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

Study Protocol

March 25, 2015

PROJECT OVERVIEW

Protocol Summary

This study seeks to provide understanding -- through qualitative data collection -- on the many factors that keep some men who have sex with men (MSM) and young MSM (YMSM) from contracting HIV. Gaining an understanding about prevention and protective factors is crucial to CDC's ability to create programs and interventions that may help reduce the high proportion of new cases among some groups in the population. We will qualitatively examine how socio-geodemographic factors such as HIV risk perception, perceptions of community relationships and social support serve as contributors and inhibitors to remaining HIV negative. In addition, we will examine how MSM and YMSM perceive their own health, HIV testing and knowledge of PrEP and their recommendations on how to improve HIV prevention efforts in their communities. We will explore how MSM view risk by examining the roles of many individual factors such as resiliency and discrimination in relation to partner and social dynamics (e.g. condom use, social support, partner selection) against larger social and structural operants. Understanding what combinations of protective elements keep MSM safe and healthy is key to CDC's ability to plan interventions, communications, and other campaigns aimed at reducing the number of incident infections among MSM.

Investigators, Collaborators, and Funding Mechanisms

Research Support Services, Inc. (RSS) has joined with two outstanding partners that provide expertise critical to the success of this project – Emory University (Emory) and IMPAQ International, LLC (IMPAQ). The overall structure for this study is as follows. Dr. Schoua-Glusberg (RSS) is the Project Director, who has overall management authority for the RSS team, including subcontractors and RSS staff assigned to the task order, and functions as the technical liaison to the CDC Contracting Officer Representative (COR) and Technical Monitor (TM). Schoua-Glusberg is supported by Katherine Kenward as Project Manager, whose responsibilities are to maintain day-to-day contact with the subcontractors, to monitor progress and timeline, and lead contact with the TM. Leading the Emory staff is Dr. Paula Frew, Principal Investigator. Dr. Susan Berkowitz (IMPAQ) is acting as Task Order Lead at IMPAQ and will lead analysis of the data.

The following table shows the key staff, together with their main responsibilities.

Staff Name (Affiliation)	Main Activities
Schoua-Glusberg (RSS)	**Project Director/Interview providers/Design/Analysis/Report**
Frew (Emory)	**Principal Investigator/ Design/Analysis/Report/IRB**
Berkowitz (IMPAQ)	**Data Management and Data Security Director/ Design/Coding/Analysis/Report**
Kenward (RSS)	**Project Manager/Recruitment Manager/OMB Package**
Gall (IMPAQ)	**Lead Coder/Preparation of electronic codebook**

Table 1. Project Staffing and Staff Responsibilities

This research study is funded and supported by the Centers for Disease Control and Prevention (CDC), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of HIV/AIDS Prevention (DHAP). The following persons have been designated as CDC project collaborators; however, they are not engaged in research activities.

CDC, NCHSTP, DHAP, Prevention Research Branch

1. **James W. Carey, MPH, PhD, Contracting Officer Representative (COR)**
2. **Damian J. Denson, MPH, PhD, Technical Monitor (TM) for iQual Pulse**
3. **Deborah Gelaude, MA, Acting Team Lead, Operational Research Team**
4. **Aisha Wilkes, MPH, Consultant, Prevention Research Branch**
5. **Robert Swayzer, DrPH, MPH, Consultant, Prevention Programs Branch**
6. **Sharon Wong, MPH, Consultant, Division of Adolescent and School Health**
7. **Catherine Rasberry, PhD, Consultant, Division of Adolescent and School Health**
8. **Nicole Pitts, Project Coordinator, Engility (Contractor)**

The CDC COR and Technical Monitor 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 review; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC team will neither collect data from nor interact with research participants. Data will be collected by

Contractor staffs. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff.

INTRODUCTION

Background

Every year in the United States, an estimated fifty-thousand men and women are infected with HIV; over 1.1 million individuals aged 13 years and over are currently living with HIV/AIDS.[1, 2] The burden of HIV infection in the United States is disproportionately higher among minority groups, such as men who have sex with men (MSM) and racial and ethnic minorities.[3, 4] In 2012, Black/African-Americans and Hispanic/Latinos had the highest rate of HIV diagnoses (58.3 and 18.5 per 100 000, respectively).[4] Compared with all other races, Black/African Americans account for a higher proportion of people living with HIV (PLWH) at every stage from new infection to death.[5] Young adults aged 20-24 years experienced more new HIV infections (7,087) than any other age group[4]. The majority (67%) of HIV infections were due to male-to-male sexual contact.[4]

Young men who have sex with men (YMSM) are disproportionately burdened with HIV.[6] Young MSM (13-24 years of age) experienced a 26% increase in new HIV infections between 2008 and 2011.[3] The CDC estimates that 93% of all diagnosed infections among young adults aged 13-19 years were from male-to-male sexual contact. Additionally, 91% of all diagnosed infections among young adults aged 20-24 were transmitted via male-to-male sexual contact.[7] The burden of HIV infection also remains disproportionately high among racial and ethnic minority populations. As of 2011, nearly 60% of all HIV infections in YMSM between 13-24 years of age were among Black/African American males, and 20% of HIV infections were among Hispanic/Latino males.[3] HIV diagnoses among Black YMSM between ages 13-24 years have greatly increased in recent years, from 3,762 reported cases in 2008, to 4,619 reported cases in 2011.[3]

In the Southern United States, factors such as poverty, unemployment, inadequate access to healthcare, and sociocultural environmental factors may explain the higher HIV burden among MSM [10, 11]. Sociocultural factors that can impact risk behaviors include racial disparities, a lack of access to prevention and education, high levels of poverty and homelessness, suboptimal healthcare, and the inability to obtain adequate health insurance due to low income levels [12]. Issues such as mistrust in the medical system also prevail [11, 13], resulting in greater HIV-related health disparities among minorities. Black/African Americans comprise 19% of the population in the South (19 million persons), making this racial/ethnic group much larger in this geographic setting compared to other regions such as the Midwest (6.5 million) [12]. Black/African Americans who engage in high risk behaviors in the South may experience greater stigmatization with HIV prevention or care service utilization [11, 12].

