

**ASSESSING THE KNOWLEDGE AND ATTITUDES OF BLACK/AFRICAN  
AMERICAN MEN WHO HAVE SEX WITH MEN ON HIV PRE-EXPOSURE  
PROPHYLAXIS**

by

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**Background:** African American men who have sex with men (MSM) represent 37% of the HIV incidence among all MSM and young Black MSM observed a significant increase of 48% in new infections during 2006-2009. There were 6,500 infections in Black MSM aged 13-29 exceeding the number of infections of White MSM aged 13-29 and 30-39 combined. In 2010, results from the Global iPrEX clinical trial showed 44% efficacy of oral pre-exposure prophylaxis among MSM. The implementation of PrEP as a HIV prevention tool may have positive implications in reducing the disparity of HIV infection among Black MSM.

**Methods:** Participants were recruited and sampled for an online survey using the social networking sites Facebook and Twitter. Eligibility for participation was contingent upon self-reported response as Black/African American, an MSM, HIV negative or unaware of HIV status, and over 18 years of age. Informed consent was obtained. Behavioral data was collected from participants on sexual behaviors, HIV testing, and self-perceived susceptibility to HIV infection. Participants were asked specifically their knowledge of PrEP and likeliness of using PrEP to reduce risk of HIV infection.

**Results:** The sample pre-eligibility included 178 respondents. 20.5% (32) respondents reported being HIV positive. After eligibility was determined 99 respondents were included in the analysis. 56.4% of the sample reported having little or no knowledge of PrEP yet would use

PrEP to reduce their risk of HIV infection. Age was the strongest indicator of all the independent variables on PrEP acceptance being statistically significant in all models of the regression analysis.

**Conclusions:** Contrary to the original hypothesis, an inverse relationship between PrEP knowledge and acceptance was ascertained in the current study. Some possible explanations for this interesting finding are that respondents were unaware of the risks and benefits of pre-exposure prophylaxis and were concerned about preventing themselves from contracting HIV. Also if respondents were to use PrEP, it would likely have to be at little or no individual out of pocket costs. There are a number of factors influencing such high acceptance of PrEP among Black MSM and the current study was able to ascertain some of these factors. These findings have public health significance to the current epidemiology of HIV infection in the United States and further prevention efforts.

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## **PREFACE**

I would like to thank my thesis committee chair and academic advisor Dr. Rodger Beatty. He has been so supportive and helpful throughout this entire process. I would also like to thank my other committee members Dr. Chris Keane and Dr. Linda Frank. Both of these individuals are leaders in HIV prevention and I greatly appreciate them taking time out of their busy schedules to serve on my committee. I also like to thank Jonathan Baker and Anne Davis of the Microbicide Trials Network who provided technical assistance and feedback on my research. Lastly, I would like to thank my family and friends for their support but a special thanks to my mother, grandmother, and aunt for their endless encouragement and support in life and throughout my graduate school tenure; without these individuals, this thesis would have been impossible.

## **ABBREVIATIONS**

**HIV** – Human Immunodeficiency Virus

**AIDS** – Acquired Immunodeficiency Syndrome

**STI** – Sexually Transmitted Infection

**MSM** – Men who have sex with men

**PrEP** – Pre-Exposure Prophylaxis

**CDC** – Centers for Disease Control and Prevention

**iPrEX** – Global iPrEX Clinical Trial

**UAI** – Unprotected Anal Intercourse

**URAI** – Unprotected Receptive Anal Intercourse

**PEP** – Post Exposure Prophylaxis

**Truvada** – Emtricitibine + Tenofovir

**NRTI** – Nucleoside Reverse Transcriptase Inhibitor

**HPTN** – HIV Prevention Trials Network

**HBV** – Hepatitis B Virus

## 1.0 INTRODUCTION

More recently, extensive research has been conducted on biomedical interventions to human immunodeficiency virus (HIV) prevention to elucidate the efficacy of chemoprophylaxis in preventing the transmission of HIV in HIV negative individuals. This paper will provide context of the HIV transmission and the epidemic in the United States, followed by an overview of the disparity of HIV infection experienced by African Americans and African American MSM. Next, there will be a review of relevant literature on HIV pre-exposure prophylaxis followed by an evaluation of the participation of African American MSM in HIV biomedical and prevention research. Findings will be presented from the current study which surveyed African American MSM on their knowledge and attitudes of HIV pre-exposure prophylaxis. Finally, the author will offer recommendations for HIV prevention policy and suggestions for integrating pre-exposure prophylaxis into the existing HIV prevention toolbox.

More research and information must be gathered on PrEP before it can be disseminated to HIV negative Black MSM as an HIV prevention strategy. Very little information exists on the knowledge and attitudes that Black MSM have on PrEP. Throughout this paper, PrEP refers to oral pre-exposure prophylaxis, not topical microbicides. There are several questions that the author hopes the current study may answer. What is the knowledge that Black MSM have on PrEP? How likely are Black MSM to take a pill daily to reduce their risk of HIV infection? What is the individual perceived susceptibility of Black MSM to HIV/STI infection and are they even

concerned about the high rates of infection in the Black MSM community? What are the circumstances for under which Black MSM have unprotected receptive anal intercourse? A goal of this thesis research is to provide insight and possible policy recommendations on how PrEP could possibly be used amongst Black MSM. It is hypothesized that if Black MSM have little knowledge of PrEP and lower perceived susceptibility to HIV infection, they would be less likely to use PrEP to reduce their risk of HIV infection.

## **2.0 LITERATURE REVIEW**

In 1981, the world changed as the HIV pandemic was brought to the public's forefront. Little was known about HIV in the beginning however, one thing was evident; people were dying and dying fast. It appeared that HIV only affected gay men, but soon thereafter heterosexuals began to become infected as well. We now retain extensive information on the virus; the mode of transmission, the biology and immunology, and how to treat the virus.

### **2.1 HIV OVERVIEW**

#### **2.1.1 HIV Epidemiology**

HIV can only be transmitted if one comes in contact with infected blood, semen, vaginal secretions, and breast milk. In the worldwide context of HIV infection, unprotected heterosexual intercourse is the predominant mode of transmission for the virus (The Henry J Kasier Family Foundation, 2007). Unprotected anal and vaginal intercourse represents greater than 80% of the annual HIV incidence in the United States (Centers for Disease Control and Prevention, 2012).

Other modes of HIV transmission include the perinatal transmission, and intravenous drug use through needle sharing.

HIV transmission can be prevented through the consistent and correct use of condoms. Condom availability and accessibility has significantly increased, with individuals being able to access them free of charge from health departments and public health agencies. Despite the gamut of information on HIV infection, the incidence in the US has remained relatively stable at about 50,000 new infections per year (CDC, 2011). It is estimated that 1 in 5 or 20% of individuals who are HIV infected in the US are unaware of their infection and responsible for roughly half of the annual incidence (CDC, 2012). The aforementioned statistic enumerates the implications of HIV testing and being aware of HIV status. HIV tests only test for HIV antibodies, therefore an HIV infected person who is seroconverting from negative to positive is infectious, yet may fail to test positive on a test if he/she had in fact been tested while they were within what is known as the window period

It is during the window period that HIV infected individuals are oftentimes unaware of their status yet are able to transmit the virus to partners. This brings up the importance of getting an HIV test within three to six months after a high risk exposure. When an individual is in the process of HIV seroconversion, the symptoms of acute HIV infection may mimic common cold or flu symptoms which cause extreme difficulty in recognizing infection and accessing testing and treatment. In fact, some individuals who are infected do not become aware of their infection until the disease progression has reached Acquired Immunodeficiency Syndrome (AIDS). Essentially, HIV testing goes hand in hand with prevention and may have implications on the applicability of PrEP to individuals at risk for HIV infection.

### **2.1.2 HIV Diagnostic and Prognostic Indicators**

HIV being an infectious disease has different physical and biological manifestations in the individuals infected. The disease progression and prognosis is multifactorial; time of diagnoses, linkage into care and treatment, medical adherence, comorbidities and other factors affect an individual's response to HIV infection. Two prognostic indicators that are used in HIV infection are the CD4 cell count and the viral load. The CD4 count is the measure of the immune function of the infected person. A lower CD4 count represents poorer immune function and increased susceptibility to HIV opportunistic infections such as pneumocystis jirovecii pneumonia and Kaposi's sarcoma which result in further disease complications. A person in the US is diagnosed as having AIDS if his /her CD4 T cell count drops below 200 per milliliter of blood. Once an individual is diagnosed as having AIDS, the CD4 count may return to over 200. However, that individual is still classified as a person with AIDS (CDC, 2011). The viral load is the indicator of how much virus is in the infected person's blood. The higher number of copies of virus, the more infectious the individual in terms of transmitting HIV infection to others

The gold standard for an HIV treatment is to reduce the patient's viral load to "undetectable" that is having fewer copies than can be detected by the viral load assay. Having a viral load that is undetectable significantly reduces the risk of transmitting the virus in comparison to someone who has a higher viral load. The relationship between viral load and CD4 count is inverse. Typically, an HIV positive individual with a higher viral load usually has a lower CD4 count.



