

**Understanding Decisions and Barriers about PrEP Use and Uptake Among Men Who
Have Sex With Men**

**0920-New
Section B: Supporting Statement**

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TABLE OF CONTENTS

1. Respondent Universe and Sampling Methods.....	1
2. Procedures for the Collection of Information.....	3
3. Methods to Maximize Response Rates and Deal with No Response.....	7
4. Tests of Procedures or Methods to Be Undertaken.....	8
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....	8

EXHIBITS

Exhibit B1.1. Summary of Recruitment Targets	2
Exhibit B1.2. Target Distribution by City	2
Exhibit B2.1. Summary of Demographic Eligibility Criteria	4
Exhibit B5.1. Statistical Consultants	8

This information collection request is for in-depth interviews or focus groups, and structured behavioral assessments (aka surveys) with 300 high-risk men who have sex with men (MSM) to explore the decision-making processes about pre-exposure prophylaxis (PrEP: is an FDA-approved regimen of Tenofovir/emtricitabine (aka, Truvada[®]), shown to have greater than 90% efficacy in reducing HIV infections among MSM, when taken in accordance with its prescribed daily schedule).¹ For this study we are interested in MSM who were: 1) offered PrEP but refused it; 2) interested in or started PrEP but did not follow through; and, (3) are not on PrEP but are eligible per CDC guidelines (condomless anal sex within the last 3 months).

1. Respondent Universe and Sampling Methods

Target Population and City Selection

We will conduct the study in three geographically diverse cities – Atlanta (GA), Chicago (IL) and Raleigh-Durham (NC), which represent some of the most impacted communities in the U.S. based upon recent HIV prevalence and incidence estimates. We will target MSM over 18 years of age, with no less than 35% and no more than 65% of the sample being white or a racial/ethnic minority. The demographic composition of these cities will better enable us to recruit from MSM populations that not only have a highly diverse racial and ethnic composition, but also have varying rates of PrEP uptake.

In 2015, Atlanta had the fifth highest number of new HIV diagnoses in the United States²; 67% of the new cases diagnosed in Georgia were attributed to male-male sexual transmission.³ Black/African American MSM are disproportionately affected compared to White MSM, with the highest HIV incidence rate of 11% per year among Black/African American MSM aged 18-24 years.⁴ However, rates of PrEP uptake in Atlanta have been low compared to other metropolitan U.S. cities; recent data show that only 2% of MSM in Atlanta report using PrEP.⁵ As such, there is a clear and urgent need for the scale up of effective HIV prevention interventions, notably PrEP, in Atlanta, particularly among Black/African American MSM.

In Chicago, 81% of new diagnoses between 2010 and 2014 were among men; of those new diagnoses, 78% were due to male-to-male sexual contact.⁶ Further, the rate of Black/African American MSM living with HIV in Chicago is double that of white MSM.⁶ In a population-based study of younger Black/African American MSM in Chicago (n=622), only 40.5% had ever heard of PrEP and 12.1% knew someone who had used PrEP.⁷ Low awareness was negatively associated with various clinical engagement activities (e.g., having a primary care provider, having an anorectal STI test, and meeting with an HIV outreach worker). This study illustrated that understanding barriers to PrEP uptake among a population with the highest HIV incidence is critical to increasing HIV prevention efforts in a variety of healthcare settings.

Between 2010 and 2014 in Raleigh-Durham, 81% of new HIV diagnoses were among men, and

61% of new diagnoses were Black/African American; of those living with HIV, male-to-male sexual contact was the reported transmission risk for 60.3%.⁸ Although the majority of the population of Wake County is White (62.8%), 60% of those living with HIV are Black/African American; the rate of Black/African American males living with HIV is approximately 6 times that of White males.⁹ According to Advance Community Health (personal communication), a collaborating community based organization (CBO), their PrEP clinic has received at least 62 referrals from the Wake County Health Department STD clinic; of these, 22 referred patients never scheduled an initial appointment and 26 of the remaining 40 referred patients failed to keep their first appointment. Thus, there is a clear and urgent need to better understand what deters these individuals from initiating a PrEP regimen.