Study Justification and Potential Findings

The increased risk of HIV transmission and outcomes among minority adult MSM and YMSM [8, 9] necessitate targeted interventions towards this group. In order to develop effective programs that decrease risk of transmission and increase preventive behaviors, studies are needed to improve understanding of the specific risk factors faced by this vulnerable population. By using qualitative methods to understand the contributors to the increasing prevalence of HIV among YMSM of color, the public health community may improve outcomes and contribute significantly to decreasing overall HIV prevalence, morbidity and mortality in the United States.

We believe we are among the first to take such a comprehensive approach to examining MSM and YMSM's risk factors, resilience, and potential intervention points that have not yet been identified. Understanding and bridging population disparities in HIV/AIDS is a primary aim of the 2010 National HIV/AIDS Strategy (NHAS). By identifying the barriers, as well as the healthful benefits, that minority MSM face with regard to HIV prevention and protection we can decrease new incidences of HIV infection, improving overall health outcomes in the population. This project seeks to understand the issues discussed above such as stigma and resiliency, in the context of the individual, in particular, the social, structural, and environmental factors that influence minority MSM with high-risk sexual behavior. This knowledge is crucial in order to increase access to care, improve health outcomes, and reduce HIV-related disparities and health inequities among minority MSM.

By sampling MSM from five US cities, we will develop a more "generalizable" model to help understand the factors associated with specific health risks encountered as well as the protections utilized by MSM. By exploring the array of socioecological factors across a wide age spectrum and in highly HIV prevalent cities, we also will be able to identify optimal points of entry for younger and older MSM in HIV prevention care for a lifetime. Since much testing and care is conducted through health departments, we will partner with health departments and community-based organizational colleagues also funded by CDC to help fit our results into a concise model that can frame how health departments and other sources of care structure HIV testing, referrals and risk reduction strategies.

The challenge for MSM who are at risk for HIV is to enter into and remain "prevention-oriented" toward HIV and STIs in order to remain healthy and productive. In addition, with the advent of PrEP, if they chose to take it, they need to achieve and maintain high levels of adherence to specific medications amidst the formidable obstacles encountered living their day-to-day lives. The challenge for health care professionals, then, is to provide consistent and easy access to prevention and care when resources are limited and obstacles such as geographic location, living situation, economics, substance use, poor health, stigma, depression, and lack of health insurance, may preclude MSM's regular health care follow-up. Fulfilment of the aims of this study will inform development of tailored, feasible community- and clinic-oriented interventions that could reduce risk for MSM and, relatedly, improve their overall health outcomes.

Study Design and Location

The present research will be conducted in the top five Southern metropolitan areas in the United States with the highest HIV diagnoses for MSM– Atlanta, Georgia; Jackson, Mississippi; Miami, Florida; and New Orleans and Baton Rouge, Louisiana. These cities rank among those in the South with the highest prevalence and incidence of HIV and STIs among young Black/African American and Hispanic/Latino MSM.[16]

Our study population will consist of Black/African-American and Hispanic/Latino 1) male adolescents who are attracted to men and report they are HIV negative or have not been tested and 2) adult MSM who are HIV-negative. All study participants will be 13 years of age or older.

Participants will be recruited in the selected cities through referrals from Health Departments, clinics and other HIV testing centers. In addition, we will recruit via word-of-mouth referrals or flyers given out by community-based, advocacy, faith-based, and service-providing agencies.

For the purposes of this study, we will use a primarily qualitative research design. The first portion of the in-depth interview will consist of close-ended questions, which can be used for demographic analysis purposes. The remainder of the interview will consist of open-ended qualitative questions, and will elicit the bulk of our research data. This research design was chosen based on the exploratory nature of our study question and purpose. The primary purpose of this study is to examine the many factors that contribute to how MSM residing in high risk cities remain HIV-negative. A qualitative design is best suited to this purpose, as it will allow study participants to raise topics of concern that researchers may not have even thought about asking. The in-depth interview guide will provide a format for the interviewer to engage the participant in a rich conversation on such topics as perceived risk status, understanding of prevention and engagement in preventive behaviors as well as issues such as finances and role of partners; however, the participant will identify issues that he has felt are most critical to HIV prevention and will be given the opportunity to elaborate on these issues.

The combination of demographic and quantitative data will provide a rich variety of data that can be analyzed to generate hypotheses on important barriers and facilitators to HIV prevention and protection.

Study Objective

The study objective is to examine the many factors that keep some MSM/YMSM with high risk sexual behavior from contracting HIV in some of the metropolitan areas with the highest infection rates. Gaining an understanding about prevention and protective factors is crucial to CDC's ability to create programs and interventions that may help reduce the high proportion of new cases among some groups in the population.