### **2.1.3 Disparities in HIV Infection**

The National HIV/AIDS Strategy suggests a need to end segmented prevention efforts in MSM and African American populations to address the HIV disparity in Black MSM (National HIV/AIDS Strategy, 2010). This paper will address the health disparity of HIV infection amongst African Americans in the United States, specifically African American MSM. These men are the highest at risk population in the U.S. accounting for roughly half of the HIV prevalence and more than half of the annual incidence estimated at 28,700 new infections (CDC, 2011). African American MSM represent 37% of the HIV incidence among all MSM and young Black MSM observed a significant increase of 48% in new infections during 2006-2009; there were 6,500 infections in Black MSM aged 13-29 exceeding the number of infections of White MSM aged 13-29 and 30-39 combined (CDC, 2011). “Unprotected anal intercourse (UAI) is the single most important risk factor for HIV transmission among MSM (Millet, et al., 2006).” There are some estimates that unprotected receptive anal intercourse (URAI) is approximately 20 times a greater risk as opposed to unprotected vaginal sex because the rectal lining is thinner and less acidic than the vaginal lining (Microbicide Trials Network, 2011). As a result of the biological differences between the anus and the vagina, HIV can penetrate rectal tissues easier and penetrate the host’s immune system. Despite therapeutic advances in HIV care that have been facilitated by the use of highly active anti-retroviral therapy(HAART), disease progression and mortality for HIV positive Black MSM have fared worse in comparison to White MSM.

In the context of the HIV epidemic among Black MSM, several causal factors contribute to higher incidence including testing patterns and awareness of status. Having a prior or current sexually transmitted infection enhances the susceptibility and transmission of HIV infection (Millett, et al., 2006). According to CDC STD surveillance reports, Black MSM were more

likely than any other group of MSM to report ever having a urethral chlamydia infection, urethral gonorrhea, and pharyngeal gonorrhea infection, contributing to the racial disparity of HIV infection among MSM (Millett, et al., 2006). Another factor contributing to higher HIV incidence amongst Black MSM alludes to testing and awareness of status. Several studies that have corroborated evidence that Black MSM obtain HIV testing less frequently than MSM of other races and are diagnosed later in the disease progression. It is estimated that approximately 116,750 people in the African American community are unaware of their HIV infection (CDC, 2011). Lack of awareness of status among Black MSM does not seem to be influenced by age. In one study 91% of the young Black MSM aged 15-22 was unaware of their HIV infection as compared to only 69% of Latino MSM and 60% of White MSM. In a similar study that recruited older MSM age 18-81, 64% of HIV positive Black MSM were unaware of their status as compared to 18% of Latino MSM and 11% of White MSM (Millett, et al., 2006). Prior studies show that being aware of HIV status can lead to sexual behavioral risk reduction. Findings from the 2008 National HIV Behavioral Surveillance System showed that young Black MSM aged 15-22 had higher HIV prevalence (14.1%) in contrast to young Latino and White MSM, 6.9% and 3.3% respectively (Phillips, et al., 2011). At the baseline, 37% of the Black MSM reported having UAI in the previous 6 months. At the conclusion of the 12 month follow-up, participants who were new to care were more likely to not have multiple sexual partners and UAI as compared to participants who had already been in care (Phillips, et al., 2011). Black MSM are less likely to be tested frequently for HIV which results in a lack of awareness of status, can result in higher risk taking behaviors than someone who is aware of their status, and ultimately higher HIV prevalence amongst Black MSM (Millett, et al., 2006) Also contributing to the HIV epidemic in Black MSM is the social determinants of HIV such as lower socioeconomic status,

racism, internalized and external homophobia, religious persecution, and negative medical perceptions (CDC, 2011). With African American MSM currently being at the highest risk for HIV infection in the U.S., effective interventions and strategies for Black MSM must explore both behavioral and biomedical approaches of alleviating the HIV epidemic within this community.

## **2.2 PRE-EXPOSURE PROPHYLAXIS**

### **2.2.1 Pre-Exposure Prophylaxis Pharmacology**

The CDC has begun to implement “high impact prevention” which targets the highest risk populations and areas of highest HIV prevalence. Currently in the US, Black MSM are observing significant increases in HIV infection while other racial and sexual groups have observed stable or decreasing incidence. PrEP that has been approved for use in MSM involves the medicalization of HIV negative individuals with the HIV medication Truvada (emtricitabine +tenofovir). “Antiretroviral drugs are currently used for HIV prevention in other settings, including after high risk HIV exposures such as needle sticks (post exposure prophylaxis [PEP]), post rape or high risk sexual exposures (non-occupational PEP), or for prevention of mother to child transmission (Anderson, et al., 2010).” Truvada belongs to the class of HIV pharmaceuticals known as nucleoside reverse transcriptase inhibitors (NRTIs) whose objective is to inhibit the viral replication stage of the HIV virus and limit the copies of that is created in an infected host (Gilead Sciences, 2011). Anderson et al. (2010), asserts that an antiretroviral drug

selected for prophylaxis should have limited drug-drug or food-drug interactions, proven safety and efficacy, lower dosing, and minimum risks for HIV drug resistance. It was for these reasons that Truvada was selected for the iPrEX trial because of its excellent record for safety and efficacy. Gilead Sciences, the producer of Truvada and Tenofovir (TDF) estimate that currently at least 1.5 million people worldwide are using a Tenofovir based regimen (National Institute of Allergy and Infectious Diseases, 2010)

Considerations of PrEP drug toxicity and efficacy must be addressed. Anderson et.al asserts that no surrogate marker exists for optimal dosage or drug concentration in terms of PrEP resulting in subjective analysis of variability in drug effectiveness and toxicity (Anderson, et al., 2010) In other words, even with proven safety and efficacy, there is no clinical marker that enumerates a specific amount of drug concentration that must be present for a prophylactic effect. This brings up concerns since medications are not metabolized the same by everyone and it is possible that one person would need a higher dosage or concentration of drug to be effective. Distribution of emtricitabine and tenofovir to tissues necessary for HIV prophylaxis has been proven with detectable drug levels in the vagina being observed within 2 hours after dosage and accumulation in semen 4 times faster than in plasma (Anderson, et al., 2010). Tissue absorption is essential to PrEP effectiveness as the objective is to prevent the invasion of the HIV virus into tissues exposed during high risk behaviors such as unprotected sex.

The toxicity of Truvada is not a major concern however, new or worsening renal insufficiencies have been documented which bring up the necessity for pre-screenings prior to beginning a PrEP regimen. Gender differences may exist in the pharmacology and metabolism of NNRTIs. One study of women and men receiving indinavir, zidovudine, and lamivudine found that lamivudine concentrations were higher in women (Anderson, et al., 2010). Another study of

tenofovir plus lamivudine with either nevirapine or lopinavir/ritonavir observed lamivudine/tenofovir concentrations that were higher in women than in men as well (Anderson, et al.,2010). Despite these studies being relatively small, the findings bring up some safety concerns and future research is warranted. If it is found through further research that gender or racial differences exists in drug metabolism and concentration, formal PrEP recommendations would need to be formulated to reflect these differences.

### **2.2.2 The Global iPrEX Clinical Trial**

In December of 2010, the findings from the Global iPrEX study, a clinical trial evaluating the efficacy of oral HIV pre-exposure prophylaxis sex within transgendered women and MSM was published. The study took place at 11 different sites in Ecuador, Peru, South Africa, Brazil, Thailand, and the US. The US had two of the 11 sites in Boston, MA and San Francisco, CA. Truvada was chosen as the study drug because of the protective effect against HIV in its two active drugs, emtricitabine and tenofovir in mice transplanted with human immune cells and non-human primates (Grant, et al., 2010). From all of the study sites, 4,905 participants were screened for participation in the study with a total of 2,499 enrolled in the study. Participation in the study was contingent on the participant being over the age of 18, being born as a male, HIV negative, and at high risk for HIV infection. Some of the parameters that were used to access high risk for HIV infection were unprotected anal intercourse with a partner of unknown positive HIV status within 6 months prior to screening, unprotected receptive anal intercourse within 12 weeks prior to screening, and or transactional sex. 59% of the participants in the treatment arm and 60% in the placebo arm reported having URAI within 12 weeks of screening which has been described as very high risk for HIV infection (Grant, et al., 2010). Participants who were at high

risk for Hepatitis B infection (HBV) were offered the vaccine with 94% acceptability (Grant, et al., 2010). 13 individuals were enrolled with chronic HBV infection and any acute HBV infections were treated. Excluding HIV positive individuals from participating in the study was critical to the design because including an HIV positive individual would negatively affect the internal validity and generalizability of the results. Any individuals who came up positive during the treatment process and during the clinical trial were linked into care and treatment.

The iPrEX trial design was a randomized, controlled, double blind trial meaning that participants were randomly assigned to either the treatment group (Truvada) or placebo group. Neither the participants or the researchers were aware of which arm of the study in which they were included. Follow up varied by participant however, the maximum time that a participant was followed up was 2.8 years. From baseline to follow up, all participants received a range of prevention services during every scheduled visit which included diagnoses and treatment of symptomatic sexually transmitted infections, rapid HIV testing, risk reduction counseling, and condoms. It was stressed to the participants to continue conventional preventative measures against HIV infection such as condom use since they were unaware of the specific study arm. This aspect of the study design addresses possible risk compensation behaviors that could arise in some participants such as if they presumed they were in the treatment arm and discontinued condom use. During follow up intervals, participants received the diagnoses and treatment of asymptomatic sexually transmitted infections, pill distribution and count, medical adherence counseling, and medical history. The comprehensive prevention package that iPrEX participants received was important to the integrity, ethics, and efficacy of the trial however, efficacy does not equate to real world effectiveness.

