Infrequent HIV Testing and Late HIV Diagnosis Are Common Among A Cohort of Black Men Who Have Sex with Men (BMSM) in Six US Cities

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# **Running Head:**

HIV Testing and Late Diagnosis in Black MSM

**Objective:** US guidelines recommend at least annual HIV testing for those at risk. This analysis assessed frequency and correlates of infrequent HIV testing and late diagnosis among black men who have sex with men (BMSM).

**Methods**: HIV testing history was collected at enrollment from participants in HPTN 061, an HIV prevention trial for at-risk US BMSM. Two definitions of late HIV diagnosis were assessed: CD4 cell count <200 cells/mm3 or <350 cells/mm3 at diagnosis.

**Results**: HPTN 061 enrolled 1553 BMSM. HIV testing questions were completed at enrollment by 1284 (98.7%) of 1301 participants with no prior HIV diagnosis; 272 (21.2%) reported no HIV test in prior 12 months (infrequent testing); 155 of whom (12.1% of the 1284 with testing data)

reported never testing. Infrequent HIV testing was associated with: not seeing a medical provider in the prior 6 months (relative risk [RR]: 1.08, 95% confidence intervals [CI]: 1.03-1.13), being unemployed (RR 1.04, CI: 1.01-1.07), and having high internalized HIV stigma (RR: 1.03, CI: 1.0-1.05). New HIV diagnoses were more likely among infrequent testers compared to men tested in the prior year (18.4% vs. 4.4%; OR: 4.8, 95% CI: 3.2-7.4). Among men with newly diagnosed HIV, 33 (39.3%) had a CD4 cell count <350 cells/mm;3 including 17 (20.2%) with CD4 <200 cells/mm.3

**Conclusions**: Infrequent HIV testing, undiagnosed infection, and late diagnosis were common among BMSM in this study. New HIV diagnoses were more common among infrequent testers, underscoring the need for additional HIV testing and prevention efforts among US BMSM.

Keywords: HIV; HIV testing; Late HIV Diagnosis; men who have sex with men (MSM); Black men; African American men

### Introduction

Men who have sex with men (MSM), particularly Black MSM (BMSM), are disproportionately affected by HIV in the US,<sup>1-4</sup> and national guidelines recommend at least annual HIV testing for MSM.<sup>5</sup> Recent reports of high infection rates among MSM who reported testing within the prior 12 months have led to recommendations for more frequent testing for all sexually-active MSM, as often as every 3 to 6 months.<sup>6-10</sup> Reports have shown that not testing at least annually is common among MSM.<sup>11</sup> In recent surveys from the US Centers for Disease Control and Prevention (CDC), 38% of MSM reported not testing for HIV in the prior 12 months<sup>6</sup> and 17% of MSM reported that they had never been tested for HIV.<sup>12</sup>

The disparity in HIV infection among BMSM has not been linked to racial differences in sexual risk behavior. Potential factors reported to be driving disparities in HIV infection among BMSM include racial differences in rates of untreated sexually transmitted infections (STIs), HIV viral load suppression, and assortative sexual mixing (choosing sexual partners of the same race/ethnicity). Social determinants such as discrimination, stigma, and poverty also likely contribute to HIV racial disparities. It also has been hypothesized that the disparity may be at least in part attributable to the higher likelihood of BMSM being unaware of their HIV status 11,13,20,25,26,27 or being diagnosed late.

Receiving an initial HIV diagnosis late in the course of HIV disease can have serious consequences for the individual. Late initiation of antiretroviral therapy (ART) is associated with a diminished response to treatment, <sup>28</sup> and a higher risk for both progression to AIDS and mortality. <sup>29-33</sup> Late HIV diagnosis also has public health implications, since individuals unaware of their HIV status may be more likely to transmit HIV to others. <sup>19,34,35</sup> The phenomenon of late HIV diagnosis has a variety of names (e.g., late diagnosis, late testing, late presentation) and definitions in the literature. <sup>30-32,36-44</sup> Late diagnosis and late presentation definitions have ranged from having concurrent AIDS at the time of HIV testing; <sup>43</sup> having an initial CD4 cell count

<200 cells/mm;<sup>3 30,43</sup> developing a CD4 cell count below 200 cells/mm<sup>3</sup> or AIDS within three months,<sup>41</sup> one year,<sup>31,36</sup> or three years <sup>39</sup> after HIV diagnosis; to having an initial CD4 cell count <350 cells/mm<sup>3</sup> at time of HIV diagnosis,<sup>38</sup> or within three months of diagnosis.<sup>44</sup> In 2009, the European Late Presenter Consensus Working Group suggested a consensus definition for late presentation: persons presenting for care with a CD4 cell count below 350 cells/mm<sup>3</sup> or presenting with an AIDS-defining event, regardless of CD4 cell count.<sup>42</sup> The group also proposed a second category of "presentation with late disease," defined as persons presenting for care with a CD4 cell count <200 cells/mm<sup>3</sup> or presenting with an AIDS-defining event, regardless of CD4 cell count.<sup>42</sup>

