about what they think providers could do to build trust and respond to mistrust, based on our interviews with HIV care consumers during the formative stage of this study. The background section will serve as a crucial foundation for module 2 skill building. There will also be a workbook that the participants will use to write down responses to discussion questions while viewing the recording; the participants will be asked to return the workbook to the study coordinator via email. The recording link will be sent to the participants via email following the completion of baseline assessment and a reminder to complete module 1 will be sent one week prior to the module 2 live training session. We will also schedule an optional live session the participants can join to view module 1.

Module 2 (skill building) includes a section on validation skills and a section on basic motivational interviewing skills, such as asking for permission before sharing, offering information in elicit-offer-elicit format, using open questions, and responding in a non-judgmental and non-confrontational style. The skill building will include didactic presentations about the skills (e.g., definitions, examples) and interactive exercises to practice the skills via role-play exercises in pairs in breakout rooms and group discussions.

Module 3 (review/reflection and planning ahead) is a workbook that the participant will be asked to complete on their own and submit to the study coordinator within 1-2 weeks of completing the training. The workbook includes 1) a review of key skills learned during the training, 2) written exercises on how to respond to hypothetical patient scenarios, and 3) written responses to open questions about goal setting and action plans to uptake the skills learned in this training. We will also offer an optional live session facilitated by the trainers for those who would like to complete this workbook with the opportunity for questions and discussion.

Assessment Procedures

All participants will be asked to complete the assessment protocol at baseline, immediately post-training (or approximately 4-6 weeks following baseline for control group participants), and 6-month follow-up. There are three types of assessment: 1) online survey (about 30 min), 2) role-play simulation (about 30 min), and 3) qualitative feedback interview (about 45 min) for process evaluation. The role-play simulation and qualitative feedback interview data collection will be led by an experienced project coordinator at RAND, who identifies as a Latina cisgender woman, is experienced with supporting HIV and stigma research, and is trained in motivational interviewing (e.g., is a certified MITI coder). Participants will receive $50 for completing each of the three assessments at baseline, post-training, and 6-month follow-up ($150 total).

The online survey includes sociodemographic characteristics (e.g., race, ethnicity, age) and clinical practice characteristics (e.g., position, years in practice), provider training outcomes (e.g., written responses to short

patient scenarios), self-reported HIV service delivery outcomes (e.g., percentage of patients/clients lost to follow-up), and process evaluation outcomes (e.g., ratings of the intervention acceptability). Below we describe each measure in detail.

Provider Training Outcomes: *Provider's helpful/empathetic responses toward medical mistrust* (primary outcome) will be assessed using the paper-and-pencil Helpful Response Questionnaire, adapted specifically for this study following other adaptation examples in prior research. The adapted HRQ includes six hypothetical patient scenarios presenting mistrust-related statements that patients experiencing intersectional stigma and discrimination may express. During the adaptation, we tried to patient's demographic characteristics (e.g., gender, age, sexual orientation, racial/ethnic groups) in the hypothetical scenarios. Helpful/empathic responses will be operationalized as the number of MI-consistent statements and validation used in the written responses, following prior studies. The number of reflections/validation and MI-consistent statements will be coded using the Motivational Interviewing Skills Coding.

Provider's ability to use strategies learned in the provider intervention (primary outcome) to address medical mistrust related issues will be assessed via role-play simulation, which includes two short role-play exercises (5-10 min each). The research assessor will play the role of the patient/client and the participant will play the role of the provider. We developed two hypothetical mistrust-related patient scenarios. The audio recording of the role-play will be transcribed and coded for skills that are learned and practiced during the provider training, including 1) the number of reflections/validation as well as MI-consistent statements and 2) the number of behavior change techniques used. The number of reflections/validation and MI-consistent statements will be coded using the Motivational Interviewing Skills Coding. The number of behavior change techniques (e.g., evaluating the pros and cons of initiating a new medication) will be coded using the behavior change techniques taxonomy. The coding of behavior change techniques is added to the coding procedure of the role-play simulation because the role-play allows for room to show and apply behavior change techniques (e.g., to promote change in adherence behavior) with a MI style.

Perceived importance of the topics (other/exploratory outcome) of the impact of intersectional stigma and medical mistrust on patients' or clients' health outcomes will be assessed. We developed three survey items that ask about the perceived importance of stigma, medical mistrust, and provider's trustworthiness on patient's/client's health outcomes.

