Expanding PrEP in Communities of Color (EPICC+)

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Section B: Supporting Statement

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EXHIBITS

1. Respondent Universe and Sampling Methods

The Expanding PrEP in Communities of Color (EPICC+) project will train HIV pre-exposure prophylaxis (PrEP) providers and will adapt and implement existing evidence-based tools to facilitate PrEP use. The project will enroll and follow a longitudinal cohort of racially diverse young men and non-binary persons who have sex with men or persons with a penis (hereafter referred to as YMSM) using PrEP in order to better understand real-world patterns of PrEP use and the impact of the implementation of provider training and evidence-based PrEP support tools.

EPICC+ is focused on YMSM because of the disproportionately high rate of HIV diagnoses in this population. In the United States, men who have sex with men (MSM) have the highest annual rates of HIV incidence each year. Among MSM, the highest HIV incidence is among 13-24 and 25-34 year olds.[1] In particular, MSM who are African American or Black (hereafter referred to as Black) account for the vast majority of new infections – 25% (9,444) of the 37,968 HIV infection diagnoses and 38% of diagnoses among all MSM.[1] Rates of new infections among Hispanic/Latino YMSM are similarly striking.

Despite the efficacy and availability of PrEP, uptake and adherence to PrEP among YMSM remains low, limiting its impact on prevention of HIV infection. Adherence to PrEP is crucial for protection against HIV infection, yet youth struggle to use PrEP daily.[2-6] The EPICC+ project is focused on Black and Hispanic/Latino YMSM due to the need for enhanced HIV prevention efforts in these populations.

Location Selection

EPICC+ sites include clinics located in the following cities: Bronx, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Tampa, FL; and Houston, TX. These sites have been strategically selected from counties and states with substantial HIV incidence and significant populations of Black and Hispanic/Latino YMSM. Additionally, the sites provide regional diversity as they range across the US Census regions of Midwest, Northeast, and South.

EPICC+ has selected clinic sites that provide services to the focus populations, including HIV testing and PrEP services. These locations are sites that have worked collaboratively and successfully in the past on studies focused HIV prevention research and implementation, particularly among youth. The clinic locations provide setting diversity as they range from health departments to academic medical centers to independent community clinics. In these clinic sites EPICC+ will implement innovative provider PrEP training and tailored PrEP support tools. EPICC+ participants at these sites will be provided with the EPICC+ mobile app to support their PrEP use. Consenting participants will also be enrolled in a longitudinal cohort that will provide data about longitudinal PrEP use patterns and choices among PrEP modalities. Clinic sites at each study location are:

- The Montefiore's MAYS Clinic, and the Walk-In Sexual Health (W.I.S.H.) Clinic in Bronx, NY
- Adolescent Initiative (Children's Hospital of Philadelphia), a hospital-based clinic in Philadelphia, PA
- The Amity Medical Group, a community-based clinic in Charlotte, NC
- The Wake County Health Department, a health department-based clinic in Raleigh, NC
- Five Horizons Health Services, with community-based clinics in Tuscaloosa, AL, Montgomery, AL, and Dothan, AL.
- Ybor Youth Clinic (University of South Florida), a community-based clinic in Tampa, FL
- Harris Health PrEP Clinic at Thomas Street, a health system-based clinic in Houston, TX

Target population
The EPICC+ study will enroll 400 YMSM including persons who identify as non-binary, gender nonconforming, or genderqueer who reside in one of the seven participating cities (Bronx, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Tampa, FL; and Houston, TX). These 400 YMSM participants will receive the PrEP support tools including the EPICC+ mobile app.

The study will also enroll 30 health care providers who work at study clinic locations to participate in PrEP provider training. Additionally, 48 health care providers and other clinical staff will be enrolled in focus group discussions to reflect on the study and topics important to understanding PrEP services. PrEP training and focus group participants will include but are not limited to medical doctors, nurses, adherence counselors, pharmacists, and social workers. A provider can include any site employee who discusses PrEP with a patient.