Despite intensive efforts to promote routine HIV testing in the US, late HIV diagnosis remains common. 31,37,39,41,45 Recent data revealed that approximately 38% of those diagnosed with HIV infection in the US developed AIDS within a year of their HIV diagnosis. Several factors have been associated with late diagnosis, including Black or Latino race/ethnicity, older age, and male gender. The most commonly reported reasons for not testing or late testing/late diagnosis include low perceived risk of HIV and fear of HIV diagnosis. Structural barriers, confidentiality concerns, lack of social support, and marginalized status have been identified as additional risk factors. Additional barriers to testing identified among BMSM include medical mistrust, stigma, and fear of discrimination. A3,46,50

This study analyzed HIV testing data collected from BMSM participants in the HIV Prevention Trials Network BROTHERS study (HPTN 061) to assess the prevalence and covariates of infrequent HIV testing, defined as not testing for HIV in the 12 months prior to enrollment. This study also evaluated the frequency of late HIV diagnosis among those newly diagnosed with HIV infection, and identified factors associated with late HIV diagnosis. Understanding factors associated with not testing and late HIV diagnosis are critical for developing more effective HIV prevention interventions for high-risk populations, including BMSM.

#### Methods

This analysis utilized data collected from participants in HPTN 061, a multi-site study designed to determine the feasibility and acceptability of a multi-component HIV prevention intervention for BMSM. Study details have been previously described. In HPTN 061, BMSM were recruited in six US cities (Atlanta, GA; Boston, MA; New York, NY; Los Angeles, CA; San Francisco, CA; and Washington, D.C.) from July 2009 to October 2010. HPTN 061 enrolled HIV-uninfected men, HIV-infected men who reported that they were unaware of their HIV status (newly diagnosed) and HIV-infected men who reported that they were aware of their status (previously diagnosed); a maximum of 10 men per study site were enrolled who reported that they were in HIV care. Men were eligible to participate in the study if they: self-identified as a man or were male at birth; self-identified as Black; were at least 18 years old; reported unprotected anal intercourse with a man in the prior 6 months; and resided in the metropolitan area where they were recruited. At the enrollment visit, eligibility was confirmed and written informed consent obtained.

Participant interviews were conducted to collect demographic data (age, sexual identity, education, employment, household income, housing, and student status) as well as health-care related information (health care insurance coverage, usual place of care, visits to a health care provider in the prior 6 months, and unmet health care needs in the prior 6 months). Prior HIV testing history was obtained via audio computer-assisted self-interview (ACASI) at baseline. Participants who answered "No," to the question "Have you ever been tested for HIV?" or who reported "zero" for number of times tested for HIV in the last year were considered to have infrequent HIV testing. Other data collected via ACASI included history of incarceration, sexual identity, and sexual risk behaviors in the 6 months prior to enrollment; partner HIV status; alcohol and other substance use;<sup>53</sup> internalized homophobia;<sup>54</sup> perceived racism;<sup>55</sup> internalized HIV stigma;<sup>56</sup> HIV conspiracy;<sup>57</sup> mistrust; and symptoms of depression.<sup>58</sup>

Perceived racism was measured with 28 items ( $\alpha$ =0.95), such as "being treated rudely or disrespectfully" because of "my race." The extent that the event bothered the participant

was measured with a 5-point scale from "not at all" to "extremely." Scores were summed for participants who answered all questions in the scale. The of racism scale ranged from 0 to 140; the variable was categorized as "never happened/low" (score <48), "medium" (score from 48–94), and "high" (score >95).

Internalized HIV stigma was measured based on a scale developed by Sayles, et al. <sup>56</sup> to capture stigma as perceived and experienced by the individual living with HIV. Participants responded, using a 5-point Likert scale from "disagree strongly" to "agree strongly" ( $\alpha$ =0.82), to five items, such as "I am concerned that if I go to an AIDS organization someone I know might see me." Scores were summed for participants answering all five questions. A participant was categorized as having low (score <15) or high (score >15) internalized HIV stigma.

Conspiracy theory about HIV/AIDS was measured with a 9-item scale adapted from Bogart and Thornburn, which included statements such as, "There is a cure for AIDS, but it is being withheld from the poor," with responses on a 5-point Likert scale from "disagree strongly" to "agree strongly" ( $\alpha$ =0.92).<sup>57</sup>

Participants also were asked to respond to the statement, "I trust the health care providers I see in my health care setting," using a 5-point Likert scale from "disagree strongly" to "agree strongly." Those who answered strongly disagree or disagree were coded as having mistrust.