General Approach

This research project is an exploratory, hypothesis-generating study of the socioecological factors that may influence HIV prevention, grounded in the socioecological model of health behavior. For the purposes of this study, we will identify socioecological barriers and facilitators to HIV prevention and protection that are important to racial and ethnic minority MSM living in metropolitan areas with highest rates of HIV infection.

PROCEDURES/METHODS DESIGN

Research Design

As a qualitative study, our research design meets the study objective of exploring salient obstacles to HIV prevention and protection faced by minority MSM/YMSM living in high risk cities and thus particularly vulnerable to contracting HIV. By using a qualitative design, we allow the participants to identify the factors impacting their success in maintaining an HIV-negative status.

The study will be conducted in three phases. Phase I involves preparation of materials, and submission to OMB. Phase I takes place from October 2014 through December 2014. Phase II will involve the implementation of the protocol including training and, after final OMB approval, recruitment and interviewing of participants. It is anticipated to begin in the Spring of 2015 and run through the Fall of 2015. Phase III involves data coding, analysis, and creation of a final report. Phase III is expected to take place in Summer and Fall of 2015.

Audience and Stakeholder Population

The audience for this study includes researchers and decision makers who are working to reduce HIV transmission rates among adult and adolescent MSM of color who reside in high-risk areas.

The Emory University Community Advisory Board (CAB) will review all instruments to ensure cultural and literacy compatibility. In addition, Emory University CAB will participate in pretesting of the instruments to ensure comprehensibility and ability to elicit responses from target audience participants.

PROCEDURES/METHODS STUDY POPULATION

Study Population

Examples from major metropolitan areas in the United States demonstrate that YMSM and MSM in high risk urban areas may face stigma and barriers to care. DHAP 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.

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 YMSM between the ages of 13 and 24. Of these, we expect to include 15-20 minors aged 13-17. See Exhibit 1 below. Respondents will have the option to complete the interview in English or Spanish.

Exhibit 1: Summary of Recruitment Targets

13-24: 50 cases - Further divided:

Ages 13-17: 15-20 cases

Ages 18-24: 30-35 cases

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

45+: 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 African American MSM may also be recruited.

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

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

Exhibit 2. Target Distribution by City

Location	Latino	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 1 and 2, in the event that it is not possible to fill a target, we will work with the TM to determine the best alternatives available. It may, for example, be necessary to shift counts slightly between 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 CDC decides that targets need to be shifted, a total of 150 MSM IDIs will be completed for the study.

Case Definition

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[1]. 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,

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

ethnic/racial identification, age, language proficiency, gender, and MSM status. These criteria are detailed in Exhibit 3.

Exhibit 3: 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**
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 of Exclusion of Population Segments

This research focuses on the subpopulation with highest HIV incidence and prevalence: racial and ethnic minority 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, 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 non 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 confidentiality, logistical and timing issues inconsistent with the needs of the project.

Proposed Number of Respondents

One hundred fifty total participants are anticipated from the five cities (Miami, FL; New Orleans & Baton Rouge, LA; Jackson, MS; and Atlanta, GA) including 50 YMSM between the ages of 13 and 24. Of these, we expect to include 15-20 minors.

Sampling

In order to address the issues discussed above we plan to recruit 105 Black/African-American and 45 Hispanic/Latino MSM whose residence in high HIV incident areas make them particularly vulnerable to contracting HIV.

About equal numbers of minors (i.e. 7-10 males) will be recruited in the Deep South (Atlanta, GA and Jackson, MS) and in the Gulf Coast area (Baton Rouge and New Orleans, LA) combined with the South Florida (Miami, FL) area.

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

Recruitment

Location

Participants will be screened over the phone by trained recruiters from RSS, Inc. and the Emory University Vaccine Research Center. Face-to-face interviews will be conducted in the respective cities from which participants are recruited. RSS, Inc. will conduct interviews in Miami, New Orleans and Baton Rouge under the supervision of the RSS Project Director, Dr. Schoua-Glusberg. Emory University will conduct interviews in Atlanta and Jackson under the supervision of the Principal Investigator Dr. Paula Frew. These cities were chosen because of the heavy burden of HIV incidence among MSM.

Methods of Recruitment

Recruiters will consist of staff members at RSS and Emory that are involved in other roles of the project as well as Graduate Student Assistants supervised by Dr. Paula Frew at Emory.

The high prevalence of HIV, including undiagnosed HIV infection among these populations, in these jurisdictions makes it essential to verify HIV-negative status. 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 YMSM and MSM social organizations**
- **Faith based centers and organizations that serve and support MSM and YMSM (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 HDs 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 post-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 a PLWH 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 HDs and HIV testing facilities that they fund to encourage cooperation, especially in the process of confirming HIV-negative status and providing 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[2]) and lower SES MSM are well represented in the population as well as minor YMSM (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 2a.]. The screening process should take approximately five minutes to complete.

Recruitment Materials

Fliers for the study and advertisement wording will be submitted for approval, and have been attached in this package [Attachment 5c, 5d].

Plans to Monitor Equitable Recruitment

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 on pg. 8. If recruitment falls short we will work with the CDC COR and 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.

Informed Consent

The informed consent for adults and the informed assent and parental consent waiver for minors application were approved by Emory's IRB. We requested this waiver because it was anticipated that many of the young men and adolescents may be homeless, runaways, or may not be living with parents or guardians. Or, parents may not be aware of their child's sexual orientation or activity. We also recognized that this population is highly vulnerable to domestic violence or other negative consequences if they do disclose their male romantic and/or sexual preferences to family members or caregivers.