A smaller percentage of the iPrEX participants in either the placebo and treatment arm were enrolled at the US sites. Boston had 44(3%) participants in the treatment arm and 44(4%) participants in the placebo or 7% of the entire cohort. The San Francisco site enrolled 60 participants in both study arms for a participation rate of 5% in each arm and 10% of the cohort. Overall just 8% of participants in the treatment arm and 9% in the placebo arm were from the US. When the demographic of the participants are examined, a majority of the iPrEX participants were Hispanic, accounting for 72% and 73% in the treatment and placebo arms respectively. Blacks had relatively low recruitment and participation in the iPrEX trial accounting for 9% in the treatment arm and 8% in the placebo arm.

Among MSM, when subjects in the treatment group took once, daily oral Truvada, there was a 44% reduction in HIV infection as compared to the control group (Grant,et al., 2010). Throughout the entire trial, there were 100 HIV infections, 36 in the Truvada arm and 64 in the placebo arm. Variance in efficacy of prophylaxis among participants in the treatment group was monitored through medical adherence or rate of pill use which was recorded based on pill counts, self-reports, and distribution records at 81% of visits where efficacy was 50% (Grant, et al., 2010). Longer follow up and the rate of pill use did not result in significant changes in efficacy however, it is important to note that efficacy was higher (58%) in participants who reported having URAI at least 12 weeks prior to screening in comparison to those who did not (Grant, et al., 2010). These results show that efficacy was higher for the individuals that were of higher risk for HIV infection. The observed difference may not be attributable to just the drug but other factors such as risk reduction. Adherence appeared to have a positive impact on efficacy with 73% reduction in infections among participants with pill use greater than 90% (Grant, et al.,

2010). Similar to HIV treatment, medical adherence is vital to drug effectiveness and protective benefit, therefore it is not surprising that the results from the iPrEX trial corroborated that.

Some of the concerns of conducting the trial were possible onset of drug resistance, drug absorption and prophylactic effect, safety, and differences in efficacy amongst participants. There were no observed differences in efficacy between the treatment and control groups based off of region, race or ethnicity, male circumcision, educational attainment, alcohol use or age (Grant, et al., 2010). In other words, the variables and factors mentioned did not confound the efficacy of the pre-exposure prophylaxis. These findings are significant for the external validity of the results and the generalizability to MSM regardless of certain demographic factors. Drug absorption was essential to the efficacy of the study results as well. When participants were screened for the drug, an assay was used that could detect whether dosing had taken place within 14 days of the screening. Out of 34 of the participants in the treatment arm who became HIV positive during the course of the study, 3 of the participants had detectable levels of at least either emtricitabine or tenofovir (Grant, et al., 2010). Once again the issue of adherence is brought up. PrEP cannot be used as a “morning after” pill, efficacy and higher levels of drug absorption can be achieved by adherence to daily dosing requirements. It is assumed that the individuals in the treatment arm who had detectable drug levels may have had poor adherence to the regimen which lowered prophylactic effect. Another concern of the iPrEX trial was participant risk compensation which is engaging in unsafe sexual behaviors while on treatment. The study found that high risk behavior decreased significantly after enrollment and remained lower than baseline throughout the trial, condom use increased, and UAI decreased (Grant, et al., 2010). Concerns of drug resistance to either of the drug components in Truvada were also a concern in the iPrEX study. Each participant who was determined to be HIV seropositive was



screened for resistance to emtricitabine and tenofovir. Out of 100 infections that occurred in the treatment and placebo arms of the study, no drug resistance from either component was detected nor was there any delay of seroconversion amongst the participants in the treatment group (Grant, et al., 2010). Other than minor side effects such as nausea, there were 41 cases of elevated serum creatine, with an additional 2 elevations in creatine level for a total of 43 adverse events (Grant, et al.,2010). It is essential that drug safety was ensured for the participants and anyone using Truvada. With Truvada being in the NRTI class, having high acceptability, efficacy, and low dosing, it would be a major setback in treatment options if drug resistance were to arise.

Despite some of the promising results of the iPrEX trial, there are some limitations that should be discussed. No biomarker exists for the minimum level of drug absorption for prophylactic effect. Further research must be conducted into how much drug must be present for effectiveness. In spite of all of the prevention services that were offered to participants, the feasibility and practicality of replicating these findings among high risk populations in a real world setting is brought into question. The iPrEX study showed that some commonly used variables such as age, race, and region did not affect the efficacy of the study but it has yet to be seen if these findings will be replicated in other studies. Further research must be conducted on the acceptability and adherence of PrEP among high risk populations as well as any long term effects that may arise from PrEP use.

### **2.2.3 Other MSM PrEP Trials**

The iPrEX trial was the basis for which current recommendations for PrEP have been established. It is important to note other PrEP trials that have been conducted or planned among

MSM populations. In 2010, the CDC completed a U.S. Tenofovir Extended Safety Trial to look at the safety of daily oral PrEP amongst MSM. The sites were located in Atlanta, Boston, and San Francisco. 400 HIV negative MSM were recruited based on self-reports of UAI within 12 months prior to screening. The trial was double blind trial and participants were randomized to one of four study arms. In two of the arms, participants received either Tenofovir or a placebo immediately following enrollment. In the other two arms, participants received Tenofovir or a placebo 9 months after enrollment. The results of the trial have yet to be published however, preliminary findings suggests that there were no significant differences in sexual risk behaviors between the two study arms at enrollment and the two arms 9 months after enrollment and no adverse events were reported amongst participants (CDC, 2010). The CDC trial was implemented to evaluate the effectiveness of PrEP, not efficacy as was evaluated in the iPrEX study. Despite no major differences in risk compensation between the study arms, participants were provided with a prevention package which included STD testing and treatment, HIV counseling and education, and condoms throughout the study.

The HIV Prevention Trials Network (HPTN) 067 began in late 2011 and recruited 180 MSM to evaluate PrEP adherence. Participants were randomized to one of several treatment arms; Truvada will be taken either daily, twice a week and after sex, and before and after sex (AVAC, 2011). The NEXT-PrEP study or HPTN 069 is scheduled to begin in early 2012 and will have 400 MSM participants and evaluate the safety and tolerability of daily oral Maraviroc or Maraviroc in combination with Tenofovir or Truvada. This trial is being conducted using Maraviroc as a study drug because some evidence points to that Maraviroc may be safer than and just as effective as Truvada. The iPrEX Open Label Extension trial is scheduled to begin in 2013. This trial will evaluate the safety and adherence of once a daily oral Truvada amongst iPrEX

participants (AVAC, 2011). PrEP demonstration projects across the U.S. are being planned with one project at the University of California at Francisco already being awarded funding from the National Institutes of Health in which 300 participants will be recruited from sites in San Francisco and Miami. The study is intended to evaluate monitoring and programming for PrEP (AVAC, 2011). The Microbicide Trials Network (MTN) 017 study is a phase II clinical trial that is to be conducted starting in 2012 recruiting 120 MSM from sites in Peru, South Africa, Thailand, and the US (AVAC, 2011). The MTN study will not only be evaluating the safety, adherence, and drug detection in relevant body fluids from oral PrEP, but from microbicides as well. Participants will be required to take oral Truvada depending on the arm of the study randomization. The ANRS IPERGAY study is scheduled to begin in 2014 at sites in Canada, France, and other European countries to be announced. In this study of MSM, the safety and efficacy of Truvada taken intermittently and before and after sex will be evaluated (AVAC, 2011). There are many PrEP trials and studies which are ongoing or planned for the future. There is little information on the efficacy of PrEP amongst MSM aside from the iPrEX trial. In order to ascertain the effectiveness and practicality of PrEP use among MSM of different races/ethnicities and regions, more demonstration projects and research is needed. In the meantime, we must wait for the ongoing studies to be completed so that many factors around PrEP such as efficacy, acceptability, adherence, and risk compensation can be evaluated contribute to the evidence base of the iPrEX results. From the research that is conducted, formal and tailored recommendations can be made for PrEP use among MSM.

#### **2.2.4 PrEP Trials in Other High Risk Populations**

PrEP trials have not only been conducted and planned for MSM, but other high risk populations as well including intravenous drug users (IDUs) and heterosexual women. Even though results among these populations cannot be extrapolated to MSM, they are important to note. The Bangkok Tenofovir Study is a CDC led clinical trial that recruited 2,400 IDUs in Thailand and observed the safety and efficacy of daily oral Tenofovir. Results and publications from this study are pending. To reiterate what was stated earlier, it was shown that (emtricitabine + tenofovir) or Truvada was proven to be more efficacious than either medication alone. If Tenofovir is proven to be efficacious amongst this population of IDUs in Thailand, the CDC will further assist in providing access for participants to PrEP. The TDF2 study was conducted in 1,200 young heterosexual men and women living in Botswana in which participants received daily oral Truvada. The purpose of the study was to evaluate the efficacy, safety, and adherence among participants; the study has concluded and results show that daily oral Truvada reduced the risk of HIV infection by an average of 62.6% in young heterosexual men and women (AVAC, 2011). Another PrEP study was the Partners PrEP study which recruited 4,700 serodiscordant heterosexual couples in Kenya and Uganda to evaluate the safety and efficacy of daily oral Tenofovir and Truvada. An HIV discordant couple is a couple in which one individual is HIV infected and the other individual is HIV negative. In the Partners PrEP study, the HIV negative partners received either the daily oral Truvada or Tenofovir. Preliminary results from the Partners PrEP study showed that daily oral Tenofovir led to a 62% reduction in HIV infections as compared to a 73% reduction in infections from daily oral Truvada (AVAC, 2011). A continuation/follow up phase III trial to the Partners PrEP study is scheduled to begin in 2013. Participants who were randomized into the original treatment arms will continue daily oral

prophylaxis. Participants who were originally randomized into the placebo arm will be randomized to either the daily oral Tenofovir or the daily oral Truvada. The VOICE study recruited 5,000 heterosexual women in South Africa, Malawi, Uganda, Zambia, and Zimbabwe who were to be a part of different study arms. Treatment arms included participants who received daily oral Tenofovir, daily oral Truvada, and daily Tenofovir gel microbicide. Due to there being no proven benefit from daily oral Tenofovir, that arm of the study was discontinued with the study going forward with the other two treatment arms (AVAC, 2011).