Exhibit B1.1: Summary of Recruitment Targets

HIV-uninfected MSM 18+ years old: 300 cases – Further subdivided:

White/Caucasian: 105 – 195 cases

Hispanic/Latino or Black/African American: 105 - 195 cases

In order to incorporate the target demographic groups, respondents will be recruited as follows:

Exhibit B1.2. Target Distribution by City

	White/Caucasian (range)	Hispanic/Latino and Black/African American (range)	Total
Atlanta	35-65	35-65	100
Raleigh-Durham	35-65	35-65	100
Chicago	35-65	35-65	100
Total N	105-195	105-195	300

Although we expect it will be possible to recruit enough respondents to fill each target identified in Exhibits B1.1 and B1.2, in the event that it is not possible to fill a target, we will work with partnering agencies to determine the best alternatives available. All efforts will be made to maintain the targets listed above and even in the event that we decide that targets need to be adjusted, a total of 300 behavioral assessments will be completed with MSM for the study.

We will use a three-stage purposive sampling plan: 1) selection of the sites: Atlanta, GA, Raleigh-Durham, NC, and Chicago, IL; 2) selection of partner agencies and organizations capable of enrolling the required number of eligible MSM in each site; and 3) recruitment and enrollment of 100 MSM in each site.

Eligible respondents will be screened and grouped into one of three categories: a) PrEP refusers, b) unsuccessful PrEP initiators, or 3) PrEP-eligible MSM. If a respondent is eligible for Phase 1 (because they refused PrEP or unsuccessfully initiated PrEP), they will be offered participation in a focus group. If the respondent is unable or unwilling to join a focus group, or the appropriate group is already full, they will be asked to participate in an in-depth interview (IDI). All Phase 1 respondents will complete a behavioral assessment after their respective focus group or IDI.

If the respondent is screened as PrEP-eligible yet report never having been offered PrEP, they will complete the behavioral assessment upon providing voluntary, informed consent.

Purposive sampling is based on having strong theoretical reasons for the choice of cases to be included in the sample. Rather than using probabilistic methods (i.e., random selection with known, non-zero chances of selection for each unit in the population) to generate a sample, purposive sampling draws on theory (i.e., the academic literature) and practice to select the most information-rich cases to inform the research question(s) being explored. Unlike probability sampling, the goal of purposive sampling is not to achieve statistical generalizability to a wider population, but rather to have sufficient variation to enable making salient analytic comparisons of interest. In addition, to select a representative, probability sample, it would be necessary to find or build a sampling frame of HIV-negative men in the cities of interest, which is not currently available and -- if feasible -- would require a long lead time. Therefore, using a non-representative sample shortens the period of data collection and allows for quick analysis of results, thus meeting study goals.

For all groups, based on the demographics of the selected sites as well as the composition of the client population of our partner agencies, we will also strive for meaningful racial/ethnic diversity. Overall, we want to maintain a 35-65% range of minority (all race/ethnicities and white respondents) across both phases of the study with no less than 35% or no more than 65% per group.

Study participation will be limited to men who can speak and read English. Sample sizes are small and adding Spanish would necessitate conducting some of the focus groups in that language as well as offering the behavioral assessment in Spanish. Small subsamples would not generate meaningful findings.

2. Procedures for the Collection of Information

This project will use a mixed methods study approach (n=300) that includes qualitative in-depth interviews (IDIs) and focus groups, complemented by a structured behavioral assessment. A mixed methods approach produces data that speaks to the breadth and depth of a new or emerging concern, such as PrEP refusal or unsuccessful uptake.¹⁰ All data collection will occur in Atlanta, GA, Raleigh-Durham, NC, and Chicago, IL with the cooperation of designated local partners, such as CBOs, community health clinics, health departments, and other service providers in each of the selected cities. Local partnering agencies will assist in recruiting eligible HIV-negative, high risk MSM aged 18+ into the study.

Data collection will occur in 2 phases:

Phase 1: Qualitative and quantitative data collection. Eligible MSM will participate in either an IDI (n=60) or a focus group (n=60; 12 focus groups of 5 respondents each) along with a 30-minute self-administered structured behavioral assessment (n=120). Phase 1 respondents will be divided characteristically into two groups: 1) MSM who were offered PrEP but refused (‘PrEP refusers’), and 2) MSM who agreed to start PrEP but did not follow through, or who started but stopped within a week (‘unsuccessful initiators’).

Qualitative investigation will allow us to drill down into the meanings behind the associations and provide context for findings in this study and in the literature, including epidemiological data. IDIs will focus in individual decision-making and the barriers and facilitators encountered when considering or starting PrEP, such as impact on sexual behavior and partners. Focus group discussions will focus on the impact social relationships have on PrEP decision-making, such as the influence of family and friends, as well as experiences of stigma. In the IDIs and focus groups we will ask about alternatives to daily PrEP, such as risk event-based dosing, injectable PrEP, and microbicidal PrEP. Quantitative behavioral assessment data will be collected on all 120 MSM that participate in one of the two qualitative mechanisms.

