Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex with Men (MSM) – Pulse Study

OMB# 0920-New

Section B: Supporting Statement

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EXHIBITS

1. Respondent Universe and Sampling Methods

Target Population and City Selection

This study offers the opportunity to explore the reported facilitators and barriers of HIV prevention in some of the most impacted geographical regions in the country. We have chosen to focus our study in metropolitan areas in the United States with some of the heaviest burdens of HIV/AIDS. We will specifically target men who have sex with men (MSM) who are minors (13-17 years old) and young adult MSM (18- 24 years old). The sampling approach will include the selection of 105 black/African-American and 45 Hispanic/Latino HIV-negative MSM[1] whose residence in high HIV prevalence areas make them particularly vulnerable to contracting HIV. The following section serves to briefly summarize the sampling plan for this project.

HIV-negative MSM Sampling Plan

Examples from major metropolitan areas in the United States demonstrate that MSM in high risk urban areas may face stigma and barriers to care. CDC has chosen to focus this study on the top five metropolitan areas in the United States with the highest HIV diagnosis for MSM– Miami, FL; New Orleans & Baton Rouge, LA; Jackson, MS; and Atlanta, GA. The demographic composition of these cities will enable us to recruit heavily from the racial and ethnic minority populations with highest incidence of HIV infection.

This is a qualitative research study and is not designed to make comparisons between groups or to make generalizations. We intend to use a standard qualitative purposive sampling methodology that ensures a wide range of experiences are captured. Purposive sampling is based on strong theoretical reasons for the choice of cases to be included in the sample. The statistics of HIV infection presented earlier in this SSA provide the justification for our choices. 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, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest. Instead, researchers following a qualitative research design that includes purposive sampling, tend to be interested in the intricacies of the sample being studied. This focus allows us to respond to the specific questions DHAP has been tasked to study, such as how a sample of MSM maintain their HIV negative status and what factors contribute to resiliency in their lives.

Qualitative investigation will allow us to drill down into the reasons and the mechanisms, beyond simple associations. 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,

[1] For the purposes of this document, MSM includes both minor (13-17 years old, young adult (18-24 years old), and adult (25 and older) men who have sex with men unless otherwise specified.

using a non-representative sample shortens the period of data collection and allows for quick analysis of results, thus meeting DHAP goals.

In order to address the issues discussed above we plan to recruit 105 black/African-American and 45 Hispanic/Latino HIV-negative MSM whose residence in high HIV prevalence areas make them particularly vulnerable to contracting HIV. Among this sample, we will target 50 MSM between the ages of 13 and 24. Of these, we expect to include 15-20 minors aged 13-17. See Exhibit B1.1 below. Respondents will have the option to complete the interview in English or Spanish.

Exhibit B1.1: Summary of Recruitment Targets

13-24 years old: 50 cases - Further divided:

Ages 13-17: 15-20 cases

Ages 18-24: 30-35 cases

25-44 years old: 60 cases - Effort to skew to younger end -- under 30 as much as possible

45+ years old: 40 Cases

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

Miami: Recruitment will be aimed at Hispanic/Latino MSM including Spanish speaking MSM. A small number of black/African American MSM may also be recruited.

Atlanta & Jackson: Recruitment will be aimed at black/African-American MSM. A small number of Latinos will be recruited in Atlanta.

New Orleans and Baton Rouge: Recruitment will target black/African-American as well as a small number of Latino MSM.

Participant accrual rates will be monitored by the recruitment manager to maintain consistent and accurate procedures. Age and socioeconomic status will be tracked as cases are completed to ensure that young (13-24) and lower SES MSM are well represented in the population as well as YMSM (13-17). We anticipate a sample size of 150 for analysis with targets as detailed previously. If recruitment falls short we will determine the best course of action, including recruiting additional participants at alternative HIV/AIDS clinics and MSM venues in the city or cities where additional participants are needed or modifying eligibility criteria. In addition, purposive sampling strategies emphasize variability, which is why we have sampling quotas to ensure variability across the study and in accordance with the HIV epidemic in each site.

Exhibit B1.2. Target Distribution by City

Location	Latino	Black/African American	Total	Minors
Atlanta	5	35	40	7-10

Jackson	0	35	35	
New Orleans/ Baton Rouge	5	30	35	7-10
Miami	35	5	40	
Total	45	105	150	15-20

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 the Technical Monitor (TM) to determine the best alternatives available. It may, for example, be necessary to shift counts slightly between black/African Americans and Hispanics, or between age groups. All efforts will be made to maintain the targets listed above and even in the event that we decide that targets need to be shifted, a total of 150 interviews will be completed with MSM for the study.