The FEM-PrEP trial which was composed of 3,900 heterosexual women recruited from sites in Kenya, Malawi, South Africa, Tanzania, and Zambia. The FEM-PrEP trial was similar in iPrEX in that the safety and efficacy of oral daily Truvada was to be evaluated. The FEM-PrEP trial was discontinued because during the trial it was shown that there was no observed benefit from the women enrolled in the treatment arm taking daily oral Truvada in comparison to participants in the placebo arm (AVAC, 2011).

### **2.2.5 MSM PrEP Knowledge, Perceptions, and Acceptance**

In conducting the literature search, it was important to find any behavioral analysis conducted on MSM knowledge and attitudes on PrEP in addition to the actual biomedical interventions. There were few published articles found in the literature which addressed MSM knowledge and attitudes of PrEP. Limited information exists in the literature on the knowledge and attitudes that Black MSM have on PrEP. Studies which have retained Black MSM had relatively low amounts of participants, similar to the Global iPrEX study. One study recruited MSM from two New York City bath houses and recruited 54 MSM. 63% of the survey respondents reported having unprotected sex with another male within the previous 90 days and

7% reported having unprotected sex with a known HIV positive male partner. Only 36% of the survey respondents reported awareness of non-occupational post exposure prophylaxis (nPEP) or PrEP (Mehta, et al., 2011). The study found awareness of PrEP and nPEP regardless of race/ethnicity, educational attainment, and other factors was correlated with having a primary care physician who was aware of their sexual behaviors (Mehta, et al., 2011).

Irvin, et al. (2011), conducted an online survey of MSM recruited from Facebook and BlackGayChat and which had a participant demographic of 73% White, 7% African American, and 12% Hispanic. In this particular survey, participants were educated about the efficacy of PrEP and then asked about their perceived sexual behaviors if they were to use or not use PrEP. Out of 1,155 respondents, the mean age was 33 years old and it was concluded that 75% of the respondents would continue to use condoms regardless if they were on PrEP or not (Irvin, et al., 2011). Despite the significant number of survey respondents who would continue safer sexual behaviors, 39% of participants reported less perceived risk of HIV infection from URAI on PrEP. The implications of these numbers are that if MSM have lower perceived risks of HIV infection while on PrEP they may be more likely to engage in higher risk sexual behaviors for HIV transmission. Conversely, Brooks et al., (2011) recruited 25 HIV negative MSM who were a part of a serodiscordant relationship and evaluate their perceptions on PrEP. In which 60% of the respondents indicated likelihood of discontinuing condom use with their HIV positive partner if they were on PrEP. Despite the relatively small sample size, these findings provide some guidance on how PrEP should be used amongst serodiscordant couples. According to the results, HIV negative partners in a serodiscordant couple would be likely to engage in high risk sexual behaviors and unprotected sex while on PrEP which is not the intended purpose of PrEP. A sample of 180 HIV negative MSM were recruited in New York City which found that 70% of

the respondents would use PrEP contingent upon 80% efficacy in preventing HIV infection and among respondents who reported that they would use PrEP, 35% reported a reduction in condom use (Golub et al., 2010). At the time of publication, the Global iPrEx results had not yet been released which showed 44% PrEP efficacy in reduction of HIV infection. It is possible that had respondents known PrEP efficacy at the time of the study, less individuals would be likely to use PrEP.

Another online survey on likeliness and knowledge of PrEP was conducted by Sullivan et al. (2011), recruited 1,333 self-identified HIV negative MSM, 71% which were white, 13% Hispanic, and 8% black. The survey found that 29% of the participants had not heard of the iPrEX study results and that nonwhite participants (71-78%) were more likely to use PrEP to as opposed to only 64% of white participants (Sullivan, et al., 2011). Whiteside, et al. (2011), recruited participants for a survey on PrEP from a STD clinic in South Carolina, which is located in a region of the country heavily affected by HIV/AIDS. 89% of the participants were African American and 56% male; 8% of the participants were either homosexual or bisexual. It was undetermined whether or not these participants were MSM from the analysis. Only 9.4% of the 358 respondents reported having any knowledge of PrEP and when participants were asked to rate their difficulty in being able to use condoms and take a daily pill to prevent HIV infection, 38% of the participants strongly agreed that they would be capable of doing so and 32% agreed that they would have some difficulty (Whiteside, et al., 2011). Despite there being a smaller sample size of homosexuals in the sample population, homosexuals were significantly more likely to report awareness of PrEP (Whiteside, et al., 2011). These findings may have implications on how information about PrEP is disseminated among different populations.

Barash and Golden conducted a survey on PrEP amongst MSM at a gay pride event in Seattle, Washington and found that 44% of the respondents would take PrEP daily if reduced their risk of infection. There were no observed differences in sexual risk behaviors and PrEP use (Barash & Golden, 2010). A study conducted at the Fenway Institute in Boston, Massachusetts used peer recruitment and subsequent incentives for a survey and data collection on PrEP awareness. 227 participants were recruited with a mean age of 40 and 44% of the participants being Black. In the informed consent process of the survey, participants were provided a statement on what PrEP was and its intended use. The study concluded that 19% of the respondents had ever heard of PrEP and that lower educational attainment, no individual costs, and minimal side effects correlated with higher probability of using PrEP to reduce risk of HIV infection (Mimiaga, et al., 2009). A survey of 1819 MSM in California found that only 16% of the respondents had PrEP awareness and unprotected sex and sex under the influence of a drug were positively associated with PrEP awareness (Liu, et al., 2008). Out of the 4 survey sites, African American participation ranged from 3-8% of the sample population and only 12% of the African American respondents reported PrEP awareness (Liu, et al., 2008).

Several examples have been provided from the literature which surveyed MSM knowledge, attitudes, and perceptions on PrEP. Despite the wealth of information that these studies provide, they are not without limitations. Most of these surveys were conducted prior to the release of the iPrEX results and PrEP efficacy among MSM. Also, a majority of these surveys have few Black MSM in the sample, less than the incidence and prevalence of HIV being observed in Black MSM. Limited research exist post PrEP efficacy and/or recruits a larger sample of Black MSM on their knowledge and likeliness to use PrEP as a method to prevent HIV infection. The HPTN 061, Broadening the Reach of Testing, Health Education, Resources



and Services for Black MSM (BROTHERS) study enrolled Black MSM from sites in Boston, Atlanta, Washington DC, New York City, Los Angeles, and San Francisco. The study population was diverse in demographic factors such as educational attainment, recruited both HIV positive and negative participants and the mean age was 39. Only 9.5% of the sample had knowledge of PrEP with knowledge ranging from 7.0% in Los Angeles to 14.5% in New York City (HIV Prevention Trials Network, 2011). Despite overall PrEP knowledge being low in the sample, these observed regional differences may need to be addressed in terms of the dissemination of health information. Publications from results of the BROTHERS study have yet to be released. Prior to PrEP efficacy studies, information exist that MSM have been using PrEP via self-medication from an HIV positive person without a prescription. MSM were surveyed at minority gay pride events in 2004 in Oakland, CA, Detroit, MI, Baltimore, MD, and San Francisco, CA on their knowledge of PrEP and if they had ever used PrEP. The study recruited 1041 people, 43% who were Black; the study found that in the overall sample the knowledge of PrEP was 25% with Black MSM being most likely to ever report using PrEP (Kellerman, et al., 2006). The same study at minority gay pride events was replicated in 2005 and 2006 yielding similar results to the 2004 study. Participants were recruited from events in San Francisco, CA, Jackson, MS, Charlotte, NC, St. Louis, MO, Washington DC, Chicago, IL, and Detroit, MI. 78% of the entire sample which included HIV positive and negative individuals was Black. Among the sample of 356 self-reported HIV negative individuals who took the survey PrEP and PEP knowledge was 19.7% among the African American participants (Voetsch, et al., 2006). Prior studies have been conducted that recruited a majority of MSM to determine knowledge, attitudes, and likeliness to use PrEP. Despite these were conducted pre PrEP efficacy and used PrEP and PEP concurrently during data collection and analysis.

## **2.2.6 The Internet as a Portal for HIV Research and Intervention**

The Internet has the potential to be a cost effective method of HIV education, research, and health promotion. Data collected from the Pew Research Center suggests that 79% of Americans have internet access and 83% have used the internet at least once to obtain health related information (Glickman, et al., 2012). The current study rationale for using the internet as the setting and for recruitment was the perceived benefits and low difficulty. Prior evidence also suggests that online interventions have been effective in reducing risk behaviors such as smoking cessation and obesity (Chiasson, et al., 2010).

