Study Protocol and Statistical Analysis Plan

Title: Planning a Multi-Level Intervention to Reduce Substance Use Stigma in HIV Prevention and Care

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Study Protocol

Background

Both substance use disorders (SUDs) and HIV are subject to stigma, namely, the process by which an attribute is deemed deeply discrediting and prone to prejudice and discrimination. Stigma toward SUDs and HIV arises from multiple sources, including policies or individuals who carry out policies ("structural stigma") and health professionals ("provider-based stigma"). Stigma from health professionals experienced or anticipated by people with SUDs can create barriers to accessing high-quality health services. For people with SUDs who need HIV prevention or care, the added stigma of HIV may compound substance use-related stigma to enhance social barriers to healthcare. However, few studies have examined the role of substance use stigma in HIV healthcare contexts, or how to intervene on substance use stigma in this doubly-sensitive area of healthcare. Extant studies on substance use stigma in other healthcare contexts found that educational interventions incorporating critical reflection techniques and opportunities for contact with people who use drugs may significantly reduce provider-based stigma. An even greater limitation is that provider-based stigma intervention studies fall short of practical application: they largely focus on attitudinal outcomes among professionals, but do not measure the effects of policies or how stigma interventions affect healthcare utilization or patient health outcomes. For HIV prevention and care contexts to improve healthcare quality and outcomes among people with SUDs, interventions are needed to reduce provider-based and structural stigma perennially attached to substance use.

Objective

Aim 1: Create a substance use curriculum for HIV prevention and care contexts that pilot testing demonstrates significantly improves knowledge, attitudes, and planned actions related to professional stigma toward PWUD.

Aim 2: Use qualitative interviews with facility administrators and personnel to identify organizational policies related to clinical interactions and referrals to SUD treatment services that may enhance the effects of professional education on SUD stigma reduction.

Aim 3: Develop, optimize, and finalize a trial design and protocol that is intended to test how the multi-level SUD stigma intervention influences intermediate patient SUD outcomes (safer substance use, treatment engagement) and professional and patient stigma outcomes (provider attitudes and actions, and patient attitudes and experiences) and principal HIV outcomes related to prevention (PrEP adherence and syringe services program use) and care (HCV screening and linkage to care, ARV adherence).

Design

The trial planning process will use a community-engaged and collaborative team approach drawing on the expertise of all scientific team members, as well as a community advisory board composed of patients living with HIV and/or SUD and a professional advisory board of Michigan primary care collaborators to build a multi-level stigma intervention that uses education to address bias and alter professional practices, and changes to organizational policy to improve the conditions of professional decision-making. Initial planning will focus on developing an educational curriculum (Aim 1) that addresses key drivers of provider-based stigma and primary care facility recruitment and participation in policy development to address structural stigma

(Aim 2). The latter half of the planning process will focus on refining and finalizing the trial design, survey instruments, data collection and management procedures, and drafting the trial protocol (Aim 3).

Methods

Training Intervention

The educational intervention will be pilot-tested in year 2 using a group of 33-35 professionals who work in primary care, including providers, nurses and other support staff, and reception staff. Pilot participants will not be employed at primary care facilities identified for participation in the subsequent trial. Training participants will receive $100 for participation in pre- and post-training surveys and attending the training. Training will be held face-to-face and last 2-hours.

Quantitative data collection

Pre- and post-training surveys will measure stigma, knowledge, and individual-level factors (Aim 1). Stigma is complex and requires measurement of multiple dimensions, thus several approaches will be used. Enacted provider-based stigma will be measured with questions about plans to provide care to PWUD. Endorsed provider-based stigma will be measured using the Medical Condition Regard Scale (MCRS) and a modified Bogardus Social Distance Scale (SDS). Surveys will also ask about professional roles, years of experience, prior professional work with PWUD, burnout, and sex. Pre- and post-training surveys will contain the same questions, with the exception of demographic and professional experience questions (only in pre-training survey) and several open-ended questions in the post-training survey to allow for qualitative feedback on the training.

Qualitative data collection

Focus group assessing the training: A sample of 5-10 primary care professionals who participated in the training will be invited to participate in a 1-hour focus group providing qualitative feedback on the feasibility of the training (Aim 1). The focus group will be held virtually via video call. The focus group will follow a Qualitative Description Approach, a methodology used in health services research to explore participant perspectives. Focus groups will provide a venue for participants to express views on the format and content of the curriculum and provide opportunities for participants to suggest changes to the piloted curriculum. Questions for the focus group will be guided by the methodology and initial quantitative results, and decided by the project team.

In-depth interviews on stigma policies: Qualitative interviews will be used to assess feasibility of policies that could reduce stigma toward PWUD (Aim 2) The project team will develop a semi-structured interview guide to collect programmatic information about services for HIV prevention and care and PWUD, as well as information about professional perceptions and experiences. Interviews will focus on three topics after establishing an overview of current practice: 1) exploring experiences with care provision in the context of existing facility policies for PWUD who are at risk of HIV or living with HIV; 2) examining perceptions of policies shown to reduce provider-based stigma (e.g., reducing time pressure by extending clinical interactions and increasing inter-group contact); and 3) allowing participants to propose ideas about how to address stigma toward PWUD in the context of their facility. Participants will be recruited using a purposive sampling frame that targets individuals with varied roles within the facility, including administrators, providers, and non-clinical personnel. In-depth interviews using this guide will last 30-90 minutes

and be digitally recorded and transcribed. Interview participants will receive $100 for participation. Interviews will be conducted until new information no longer emerges from additional data collection. While the exact number of interviews cannot be pre-determined, we expect to complete between 15 and 20 interviews.

Qualitative Analysis Plan

Recorded transcripts of the pilot focus group and qualitative survey responses will be analyzed by using thematic analysis to identify opportunities to revise the training. In-depth interviews will also be recorded and transcribed and analyzed using thematic analysis, but with the goal of identifying feasible policies that could reduce stigma operating in primary care.

For all data, two team members will code the data independently by hand. Initial themes and associated codes will be jointly reviewed and refined by these team mebers before entering them into Dedoose qualitative coding software and coding the entire dataset. After all data are coded in Dedoose and major themes identified, the results will be reviewed in video call meetings with the entire authorship team, followed by recorded 2-hour video calls with the patient community advisory board and another with the professional advisory board of primary care clinicians and senior administrators for feedback. We will solicit their impressions of the validity of the themes and ask them to raise any concerns about our interpretations. If themes are not sufficiently elaborated according to concerns raised in these meetings by members of our community and professional advisory boards, we will collect additional qualitative data (interviews or additional focus groups).

Statistical Analysis Plan

Quantitative survey measures will be analyzed for internal consistency and sample means and standard deviations (or medians and interquartile ranges if data are skewed) will be used to describe continuous variables while frequencies and relative frequencies will be used to describe categorical variables. To evaluate the effect size of the intervention, a paired t-test on the pre and post-training outcome scores will be employed overall and by levels of the predicting factors.

Primary Outcomes: Scores from four survey measures will be used as outcomes to be analyzed. These include: quantified measures of stigmatizing attitudes from the SDS, the MCRS, and a measure of planned stigmatizing actions.

Predictors and Covariates: Analyses will examine pre- vs. post-training scores. We will also look into how scores may differ by professional factors including role (e.g., physician, other clinical support staff, receptionist), years of experience, and prior professional experience caring for PWUD, respondent sex, and burnout.