STATISTICAL ANALYSIS PLAN

Official Grant Title: Improving HIV treatment outcomes for people who use drugs: adapting and piloting a drug-use stigma-reduction intervention in HIV care and treatment clinics in Tanzania

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Statistical Design and Power

The first phase of the study will be qualitative, so will not involve any statistical analysis. The second phase of the study uses mixed methods to evaluate the pilot intervention, so power analysis was calculated only for the survey portion of the evaluation.

Power Analysis

Using the PASS software program, we estimated the power for comparisons of mean scale scores from pre- to post-intervention, assuming a p-value of 0.05 and a final sample size of 131 with both measurements (i.e., 13% attrition from the initial sample size of 150). We would have 85% power to detect a small- to medium-sized effect based on standardized mean difference (d=0.32).

Statistical Analysis

We will collect outcome measures through baseline and endline surveys (collected 3 months after the intervention is complete in each facility) with HIV care and treatment (CTC) staff using three validated scales (the Opening Minds Scale for health providers (OMS-HC), a modified Bogardus Social Distance Scale, and the Addiction Belief Scale). We hypothesize that respondents' scores on these scales will decrease between the pre- and post-intervention surveys, which would represent a reduction in drug use stigma. In addition, we will include a survey section on self-assessed and self-reported degree of knowledge about drug use and how to provide services to people who use drugs, which we hypothesize would increase between the pre- and post-intervention surveys. Given the sensitive nature of questions about drug use, we include a version of the Marlowe-Crowne Social Desirability scale validated in the East African context for use as a control. As contact with people of a stigmatized group often decreases stigma felt toward that group, we include a measure of contact with people who use drugs. We will also collect socio-demographic measures on participants' sex, age, education, religion, position in the HIV care and treatment clinic (CTC) (clinical vs non-clinical staff), length of service in health care, length of service in HIV CTC, and frequency of contact in the CTC with clients who use drugs. At endline only, measures of intervention acceptability, appropriateness, and feasibility will be asked. Endline data will be collected 3 months after the intervention is complete in each facility.

As the scales have not been previously validated in the Tanzanian context, we will modify them based on the formative research and consultation with experts in Tanzania. The validity of the scales will be confirmed through confirmatory factor analyses (CFA) on the scales we do not modify and exploratory factor analyses (EFA) on those we do. Exploratory factor analyses will be conducted in SAS version 9.4, applying a Promax rotation with the final number of factors selected based on variance explained, scree plot, and interpretability of the factors. Confirmatory factor analyses will be conducted using Mplus version 8.6. Model fit will be assessed based on the comparative fit index (CFI), Tucker-Lewis fit index (TLI), and root mean square error of approximation (RMSEA).

We will calculate descriptive statistics for all collected variables: counts and percentages for categorical variables, means and standard deviations for continuous variables. We will also calculate participants' scale responses using additive or averaging methods as recommended by the literature. To examine the changes in our outcome variables between the pre-intervention and post-intervention surveys, we will fit linear mixed effect regression models using the R package *lme4* with each outcome variable as our dependent variable and time (pre- vs. post-intervention) as our primary independent variable. In these linear mixed effect regression analyses, we will control for repeated measures by individuals by including random intercepts by individual respondent; all other parameters will be included as fixed effects. We will use the function *lme4::confint* to generate bootstrapped 95% confidence intervals with 1,000 replicates. To assess model fit, we will use likelihood ratio tests (alpha = 0.05). We will visually inspect residual plots for homoscedasticity and normality.

In addition to univariate regression analyses for each of our outcomes of interest, we will conduct regression analyses that control for clinic, type of staff, gender, age, years of service in health facilities, years of service at an HIV health clinic, number of clients who use drugs treated within the last month, and social desirability bias. In addition, we will individually test each control parameter for an interaction with time, which would indicate a differential change in the outcome of interest over time by the parameter in question.