MSM seek sex online more frequently than other sexual groups and evidence suggests that MSM who seek sex online report more sexual partners, casual sex, and unprotected anal intercourse (Chiasson, et al., 2010). The internet is a portal for the transmission of HIV and provides opportunity for intervention among high risk MSM for research and education. The internet can facilitate HIV prevention initiatives and linkage to testing, treatment, and health information. MSM chat room intervention with health educators have a positive impact of internet outreach on HIV testing, risk reduction, education, and social support (Rhodes, 2004). The Student Health Action Coalition Against HIV (SHAC-HIV) at the University of North Carolina at Chapel Hill used online outreach to link high risk MSM to testing with a 2.3% positivity rate (Feldacker, et al., 2010). With the current HIV epidemiological figures suggesting that 1 in 5 individuals in the US being HIV positive and unaware of their status, online outreach has the potential to find undiagnosed cases. HIV prevention must adapt to the dynamics of the epidemic which means that the internet and other technologies must be utilized for prevention.

The internet has the opportunity to reach marginalized MSM. Bowen, et al. (2008), conducted a randomized control trial as an online intervention resulting in acceptability among MSM and efficacy in risk reduction among rural MSM. The presence of Black MSM on hookup and social networking sites provides an opportunity to this population in novel and untraditional ways. With the input of Black MSM, HEALTHMPOWERMENT.ORG was created as a tailored and culturally appropriate online intervention for young Black MSM and serves as a model for future initiatives (Hightow-Weidman, et al., 2011). Future HIV prevention initiatives must utilize the potential that the internet and other technologies such as cell phone applications and text messaging provide in accessing at risk populations.

### **3.0 METHODOLOGY**

#### **3.1 CURRENT STUDY**

The objective of the current study was to ascertain the knowledge, attitudes, and beliefs of Black MSM on PrEP as well as self-perceived susceptibility to HIV infection. The current study is approved by the University of Pittsburgh Institutional Review Board, study number; TPRO11110431. Participants were recruited for an online survey between the dates of January 13<sup>th</sup>, 2012 and January 30<sup>th</sup> 2012. The survey link also remained open during this period. There were a few questions which were essential to data analysis; what is your knowledge of PrEP? Currently, would you take a pill daily to reduce your risk of HIV infection? What is your risk of HIV/STD infection? The rationale for the current study was developed during the author's master's practicum at the Pittsburgh AIDS Task Force working with the Man 2 Man Project (M2M), a behavioral intervention addressing substance use and high risk sexual behaviors in MSM.

## 3.2 METHODS

A quantitative method of survey was used in the analysis of the current study. Survey participants were allowed to answer some of the questions open ended yet many did not. A survey was chosen as the instrument of data collection for several reasons. First, cross sectional surveys have shown to be effective in capturing a snapshot and determining very important health information from populations. Surveys are less invasive and usually less time consuming than other methodologies which can result in increased participation and higher retention rates in research. Lastly, due to limited fiscal resources the use of a survey was cost effective, practical, and appropriate for the current study.

Wording of the survey was essential for readability and cultural relevance of the questions. Therefore the author used prior experiences with the MSM population to word questions appropriately. The survey was not tested for reliability and validity. Individuals were consulted who were either MSM or conducting HIV prevention research for technical assistance. Per the suggestion of Jonathon Baker of the Microbicide Trials Network, a Likert scale was used on many of the survey questions. A Likert scale of 1-10 was used on the survey to give respondents a broader range of options in answering the survey questions. It was appropriate to use a Likert scale for the survey given that a majority of the questions were of a participant's perception of what was being asked.

Ultimately, the author had the final decision of how survey questions were worded and which questions were on the survey. Many of the suggestions made by consultants were taken into consideration in the survey development. Prior studies that have been conducted provided formal explanations of PrEP prior to asking respondents knowledge and awareness of PrEP.

Questions were formulated and structured so respondents were asked of their knowledge on PrEP after they were asked if they would take a daily pill to reduce their risk of HIV infection. More information on the wording and structure of the survey may be found in Appendix A.

### **3.2.1 Setting**

The surveys were disseminated online using the social networking sites Twitter and Facebook. Social networking sites have the potential to draw large survey samples as well as disseminate health information. Social networking outreach and marketing is currently being used by many entities in HIV prevention because of the increasing number of people who are present on these sites. An estimated 75% of Americans aged 18-29 are using social networking which corroborates the epidemiology of HIV infection and high risk sexual behaviors (Chiasson, et al., 2010). Constructing and disseminating a survey instrument online was relatively easy and facilitated optimal sampling and participant anonymity.

### **3.2.2 Eligibility**

Eligibility in the current study was contingent upon participant self-reported response of being over the age of 18, HIV negative or unaware of HIV status, Black/African American, and MSM. A stratified sample was selected in order to collect the most information possible about the sample population. As a consequence of strict eligibility requirements, results may not be

generalized to other populations. Despite teenagers over the age of 18 being able to give consent to an HIV test, they were excluded from the sample because of the online setting and to prevent obstacles from obtaining informed parental consent. Only MSM were allowed to take the study since the iPrEX efficacy trials were conducted among MSM thus external validity is contingent amongst MSM populations. HIV positive individuals were excluded from the sample since many of the questions on the survey were about pre-exposure prophylaxis of HIV in HIV negative individuals. Including HIV positive individuals in the sample may have introduced confounding and biases into the sample population subsequently affecting external and internal validity.

### **3.2.3 Recruitment**

The author wanted to recruit from the MSM hookup websites BlackGayChatLive (BGCLive) and Adam4Adam and was unable to do that because of costs. This is a possible limitation of the sample potentially because a larger pool of respondents could have been achieved. Participation for the survey was solicited with a script which included an explanation of survey as a tool for research, time required to complete, respondent anonymity, and minimal risks. The script can be found in appendix B. Social networking sites provide the opportunity for the dissemination of information. The author being a part of the Black MSM community utilized a following of members of Facebook and Twitter to recruit for and disseminate the survey. The survey script along with the embedded link was sent to an initial wave of individuals whom the author knew were MSM but did not know personally. These individuals were solicited for participation in the study as well as to recruit other participants. At their discretion, participants subsequently posted the survey link on their profile and forwarded to their friends. Since the survey was anonymous, the author retains no information on which participants actually

completed the survey or actively recruited other participants. To ensure that one individual would not complete the survey multiple times, IP addresses were checked for duplication during data analysis in which none were found.

### **3.2.4 Consent**

Prior to beginning the survey, respondents provided consent to taking the survey and answered the screening questions correctly. Participants were provided a script which included statements that the survey was for research, took approximately 5 minutes to complete, explanation of risks to the respondent, and notified respondents that they had no obligation to complete the survey. Participants were also notified that the survey was anonymous and that no personally identifiable information would be collected. A total of 2 participants did not consent to the survey with others dropping out before survey completion. Participants who were ineligible for the study were forwarded to a disqualification page where they were provided access to information on PrEP, HIV testing, and other resources including my contact information.

### **3.2.5 Incentive**

There was no compensation or incentive for participants to complete the survey. There were limited resources to provide respondents with incentives and providing incentives may have introduced bias into the study. The lack of an incentive did not appear to have an effect on participation and it is likely that respondents participated because of the relatively ease of



questions, the amount of time needed to complete the survey, and the possible utility of the research.

### **3.2.6 Data Collection**

The author created an account with Survey Monkey, a secure website for survey development and dissemination and it also provides encrypted data storage capabilities. The data was monitored daily throughout the course of the study to observe participation and to assure participant confidentiality. Throughout the course of the study there were no breaches in confidentiality. The author had sole access to the Survey Monkey account and the data which was accessed from an encrypted personal laptop computer. Upon the completion of the study, the survey was closed, preventing the collection of any further responses. All of the data was compressed in a excel zip file and saved a personal computer. Data was integrated from the excel file into Software Package for the Social Sciences (SPSS) software for analysis. After IP addresses were scanned for duplication, they were deleted from the file spreadsheet.

### **3.2.7 Confidentiality**

Ensuring confidentiality was paramount to the survey participation and retention. Participants were asked personal information such as HIV status and sexual history. No personally identifiable information collected during any section of the survey. Several survey questions allowed open ended responses which could have been an opportunity for confidentiality breaches. Participants were informed of their anonymity in the survey in both the recruitment scripts and informed consent. No personal identifiers were left by participants on the

survey and if they had, participants were notified in the informed consent process that those responses would have been deleted. Participant Feedback

Per IRB requirements, the author's personal contact information was placed on the survey so respondents could forward all concerns to the author. There was one instance noted when a participant was very upset with the survey questions. The participant contacted the author via email and stated that he felt the survey questions were very offensive. The author promptly responded to the respondent apologizing to the participant if he felt the survey questions was offensive to him. The author also reiterated to the participant that he did not have any obligation to complete the survey and could discontinue you at any time. Follow up with the participant thus ended and the anonymity of the participant was retained.

### **3.2.8 Data Analysis**

All of the survey data that was collected on Survey Monkey was downloaded from the server and formatted into a Microsoft Excel spreadsheet. The data was then cleaned in preparation for transport to SPSS. Participant responses that were ineligible from the survey were deleted from the spreadsheet to be used for analysis as well as participants who did not complete the survey. These responses were deleted because both the dependent and independent variable(s) were unable to be ascertained for analysis. Age responses were recorded as separate questions on the Survey Monkey server; therefore a new variable and column for participant age was created to facilitate data translation into SPSS. Survey questions were also coded into variable names so that it could be formatted in a SPSS spreadsheet and to facilitate analysis.