Individuals who are interested in participating will be screened over the phone by either RSS or Emory recruiters. If they are deemed eligible to participate in the face-to-face interview they will be given a detailed explanation of the study, their role in the study, study requirements (including providing proof of HIV negative status for adult MSM), time commitment, and any additional questions they may have will be answered. Eligible participants will be invited to participate in the face-to-face interview. Prior to beginning the face-to-face interview, participants over the age of 18 years will be asked to sign an informed consent form (Attachments 3a, 3b) that has been approved by the Emory IRB. All minors 13-17 years will be required to assent to participation (Attachment 3c, 3d). A waiver of parental/guardian consent was granted by the Emory IRB due to the social risks that young

[2] 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.

MSM fear from disclosing their sexual preference to parents/guardians. It is also highly likely that we will encounter young 13-17 year old MSM who are runaways, living on the streets or in shelters, or in safe homes where parental/guardian consent is not feasible to obtain.

We anticipate that the documents presented to prospective participants will include an explanation of the study, risks and benefits of participation, duration of participation, contact person for the research including the chair of the IRB, the voluntary nature of participation, and the right to withdraw without penalty. The form will also detail the types of disclosures that would necessitate an interviewer reporting the disclosure to authorities. Participants may ask any additional questions they may have. If they choose to participate and sign the consent or assent form they will be given a copy of the form for their records. The consent form will be read to respondents uncomfortable or unable to read it themselves. The assent form will be read to all minors.

PROCEDURES/METHODS VARIABLES/INTERVENTIONS

Variables

The study instrument will address domains of information related to the socioecological aspect of HIV prevention and protection. Social and structural factors shape individual health decision-making behavior among racial and ethnic minorities, including minority MSM. Past HIV-related intervention approaches have successfully employed the socioecological model of health behavior as a basis for prevention activities. As such, the study categories will address individual, social, and structural domains of influence on behavior.

Study Instruments

As described above this includes English (Attachment 2e) and Spanish (Attachment 2f) versions of an in depth interviewer's guide which contains a section of close-ended demographic questions

Outcomes and minimum meaningful differences

We anticipate that the findings will offer important insight on the role of socioecological factors impacting racially and ethnically diverse MSM's experience. Our framework for this project is the Socioecological Model (SEM) of behavior. The model posits that factors across individual, family/peer/social network, and community/societal levels may serve as facilitators or barriers to the achievement of HIV prevention. The SEM will frame how we examine variables contributing to and that could ameliorate MSM risk such as housing, education, peer support and norms, PrEP use and adherence, condom use skills among others.

The results will inform the development of culturally appropriate, tailored interventions for MSM from various socioeconomic categories and geographic locations to reduce the risk of

becoming infected with HIV. The findings will also provide important information to guide program development and treatment access.

Training Research Personnel

Interviewers from RSS, Inc. and the Emory University Vaccine Research Center will be trained to conduct the telephone screening and face-to-face interviews. An interview manual will be developed and used as the basis for interviewer training. It will include all of the important elements of interviewing as well as specific information related to each item on the questionnaire. A standardized script will be used to introduce the participant to the study and explain the questionnaire. In advance of the training, the PI and the PD will each pretest the interview with a respondent who is behaviorally MSM, and will share any findings with the CDC TM and each other with an eye toward modifying the instrument as needed before others are trained.

Training materials will be distributed in advance to Emory and RSS data collectors for review. Approximately ten interviewers will be trained. Interviewers are expected to read and to be prepared prior to the in-person training held in Atlanta. Training in person will focus on ensuring that all interviewers utilize the same procedures, administer the instrument consistently following a standardized protocol, probe exhaustively, keep the thread of the conversation focused, and protect personally identifiable information (PII).

Training will continue during the field period for quality assurance both individually and in group sessions as needed. Weekly meetings and regular contact with the PI will be held to discuss any problems or issues that may arise. All team members actively involved in research gathering activities have completed Collaborative Institutional Training Initiative (CITI) training.

PROCEDURES METHODS DATA HANDLING AND ANALYSIS

Data Analysis Plan

The analysis will be done taking into consideration decisions for data dissemination. As we discuss in the last section of this report, dissemination vehicles should drive aspects of the analysis. The original goals and objectives of the project will drive the overall direction of manuscript development. Gaining an understanding about prevention and protective factors is crucial to CDC's ability to create programs and interventions that may help reduce the high proportion of new cases among some groups in the population. Specific papers may only focus on a small fraction of that very wide topic. In addition to plans we may draft ahead of data collection, there will also be themes that emerge from the data (grounded theory) and we will be prepared to analyze those and include them in the findings.

Analysis will include descriptive characteristics of the study participants based on the data collected in the first part of the interview. The bulk of the analysis will be done as traditional qualitative analysis, describing how participants with different characteristics (e.g. race/ethnicity, city, age, etc.) find different barriers and facilitators.