Participants reporting prior HIV negative or unknown status were offered HIV counseling and testing at study enrollment. HIV rapid testing was conducted after completion of interviews and pre-test HIV/STI risk-reduction counseling. Reactive rapid HIV test results were confirmed by Western blot testing performed at a local laboratory. Quality assurance testing was performed retrospectively at the HPTN Laboratory Center to confirm the HIV infection status of all study participants at enrollment. Men who were HIV infected at enrollment and reported no prior diagnosis were provisionally characterized as newly diagnosed. A subset of those men had low or undetectable HIV RNA levels (<1,000 copies/mL HIV RNA). Stored samples from those

men were tested for the presence of antiretroviral drugs at the end of the study. Some of those men were re-classified as previously diagnosed based on the detection of drugs indicative of antiretroviral therapy (ART).<sup>59</sup>

Univariate and multivariate logistic regression models were used to identify the independent correlates of infrequent HIV testing. Variables examined as possible correlates included predefined baseline participant demographics, sexual identity, prior health care utilization, substance use, incarceration history, HIV risk behaviors, HIV status of sexual partners, perceived racism, internalized homophobia, internalized HIV stigma, HIV conspiracy, symptoms of depression, and study site. In order to reduce the number of modeled covariates and avoid over-fitting the data, backward selection was implemented using the criterion for retention in the model of a p-value less than 0.1. This analysis was performed on all complete cases (908 observations). After reducing the number of covariates, the model was then refit using complete cases from only the selected variables (1127 observations). City of recruitment was also adjusted for in the multivariate model, despite not reaching the desired threshold of significance during the selection procedure. Wald 95% confidence intervals were computed for the estimated odds ratios and risk ratios. All statistical analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Men identified as newly diagnosed at study enrollment, based on testing performed at study sites, had CD4 cell count testing. Two definitions of late HIV diagnosis were used for analysis: new HIV diagnosis with a CD4 cell count <200 cells/mm,<sup>3</sup> and new HIV diagnosis with a CD4 cell count <350 cells/mm<sup>3</sup> at time of diagnosis. Correlates of late HIV diagnosis were assessed by univariate analysis using Fisher's exact tests. Variables examined as possible correlates of late diagnosis were the same as those assessed as possible correlates of infrequent HIV testing, described above. No multivariate model was fitted because of relatively small sample size (only 84 newly diagnosed men had CD4 cell count data at enrollment).

#### **Results**

Among 1553 BMSM participants enrolled, 252 (16%) participants were classified as having a previous HIV diagnosis based on self-report or information obtained by the study sites (N=185) or based on antiretroviral drug testing performed at the HPTN Laboratory Center (N=67). Of the remaining 1301 participants with no prior HIV diagnosis, 38 (2.9%) men either refused testing or did not have a sample stored to confirm HIV status. Of the 1263 men tested with confirmatory HIV data, 96 (7.6%) men were classified as newly diagnosed; 1167 (92.4%) were HIV-uninfected at enrollment.

Baseline demographics of the 1301 HPTN 061 participants with no prior HIV diagnosis at enrollment included: a median age of 38 years; 1.8% transgender; 8.0% Latino; 37.8% reported household incomes below US poverty level; 10.2% had unstable housing; 66.3% unemployed; and 41.7% reported being uninsured (Table 1).

### **Prior HIV testing history**

Among 1301 participants who had no prior HIV diagnosis at enrollment, 1284 (98.7%) answered the HIV testing history questions in the study ACASI. Infrequent HIV testing was reported by 272 (21.2%) men, including 155 men (12.1% of the 1284) who reported never having been tested for HIV before study enrollment. In the six cities in this study, participants in Atlanta, Georgia were most likely to report not testing for HIV within the prior year (28.5%); while those in Washington, DC and Boston were least likely to report infrequent testing (15.3% and 16.6%, respectively).

### Correlates of HIV testing and HIV testing outcome

Univariate analyses identified several factors associated with infrequent HIV testing (Table 2), including: older age, lower household income, being unemployed, unstable housing, being uninsured, not identifying as gay or homosexual, not having seen a medical provider in the prior

6 months, and city of residence (Atlanta, San Francisco, or Los Angeles). Variables not associated with infrequent testing included: country of origin, being a student, being transgender, injection drug use, substance use, sexual risk behavior, partner HIV status, incarceration history, perceived racism, and belief in HIV conspiracy.

By modeling the data in a multivariate framework, the number of modeled covariates was reduced from twelve significant associations (p<0.10) in the univariate case to four in the multivariate case, including an adjustment for study site. We identified four covariates of interest: employment status, housing status, internalized HIV stigma, and seeing a health care provider in the last six months. Because the outcome cannot be considered a rare event, the interpretation of the odds ratio in this setting does not reflect the relative probability of an individual not adhering to testing guidelines. Therefore, risk ratios were used to quantify this probability. In multivariate testing, three variables were independently associated with infrequent HIV testing at the 0.05 level: not seeing a medical provider in the prior 6 months (relative risk [RR] 1.08, 95% confidence intervals [CI] 1.03-1.13), being unemployed (RR 1.04, CI 1.01-1.07), and having high levels of internalized HIV stigma (RR 1.03, CI 1.00-1.05). Although the association with housing status was not significant at the 0.05 level, it was included in the final multivariate model because it improved the overall fit of the model.