Phase 2: Quantitative data collection. PrEP-eligible MSM will complete the 30-minute self-administered structured behavioral assessment only (n=180).

The quantitative instrument will ask about socio-demographics, PrEP attitudes and use, sex partners, condom use, drug use, general healthcare, and attitudes towards future prevention options. Quantitative data will allow for exploration of variables and associations between variables, important to understanding the dynamics of PrEP decision-making in this population.

2a. Eligibility

Respondents will be adult MSM (18 years old or older) and self-report as HIV negative. Respondents will be selected based on three additional criteria: he has either refused or failed to initiate PrEP, or is eligible for PrEP due to unprotected anal sex in the prior 3 months. Finally, all respondents must be able to read English.

Inclusion Criteria

Eligibility will be based on HIV status, PrEP refusal/unsuccessful initiation/eligibility, age, and MSM status. These criteria are detailed in Exhibit B2.1.

Exhibit B2.1: Summary of Demographic Eligibility Criteria

	Phase 1 IDI + Behavioral Assessment OR Focus group + Behavioral Assessment	Phase 2 Behavioral Assessment
HIV Status	Self-Report of not tested, unknown status, or HIV negative status	Self-Report of not tested, unknown

		status, or HIV negative status
PrEP	Offered PrEP by a provider/counselor and refused it OR was interested in PrEP but never followed through (made or kept clinic appointment, accepted prescription but never filled it) (self-report and clinic/partnering agency verification) OR filled the prescription, but took it for less than 7 days (self-report)	Eligible for PrEP by CDC guidelines
Race/ethnicity	Min-max range each for Whites and all minorities combined: 35% -65%	Min-max range each for Whites and all minorities combined: 35% -65%
Sex/Gender	Male	
Age	18 years of age or older	
Sexual activity	Report condomless anal sex (without PrEP use) with a male partner in the past three months	
Location	Work or reside in Chicago, Raleigh-Durham, or Atlanta	

Exclusion Criteria

Potential respondents will be excluded from the study if they are unable or unwilling to provide consent for any reason, unable to speak or read English, and are not: MSM, over 18, HIV-negative, and either a PrEP refuser, unsuccessful initiator, or are ineligible for PrEP.

Justification for Exclusion of Population Segments

This research focuses on MSM, a community with high HIV incidence and prevalence, and for whom PrEP is recommended by public health authorities. Males age 18 years or younger are excluded, as well as anyone whose birth certificate does not specify “Male”, or who currently identifies with a gender identity other than strictly “Male.”

Women, including transgender women, are excluded from the study because (1) PrEP recommendations for women differ from those focusing on MSM^{11, 12}; (2) the individual, socio-cultural and developmental factors associated with HIV risk in MSM are different from those for women; (3) the research questions and issues of relevance for MSM are not relevant or appropriate for women; and (4) transgender women have unique HIV prevention needs that differ from those of MSM. Persons under 18 are excluded because they are unlikely to qualify for insurance or public assistance and other subsidies that assist with PrEP costs. Issues related to PrEP use are likely to be substantially different for MSM under 18. Incarcerated males that are wards of the county/state/federal judicial system are excluded because their inclusion may require additional human subjects’ protection, and/or logistical and timing constraints inconsistent with the needs of the project. HIV-positive MSM, and MSM who are not eligible for PrEP are also excluded.

2b. Recruitment of Respondents

Recruitment materials, including flyers and palm cards, will include a study telephone number to call, eligibility criteria, that we are seeking input on their experiences with PrEP, and the token of appreciation information. All recruitment materials have been reviewed and approved by the study's Atlanta-based Community Advisory Board (CAB).

Partnering agency staff will recruit MSM by distributing study flyers at point of contact to potentially eligible clients, posting flyers in accessible areas such as waiting rooms, and sharing flyers through social media outlets. Partnering agency staff will be trained on the study's eligibility criteria and will work closely with study staff to target recruitment efforts. For example, if the study has available focus group slots for MSM who have unsuccessfully initiated PrEP, the partnering agency staff will focus on identifying clients with known PrEP initiation issues. Interested clients will call the phone number on the flyer and be screened for eligibility by study staff. We will also encourage snowball sampling by generally encouraging recruitment through word-of-mouth and social media.

For phase 2 data collection, study staff will work with partnering agencies to accommodate onsite recruitment during hours when targeted MSM are most likely to be available for screening and completion of the behavioral assessment. Recruiters and/or interviewers will also attend local events, such as gay Pride, where eligible MSM may be willing to be screened and enrolled on the spot. In these venues, recruiters will distribute palm cards.