Data Collection

Interviews will take place at a time and place that is convenient to the respondent and where there is access to rapid HIV testing, if required. Locations will be private. Interviews will be audio-recorded with the consent or assent of the participant, and transcribed. Emory and RSS will also collect data with pen and paper. Two recording devices will be used to ensure no data is lost due to an inferior recording. All paper materials will be kept in locked cabinets in secure locations. All personal identifiable information will be maintained on paper or in password protected or password encrypted files[3]. The exception will be any possible PII provided by the respondent inadvertently in the recorded interview; however even these files, once transferred off of the recording devices will be secured in encrypted files. Transcripts of the interviews will exclude such PII information. Recordings will be kept in locked secure areas.

Close-ended demographic questions will be asked at the beginning of the interview covering socio-demographic items, including age, gender, race and ethnicity, educational attainment, income, living situation, and other relevant study-related information. The second and main part of the interview will be designed as a qualitative in-depth interview guide to promote a conversation with the respondent. It will include questions about respondents' perception of HIV prevention, HIV risks and behaviors, personal and community relationships, contributors and inhibitors to remaining HIV negative including fatalism, perceptions of HIV prevention and care, HIV testing, knowledge of PrEP, and condom use. It will also include questions on resiliency, geo-social considerations, and ideas on improving HIV prevention in the community.

Following each interview, the interviewer will immediately check the quality of the recordings. If any issues are found the interviewer will immediately fill out the notes from memory to supplement the audio recording. Physical materials from the interview will be kept locked and secured by the interviewer. While travelling, interviewers will use a locked briefcase or bag to secure materials.

In the event of an emotional or anxious response from the participant during the interview, participants will be provided with a city-specific list of LGBT, YMSM and mental health care contact numbers as needed. Participants will be informed they may stop participation at any time if the interview becomes too stressful for them. Interviewers will also be trained specifically in the potential needs of minors.

[3]Based on C&A agreement TBD.

When the interview is concluded, participants will receive $40 in the form of a gift card in Atlanta and Jackson and $40 in cash in Miami, New Orleans and Baton Rouge. Forty U.S. dollars is a standard amount for OMB-approved qualitative interviews and is not considered a coercive amount for participation. In addition, this amount is consistent with similar studies conducted with a nationwide sample of MSM, accounting for the inconvenience of travel and time. It is also consistent with both CDC and other OMB approved qualitative studies with minors. Respondents will be reminded during consent/assent process that all answers are voluntary, that they may choose to not answer any question and that they will receive the $40 without regard to their participation in the interview or whether or not they choose to answer any question. Participants who need an HIV test in order to verify HIV negative status will not be compensated for complying with eligibility requirements by getting tested, however, we will direct potential respondents to testing centers where the tests are free.

Other Interactions

Participants will receive a reminder call, text or email regarding their face-to-face interview appointment[4]. During the initial screening, permission to leave a voice, text and email message will be determined. Permission to leave messages will be checked prior to any reminder calls or messages. Reminder messages will not identify the respondent by name nor the purpose the interview. They will remind the respondent time of the interview and for adults that they should remember to bring the test results if they have them. The type of test will not be included in the message. The interviewer contact information will also be included in the message.

Respondent Burden

The phone screening will take approximately five minutes to complete. We expect to screen approximately 600 callers to enroll 150 respondents. However, the number may need to be higher if, for instance, interested callers are not willing to produce HIV test results.

For the qualitative study, participants will participate in a face-to-face interview lasting approximately one hour depending on the length of participant's responses.

Benefits to Subject or Future Benefits

The benefits of participating in the study include contributing to new understanding about prevention and protective factors in order to create programs and interventions that may help reduce the high proportion of new cases of HIV among African-American and Hispanic/Latino MSM. Interview respondents will receive a $40 token of appreciation in the form of a gift card or cash regardless of whether or not they answer any questions during the in-person interview.

Information Management and analysis software

[4] Based on C&A agreement TBD.

All data (transcripts without PII) will be kept in encrypted or password protected files or as directed by the CDC TM. Analysis will be done on secured network systems or on stand-alone (non-networked) password protected computers in secured locations as directed by the CDC TM. Analysis software will be N-Vivo 10.1.

Data Management, Monitoring and Statistical Analysis

RSS and Emory will collect data by paper and pencil in face-to-face interviews. Interviews will also be audio-recorded on two devices and transcribed by RSS and Emory on password-protected computers or as directed by the CDC TM. Interviewers will remind respondents not to use PII when responding to questions while being recorded. Recordings will be transcribed exclusive of PII. Descriptors will be used to replace PII mentioned in the transcripts. Access to the encrypted transcript files will require a password and is restricted to staff working on the project. Interviews that were conducted in Spanish will be transcribed directly into English by RSS. Spanish-language interviews are anticipated to take place primarily in Miami. The transcription process for the short response data will include entering those values into an Excel password protected file or encrypted SPSS file as directed by the CDC TM. Encrypted PII-free transcribed data will be transferred to IMPAQ via email, FTP transfer or as the CDC TM directs. IMPAQ will lead security protocol development. Qualitative data (transcriptions without any PII) will be stored on a secure network within the secure areas of IMPAQs FISMA compliant operation or as directed by the CDC TM. Users are restricted. IMPAQ's information technology security will review all use of the system and take the appropriate corrective actions for improper use.

IMPAQ staff will code data using N-Vivo 10.1 on a secure network or in accordance with the security stipulations of CDC TM. Transcripts will be structurally-coded based on a careful reading of the selected transcripts to systematically identify recurrent pertinent themes and patterns in the data (e.g., perceptions about prevention and prevention behaviors), the IMPAQ lead qualitative analyst will develop a coding structure which will be discussed and further refined in collaboration with the head coder, who will have read the same transcripts. [Attachment 7a.]