### **3.2.9 Limitations**

The current study has some limitations which should be mentioned. Firstly, the study is a sample of Black/African American MSM, thus the results from the study may not be generalizable to MSM of other races and ethnicities. Secondly, all MSM are not either online or have accounts on Facebook and Twitter, therefore a percentage of MSM were unable to be reached from the recruitment methods used. Participants were also asked questions about past behaviors which they may have under or overestimated, resulting in the introduction of recall bias into the sample. The survey instrument was not tested for reliability and validity and would need further refinement and testing for future dissemination. Respondents were not recruited from a specific geographic were participants asked about their residence. This was done in attempt by the author to limit bias as much as possible and to protect the participant confidentiality. Not collecting geographic location is a limitation and may affect external validity. However, results from the Global iPrEX trial showed that geographic location did not confound the study results. The epidemiology shows that Black MSM in the United States are currently the highest at risk group for HIV infection, therefore the pool was drawn from this population.

## **4.0 RESULTS**

### **4.1 SAMPLE**

The original, raw sample included individuals who were ineligible for the survey however, it is important to note the self-reported HIV status of the participants. Out of 156 respondents who responded on HIV status, 32 or 20.5% reported being HIV positive. This is an important finding because it supports the HIV epidemiology that 1 in 5 MSM are HIV positive. After eligibility was determined, a total of 118 participants began the survey, with 99 participants completing the survey with a response rate of 83.9%. The table below provides the age of the sample. 81.8 % of the sample was between the ages of 18-30 years old. This may have positive implications on the external validity of the results because currently Black MSM age 18-29 has the highest disparity of HIV incidence. It is possible that older MSM were not heavily represented in the sample because they are not on Facebook and Twitter and were not reached through recruitment efforts thus weakening external validity of their results.

**Table 1.** Participant Age

	Frequency	Percent	Cumulative Percent
18 - 24	35	35.4	35.4
25 - 30	46	46.5	81.8
31 - 40	13	13.1	94.9
41 - 50	4	4.0	99.0
50+	1	1.0	100.0
Total	99	100.0	

## 4.2 PREP

One of the main objectives of the current study was to ascertain whether Black MSM would use PrEP to risk their risk of HIV infection and to assess their knowledge of PrEP. Table 2 represents a cross tabulation of the respondent knowledge and acceptance of PrEP. Acceptance was ascertained from the survey question “Currently, if I could reduce my risk from getting HIV by taking a pill daily, I would.” The responses were logged on a 1-10 scale and for analysis purposes consolidated into a variable parameter set by the author. For the question on PrEP acceptance 1-2 equaled strong disagreement with the question, 3-4 (somewhat disagree), 5-6 (neither agree nor disagree). (7-8) somewhat agree), and 9-10 (strongly agree). Since there were fewer respondents who reported moderate knowledge of PrEP, 1-3 equaled no knowledge of PrEP, 4-6 (little), 7-8, (moderate), and 9-10 (great). Table 2 shows that 56.4% of the sample at a 95% confidence interval of 9.77 (46.63- 66.16) reported having little or no knowledge of PrEP yet would use PrEP to reduce their risk of HIV infection. On the other hand, of the 18.2% of the sample that had moderate or great knowledge of PrEP, 10% of these respondents reported that

they were either unsure or in some level of disagreement of using PrEP to reduce risk of HIV infection.

**Table 2. PrEP Acceptance and Knowledge**

		PrEP Knowledge, % (n=99)				Total
		None	Little	Moderate	Great	
PrEP Acceptance	Strongly Disagree	4 (4.0)	2 (2.00)	2 (2.00)	1 (1.0)	9 (9.1)
	Somewhat Disagree	2 (2.0)	0 (0.0)	0 (0.0)	1 (1.0)	3 (3.0)
	Unsure	9 (9.1)	6 (6.0)	3 (3.0)	3 (3.0)	21 (21.2)
	Somewhat Agree	7 (7.0)	11 (11.1)	1 (1.0)	1 (1.0)	20 (20.2)
	Strongly Agree	31 (31.3)	9 (7.0)	3 (3.0)	3 (3.0)	46 (46.5)
<b>Total</b>		<b>53 (53.5)</b>	<b>28 (28.3)</b>	<b>9 (9.1)</b>	<b>9 (9.1)</b>	<b>99 (100)</b>

\*Percentages are in parentheses

Participants were asked if they were willing to pay full out of pocket costs for PrEP to prevent them from getting HIV. Truvada is thought to cost about \$36 a day or \$13,000 annually and it was these figures that were used in the survey question. 49.5% of the sample stated that they were strongly against paying out of pocket costs for PrEP while another 37.1% were unsure.

**Table 3. PrEP Costs**

		Frequency	Percent	Cumulative Percent
	Strongly Disagree	49	7.1	49.5
	Somewhat Disagree	9	3.0	58.6
	Unsure	30	2.0	86.9
	Somewhat Agree	4	1.0	90.9
	Strongly Agree	9	8.1	100.0
	<b>Total</b>	<b>99</b>	<b>100.0</b>	

### 4.3 RISK BEHAVIORS

In order to ascertain respondent self-perceived susceptibility to HIV infection, it was hypothesized that a respondents lower self-perceived susceptibility to HIV and had little or no knowledge on PrEP would result in lower PrEP acceptance. Table 4 below shows the cross tabulation of respondent self-perceived susceptibility and condom use. 58.6% of the sample strongly agreed that they used condoms during anal intercourse whether insertive or receptive. 43.4% of the sample felt that their susceptibility to HIV infection was either no or low risk however, 72.1% or 31 respondents from this stratified population strongly agreed that they use condoms during anal intercourse. Participants were also allowed to enter non-applicable and leave an open ended response on this question. Four participants answered N/A and their responses were as followed:

“I am a virgin, 20 years of virginity”

“I’ve only had anal sex with one person for the past 3 years, monogamous relationship in that regard”

“I typically use a condom when having sex, however, with my current, long-term partner, I don’t”

“Not all of the time”

These numbers reveal that respondents already possess some level of information on HIV prevention and are aware that condoms are an effective primary prevention method.

**Table 4. Self-Perceived Susceptibility for HIV Infection and Condom Use**

		Condom Use					Total
		Strongly Disagree	Somewhat Disagree	Unsure	Somewhat Agree	Strongly Agree	
Self - Perceived Risk	No Risk	1	0	0	0	12	5
	Small	3	4	1	3	19	26
	Unsure	1	2	1	4	10	8
	Moderate	1	3	0	7	8	14
	Great	0	0	2	4	9	10
<b>Total</b>		<b>6</b>	<b>9</b>	<b>4</b>	<b>18</b>	<b>58</b>	<b>99</b>

HIV testing is important to prevention and would be vital to implementing PrEP as a prevention strategy. Participants were asked the degree to which they agreed with the statement “I get tested for Human Immunodeficiency Virus (HIV) at least once or twice a year.” 58.6% of the sample either strongly or somewhat agreed that they get tested for HIV at least once a year. 16.2% of the sample strongly or somewhat disagreed that they were tested at least once or twice a year for HIV. While not a significant percentage of the sample, individuals in this group may be engaging in riskier sexual behaviors and/or are unaware of their HIV infection. Another explanation for individuals who are not tested regularly could be an issue of access. More information should be gathered on the reasons why MSM are tested or not.

**Table 5. Annual HIV Testing**

	Frequency	Percent	Cumulative Percent
Strongly Disagree	12	4.0	12.1
Somewhat Disagree	4	1.0	16.2
Unsure	7	2.0	23.2
Somewhat Agree	18	1.0	41.4
Strongly Agree	58	51.5	100.0
<b>Total</b>	<b>99</b>	<b>100.0</b>	



#### 4.4 ANALYSIS OF VARIANCE

To ascertain the relationship of different independent variables measured on the dependent variable of PrEP acceptance, the author chose a univariate regression analysis. In each model, I added more independent variables and it was determined if the variable was statistically significant and how much variance was explained in the relationship of the independent variables on the dependent variable. If an independent variable was statistically insignificant in all of the models in which it was included then it was removed from the analysis in the 5<sup>th</sup> model. Condom use, substance use influencing high risk sexual behaviors, HIV testing, and concern with HIV were all statistically insignificant in each model they were included thus having minimum influence on whether or not a respondent would take a daily pill to reduce their risk of HIV infection. Age appeared to be the strongest indicator across all models of PrEP acceptance. PrEP costs were more statistically significant than age in the two models in which it was included in the analysis with age. Model 4, which included all of the independent variables observed had an r-squared value of 0.387, thus explained 38.7% of the variance between the independent variables and the dependent variable.