Fifty (18.4%) of the 272 participants with infrequent HIV testing were newly diagnosed with HIV at study enrollment, compared to only 45 (4.4%) of the 1012 participants who had an HIV test in the prior year (OR: 4.8, 95% CI: 3.2, 7.4, p<0.0001).

#### **Late HIV Diagnosis**

Among 1301 BMSM participants with no known prior HIV diagnosis, 96 (7.6% of the 1263 men who agreed to testing) were found to be HIV infected at enrollment, including three later identified as having acute HIV infection at enrollment. Acute infection was defined as having detectable HIV RNA with negative HIV antibody tests or with positive HIV antibody tests with a

negative or indeterminate Western blot. All three men had positive Western blots at their 6-month visits. CD4 cell count data from enrollment was available for 84 (87.5%) of the 96 men with newly diagnosed infection. CD4 data was missing for 12 participants. In eight cases, CD4 cell count testing was not performed because the initial HIV rapid test was non-reactive; those men (including three with acute HIV infection) were retrospectively identified as HIV-infected at the HPTN Laboratory Center. The median CD4 cell count for the 84 men was 404 cells/mm (interquartile range [IQR]: 209, 581); 33 (39.3%) had a CD4 cell count <350 cells/mm at enrollment, including 17 (20.2%) who had a CD4 cell count <200 cells/mm. In a univariate analysis of correlates of late testing, only age over 30 years was associated with late diagnosis using the definition of CD4 cell count <350 cells/mm (47.4% vs. 22.2%; p<0.05). Infrequent testing was not associated with an increased risk of late diagnosis in this small sample. The median CD4 cell count for the 37 newly diagnosed participants who had an HIV test in the prior year was 373 cells/mm [IQR: 201, 499], compared to 443 cells/mm [IQR: 247, 588] for the 46 newly diagnosed participants reporting infrequent testing (p=0.35). No other variable was found to be associated with late HIV diagnosis by either definition.

#### Discussion

Despite US guidelines recommending at least annual HIV testing for sexually active MSM and more frequent testing (every three to six months) for those at higher risk, over one in five BMSM participants reported not testing in the year prior to study enrollment and 12% reported never having had an HIV test. While testing rates among BMSM in the current study were better than those reported previously, <sup>6,12</sup> infrequent testing was associated with severe consequences, namely a significantly higher frequency of newly diagnosed HIV infection compared to that among BMSM tested in the prior 12 months. Infrequent testing, however, was not associated with lower CD4 cell counts or late diagnoses in this sample. Many factors could have contributed to the lack of difference in CD4 between groups, including the small sample size and the possibility of men in either group being recently infected, which could transiently reduce CD4 cell count. Infrequent testing has the potential to result in later

presentation with more advanced disease and ongoing HIV transmission by those unaware of their diagnoses. These findings highlight the need for further expansion of HIV testing in populations such as BMSM who are at high-risk for HIV infection. The high prevalence of newly diagnosed infections among those who were tested within the previous 12 months (over 4%) confirms the need for even more frequent testing, as recommended by the CDC. <sup>6-10</sup>

Being unemployed, not seeing a medical provider in the prior six months, and having high levels of internalized HIV stigma were all independently associated with infrequent HIV testing. Presumably, those who had seen a medical provider in the prior six months would have had better access to HIV testing, which may explain this finding. Similarly, those participants who were employed may have had better financial resources and health insurance coverage to facilitate access to medical care and HIV testing, though insurance status by itself was not independently associated with HIV testing within the previous year. The recent US Preventive Services Task Force recommendations for routine HIV testing, rather than risk-based testing, should increase testing rates among BMSM who may be less likely than White MSM to disclose their sexual identity to health care providers. <sup>33,61,62</sup> In addition, health care reform has the potential to improve access to care and to HIV testing for populations lacking in resources, including health insurance. HIV-related stigma has been identified as a barrier to HIV testing in previous studies as well. 46,63 Greater outreach and prevention efforts are likely to be needed to reach at-risk populations such as BMSM, to increase awareness, overcome additional barriers such as stigma, and improve HIV testing rates. Anti-stigma social media campaigns targeting HIV-negative individuals have been suggested as one possible way to address stigma as a barrier to HIV testing. 63 The reasons for the differences seen in prior HIV testing rates between cities are unknown, although differences in recruitment strategies between sites may have been a contributing factor.

In this HIV prevention study conducted in six US cities, there was high uptake of HIV testing among BMSM study participants, with 97% agreeing to testing. Though this was a select sample of men who agreed to participate in an HIV prevention trial, the high uptake of testing

suggests that expanded testing is possible for BMSM, particularly if recruitment and testing are conducted by trained staff focused on reaching this community.

Over one-third of those men met one of the two definitions for late HIV diagnosis; 39% had a CD4 cell count <350 cells/mm³ at diagnosis, and a subset of those (20% of those with newly diagnosed HIV infection) had a CD4 cell count <200 cells/mm.³ Thus, 20% had concurrent AIDS at the time of HIV diagnosis. Late diagnosis was significantly associated with older age in this study. There was no association between late diagnosis and infrequent HIV testing in this study, though the sample was small with CD4 cell count data available for only 84 participants. The high prevalence of late diagnosis and concurrent AIDS again underscore the urgent need for expanded HIV testing among BMSM in the US.