Recruitment venues may include, but are not be limited to:

- Health Departments, hospitals, HIV/STD testing locations, community health clinics, PrEP clinics
- Community-based organizations, community centers
- Use of social networking sites, including but not limited to Facebook, and other online groups and venues; however, no sexually explicit sites will be used.
- Print marketing materials
- Universities/colleges groups and social organizations
- Community events, such as Pride
- Other venues frequented by MSM including gay bars and clubs, bathhouses, gyms, coffee houses, restaurants, and bookstores

In order to enroll sufficient numbers, study staff will work closely with partner agency staff to identify and enroll respondents. Outside of the clinic setting, we will concentrate our recruitment on word-of-mouth and advertising within the extensive network of community-based, and service-providing agencies and organizations as well as in bars, clubs, bookstores, and events we have worked with in the past.

Partnering agencies will distribute flyers that invite potentially eligible MSM to participate in the study. Some partnering agencies will also provide space for interviews. Agencies that require a review through a research oversight committee will be accommodated as much as possible. That is, we will:

- Complete study request applications
- Provide information about the study goals, protocol, instruments and informed consent forms
- Attend, by phone, research approval committee meetings upon request

In Phase 2, when we are recruiting for the quantitative behavioral assessment only, we will hire local agency staff to recruit, screen, and implement the survey. Local staff will be trained in administering consent and setting up the assessment for respondents.

Participants will be recruited in the three cities: Raleigh-Durham, NC; Chicago, IL; and Atlanta, GA until the target 300 respondents is met. Race and ethnicity status will be tracked continuously to ensure that African American/Hispanic/Latino and other race/ethnic minority MSM are well represented in the population in addition to white MSM. Advertisements in publications geared towards the sexual minority community will be used as needed. Individuals who are interested in participating may contact the phone number provided. They will be screened to assess eligibility (**Attachment 3a**). The screening process should take approximately five minutes to complete.

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize cooperation and to achieve the desired response rate:

- Respondent accrual rates will be monitored by the recruitment manager to maintain consistent and accurate procedures, as well as adjust recruitment processes according to the participation rates by site and eligibility status. For example, race and ethnicity will be tracked as responses are completed to ensure that no fewer than 35% - or no more than 65% - of participating MSM are minority or white. Furthermore, if the accrual rate among PrEP refusers is low in one site, the recruitment manager can shift attention and resources to target this sampled population.
- If recruitment falls short CDC staff and population experts will be consulted to determine the best course of action, including recruiting additional respondents at alternative partnering agencies and venues in the targeted sites, or modify eligibility definitions, e.g. PrEP unsuccessful may need to consider a month or less on PrEP timeframe rather than less than a week.
- A token of appreciation of in cash will be provided to all respondents upon completion of their participation. The size of the token is dependent on the amount of time the respondent is engaged in the study, ranging from \$20 for a behavioral assessment to \$75 for a focus group (with a behavioral assessment).

- Telephone screening of interested individuals will be used to determine eligibility in phase 1. Phase 2 respondents may be telephone screened or screened in-person just prior to participation, so as to not lose their response due to a delay from screening to study completion.
- To boost participation among potentially eligible and interested respondents, we will ask existing respondents to share the study's contact information with their network.
- Finally, to maximize participation and minimize non-response, all parties will be informed of the voluntary nature of the study as well as the privacy protections and rights they retain throughout the course of the study. This information will be shared during the screening process as well as informed consent process.

4. Tests of Procedures or Methods to Be Undertaken

Our team includes experts with the target population, as well as with qualitative and quantitative research methods, including screening, instrument development, and pilot testing. We will conduct piloting of the screening tool and instruments with three to five of the CAB members who are socio-demographically similar to the target population, in order to assess skip patterns, ease of use of the self-administered electronic behavioral assessment, and overall flow and timing of the instruments.

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

Exhibit B5.1 below lists the project team members who were consulted on the study population, and aspects of the research design, as well as those who will be collecting and analyzing the data. Please note: The CDC COR and Technical Monitors 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 IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff (Project Officer Consultants/COR/TM) will neither collect data from nor interact with research respondents. Data will be collected by members of contractor project staff listed below in Exhibit B5.1 (RSS, IMPAQ, and Emory). No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff.

Exhibit B5.1. Statistical Consultants

Jim Carey	Contracting Officer Representative (COR)	jfc9@cdc.gov
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