**Table 6. Regression Analysis of Covariates Influencing PrEP Acceptance**

<b>Independent Variables</b>	<b>Model 1</b>	<b>Model 2</b>	<b>Model 3</b>	<b>Model 4</b>	<b>Model 5</b>
<b>Age</b>	<b>3.115*</b>	<b>3.529**</b>	<b>6.901*</b>	<b>17.593*</b>	<b>18.820*</b>
<b>Self-Perceived Risk</b>	<b>7.334**</b>	<b>8.116*</b>	<b>2.933**</b>	<b>1.828</b>	<b>1.512</b>
<b>HIV Concern</b>	<b>0.189</b>	<b>0.170</b>	<b>0.165</b>	<b>0.002</b>	
<b>Black MSM</b>		<b>2.344</b>	<b>2.286</b>	<b>3.282**</b>	<b>5.355*</b>
<b>STD Prevention</b>		<b>0.561</b>	<b>0.593</b>	<b>3.441**</b>	<b>3.105**</b>
<b>Condom Use</b>			<b>0.014</b>	<b>0.217</b>	
<b>HIV Test</b>			<b>0.113</b>	<b>0.805</b>	
<b>Substance Use</b>			<b>0.001</b>	<b>0.941</b>	
<b>PrEP Knowledge</b>				<b>2.410</b>	
<b>PrEP Attitude</b>				<b>7.204*</b>	<b>9.613*</b>
<b>PrEP Cost</b>				<b>21.756*</b>	<b>19.191*</b>
<b>R<sup>2</sup></b>	<b>0.087</b>	<b>0.120</b>	<b>0.121</b>	<b>0.387</b>	<b>0.350</b>
<b>* Significant at <math>\alpha = .05</math></b>					
<b>** Significant at <math>\alpha = 0.1</math></b>					

## 5.0 DISCUSSION

PrEP has the potential to be a promising HIV prevention strategy among Black MSM. Despite having little knowledge on PrEP, Black MSM are willing to use PrEP to reduce their risk of HIV infection. This has been a consistent finding throughout the literature and further research is needed to ascertain other variables responsible for this relationship. Black MSM also desire to be educated on PrEP. If PrEP is used among Black MSM, the medications will likely have to be provided at little to no cost to the recipient. Currently, the costs of PrEP medications are either paid for in part by private medical insurance providers and or out of pocket. It is highly unlikely that young Black MSM will have the capacity to pay out of pocket costs for PrEP, therefore alternative methods must be explored such as drug subsidies. PrEP education and awareness must be heightened and integrated with existing HIV prevention methods. It is important that MSM have access to health literature, information, and counseling that promotes the use of condoms as an effective primary prevention behavior against the transmission of HIV as well routine HIV testing and awareness of HIV status.

The CDC has yet to release formal guidelines on PrEP. In interim guidance recommendations the CDC suggests that “PrEP must be obtained and used in close collaboration with healthcare providers to ensure regular HIV testing, risk reduction and adherence counseling, and careful safety monitoring. Anyone considering PrEP should speak with their doctor (CDC,

2011).” Given the current climate of healthcare access and coverage in the U.S. with over 40 million lacking healthcare insurance, it is likely that many young Black MSM will not have a primary care physician in which they see regularly if at all. In addition to primary care physicians, these guidelines should be extended to include building the capacity of community based organizations and health centers to educate and serve individuals who may inquire about PrEP. Research on PrEP acceptability and effectiveness is ongoing and it essential that until more formal guidelines becomes available, PrEP is not publicized as a silver bullet to prevent HIV. Instead PrEP should be promoted as an additional line of defense against HIV infection to be used in conjunction with condom use, HIV testing, and adherence.

PrEP implementation also does not come without some ethical considerations as well. As of March 15, 2012, there were 3,840 HIV positive individuals on the AIDS Drug Assistance Program (ADAP) waiting list (TheBody.com, 2012). These individuals need HIV medications to survive and do not have the financial capacity to pay for the medications. In 2011, the HIV Prevention Trials Network Study 052 better known as “Treatment as Prevention” showed that an earlier HIV diagnoses and initiation of treatment resulted in a significant reduction in transmission to infected partners. A cost benefit analysis of the effectiveness of HIV treatment versus PrEP may need to be conducted to determine how both may be used in conjunction most appropriately to reduce new infections and improve the health and quality of life of infected individuals. PrEP has the potential to be advantageous to the HIV prevention toolbox. More biomedical, social, and economical research is needed for most effective and appropriate use.

## 5.1 RECOMMENDATIONS

### 5.1.1 Prior Studies

Voetsch et.al (2006) recruited Black MSM from minority gay pride events and found that knowledge of PrEP was relatively low regardless of age. A limitation of the results is that knowledge of PrEP and PEP were asked concurrently therefore it is possible that more respondents actually had awareness of PEP rather than PrEP. Nevertheless awareness of PrEP alone is unable to be ascertained from the results. Also the study was conducted prior to the release of PrEP efficacy amongst MSM which also may outdate the results.

The 2002 BROTHERS study (HPTN 062) also found PrEP knowledge to be low amongst Black MSM, however PrEP acceptance was not studied. Also HIV positive individuals were included in the sample which could confound the results. Having a person who is already HIV positive and asking them questions about preventing HIV in uninfected individuals who introduce bias into study results. MSM minorities having higher PrEP acceptance concurrent with little knowledge has been replicated in the literature. Many of the variables explored are demographic variables such as educational attainment and income however, behaviors, perception of risks, and knowledge are collected to ascertain the explanation of the relationship or variance in regards to PrEP acceptance.

Demographic information undoubtedly are important variables to collect however, these studies did not conduct variance analyses to ascertain whether or not these variables had any influence on PrEP knowledge or acceptance. Overall, there has been very little research published in the literature post PrEP efficacy assessing the knowledge and attitudes that MSM

have towards PrEP. With several PrEP demonstration and acceptability projects ongoing and in planning, it is expected that more information will be gathered in the near future.

### **5.1.2 Current Study**

A large percentage of Black MSM are aware of HIV prevention strategies and are already implementing them in their daily lives. There is a population of Black MSM however, who are taking risks and likely putting themselves at risk of HIV infection through unprotected anal intercourse and not being aware of their status. Despite lacking basic knowledge on PrEP, Black MSM are willing to use PrEP to reduce their risk of HIV infection. A possible explanation is the wording of the survey questions. Participants were not given any prior information on PrEP other than it is preventing the transmission of HIV in uninfected individuals. Without any explanation of risks or benefits of PrEP, respondents may have been predisposed to acceptance to some extent. In terms of the out of pocket costs of PrEP, Black MSM are unwilling to pay for medications, bringing up the discussion of how PrEP will be funded if used to reduce the risk of transmission and incidence.

Currently, HIV prevention funding is strained throughout the country and providing PrEP at no cost outside of any ongoing studies is highly unlikely. Analysis of variance was an appropriate method of analysis for the current study in order to observe the relationships and interactions of the independent variables on PrEP acceptance. Relevant behavioral data on participants was prioritized for the current study rather than demographic data. Results from the current study show that risk behaviors have minimal influence on the acceptance of PrEP amongst Black MSM and that age is the strongest predictor of PrEP acceptance. Despite an extensive number of variables being observed, an ideal explanation of variance was not achieved

suggesting that there are other variables not included in the current study which may influence PrEP acceptance.

### **5.1.3 Comparison of Studies**

In comparison with other studies, the current study supports prior evidence that Black MSM have little knowledge on PrEP but are likely to use it reduce their risk of HIV infection. Prior studies have concluded that PrEP acceptance and knowledge is influenced by high risk sexual behaviors, race, educational attainment, and income. The current study has collected more information on risk behaviors, perceptions and attitudes of HIV/STD infection, PrEP, and anal intercourse to study correlation with PrEP acceptance. The current study is timelier in that it was conducted post PrEP efficacy among MSM and has sampled from the population which current epidemiological figures show the highest disparity of incidence.

The current study took a different approach in comparison to prior studies in that the sample recruited had specific eligibility requirements, one being that HIV positive individuals were excluded from the analysis. The current study sample also included exclusively African American MSM which has had relatively lower levels of participation in prior studies and clinical trials. Different variables were explored under the current study that collected knowledge and attitudes on PrEP, in addition to behaviors and perceptions which are lacking in previous studies. A wider compendium of variables was collected to determine independent variable and covariate relationships on PrEP acceptance. The current study also had a large percentage of the sample that were between the ages of 18-30 which is much younger than the mean age of prior studies and increases generalizability of study results to this age group.

## **6.0 CONCLUSIONS**

### **6.1 SUMMARY**

HIV incidence among African American MSM is increasing at alarming rates as compared to other MSM racial cohorts. HIV prevention intervention has traditionally included evidence based behavioral interventions, risk reduction, and capacity building. Biomedical interventions such as oral pre-exposure prophylaxis have the potential to be another weapon included in the prevention arsenal. PrEP implementation does not come without concern however; efficacy among MSM is less than ideal, little information exists on potential long term effects, cost effectiveness and feasibility have yet to be ascertained, and it is unlikely that financial assistance will be available or sufficient which could result in PrEP use almost exclusively among those who can afford it.

PrEP alone cannot alleviate the HIV epidemic among African American MSM. PrEP must be touted as an additional line of defense of HIV transmission to be used concurrently with condoms, routine HIV testing, risk reduction, capacity building, education, awareness, and intervention. Despite possessing little knowledge of PrEP, Black MSM are willing to use PrEP to



reduce their risk of HIV infection if they are not required to pay out of pocket expenses. One explanation for these findings is that due to the function of the survey instrument, respondents were unaware of the risks and benefits of PrEP and more inclined to acceptance. One thing that is undisputed from prior research is that acceptance is relatively high among Black MSM. The current study was able to ascertain some of these reasons. More research and information must be conducted around PrEP and there must be higher recruitment and retention of Black MSM in these studies.