HIV service delivery outcomes *(other/exploratory outcome).* Providers will be asked to estimate to the best of their ability the approximate *percentage of patients or clients lost to care over the past 6 months, percentage of patients who were virologically suppressed over the past 6 months,* and *percentage of PrEP initiation over the past 6 months.* The participants will be asked to provide an estimate between 0 to 100% and will be given the option for N/A and Don't Know. Because this is a pilot RCT conducted online/remotely with providers, collecting direct patient-level outcomes will not be feasible and there are no existing provider-reported measures for these outcomes; however, we were encouraged by the funding agency to include HIV-related outcomes. If the results from the current study are promising, we plan to include patient/client-level outcomes in future research (e.g., patient/client experience, trust toward provider and healthcare organization, patient/client adherence to treatment recommendations and medication, and care engagement).

Process evaluation outcomes (intervention participants only). Participants who are randomized to receive the provider training will be asked in the survey at post-training to rate the *acceptability*, *appropriateness,* and *feasibility* of the provider intervention. These items are adapted from the Acceptability of Intervention Measure, Intervention Appropriateness Measure, and Feasibility of Intervention Measure. We will ask participants to rate the format and content of the provider intervention separately. Participants will also complete a qualitative interview at post to provide feedback on the acceptability of the intervention. The interview will cover four acceptability constructs, including attitude (e.g., overall satisfaction), opportunity costs (e.g., barriers to participation), perceived effectiveness, and self-efficacy (e.g., participant's confidence that they can perform the skills learned in the intervention). We have piloted the interview protocol during the usability test.

Potential covariates. We will assess the provider's *socio-demographic characteristics* (e.g., age, race and ethnicity, sexual orientation and gender identity) and *clinical practice characteristics* (e.g., years of experience) as a provider working with patients at risk or living with HIV.

Interim Data Monitoring

We will check over data weekly as it is collected, and conduct interim analyses as participants complete the study.

Statistical Analytic Plan

Consistent with R34 guidelines, our primary purpose is to collect preliminary data and exploratory analyses on feasibility, acceptability, and outcomes, to calculate effect size estimates to assist planning for a fully powered RCT. Hence, we do not expect to have sufficient statistical power to adequately examine effects, and conducting formal tests for measures of effect size is not justified with limited sample size. Multilevel modeling will be used to account for multiple observations nested within providers. The intervention effect of interest will be a significant interaction between intervention condition (intervention vs. control) by time (pre, post, 6-month follow-up) on outcome variables. We hypothesize that participants in the intervention condition, compared to those in the control condition, will show greater increases in the number of empathic responses to medical mistrust, perceived importance, and the number of strategies (e.g., validation, MI-consistent statements, behavioral change techniques) used during simulated role-play, and perceived importance from pre to post and 6-month follow-up; intervention participants will also show a greater reduction in the percentage of patients lost to care, a greater increase in the percentage of patients virologically suppressed, and a greater increase in the percentage of patients who initiated PrEP, relative to control participants, from pre to post and 6-month follow-up. Analyses will use the standard intent-to-treat approach, in which we will analyze participants as belonging to the intervention condition they were randomized to, regardless of later non-response or loss at follow-up. The multilevel modeling approach uses a full information maximum likelihood estimator, meaning that all information is included in the analysis under the assumption that the data are missing at random or missing completely at random. For the quantitative process evaluation measures (i.e., AIM, IAM, FIM), we will report the descriptive statistics (e.g., mean, standard deviation, and range).

Protocol Amendment

The study protocol was last reviewed by the study Data Safety and Monitoring Board (DSMB) in April 2023, prior to recruiting the first participant. Since then, there have been several changes to the protocol. Initially, we planned to conduct post-assessments approximately 4-6 weeks following the baseline for control participants. However, scheduling training participants proved to be time-consuming (particularly during the summer), resulting in the interval between the baseline and immediate post-assessment extending to approximately 2-3 months. Consequently, control participants were also assessed 2-3 months following their baseline assessment. Secondly, the study team decided to eliminate the collection of role-play assessments at 6 months due to several considerations: 1) the primary interest and timeframe for the primary outcomes are changes from pre to post, 2) the response rate for role-play was low at post-assessment (see Table 2), 3) the participant burden was high compared to surveys, 4) conducting role-play assessments was time-consuming for the study team, necessitating a reallocation of resources to focus on pre-to-post changes, and 5) the surveys collected from baseline to 6-month follow-up include open questions on helpful responses to mistrust in hypothetical patient scenarios, which serve as proxies for provider responses in role play simulations. Thirdly, we increased the incentives for completing the survey and the brief role-play assessment at post-assessment or follow-up. Previously, we offered $50 for completing both the survey and the assessment with a study coordinator or research assistant. However, participants in the control group received no training and had limited contact with the study team after the baseline assessment was completed (in contrast, the training group received numerous scheduling calls and completed training, including a 2-hour live session). We observed a relatively low response rate for the post-assessment in the control group. Therefore, we increased the incentives to $50 for completing the survey and an additional $50 for the assessment. This amendment was approved by RAND's Human Subject Protection Committee (RAND's IRB) in November 2023.