A strength of this study was the large number of BMSM participants in HPTN 061, recruited in six US cities with high HIV prevalence. One limitation of the study is that the men were selected based on an eligibility requirement of unprotected anal intercourse, and thus are not representative of all BMSM in the US, but do represent a high risk population. The study population also had high rates of poverty and unemployment, which is not representative of all BMSM populations in the US, but is consistent with disparities seen among populations with HIV. 18,22 Being a study of entirely BMSM with few Latino men, this study could not assess differences in HIV testing behavior between Black MSM and MSM in other racial/ethnic groups; though few racial differences have been seen in prior studies. <sup>20,22</sup> Another limitation that the study relied primarily on HIV testing history obtained by self-report. Though HIV testing data was collected via ACASI, it is possible that participants could have over-reported recent HIV testing due to social desirability. This could potentially have contributed to the lower than expected CD4 cell count among the group that reported testing within the prior 12 months. Antiretroviral drug testing was performed as a supplement to self-report for a subset of study participants likely to be on ART, who did not disclose knowledge of their HIV status. This testing was performed only for men with low or undetectable HIV RNA at enrollment, and only

assessed three antiretroviral drug classes (nucleoside reverse transcriptase inhibitors, non-nucleoside reverse transcriptase inhibitors, and protease inhibitors). <sup>59</sup> It is possible that some of the men classified as newly diagnosed in this report could have been on ART without viral suppression, or could have been taking medications in another drug class. Nondisclosure of HIV status and/or ART use has been identified previously in other settings, including in other HIV prevention trials and in STI clinics. <sup>64-66</sup> Some participants in HPTN 061 also did not agree to HIV testing or did not have samples stored for confirmation of HIV status, and some men with HIV infection were missing CD4 cell count data. Finally, because the current analyses used data collected in a large HIV prevention study, it was not possible to assess all factors or barriers potentially associated with testing.

The findings of this study highlight the fact that sexually-active BMSM are not being tested for HIV according to the CDC guidelines. The results also underscore the need for expanding HIV testing and prevention efforts for this population at significant risk of HIV infection, as recommended in the US National HIV/AIDS Strategy. The findings of this study also support recent CDC recommendations for more frequent HIV testing in BMSM. While the benefits of routine HIV testing are clear, and routine HIV testing should continue in all primary care settings, additional efforts and resources are needed to reach BMSM, particularly those not engaged in health care. Further research is needed to understand the barriers to HIV testing among BMSM and to assess interventions that reduce stigma and promote the uptake of HIV testing for BMSM.

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#### References

- 1 .Hall HI, Byers RH, Ling Q, Espinoza L. Racial/ethnic and age disparities in HIV prevalence and disease progression among men who have sex with men in the United States. *Am J Public Health* 2007;97:1060–1066.
- 2. Valleroy LA, MacKellar DA, Karon JM, et al. for the Young Men's Survey Study Group. HIV prevalence and associated risks in young men who have sex with men. *JAMA* 2000;284:198-204.
- 3. Centers for Disease Control and Prevention. HIV prevention in the United States at a critical crossroads. 2009. Available at http://www.cdc.gov/hiv/resources/reports/pdf/hiv prev us.pdf
- 4. Prejean J, Song R, Hernandez A, et al. for the HIV Incidence Surveillance Group. Estimated HIV incidence in the United States, 2006–2009. *PLoS ONE* 2011, p. e17502.
- 5. Centers for Disease Control and Prevention. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR Morb Mortal Wkly Rep.* 2006;55(RR-14):1–16.
- 6. Centers for Disease Control and Prevention. HIV testing among men who have sex with men 21 cities, United States, 2008. MMWR Morb Mortal Wkly Rep. 2011;60:694-699.
- 7. Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2010. *MMWR Morb Mortal Wkly Rep.* 2010;59 (No. RR-12).
- 8. Centers for Disease Control and Prevention. Prevalence and awareness of HIV infection among men who have sex with men—21 cities, United States, 2008. MMWR Morb Mortal Wkly Rep. 2010;59:1201–1207.
- 9. Centers for Disease Control and Prevention. HIV risk, prevention, and testing behaviors among men who have sex with men National HIV Behavioral Surveillance System, 21 U.S. cities, United States, 2008. *MMWR Surveill Summ* 2011;60:1-34.
- 10. Centers for Disease Control and Prevention. HIV Testing and Risk Behaviors Among Gay, Bisexual, and Other Men Who Have Sex with Men United States. *MMWR Morb Mortal Wkly Rep* 2013;62:958-962.
- 11. Finlayson TJ, Le B, Smith A, et al. HIV risk, prevention, and testing behaviors among men who have sex with men--National HIV Behavioral Surveillance System, 21 U.S. cities, United States, 2008. *MMWR Surveill Summ*