- *Implementation and cohort study activities, 400 YMSM:*
    - Inclusion criteria:
        - Aged 18-39 years, inclusive
        - Identify as a cisgender male or a non-binary person
        - Report ever having sex with a person with a penis
        - Have an active prescription for PrEP (includes both new prescriptions and/or refills)
        - Receive care at one of the participating study sites
        - Provide a mailing address within the 50 states where packages can be received
        - Have daily smartphone access
        - Fluent in written/spoken English or Spanish
    - Exclusion criteria:
        - Younger than 18 and older than 39 years of age
        - No active PrEP prescription
        - Does not identify as cisgender male or non-binary person
        - Does not report ever having sex with a person with a penis
        - Self-report or medical record documentation of being HIV-positive
        - Unwilling or unable to provide mailing address within the 50 states or Puerto Rico where packages can be received
        - Does not have daily access to smartphone
        - Unable or unwilling to provide informed consent
        - Unable to read and speak English and/or Spanish

- *Provider PrEP training, 30 health care providers:*
    - Inclusion criteria:
        - PrEP provider at one of the participating study sites
        - Fluent in written/spoken English
    - Exclusion criteria:
        - Not a provider at one of the participating study sites
        - Not fluent in written/spoken English

- *Provider focus groups, 48 providers:*
    - Inclusion criteria:
        - PrEP provider at one of the participating study sites

        - Fluent in written/spoken English
        - Completed aim 1 provider training or completed provider training refresher course.
    - Exclusion criteria:
        - Not a provider at one of the participating study sites
        - Not fluent in written/spoken English
        - Did not complete provider training or provider training refresher course.

Exhibit 1.1: Summary of Recruitment Targets

Participant Type	Total
Young MSM and non-binary persons • 18-39 years of age • Self-identify as cisgender male or a person who identifies as non-binary including gender nonconforming and genderqueer • Who report ever having sex with a person with a penis • Using or starting PrEP • Speak and read English or Spanish	400
PrEP Providers • PrEP provider at participating clinic site • Speak and read English or Spanish	30
Provider Focus Group Participants • PrEP provider at participating clinic site • Speak and read English or Spanish	48
Total study enrollment	**478**

EPICC+ study recruitment strategies include: 1) free and paid advertising and posting on social media sites, including but not limited to Facebook, Instagram, Twitter, Grindr, Jack'd, Reddit, Craigslist, Tik Tok, etc. 2) distribution through our community partners and other network collaborations; and 3) in-clinic recruitment. Active in-clinic recruitment could include identifying potential participants out of the clinic's patient pool, particularly among YMSM patients who present for PrEP services and HIV and STI testing and who may meet the eligibility criteria. Prior to in-clinic recruitment, all clinic staff that encounters patients will receive an overview training of the study including review of the screener. The goal of this overview training is to equip clinic staff to answer patients' questions about the study. These methods have been used by prior studies conducted by this research collaboration to successfully recruit diverse samples of YMSM.

Rationale for proposed number of subjects

For the PrEP implementation and cohort portion of the study, 400 YMSM will be enrolled. A sample of 400 YMSM with a projected loss to follow up of 15% would leave the study with adequate power (0.8 power and a 0.05 Type I error rate) to detect changes of about 5.56 percentage points in rates of key PrEP outcomes, adherence and persistence. For example, if the current PrEP persistence rate is 20%, then any increase in the study sample to 25% or to a higher percentage would be statistically significant. With regard to group comparisons, for example between persons who stop PrEP after <1 month and those who persist > 1 month, we assess the minimum detectable difference when the groups are compared on a continuous outcome. In this case, the projected study sample size will allow detecting

differences as small as 0.24 effect sizes at 0.80 statistical power and 0.26 effect sizes at 0.90 statistical power with a 0.05 Type I error rate. Smaller differences will likely go undetected, but are not expected to be clinically important. The EPICC+ study team has substantial experience and a history of success with high rates of participant retention using various strategies.

Provider training will be offered to all providers at participating clinical sites with a minimum of 30 providers enrolled in provider training. Each provider will provide individual pre- and post- training PrEP knowledge data.

For the provider focus groups (n=48), a total of six virtual focus groups will be conducted, two in each of the three regions with providers, clinic and study staff. Theoretical saturation (repetition in data and findings) inform final sample sizes and rapid preliminary qualitative analyses will begin during data collection. Existing guidelines suggest that 2-3 focus groups are enough to reach thematic saturation for a homogenous population; however, we do anticipate a diverse focus group sample. Given that our sample will be diverse, we will complete 6 focus groups to ensure thematic saturation is reached.[7,8] The EPICC+ team will use purposive sampling to ensure at least 50% of providers included in focus groups can prescribe PrEP.