2. Procedures for the Collection of Information

This project will use primarily qualitative data collection methods. Prior to the in-depth interview of HIV-negative MSM, members of contractor project staff will administer a brief structured survey to each respondent in the study to characterize participants, including socio-demographic questions and questions about health care, HIV testing history, and other information used to characterize the population studied.

We will recruit HIV-negative black/African American and Hispanic/Latino MSM aged 13-45+ from different cities, and different types of clinics and community based organizations, in high prevalence areas of the U.S. South. While each subgroup will be sufficient for qualitative analysis, their size is too small for generalization to the larger population. Recruiting a probability sample is unnecessary for this type of research and findings could be misleading to the broader scientific community and the general public. We intend to use a purposive sample that is designed to ensure that a wide range of experiences are available including recruiting respondents from within as well as outside of the clinic setting. Purposive sampling is based on strong theoretical reasons for the choice of cases to be included in the sample. The statistics of HIV infection presented earlier in this plan provide the justification for our choices. 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, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest. Instead, researchers following a primarily qualitative research design that includes purposive sampling, tend to be interested in the intricacies of the sample being studied.

This focus allows us to respond to the specific questions, such as how a sample of MSM maintain their HIV negative status and what factors contribute to resiliency in their lives.

Qualitative investigation will allow us to drill down into the reasons and the mechanisms, beyond simple associations. 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 goals.

Eligibility

An adult MSM respondent will have a status of HIV negative based on his most recent HIV test. His most recent test must have been conducted in the past six months and results must be brought to the interview for verification[2]. He will self-identify as being a black/African American and/or Latino/Hispanic male and be 18 years of age or older. He must have had anal and/or oral sex with another male within the past six months. He must speak and understand English or Spanish. A minor MSM will be between the ages of 13-17. He must self-report an HIV-negative test result from his most recent test, have an unknown HIV status, or never have been tested for HIV. He will self-identify as being a black/African American and/or Latino/Hispanic male and be between 13 and 17 at the time of the screening and interview. He must indicate a physical attraction to other males. He must speak and understand English or Spanish. He must not be a ward of the state.

Inclusion Criteria

Eligibility for the 150 participants will be based on demographic characteristics, location, and higher risk for contracting HIV. Demographic eligibility will be based on HIV status, ethnic/racial identification, age, language proficiency, gender, and MSM status. These criteria are detailed in Exhibit B2.1.

Exhibit B2.1: Summary of Demographic Eligibility Criteria

	Minor MSM	**Adult MSM**
HIV Status	Self-Report of not tested, unknown, or HIV negative status (No proof of status required)	Written proof of HIV negative status based on test within the past 6 months by collaborating agency referral, primary care providers, clinic, testing by CBO or health department staff or other medical provider prior to interview, or as CDC TM directs

[2] The requirement of proof of testing can be dropped by the Technical Monitor at any time if recruitment is adversely affected.

Race/Ethnicity	Black/African-American and/or Hispanic/Latino	Black/African-American, and/or Hispanic/Latino
Age	13-17 years	18 years of age and over
Language	Proficient in English or Spanish	Proficient in English or Spanish
Gender	Male	Male
Location	Resides in one of the 5 study cities: Atlanta, Jackson, Miami, Baton Rouge and New Orleans	Resides in one of the 5 study cities: Atlanta, Jackson, Miami, Baton Rouge and New Orleans
Sexual Minority/MSM status	Indicate physical attraction to other males	At least one instance of oral and/or anal sex within the past six months with another male.

Exclusion Criteria

Persons will be excluded from the study if they are: living with HIV; are a minor under 13 years of age at screening; are unable to converse easily in English or Spanish, are non-responsive, exhibit bizarre, angry, or confrontational behavior while being screened; are from an area outside of the MSA for the target cities; are female or identify as transgender; have not indicated a physical attraction to other males, or if over age 18 years, males who have not had at least one reported instance of oral or anal sex with a male in the past six months. Minors who are classified as wards of the state will not be included in the study population.

Justification for Exclusion of Population Segments

This research focuses on the subpopulation with highest HIV incidence and prevalence: black/African American and Latino/Hispanic men who have sex with men. Were the study to include other populations such as women, persons who identify as female at birth or non MSM, or other race or ethnic minorities, the subsample size would be too diluted to determine any meaningful findings. Thus, for the purposes of this study, women, persons who identify as female or are female at birth, and persons who do not identify as black/African American or Hispanic/Latino MSM will be excluded. It is hoped that future research can build upon this effort and include these subjects. Minors who are wards of the state are excluded because their inclusion may require an appointed legal advocate which would create privacy, logistical and timing issues inconsistent with the needs of the project.