## **6.2 PUBLIC HEALTH SIGNIFICANCE**

With over a million people living with HIV and over 50,000 new infections annually, reducing the incidence of HIV in the US is a public health priority. The National HIV/AIDS Strategy states that “Not every person or group has an equal chance of becoming infected with HIV. Yet, for many years, too much of our Nation’s response has been conducted as though everyone is equally at risk for HIV infection (2010).” The highest disparity of HIV infection is among African Americans and young African American MSM bear the highest percentage of the burden. It is estimated the medical expenditures that a HIV positive accrues over a lifetime exceeds 500,000 dollars. Biomedical prevention strategies such as pre-exposure prophylaxis are promising to reducing the number of infections among Black MSM and ensuing healthcare costs. Integrating knowledge, awareness, and possible implementation of PrEP among Black MSM will require a concerted, collaborative effort involving federal agencies, pharmaceutical companies,

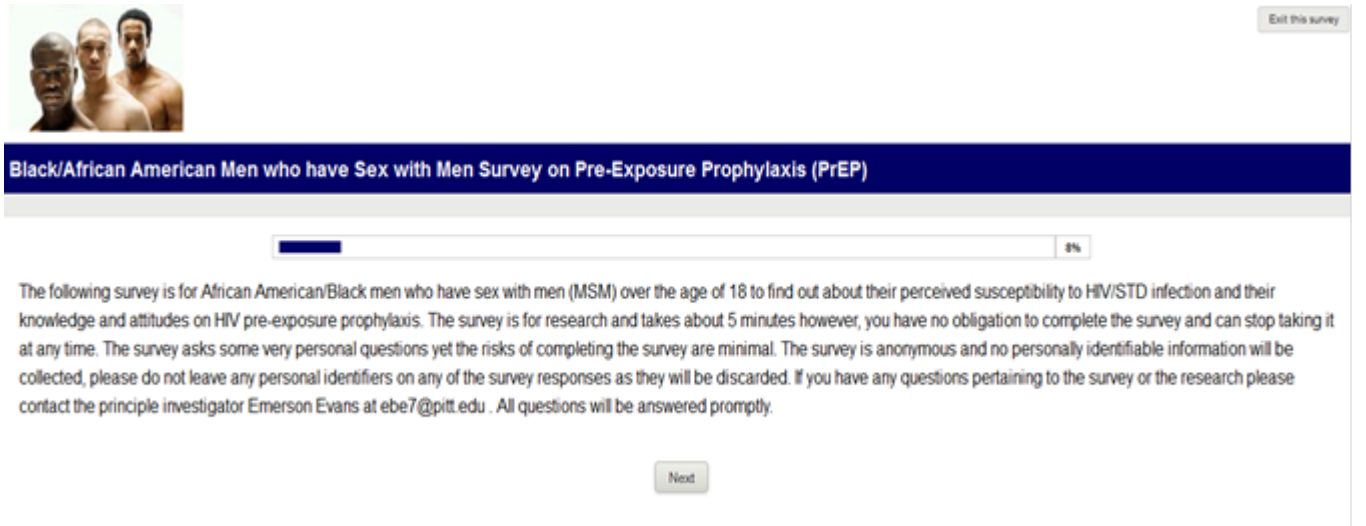
community based and AIDS service organizations, local and state health departments, Black MSM groups, and medical providers.

The findings from this study may not be applicable to all African American MSM however; insight is provided on the dynamics of HIV infection and prevention strategies among this population accessed through the collection of information on behaviors, knowledge, and perceptions. The study can provide information that can guide public health practice and biomedical HIV prevention efforts targeted to Black MSM. Lastly, this study contributes greatly to the little information that exists on Black MSM knowledge and acceptance of pre-exposure prophylaxis.


## **APPENDIX A**

### **SURVEY OF THE CURRENT STUDY**

The picture used in the survey instrument is from the Brothers Study (brothersstudy.com , 2011).



Exit this survey



**Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)**

8%

The following survey is for African American/Black men who have sex with men (MSM) over the age of 18 to find out about their perceived susceptibility to HIV/STD infection and their knowledge and attitudes on HIV pre-exposure prophylaxis. The survey is for research and takes about 5 minutes however, you have no obligation to complete the survey and can stop taking it at any time. The survey asks some very personal questions yet the risks of completing the survey are minimal. The survey is anonymous and no personally identifiable information will be collected, please do not leave any personal identifiers on any of the survey responses as they will be discarded. If you have any questions pertaining to the survey or the research please contact the principle investigator Emerson Evans at ebe7@pitt.edu . All questions will be answered promptly.

Next



**Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)**

17%

**\*1. I am African American/Black**

Yes

No

Prev Next



## Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)



\*2. I am a man who has sex with men

- True
- False

Prev Next



## Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)



\*3. What is your age

- 13 - 17
- 18 - 24
- 25 - 30
- 31 - 40
- 41 - 50
- > 50

Prev Next



## Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)



\*4. I am Human Immunodeficiency Virus (HIV) negative and/or unaware of my infection (Have not been tested)

- True
- False

Prev Next



Exit this

Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)



\*5. I consent to taking this anonymous survey and understand that my participation is voluntary and no personally identifiable information will be collected or released

- Yes, I consent to taking the survey
No, I do not consent to taking the survey

Prev Next



Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)

Personal attitudes and perception of HIV



\*6. What risk do you have of getting Human Immunodeficiency Virus (HIV) and/or a sexually transmitted disease (STD)

Scale from No Risk to Great Risk with radio buttons and a text box for other specifications.

\*7. I am not concerned about getting HIV because now there are effective medicine's for HIV

Scale from Strongly Disagree to Strongly Agree with radio buttons and a text box for other specifications.

\*8. I am concerned about the high rates of HIV infection among Black/African American men who have sex with men

Scale from Strongly Disagree to Strongly Agree with radio buttons and a text box for other specifications.

\*9. Preventing myself from getting HIV and other STDs is important to me

Scale from Strongly Disagree to Strongly Agree with radio buttons and a text box for other specifications.



**Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)**

**Sexual Behaviors**



**\*10. When I have anal sex, whether I am the bottom (receiving partner) or the top (inserting partner), a condom is used**

Strongly Disagree      Somewhat Disagree      Unsure      Somewhat Agree      Strongly Agree      N/A

On a Scale from 1-10

Other (please specify)

**\*11. The last time I had unprotected, receptive anal sex (you were the bottom), I did not use a condom because:**

- My partner forced me to have sex without a condom
- My partner and I chose not to use a condom
- There was no condom available to use
- I was drunk or high and forgot to use one

**\*12. I get tested for Human Immunodeficiency Virus (HIV) at least once or twice a year**

Strongly Disagree      Somewhat Disagree      Unsure      Somewhat Agree      Strongly Agree

On a scale from 1-10

**\*13. When I get drunk or high, I engage in high risk behaviors such as not wearing a condom during sex:**

Strongly Disagree      Somewhat Disagree      Unsure      Somewhat Agree      Strongly Agree      N/A

On a scale of 1-10

Other (please specify)

Prev    Next

**Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)**

**Pre-Exposure Prophylaxis**



The following questions ask your knowledge, attitudes, and beliefs of PrEP which is preventing the transmission of HIV in HIV negative individuals

**\* 14. Currently, if I could reduce my risk from getting HIV by taking a pill daily, I would**

Strongly Disagree      Somewhat Disagree      Unsure      Somewhat Agree      Strongly Agree

On a scale from 1-10

Other (please specify)

**\* 15. What is your knowledge of Pre-Exposure Prophylaxis (PrEP)?**

None      Very Little      Moderate      Great

On a scale from 1-10, 1 being no knowledge, 10 being great knowledge

**\* 16. I want to know more about Pre-Exposure Prophylaxis (PrEP)**

Strongly Disagree      Somewhat Disagree      Unsure      Somewhat Agree      Strongly Agree

On a scale from 1-10

**\* 17. I am willing to pay up to \$13,000 a year in out of pocket prescription costs to prevent myself from getting HIV**

Strongly Disagree      Somewhat Disagree      Unsure      Somewhat Agree      Strongly Agree

Your willingness to pay for PrEP on a scale of 1-10, 1 being the least likely, 10 being the greatest

Prev    Next



EXIT THIS SURVEY

**Black/African American Men who have Sex with Men Survey on Pre-Exposure Prophylaxis (PrEP)**



**\* 18. Would you be interested in participating in a research study/intervention where you would receive health information on HIV, STDs, and sexual health specifically catered to African American/Black men who have sex with men?**

- Yes
- No

Prev    Next



92%

**\*19. If yes, what type of study/intervention? (check all that apply)**

- Online (includes social networking sites such as Facebook, Twitter, and BGClive)
- Cell phone application
- In person
- In a group

Other (please specify)

Prev

Next

100%

Your interest in taking this survey is appreciated however, you are unable to complete this survey for one of the following reasons:

- (1) You are under the age of 18
- (2) You are HIV positive
- (3) You are not African American/Black
- (4) You are not a man who has sex with men
- (5) You did not give consent to take the survey

If you would like more information, please click the following links below:

- (1) Find an HIV Test - go to [www.hivtest.org](http://www.hivtest.org)
- (2) Access more information about HIV pre-exposure prophylaxis, visit <http://www.cdc.gov/hiv/prep/>
- (3) Access information on HIV/AIDS, visit <http://www.cdc.gov/hiv/default.htm>
- (4) To access AIDS telephone hotlines in your state, visit <http://www.thebody.com/index/hotlines/state.html>

If you have any questions about the survey please contact Emerson Evans at [ebe7@pitt.edu](mailto:ebe7@pitt.edu)

Thank you for your time

Prev

Done

## **APPENDIX B**

### **SURVEY RECRUITMENT SCRIPT**

Hey, can you please take 5 minutes and fill out this anonymous survey for my thesis research which is for Black/African American men who have sex with men (MSM). I would greatly appreciate it. The survey asks some very personal questions however, risks of completing the survey are minimal and you are able to discontinue taking the survey at any time. Please do not put any personally identifiable information on the survey (ex: Name, Phone number, etc.). If you could also forward the survey to a minimum of two of your friends on Facebook and/or Twitter. Thanks! (Link for informed consent followed by embedded survey link will be placed here)

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