2. Procedures for the Collection of Information

For the PrEP implementation and cohort portion of the study, participants will be followed for at least 12 months and up to 18 months, during which time PrEP uptake, adherence and persistence will be evaluated. These data include: self-report responses to CASI every 3 months; self-report of PrEP doses taken or missed; DBS collection to measure PrEP metabolites collected every 6 months; and medical record and prescription data which are collected from electronic health records (EHR). The CASI will be completed online with study staff available for questions by phone or email. At baseline and every 6 months, participants will be mailed a DBS collection kit which includes detailed self-collection instructions. Study staff are available for questions by phone or email. Remote DBS collection allows participants to complete the collection at a time most convenient to them and provides maximum autonomy. Of note, the EPICC+ study team has successfully managed remote DBS collection for past studies. EPICC+ will also collect and evaluate EPICC+ app paradata, which reflect what participants are entering in the app. Paradata can be used to measure participant engagement based on how much the participant is using the app—overall, and by the different components of the app. Paradata can also be used to measure sexual risk behaviors; tracking PrEP medication doses taken, missed, and days not tracked; and self-reported episodes of condom use based on what the participant enters in the app. We will also utilize app paradata to analyze levels of participant engagement in the app and examine how different forms of engagement in the app impact study outcomes. To assess other aspects of PrEP care and outcomes, the EPICC+ team will extract participant EHR data every 6 months. To assess PrEP services at the clinic level the EPICC+ team will complete clinic assessment forms every 6 months.

For the provider PrEP training portion of the study, the EPICC+ team will conduct virtual training workshops with providers at participating clinical sites, pre and post-training surveys, and a post-training competency assessment, followed by competency assessment 3 months after training. The training will focus on implementation of the PrEP support tools, national PrEP guidelines, and best practices in sexual health. The post-training competency assessment will consist of an approximately 15-minute standard patient interaction assessment by video teleconference. Providers will receive personalized feedback after each assessment. Participants will complete another patient interaction assessment at three months after completing the training.

For the provider focus group portion of the study, the EPICC+ team will conduct six virtual focus groups with PrEP providers, clinic staff, and study staff; there will be two focus groups in each of the priority regions. Prior to the focus groups, providers will be sent a brief provider pre-focus group survey. This provider pre-focus group survey will include demographics, a question on whether the provider can prescribe PrEP, and how long the provider has been at their clinic. During the provider focus groups, we will gather feedback on overall perceptions of the barriers and facilitators to study implementation within their clinical site.

3. Methods to Maximize Response Rates and Deal with Non-responses

We expect attrition in this study to be minimal the EPICC+ study team has a record of success in participant engagement and retention. The innovative and engaging EPICC+ mobile app facilitates participant engagement and retention. Study staff will utilize retention strategies such as contacting hard to reach participants multiple times on different days and at different times of the day, utilizing participants' preferred methods of communication, reminding participants of appointments ahead of time, and keeping locator information up to date.

The EPICC+ team will monitor recruitment and retention rates, site compliance with study procedures, and provide technical assistance for queries and concerns. Data quality will be examined weekly (e.g., missing data, assessment of distributional assumptions, identification of outliers) allowing for issues to be identified in a timely fashion and corrective action taken if indicated. Consistent attention to data quality and completeness during data collection will facilitate study staff efforts to retain participants and ensure complete reporting from participating sites.

Participant retention will also be facilitated through tokens of appreciation, provided as follows:

For the PrEP implementation and cohort portion of the study,

- Surveys and app download:
    - $50 for baseline survey and app download
    - $50 for attending the cohort app setup visit
    - $25 for 3-month follow-up survey
    - $50 for 6-month follow-up survey
    - $25 for 9-month follow-up survey
    - $50 for 12-month follow-up survey
    - $25 for 15-month follow-up survey
    - $50 for 18-month follow-up survey
- Returning self-collected blood specimens:
    - $50 at baseline
    - $50 at 6-months
    - $50 at 12-months
    - $50 bonus for returning all three initial specimens: baseline, 6-month, and 12-month
    - $75 at 18-months

For the provider PrEP training portion of the study,

- $50 for pre-training survey
- $50 for post-training survey and patient interaction

- $50 for 3-month post-training patient interaction

For the provider focus group portion of the study,
- $25 for screening, consent and contact information
- $25 for pre-focus group survey
- $25 for focus group participation

Data comparability between sites and states will be examined. Data will be aggregated for general analysis purposes; however, if significant differences emerge, separate analyses comparing outcomes between sites or states detailing differences will be conducted. Missing scale data will not be estimated.