Recruitment of Respondents

The high prevalence of HIV, including undiagnosed HIV infection among these populations, in these jurisdictions makes it essential to verify HIV-negative status when possible. For MSM who

are minors (13-17 years old) we will allow self-report of HIV status. Adult MSM will verify their HIV status with results from a recent test.

The recruitment of HIV-negative MSM requires recruiting both within clinic settings, where HIV testing may be conducted, and outside of clinic settings where one might find MSM in the broader community. Possible recruitment venues are listed below.

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

- Health Departments, HIV testing locations, community health clinics
- Community-based organizations, community centers
- Use of social networking sites, including but not limited to Facebook, Meet Up, and other online groups and venues; however no sexually explicit sites will be used without prior approval of the TM.
- Print marketing materials
- Universities/colleges groups and social organizations
- High school/middle school administrators, clubs and social organizations
- House/ballroom communities and other MSM social organizations
- Faith based centers and organizations that serve and support MSM (e.g. affirming churches)
- Other venues frequented by MSM including gay bars and clubs, bathhouses, gyms, coffee houses, restaurants, and bookstores.

In order to enroll verified HIV-negative respondents we will work closely with Health Departments and HIV testing locations to coordinate interview travel days with HIV testing fairs or events and to inform those tested within the past six months about the study. Outside of the clinic setting, we will concentrate our recruitment efforts on word of mouth and advertising within our extensive network of community-based, advocacy, faith-based, and service-providing agencies and organizations as well as in house-ball communities we have worked with in the past. Those recruited outside of the HIV testing clinic setting will need to be screened for a recent HIV test and will be offered the locations of cooperating testing facilities to be tested and receive proof of status forms which must include both date and result of the HIV test or other indication (e.g. an approved stamp) that the respondent is eligible. Both service providers and clinics may also be able to assist in the recruitment of HIV-negative individuals who are in a relationship with an HIV-positive client to whom they provide health or social services.

Among the service providers and community organizations that work with MSM, we will specifically focus on those that work with the populations of interest to the study or the ones minority MSM are more likely to frequent. Organizations that are willing to assist in recruitment will distribute flyers that invite the target population to participate in the study. The flyers provide phone contact information for those interested in participating, and will include

information about the $40 that eligible participants will receive in appreciation for the interview. Some organizations and HIV testing centers may be willing to also provide space for interviews and more targeted distribution of flyers. Organizations 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 and instruments and consents
- Attend by phone research approval committee meetings as requested

CDC will work closely with Health Departments and HIV testing facilities to confirm HIV-negative status and provide space for interviews. Participants will be recruited in the five cities: Miami, FL; New Orleans & Baton Rouge, LA; Jackson, MS; and Atlanta, GA until the target total of 150 participants is met. Age and socioeconomic status will be tracked to ensure that young (13-30[3]) and lower SES MSM, both characteristics of hard to reach populations at risk for HIV, are well represented in the population as well as minor MSM (13-17). Advertisements in publications geared towards the LGBTQ 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 3**.]. 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 high response rate:

- Participant accrual rates will be monitored by the recruitment manager to maintain consistent and accurate procedures. Age and socioeconomic status will be tracked as cases are completed to ensure that young (13-24) and lower SES MSM are well represented in the population as well as minor MSM (13-17). We anticipate a sample size of 150 for analysis with targets.
- If recruitment falls short we will work with the CDC Contract Officer Representative (COR) and Technical Monitor (TM) to determine the best course of action, including recruiting additional participants at alternative HIV/AIDS clinics and MSM venues in the city or cities where additional participants are needed or modifying eligibility criteria.
- A token of appreciation of $40, in cash or gift card, will be provided to respondents upon completion of the interview.
- Telephone screening of interested individuals will be used to determine eligibility.
- All recruitment materials indicate the voluntary nature of the study and high participation is due in part to interest in the study and participation from individual respondents.

4. Tests of Procedures or Methods to Be Undertaken

[3] Age criteria include targets for 13-24 (50) and 25-44 (60). Of those aged 25-44 we will monitor and attempt to include proportionately more men 25-30.

Our team includes experts with the HIV population and qualitative research, including screening and interview development and testing. We will conduct pretesting of the screening tool and interviews on three to five qualified respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and screener.

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 aspects of research design and 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 local IRB reviews (Emory); 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 participants. 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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