After the data have been coded, the next analytic stage involves systematically looking for and examining recurrent thematic patterns in the data to address the main study questions. NVivo10.1 provides powerful tools that can be brought to bear in doing this, to be described shortly, which is one reason why it is so important to have a clear and focused approach that prioritizes the analytic questions of greatest or most pressing relevance. The analytic team is comprised of the RSS PI, Dr. Schoua-Glusberg; the PI, Dr. Frew; and the IMPAQ Lead Analyst, Dr. Berkowitz, working in conjunction with CDC. The team will discuss and agree to a prioritized list of the topics/questions to be explored analytically, guided by considerations including policy relevance/need; significance in addressing gaps in the literature/ knowledge base; and greatest potential impact of the findings given the qualitative nature of the results. Prioritization can be informed by concrete knowledge of thematic content and richness of the qualitative data set, the timely needs/priorities of DHAP relative to this project; and the available resources. Potentially, each topic can be linked to one or more publications.

Additional statistical analyses will be performed as appropriate for the data set. The majority of the analysis will be done as traditional qualitative analysis.

The principal analytic products for the study, "Understanding Barriers and Facilitators to HIV Prevention, Care and Treatment for Men Who Have Sex with Men (MSM)," will be several articles suitable for publication in peer-reviewed journals. These articles will present the study findings and/or methodology and focus on the topics prioritized by the analytic team, as described earlier. The publication guidelines and authorship process established for the previous task order will be followed in producing the manuscripts. Additionally, a power point presentation describing results and manuscripts that were developed will be produced.

Quality Control/Assurance

Quality assurance is measured by the quality of the respondents, their meeting eligibility requirements and by the quality of the instrument administration. Respondents will be primarily recruited through healthcare and community organizations that serve the minority LGBTQ, MSM and YMSM populations. In addition advertisements, flyers and listservs will also specifically target the population needed. Unless otherwise directed, all adult MSM will need to produce proof of a negative HIV test result obtained at least within the prior six months of the interview date. Thus, the general population of non MSM will have no or little access to recruiting materials. Screener eligibility questions are asked of respondents without alerting them to which criteria make them eligible or ineligible. Those wishing to participate but are deemed ineligible would find it difficult to know which questions affect eligibility (Attachment 2a, 2b). Instruments will be administered by highly skilled interviewers with multiple years of experience in qualitative interview techniques. Quality control will be monitored throughout the project.

Protocols will be in place to monitor the quality of the respondents as well as the quality of the interview, with initial interview transcripts reviewed by the PD or PI of the project. In person training and additional training and communication will be ongoing throughout the field period. Study data will be provided with all appropriate physical and operational security protections to minimize risks to confidentiality. Data will be stored in a physically secure location. Access to identifying data will be restricted to study staff requiring the data to complete their study-related roles. All staff will be trained in confidentiality procedures and sign a statement regarding nondisclosure of participant information.

Additionally, our team will be responsible for protocol adherence including timely data entry. The PI and PD will be responsible for conducting pilot testing of the pre/post and follow up instruments and data collection procedures (e.g., to detect difficulties in understanding questions, etc.) in order to reduce implementation problems during the conduct of the study. All site leaders will be responsible for data management and will oversee security of the data stored on the server.

Coding Analysts will continually re-review, reconcile, and revise any discrepancies to ensure consistency of later coding. IMPAQ will build the electronic codebook during this process. The PI and PD will be updated with identified themes and the relative codes that are created for their review and agreement.

Sample Bias and Study Limitations

We acknowledge that participants who express interest and agree to be in the study may differ qualitatively from those who refuse to participate in the study or refuse to be tested for HIV and therefore may not be broadly representative of our target population.

We have introduced subsample target recruitment goals to ensure that we obtain a balanced quota sample of MSMs representing geographic, racial and ethnic, and age categories. By recruiting in this manner, we will mitigate sampling bias effects. In addition, we recognize the potential for social desirability bias in the conduct of the study. Our interviewers will be trained on effective techniques to ensure that individuals are comfortable and will not be judged on the narrative responses given in the interviews.

Procedures/Methods Handling Unexpected or Adverse Events

Response/Procedures to Reduce Risks of Participation

All interviewers and recruiters will undergo training and evaluation prior to the start of the field period. Interviewers include key staff members such as Project Director Dr. Schoua-Glusberg, Project Manager Katherine Kenward, Principal Investigator Dr. Frew, and Emory Program Coordinator Diane Saint-Victor. In addition, key graduate research assistants from Emory University and other experienced RSS staff members will be trained to conduct in-depth interviews.

For all interviewers, a two-day in-person training will include qualitative interview methods as well as methods for interviewing at risk, social, and economically disadvantaged populations as well as minors. In addition, interviewers will be provided with pre-training study materials. Recruiter training will focus on the consistent administration of the screener, PII protections and protocols, and determining and selecting appropriate participants. All interviewers and recruiters will be active project team members and, at Emory, graduate student assistants.

Prior to the start of the interview, participants will be asked to sign an informed consent or assent form that details the study, including risks and benefits of participation, voluntary nature of participation and the right to withdraw without penalty, time commitment, research contact person, and IRB contact person. Participants will be given the opportunity to ask additional questions they may have before signing the consent to participate. Minors will have the consent read aloud to them. They will retain a copy of the consent for their records.