- 12. MacKellar DA, Hou SI, Whalen CC, et al. for the WHBS Study Group. Reasons for not HIV testing, testing intentions, and potential use of an over-the-counter rapid HIV test in an internet sample of men who have sex with men who have never tested for HIV. *Sex Transm Dis.* 2011;38:419-428.
- 13. Millett GA, Peterson JL, Wolitski RJ, Stall R. Greater risk for HIV infection of black men who have sex with men. A critical literature review. *Am J Public Health* 2006;96:1007–1019.
- 14. Millett GA, Flores SA, Peterson JP, Bakeman R. Explaining disparities in HIV infection among black and white men who have sex with men: a metaanalysis of HIV risk behaviors. *AIDS* 2007;21:2083–2091.
- 15. Hallfors DD, Iritani BJ, Miller WC, Bauer DJ. Sexual and drug behavior patterns and HIV and STD racial disparities: the need for new directions. *Am J Public Health* 2007;97:125–132.
- 16. Magnus M, Kuo I, Phillips G 2nd, et al. Elevated HIV prevalence despite lower rates of sexual risk behaviors among black men in the District of Columbia who have sex with men. *AIDS Patient Care STD* 2010;24:615–622.
- 17. Millett GA, Peterson JL, Flores SA, et al. Comparisons of disparities and risks of HIV infection in black and other men who have sex with men in Canada, UK, and USA: a meta-analysis. *Lancet* 2012;380:341-348.
- 18. Beer L, Oster AM, Mattson CL, Skarbinski J, for the Medical Monitoring Project. Disparities in HIV transmission risk among HIV-infected black and white MSM, Medical Monitoring Project, 2009. *AIDS* 2014;28(1):105-114. PMID: 23942058
- 19. Hall HI, Holtgrave DR, Tang T, Rhodes P. HIV transmission in the United States: Considerations of viral load, risk behavior, and health disparities. *AIDS Behav.* 2013;17(5):1632-1636.
- 20. Maulsby C, Millett G, Lindsey K, et al. HIV among black men who have sex with men (MSM) in the United States: A review of the literature. *AIDS Behav.* 2014;18(1):10-25.
- 21. Millett GA, Ding H, Mark, G, et al. Mistaken assumptions and missed opportunities: Correlates of undiagnosed HIV infection among black and latino men who have sex with men. *J Acquir Immune Defic Syndr*. 2011;58:64-71.

- 22. Sullivan PS, Peterson J, Rosenberg ES, et al. Understanding Racial HIV/STI Disparities in Black and White Men Who Have Sex with Men: A Multilevel Approach. *PLoS ONE* 2014;9(3):e90514. doi:10.1371/journal.pone.0090514
- 23. Halkitis P, Wolitski R, Millett G. A holistic approach to addressing HIV infection disparities in gay, bisexual, and other men who have sex with men. *Amer Pyschol.* 2013;68:261-273.
- 24. National Minority AIDS Council. (2013). RISE Proud: Combating HIV among black gay and bisexual: An action plan to mitigate the impact of HIV and AIDS on black gay and bisexual men. Washington, DC.
- 25. MacKellar DA, Valleroy LA, Secura GM, et al. Unrecognized HIV infection, risk behaviors, and perceptions of risk among young men who have sex with men. Opportunities for advancing HIV prevention in the third decade of HIV/AIDS. *J Acquir Immune Defic Syndr*. 2005;38:603–614.
- 26. Centers for Disease Control and Prevention MMWR Vital Signs: HIV infection, testing, and risk behaviors among youths United States. *MMWR* 2012;61:971-976.
- 27. Wejnert C, Le B, Rose CE, et al. HIV Infection and Awareness among Men Who Have Sex with Men-20 Cities, United States, 2008 and 2011. *PLoS One* 2013,8:e76878. doi:10.1371/journal.pone.0076878
- 28. May M, Sterne JA, Sabin C, et al for the Antiretroviral Therapy (ART) Cohort Collaboration. Prognosis of HIV-1 infected patients up to 5 years after initiation of HAART: collaborative analysis of prospective studies. *AIDS* 2007;21:1185–1197.
- 29. CASCADE Collaboration. Short-term risk of AIDS according to current CD4 cell count and viral load in antiretroviral drug-naive individuals and those treated in the monotherapy era. *AIDS* 2004;18:51–58.
- 30. Chadborn TR, Delpech VC, Sabin CA, et al. The late diagnosis and consequent short-term mortality of HIV-infected heterosexuals (England and Wales, 2000–2004). *AIDS* 2006;20:2371-2379.
- 31. Schwarcz S, Hsu L, Dilley JW, et al. Late diagnosis of HIV infection: trends, prevalence, and characteristics of persons whose HIV diagnosis occurred within 12 months of developing AIDS. *J Acquir Immune Defic Syndr*. 2006;43:491–494.
- 32. Gandhi NR, Skanderson M, Gordon KS, et al. Delayed presentation for Human Immunodeficiency Virus (HIV) care among veterans. A problem of access or screening? *Med Care* 2007;45:1105-1109.