Appendix. Description of the Provider Intervention

Modules: Goals	Core Components	Examples of Teaching Points
1. Background (45 min): to gain knowledge about intersectional stigma, discrimination, medical mistrust, and their impact on adherence, care engagement, and health outcomes	a) Intersectional stigma and discrimination, including various types of stigma common in Black and Latinx individuals living with HIV (e.g., HIV infection, mental illnesses, drug/alcohol use, sexual minorities, racial/ethnic minorities, immigration status) b) Medical mistrust as a result of intersectional stigma and discrimination, including the history/development of medical mistrust and the function of medical mistrust (e.g., survival mechanism) c) The negative impact of intersectional stigma and medical mistrust on treatment adherence, care engagement, and health outcomes d) Benefits of understanding and acknowledging intersectional stigma and medical mistrust	- Intersectional stigma is linked to multiple discrimination - Medical mistrust stems from knowledge of current and historical injustices in healthcare and U.S. society in general due to having one or multiple stigmatized identities - Mistrust can be a form of resilience; it is not necessarily harmful and can be viewed as an understandable and adaptive survival mechanism - HIV treatment nonadherence can be related to hearing HIV-related mistrust beliefs from social network members - Medical mistrust can negatively affect HIV prevention outcomes (e.g., condom use) and treatment outcomes (adherence to ART, detectable viral load) - Understand medical mistrust as a set of assumptions/beliefs that may affect patient's thoughts, feeling, and behavior during a specific healthcare visit or a conversation about starting a new treatment
2. Skill training (2-hour live session): **2a. Validation/Affirmation (0.75 hr):** to be able to acknowledge and validate the patient's experience of discrimination due to intersectional stigma and expression of medical mistrust	a) Empathy, reflective listening b) Acknowledge the historical and current context of intersectional stigma and discrimination as a root cause of medical mistrust c) Validate the negative feelings toward healthcare or authorities as well as their concerns that stem from medical mistrust	- In response to the expression of mistrust: "Communities who were mistreated and discriminated against often distrust the healthcare system or their doctors. This makes sense that people would want to put their guard up to protect themselves from discrimination. This may explain why some believe that the government or health care system cannot be trusted and maybe withholding treatment of HIV for Black people." - "If there is anything that I do/say, or someone at the clinic do/say, that makes you feel uncomfortable, would you let me know?"
2b. Motivational interviewing in health care and behavior change techniques (1.25 hrs): to be able to use communication strategies/styles that are consistent with motivational interviewing and that promote behavior change to address any ambivalence or resistance related to adherence, treatment recommendations, and care engagement in a sensitive manner to promote better clinical outcomes	a) Being able to identify ambivalence in patients that is related to medical mistrust b) Using a non-judgmental and non-confrontational stand, rolling with resistance c) Leaving room for the patient to bring up concerns or probe for mistrust-related concerns d) Asking short, open-ended questions e) Using listening skills (e.g., reflecting) f) Asking for permission to share information, offering choices and talk about what others do when informing g) Provide accurate information about the treatment/condition and the medical advice/recommendations	- "What concerns you most about these medications? What are some reasons to not get or get [PrEP or other recommendation or treatment]?" - "What do you already know about [HIV or other medication, recommendation, or treatment]? What would you most like to know about [HIV or other medication, recommendation, or treatment]" - "What are some benefits for believing that [medication or treatment] is harmful or poisonous? What might be some downsides for believing this?" - "Would it be alright if I shared something, and you can tell me what you think of this…. I understand there are many common assumptions and beliefs around [HIV or treatment]. A lot of them were natural responses to discrimination and mistreatment. At the same time, these doubtful feelings can deter people from getting effective treatment or coming to check-ups regularly."
3. Maintaining the progress (30 min): make action plans to maintain learning gains and increase chances of changing practice behaviors as a result of the intervention	a) Making action plans for maintaining the learning gains	- Discussing barriers and facilitators for implementing new skills - Organizing learning collaboratives for providers to raise questions, and consult about experiences with patients (e.g., through an online chat room)