Inclusion of minors in this study carries a slight risk of mandatory reporting based on the state laws within each state where interviews take place and the professional status of the specific interviewer[5]. Reporting of sexual activity (as defined in each state) would in turn require releasing of private information. In order to minimize any scenario in which a respondent's private information must legally and ethically be released, all respondents are reminded during the consenting process that disclosure of physical harm to self or others or sexual abuse of minors may require mandatory reporting.

To minimize the risks of a confidentiality breach, screening and interviews will be administered in a private area, away from others. RSS and Emory will collect data by paper and pencil and audio recording during face-to-face interviews.

All collected information will be kept in locked files in secured areas or in secured password protected or encrypted files.

All project personnel, including interviewers will use proper material handling procedures to ensure the privacy of respondents and the security of the data. Interviewers will be trained in additional data security procedures. Procedures in place to ensure this include:

- **RSS and Emory will collect data by audio recorder and on paper during face-to-face interviews.**
- **Audio recordings may contain PII if the respondent inadvertently mentions any during the interview and thus will be treated as containing PII even if there is no PII on the actual recording.**
- **Consent forms will not include a Case ID and will be kept in a separate folder from interview response data**
- **Physical (paper) contact information used to reach respondents in the field, will not include a Case ID and will be kept in a separate folder from screener or interview response data.**
- **Field collected contact information will be transferred to electronic format with CaseID as soon as practical in order to ensure the interviewer is able to recall the match of contact and study data using recall rather than written links. Mnemonics, dates or other memory aids that do not link the contact information with the screener may be used on the contact information to assist the field interviewer as long as they don't identify study data or provide additional PII (i.e. no physical descriptors)**
- **Contact forms collected within project offices will contain a Case ID. These will be stored in separate locked cabinets from any study data.This form contains no information about the project purpose or respondent type.**

[5]In Georgia and Louisiana, only Kenward is a mandatory reporter (she is a registered nurse). In Florida and Mississippi, all interviewers are mandatory reporters but only sexual activity occurring between a minor and a person responsible for that child's welfare would be a reportable event.

- **PII, such as contact information and Case ID may be maintained in encrypted electronic form in project offices. However this link will contain no information about the respondent's characteristics or study purpose but only the name, contact information and CaseID.**
- **Study data, such as the interview form and screener, will have responses to the demographic questions or short notes made by the interviewer but will not contain PII such as names or contact information. Only a Case ID will be used to identify it.**
- **While travelling to and from interviews, all materials, including audio recordings and paper materials containing study data or PII will be kept in a locked bag or briefcase until they can be safely returned to the secure office environment. Contact information will be stored in separate folders from study data and will not contain CaseIDs.**
- **PII maintained on paper is kept in locked cabinets in secure areas.**
- **Electronic Word and Excel files with PII or with any potential for respondent identification will be password protected using Word and Excel password protection features. This includes master recruitment logs; transcripts of interviews[6]; and PII logs that are maintained to ensure no respondent is interviewed twice (by double checking phone number and name prior to scheduling).**
- **Some electronic files cannot be password protected, such audio recordings, but they can be saved within encrypted zip files using software such as WinZip. All audio recordings will be stored or transferred within encrypted zip files. Audio recordings will be transferred to zip files from the audio recording device using a non-networked, stand-alone computer.**
- **Electronic files with no risk of PII disclosure or respondent identification will not be password protected or encrypted for storage or transmission. These files include monthly & weekly progress reports and other files with no PII and no possible identification of respondents.**
- **If a breach of protocol happens, study staff will report the incident to the PI and PM, who will report to the IRB and CDC TM who will report to the ADS and C&A offices.**

Transcriptions from the recordings will be completed using secure networks or as directed by the CDC TM. No PII will be included in the transcription. In places where PII is divulged in the recording, the transcriptionist will convert the PII to bracketed non-PII descriptor information (i.e. [Daughter's Name]). For additional security all transcripts will be password protected.

Transmittal of encrypted audio files and password-protected transcribed data will be done through email, using a secure FTP site, or as directed by the CDC TM. IMPAQ will receive all

[6] Recruitment logs and transcripts do not contain PII however, they are password protected at all stages of the process as a precautionary measure.

transcripts once they have been through a quality control check and it is confirmed they contain no PII.

IMPAQ will lead security protocol development. IMPAQ's security program is compliant with NIST SP 800-53. Transcriptions, exclusive of PII, will be stored on password protected computers or encrypted flash drives or as directed by CDC TM. IMPAQ staff will code data using a secure network version of N-Vivo 10.1 or as directed by the CDC TM.

Coded data will be analyzed at all three locations, IMPAQ, Emory and RSS. At Emory and RSS, both quantitative and qualitative data will be accessed on password protected PCs either in a password protected network or as directed by the CDC TM. Data will be saved and backed up onto key drives and kept locked up when not in use. No names or identifiers will be used when transcribing or analyzing the data. Names will never be linked with data.

Vulnerable Population Safeguards

Before entry into the research project, potential participants will be screened over the phone or in person by the interviewer. If participants are deemed eligible to participate, the study will be explained in detail including the purpose, the participant's role, study requirements, and time commitments involved and the voluntary nature of their participation. Potential participants will be assured that their care or services will not be affected in any way by their decision of whether or not to participate in the study. They will be given an opportunity to ask questions and receive additional information. They will then be invited to participate in a face-to-face interview. When the participant comes to the face-to-face interview they will be asked to indicate consent on an informed consent or assent form. The consent form includes an explanation of the study, the risks and benefits of participation, the duration and type of participation, description of the procedures, contact person for the study and IRB, the voluntary nature of participation, the right to withdraw without penalty, and an explanation that we ask them not to use names or other PII during the interview. If they agree to participate and indicate by signature or mark on the consent/assent form they will be given a copy of the form for their records.