In sensitivity analyses, the team will also use inverse probability of treatment weights (IPTW) to account for missing data and potential differential retention between study arms over the study period. The team will weight outcome models using stabilized inverse probability-of-censoring weights that include treatment arm as a predictor to account for differential loss to follow up. Pooled logistic regression models will be used to estimate the numerator and denominator of censoring weights, and weights will be multiplied over time. The denominator will be calculated using a logistic regression model for loss to follow up, including treatment arm. Weights will be stabilized to reduce potential bias from extreme weights. Numerator weights for the stabilized IPTW will be estimated using a logistic regression model for loss to follow up without covariates. Distributions will be examined to ensure weights have a mean of 1; extreme weights that may introduce bias will be trimmed by cutting the top or bottom 1%. Analogous weight will be calculated for missing data, including relevant covariates, and will be multiplied by censoring weights.

Several procedures will be used to conduct data analysis when data for either outcomes or covariates are missing. The first step will be to assess the extent and pattern of missing data. If data are missing for only a few cases, then data analysis will be conducted only on study participants with complete data. However, when such a strategy would result in loss of data from a substantial proportion of participants, or if this approach would lead to biased or inaccurate results, then some form of imputation will be performed. The form of imputation used will depend on the nature of the data that are missing. For example, data that are collected repeatedly might be imputed using the "last value carried forward" method; and in some instances, interpolation between neighboring points might also be used.

When the primary endpoint is missing, one data analysis will be conducted using only cases with the endpoint. Subsequent analysis will be done where missing endpoints are imputed. Hot-deck imputation or regression imputation may also be used in this context.

4. Tests of Procedures or Methods to be Undertaken

The EPICC+ study staff have considerable experience collecting sensitive data, administering technology-based interventions, and successfully managing data and processes for multi-site projects. Methods and tools used in this study, including the EPICC+ app, are based on the study team's prior study experience.[9-12] All study staff will complete training including an overview of the study; study procedures and human subjects issues (informed consent process, confidentiality); a demonstration of all technology components; methods for establishing comfort with the sensitive issues that may arise in the course of the focus groups or assessments; Human Subjects Protection; Good Clinical Practice; informed consent; quality management; confidentiality; and reporting of adverse events.

Study implementation including development of tools to support PrEP use and provider trainings are being developed as part of formative work with engagement from YMSM and PrEP providers. This engagement will ensure that study implementation addresses the needs and preferences of YMSM and PrEP providers.

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

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. CDC staff will neither interact with nor collect data from study participants. Data will be collected by members of grantee project staff listed. No individual identifiers will be linkable to collected data shared with or accessible by CDC staff, and no individually identifiable private information will be shared with or accessible by CDC staff.

6. Analysis Plan

The EPICC+ team will monitor recruitment and retention rates, site compliance with study procedures, and provide technical assistance for queries and concerns, and will examine data quality weekly (e.g., missing data, assessment of distributional assumptions, identification of outliers) and before statistical analysis is conducted. Comparability between participants across arms will be reviewed. Comparability between sites and states will be examined. Data will be aggregated for general analysis purposes; however, if significant differences emerge, separate analyses comparing outcomes between sites or states detailing differences will be conducted.
Analysis will start by describing the participant characteristics at baseline, using measures of central location (means and medians) and of variation (e.g., standard deviation) for continuous variables such as age, and frequencies for categorical variables such as sexual identity and regimen. The team will report these participant characteristics at the overall level and broken by region using tabular and graphical formats. The team will then conduct an exploratory analysis by time point of each primary and secondary effectiveness and implementation outcome, reporting percentages for categorical variables and means with standard deviations for continuous variables. In addition to the overall estimates, the team will disaggregate by regimen, region, ethnicity, level of HIV risk perception, and substance use.