- 33. Moyer VA on behalf of the US Preventive Services Task Force. Screening for HIV: US Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2013;159:51-60.
- 34. Marks G, Crepaz N, Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. *AIDS* 2006;20:1447-1450.
- 35. Hall HI, Holtgrave DR, Maulsby C. HIV transmission rates from persons living with HIV who are aware and unaware of their infection. *AIDS* 2012;26:893-896.
- 36. Centers for Disease Control and Prevention. Late versus early testing of HIV --- 16 sites, United States, 2000—2003. MMWR Morb Mortal Wkly Rep. 2003;52(25);581-586.
- 37. Girardi E, Sabin CA, Monforte A. Late diagnosis of HIV infection: Epidemiological features, consequences and strategies to encourage earlier testing. *J Acquir Immune Defic Syndr*. 2007;46:S3-S8.
- 38. Mayben JK, Kramer JR, Kallen MA, et al. Predictors of delayed HIV diagnosis in a recently diagnosed cohort. *AIDS Patient Care STD* 2007;21(3):195–204.
- 39. Centers for Disease Control and Prevention. Late HIV testing—34 states, 1996—2005. *MMWR Morb Mortal Wkly Rep.* 2009;58:661—665.
- 40. Nelson KM, Thiede H, Hawes SE, et al. Why the wait? Delayed HIV diagnosis among men who have sex with men. *J Urban Health* 2010;87:642-655.
- 41. Smith RD, Delpech VC, Brown AE, Rice BD. HIV transmission and high rates of late diagnoses among adults aged 50 years and over. *AIDS* 2010;24:2109–2115.
- 42. Antinori A, Coenen T, Costagiola D, et al. for the European Late Presenter Consensus working group. Late presentation of HIV infection: a consensus definition. *HIV Med.* 2011;12,61–64.
- 43. Dowson L, Kober C, Perry N, et al. Why some MSM present late for HIV testing: a qualitative analysis. *AIDS Care* 2012;24:204-209.

- 44. Kozak M, Zinski A, Leeper C, et al. Late diagnosis, delayed presentation and late presentation in HIV: Proposed definitions, methodological considerations and health implications. *Antivir Ther.* 2013;18:17-23.
- 45. Hall HI, Halverson J, Wilson DP, et al. Late diagnosis and entry to care after diagnosis of human immunodeficiency virus infection: a country comparison. *PLoS ONE* 2013;8(11): e77763. doi:10.1371/journal.pone.0077763
- 46. Nanin J, Osubu T, Walker J, et al. "HIV is still real": Perceptions of HIV testing and HIV prevention among black men who have sex with men in New York City. *Am J Mens Health* 2009;3:150-164.
- 47. Schwarcz S, Richards TA, Frank H, et al. Identifying barriers to HIV testing: personal and contextual factors associated with late HIV testing. *AIDS Care* 2011;23:892-900.
- 48. Mashburn AJ, Peterson JL, Bakeman R, et al. Influences on HIV testing among young African-American men who have sex with men and the moderating effect of the geographic setting. *J Comm Psychol.* 2004;32:45-60.
- 49. Lauby JL, Marks G, Bingham T, et al. Having supportive social relationships is associated with reduced risk of unrecognized HIV infection among black and Latino men who have sex with men. *AIDS Behav.* 2012;16:508-515.
- 50. Malebranche DJ, Peterson JL, Fullilove RE, Stackhouse RW. Race and sexual identity: Perceptions about medical culture and healthcare among black men who have sex with men. *J National Med Assoc.* 2004;96(1),97-107.
- 51. Koblin BA, Mayer KH, S. Eshleman SH, et al. for the HPTN 061 Protocol Team. Correlates of HIV acquisition in a cohort of Black men who have sex with men in the United States: HIV Prevention Trials Network (HPTN) 061. *PLoS ONE* 2013;8(7):e70413. doi:10.1371/journal.pone.0070413.
- 52. Mayer KH, Wang L, Koblin B, et al. for the HPTN 061 Protocol Team. Concomitant socioeconomic, behavioral, and biological factors associated with the high HIV infection burden among Black men who have sex with men in 6 U.S. cities. *PLoS ONE* 2014;9(1):e87298. doi:10.1371/journal.pone.0087298
- 53. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption--II. *Addiction* 1993;88(6):791-804.