A list of city-specific LGBTQ and mental health providers, including those which serve minors will be given to respondents who ask for more information or if the need arises.

Emergency Care/Risks to Participation

There is a remote risk of anxiety or stress related to the content of the interview questions. This kind of event cannot be controlled ahead of time, however, interviewers will be trained to react appropriately and provide participants with a referral to a mental health or other care provider when needed.

The primary risk in the study is a breach of confidentiality. As outlined in the next section, steps will be taken to ensure that data is never associated with the name of a particular participant.

Handling of Unexpected or Adverse Events

Any breach in security or risk of disclosure from materials (PII or other sensitive data) will be immediately reported to the TM at the CDC, and through Institutional Review Board (IRB) channels. All security incidents will be thoroughly documented and follow up reports will be sent to the TM. Any paper or audio data that is compromised will be reported by RSS and Emory using the same procedures previously outlined.

Additionally, because there is a slight possibility of emotional response or anxiety, interviewers will be trained to provide participants with a city-specific list of LGBTQ and mental healthcare providers, including ones that serve minors, if needed. Participants will be informed they may stop participation at any time without penalty for any reason. We will train our staff members to contact institutional security numbers as well as 911 in the event of any medical incident or security threat posed during the interview process.

Confidentiality

See "Risks to Participation" and "Procedures to Reduce Risk".

Procedures/Methods Dissemination, Notification and Reporting of Results

There are no plans to share findings with study participants. There are no anticipated products, other than as detailed above, resulting from the study. There are plans to disseminate research findings to the public in the form of one or more manuscripts, abstracts, and presentations detailing barriers and facilitators of public health importance. All disseminated data will be de-identified and stripped of personal identifying information. A list of organizations and clinics that support the recruitment process and request results will be kept and as manuscripts are published will be informed of the publication.

REFERENCES

LIST OF ATTACHMENTS

Attachment 1. Authorizing Legislation document

Attachment 2. Data Collection Forms

2a. Pulse Study Screener English

2b. Pulse Study Screener Spanish

2c. Pulse Study Contact Form English

2d. Pulse Study Contact Form Spanish

2e.Pulse In-Depth Interview Guide English

2f. Pulse In-Depth Interview Guide Spanish

Attachment 3. Consent Forms

3a. Pulse Consent Form English

3b. Pulse Consent Form Spanish

3c. Pulse Assent Form English

3d. Pulse Assent Form Spanish

Attachment 4. Human Subjects Approvals

4a. Emory University IRB Approval Letter

4b. Emory University IRB Parental Consent Waiver (Application Pending)

Attachment 5. Recruitment materials

5a. Pulse Recruitment Advertisement English

5b. Pulse Recruitment Advertisement Spanish

5c. Pulse Recruitment Flyers English

5d. Pulse Recruitment Flyers Spanish

Attachment 6. Spanish Translation Certification

Attachment 7. Data Security Plan Protocols

Conflicts of Interest

There are no conflicts of interest for this research study, financial or otherwise.

References

1. Centers for Disease Control and Prevention, HIV in the United States: At a Glance. 2013.
2. Centers for Disease Control and Prevention, Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 U.S. dependent areas—2011. HIV Surveillance Supplemental Report 2012, 2012. 18(5).
3. Centers for Disease Control and Prevention, HIV surveillance in men who have sex with men (MSM). 2012.
4. Centers for Disease Control and Prevention, Diagnoses of HIV Infection in the United States and Dependent Areas, 2012.
5. Prevention, C.f.D.C.a., HIV among African-Americans. 2013.
6. Valleroy, L.A., et al., HIV prevalence and associated risks in young men who have sex with men. Young Men's Survey Study Group. JAMA, 2000. 284(2): p. 198-204.
7. Centers for Disease Control and Prevention, HIV surveillance in adolescents and young adults. 2012.
8. Centers for Disease Control and Prevention and Prevention, Previous HIV testing among adults and adolescents newly diagnosed with HIV infection - National HIV Surveillance System, 18 jurisdictions, United States, 2006-2009. MMWR Morb Mortal Wkly Rep, 2012. 61(24): p. 441-5.
9. Ellen, J.M., et al., HIV viral load levels and CD4+ cell counts of youth in 14 cities. AIDS, 2014. 28(8): p. 1213-9.
10. Reif, S., K.L. Geonnotti, and K. Whetten, HIV infection and AIDS in the Deep South. Am J Public Health, 2006. 96: p. 970-973.
11. Whetten, K. and S. Reif, Overview: HIV/AIDS in the deep south region of the United States. AIDS Care, 2006. 18 Suppl (1): p. S1-5.
12. Southern States AIDS Directors Work Group, National Alliance of State and Territorial AIDS Directors, and CDC Division of HIV/AIDS Prevention in the National Center for HIV/STD/TB Prevention, Southern States Manifesto. HIV/AIDS and STDs in the South: A Call to Action. 2003. p. 1-39.
13. Gamble, V., Under the shadow of Tuskegee: African Americans and health care. Am J Public Health, 1997. 87: p. 1773-78.