The team will also conduct a time-to-first-discontinuation analysis and a time-to-first-nonadherence analysis using the PrEP persistence and PrEP adherence measures (i.e., a survival analysis). For this the team will initially fit separate Cox Proportional Hazards regression models by regimen, followed by a combined model with a single dichotomous outcome measure that is reflective of the regimen. The main goal of these analyses will be to determine the differences, if any, in the discontinuation and in the non-adherence hazards by regimen, and for, before and after controlling for the covariates deemed relevant from the exploratory analyses. The regimen- specific models will facilitate estimating the overall hazard function and the difference in the hazards of certain subgroups. For example, the difference in the discontinuation hazard for younger and older individuals who started in the daily oral regimen. To incorporate observations after the first discontinuation or after the first non-adherence, including allowing for the possibility of restarting on PrEP after discontinuation and for periods of non-adherence followed by period of adherence, the team will also analyze all the time point data available using

generalized multilevel linear regression models (i.e., a survival analysis with recurring events). This modeling approach is appropriate for dichotomous outcomes, accounts for the nesting of any number of repeated measures within individuals, allows for time-invariant and time-varying covariates, and will enable the team to estimate the strength of the association between PrEP uptake and adherence and the different regimen types, before and after controlling for other covariates.

The EPICC+ team will follow the same analytic strategy for other dichotomous primary and secondary effectiveness and implementation outcomes. For the composite measure of number of prescriptions (primary implementation outcome), the team will fit a multilevel linear regression model again using all the time point data available to assess the strength of the associations between the composite measure for the number of prescriptions and the predictor variables. To analyze the switching of regimens, the team will list all the switching trajectories and count and describe the participants in each trajectory. The team will use a combination of the statistical packages R, STATA, and SAS to perform statistical analyses.

Qualitative Data Analysis

Aim 2a qualitative exit interviews with patients (n=45; 15 from each region): Qualitative interviews will be conducted with a diverse sample of study participants. The team will use purposive sampling to ensure EPICC+ enrolls adequate numbers of YMSM who reported use of daily, 2-1-1 and CAB LA during the study as well as participants who experience a PrEP switch and/or discontinuation. Theoretical saturation (repetition in data and findings) inform final sample sizes and rapid preliminary qualitative analyses will begin during data collection. Existing guidelines suggest that sample sizes between 12 and 30 are sufficient for theoretical saturation 343,344. Questions will focus on understanding factors that influenced participants' selection of PrEP regimens, changes and/or discontinuations as well as perceptions of the counseling they received by providers at PrEP initiation and follow-up, receipt of tools or materials that influenced choice and feasibility/acceptability of the EPICC+ app as outlined by the Exploration, Preparation, Implementation, & Sustainment Model (EPIS) model.
Each interview and focus group will be audio recorded and transcribed and each transcript will be systematically reviewed for all thematic mentions of the following: (1) features of the inner and outer context per EPIS that facilitated EBT implementation, 1) features of the inner and outer context per EPIS that were identified as barriers to EBT implementation, and (3) overall perceptions of the EBT. Within these longer thematic lists, the team will then separate out specific categories of work-setting characteristics (e.g., leadership, incentives, and disincentives for innovating) and respondent characteristics (e.g., patients (YMSM), nurses, physicians, staff), initially using existing theory to guide categorization but also allowing themes to emerge from the data through open coding procedures335,336. This combined inductive and deductive coding approach will allow us to both validate and extend the EPIS model. Revision of our initial coding categories will occur iteratively until EPICC+ reaches saturation in the identification of new codes. During this iterative process, categories and their definitions will be refined, and subcategories of codes will be consolidated, consistent with an axial-coding process. At this point, the team will return to each interview and focus group transcript and systematically apply the final, revised set of codes. Finally, the team will write synthesis memos for each construct in the EPIS framework integrating the qualitative and quantitative findings. The team will use Dedoose a qualitative analysis software package for qualitative analyses.

Aim 2b focus groups with PrEP providers (n=36-48, 6 focus groups, 6-8 participants in each group): Post-implementation, EPICC+ will hold a total of six virtual focus groups, two in each of the three

regions with providers, clinic and study staff to gather feedback on overall perceptions of the barriers and facilitators to EBT implementation within their clinical site as outlined by the EPIS model. Theoretical saturation (repetition in data and findings) inform final sample sizes and rapid preliminary qualitative analyses will begin during data collection. Existing guidelines suggest that 2-3 focus groups are enough to reach thematic saturation for a homogenous population; however, EPICC+ does anticipate a diverse focus group sample. Given that the sample will be diverse, EPICC+ will complete 6 focus groups to ensure thematic saturation is reached. The study team will also share available data during the focus groups. We will use Dedoose a qualitative analysis software package for qualitative analyses.

Exhibit 5.1: Statistical Consultants

Name	Title	Organization	Email
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