Project NICE: Navigating Insurance Coverage Expansion

OMB No. 0920-NEW

Supporting Statement B

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B. Statistical Methods

1. Respondent Universe.

The respondent universe for the study will include Black and Hispanic men who have sex with men (MSM) and transgender persons age ≥18 years living in the Chicago, Illinois metropolitan statistical area (MSA) counties: Cook, DeKalb, DuPage, Grundy, Kane, Kendall, McHenry, and Will. The study target population includes persons at high-risk for acquiring HIV infection, or who are HIV-infected and in need of HIV care and treatment services.

Participants will be recruited to the study from community-based HIV testing events and walk-in clinics. The study will enroll 1,000 participants (500 into the intervention arm and 500 into the control arm). At least 800 of the participants will be Black and Hispanic MSM. Transgender persons can be enrolled in the study, but data collected on transgender persons will be analyzed separately because the anticipated sample size is expected to be small. At a minimum, the University of Chicago Medicine will recruit 400 participants, Chicago House Social Service Agency and Howard Brown Health will each recruit 300 participants.

Black and Hispanic MSM and transgender persons who are under the age of 18 years or who are not residents of the Chicago MSA counties will be excluded from the study, as will

cisgender women, and persons who have not had anal or oral sex with a man in previous 2 years.

2. Procedures for the Collection of Information

Individual participants will be recruited and enrolled in the study during community-based HIV testing events (venue visits) and clinic-based HIV testing visits, after they have completed an HIV test, and received their HIV test results and referrals to HIV-related care. Study participants will be recruited to the study, enrolled, and will complete all data collection activities the same day. Participant data will include basic sociodemographic and risk behavioral information, including housing status, perceptions of financial stability, incarceration, mental health concerns, and substance use. Additionally, there will be information collected on Pre-exposure Prophylaxis(PrEP) use and HIV status and attitudes towards the medical system. Data will be entered into the project REDCap database on an encrypted, password protected handheld tablet **(Attachments 5-7)**. After study enrollment, each participant will then be followed for a period of 12 months via review and abstraction of their electronic medical record (EMR) at 3, 6, 12 months.

REDCap Database

Participant data will be housed in REDCap, a secure, HIPAA compliant database system utilized by research institutions nationally. Each individual who has access to the database will have a unique username and password to log-in, enter data and access previously entered data. Each individual will be assigned to their partner agency data access group, which will limit access to participant data by enrollment agency. Only the University of Chicago Medicine PI and program and data managers will have access to the full data set including PII. This is required in order to review the system for duplicate participants and submit requests for data to CDPH. All fields containing PII will be identified as such and this data will be removed from the datasets downloaded by CDC. All download data sets will be password protected and stored on encrypted laptops that require a username and password to access. Collaborator accounts in REDCap will be verified every 6 months and any staff changes will be noted at that time. All REDCap users will be prompted to change their passwords every 6 months.

CDC staff will have collaborator accounts on REDCap and the University of Chicago Medicine will be responsible for generating and modifying access such that CDC will not have access PII, while being able to access necessary data across agencies.

3. Methods to Maximize Response Rates and Deal with Nonresponse

This study will enroll 1,000 participants. The recruitment period is 12 months. Every effort will be made to obtain complete data from all participants, including any who drop out of the study or do not complete the intervention. In particular, complete data on the primary feasibility and efficacy endpoints should be available for nearly all participants, since visit scheduling and completion will be available through the medical record. Nevertheless, some missing data due to attrition and item non-response is inevitable. To avoid potential bias and/or loss of power due to casewise deletion, we shall use Multiple Imputation (MI) with Chained Equations to impute missing values. The rich set of background, clinical, network and psychosocial data we shall collect will help to justify the Missing At Random (conditional on the observed data) assumption required by MI.

4. Tests of Procedures or Methods to be Undertaken.

University of Chicago Medicine will lead data analysis. The unit of analysis will be the individual participant.

Regarding analysis to assess the effects of the intervention on the study outcomes, index visits are defined as a participant's first HIV-related care clinic visit during the study period. The venue visit during which the participant was enrolled in the study will be time zero. Obtaining health

insurance will be defined as receipt of any service from the partner agency staff who are trained as Certified Application Counselors (e.g., new enrollment, change of health insurance policy, insurance counseling). Linkage to HIV-related care will be defined as attending an index visit within 90 days after time zero. Improved health outcomes will be defined, for HIV-infected participants, as prescription of ART at index visit and achievement of viral load suppression (<200 copies/mL) within 40 days of their index visit and, for HIV-uninfected participants, as prescription of PrEP within 40 days after their index visit and maintained HIV negativity. Retention in HIV-related medical care is defined as attending two or more HIV-related medical care appointments that are separated by three months within 12 months after their index visit.

Study participants will be recruited to the study, enrolled, and will complete all data collection activities the same day. For 12 months, the study will recruit participants. Therefore, this study will be recruiting participants and tracking EMR data from April 2018(at the beginning of data collection after OMB approval) through April 2020. Statistical power for transgender persons will not be calculated because the anticipated sample size is expected to be small. Data on transgender participants will be analyzed separately.

Kaplan-Meier methods will be used to estimate the proportion of participants who achieve intervention outcomes. The analyses may be adjusted for participant-level covariates, such as age, race, gender, and HIV status, as well as the three partner agencies.

Cost-effectiveness analyses (CEA) will compare the intervention to standard linkage to care from a societal perspective. The in-person insurance assistance intervention involves the diagnosis, linkage, and ultimate improvement of health among study participants along the HIV care continuum, therefore, several relevant measures of outcome for the CEA study will be considered. Analysis will focus on cost per new HIV diagnosis and cost per individuals linked to and engaged in care utilizing a cost-effectiveness framework, since this most naturally matches the nature of this intervention and allows comparisons to alternative interventions designed to recruit or retain individuals at-risk for HIV infection, as well as people living with HIV/AIDS. Similar analyses indicate that a cost per new HIV diagnosis below roughly $23,000 is likely to be cost-saving, and that a cost per new diagnosis below $63,000 satisfies accepted thresholds for cost-effectiveness.

In addition, more exploratory analyses to examine costs per HIV infection averted will be explored. Findings will be summarized using an incremental cost-effectiveness ratio (ICER)

between intervention arms, which estimates the additional resource consumption needed to achieve an increase in an additional unit of effectiveness. Sensitivity analyses will also be conducted to examine the impact of alternative measures of cost and outcomes for the most important parameters affecting the ICER.

The data manager at University of Chicago Medicine will use Stata and R to manage and clean the participant profile, survey, and medical data. The data manager will create the required codebooks and reports for CDC to download with the necessary data. Stata and R will be used to analyze the participant data and SAS and Stata will be used to analyze the cost-effectiveness data.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.

Individuals consulted on statistical aspects include statisticians from CDC’s Division of HIV/AIDS Prevention and University of Chicago Medicine.

University of Chicago Medicine will be responsible to collecting and managing all study data. Participant data will be collected from the partner agencies at the time of the study visit. The program and data managers from University of Chicago Medicine and partner agencies will check study data for

completeness and accuracy during the course of the study. The University of Chicago Medicine PI will track the progress of the study and report this information to the CDC on a monthly basis, or more frequently.

Lead investigators from University of Chicago Medicine, CDC and partner agencies include:

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