- 54. Herek GM, Glunt EK. Identity and community among gay and bisexual men in the AIDS era: Preliminary findings from the Sacramento Men's Health Study. In: Herek GM, Greene B, eds. *AIDS, Identity and Community*: The HIV Epidemic and Lesbians and Gay Men. Thousand Oaks, CA: Sage Publications, Inc., 1995;55-84.
- 55. Harrell SP, Merchant MA, Young SA. Psychometric properties of the Racism and Life Experiences Scales (RaLES). Paper presented at: American Psychological Association; Apr 15-19, 1997; Chicago, IL.
- 56. Sayles JN, Hays RD, Sarkisian CA, et al. Development and psychometric assessment of a multidimensional measure of internalized HIV stigma in a 2 sample of HIV-positive adults. *AIDS Behav.* 2008;12:748-758.
- 57. Bogart LM, Thorburn S. Are HIV/AIDS conspiracy beliefs a barrier to HIV prevention among African Americans? J Acquir Immune Defic Syndr. 2005;38:213-218.
- 58. Radloff LS. The CES-D Scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement* 1977;1:385-401.
- 59. Marzinke MA, Clarke W, Wang L, et al. Non-disclosure of HIV status in a clinical trial setting: antiretroviral drug screening can help distinguish between newly-diagnosed and previously-diagnosed HIV infection. *Clin Infect Dis*. 2014;58:117-120.
- 60. Piwowar-Manning E, Fogel JM, Laeyendecker O, et al. Failure to identify HIV-infected individuals in a clinical trial using a single HIV rapid test for screening. *HIV Clinical Trials* 2014;15:62-68.
- 61. Mimiaga MJ, Reisner SL, Bland S, et al. Health system and personal barriers resulting in decreased utilization of HIV and STD testing services among at-risk black men who have sex with men in Massachusetts. *AIDS Patient Care STD* 2009:23:825-835.
- 62. Bernstein KT, Liu KL, Begier EM, et al. Same-sex attraction disclosure to health care providers among New York City men who have sex with men: implications for HIV testing approaches. *Arch Intern Med.* 2008;168:1458-1464.
- 63. Golub SA and Gamarel KE. The Impact of Anticipated HIV Stigma on Delays in HIV Testing Behaviors: Findings from a Community-Based Sample of Men Who Have Sex with Men and Transgender Women in New York City *AIDS Patient Care STD* 2013;27:621-627.

- 64. Fogel JM, Wang L, Parsons Tl, et al. Undisclosed antiretroviral drug use in a multi-national clinical trial (HIV Prevention Trials Network 052). *J Infec Dis.* 2013;208:1624-1628.
- 65. Kahle EM, Kashuba A, Baeten JM, et al. Unreported antiretroviral use by HIV-1 infected participants enrolling in a prospective research study. *J Acquir Immune Defic Syndr*. 2014;65:e90-94.
- 66. Sullivan AK, Savage EJ, Lowndes CM, et al. Non-disclosure of HIV status in UK sexual health clinics--a pilot study to identify non-disclosure within a national unlinked anonymous seroprevalence survey. *Sex Transm Infect*. 2013;89:120-121.
- 67. White House Office of National AIDS Policy. National HIV/AIDS strategy for the United States. 2010 [August 2, 2010]; Available from: http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf.



Table 1. Baseline Demographics of 1301 Participants who Reported Having no HIV Diagnosis Prior to Enrolling to HPTN 061

Characteristic	<b>Total (</b> N=1301)
Age Group	
18-30	489/1301 (37.6%)
>30	812/1301 (62.4%)
Median age	38 years
Marital Status	
Married/civil union or	146/1300 (11.2%)
have a primary	
partner	
Single/divorced/	1154/1300 (88.8%)
widowed	
Participant Gender	
Male	1278/1301 (98.2%)
Female	0/1301 (0.0%)
Transgender	23/1301 (1.8%)
Partner/Spouse Gender	
No Partner/ Spouse	1154/1300 (88.8%)
Male	89/1300 (6.8%)
Female	52/1300 (4.0%)
Transgender	5/1300 (0.4%)
Exclusive Sexual Orientation	
Exclusively	361/1273 (28.4%)
Homosexual/ Gay	
Exclusively Bisexual	383/1273 (30.1%)
Other	529/1273 (41.6%)
Ethnicity	
Latino	104/1301 (8.0%)
Not Latino	1197/1301 (92.0%)
Country of Origin	
United States	1241/1301 (95.4%)
Outside United States	60/1301 (4.6%)

Highest Education	
High school or less	686/1300 (52.8%)
Some college or higher	614/1300 (47.2%)
Student Status	
Current student	269/1301 (20.7%)
Not student	1032/1301 (79.3%)
Current Employment Status	
Working Currently	438/1300 (33.7%)
Not Working	862/1300 (66.3%)
Currently	
Housing Status	
Have a stable home	1168/1301 (89.8%)
Do not have a stable home	133/1301 (10.2%)
lousehold Income	
Less than \$9.999	487/1288 (37.8%)
\$10,000-\$49,999	641/1288 (49.8%)
\$50,000 or more	160/1288 (12.4%)
requency of Insufficient Income	
Never	568/1300 (43.7%)
Once in a While	417/1300 (32.1%)
Fairly or Very Often	315/1300 (24.2%)
Current Health Care Coverage	
Yes	759/1301 (58.3%)
No	542/1301 (41.7%)
inrollment HIV Status	
Refused/unknown	38/1301 (2.9%)
Negative	1167/1301 (89.7%)
Positive,	96/1301 (7.4%)
new diagnosis	
HIV Testing History	
Never tested	155/1296 (12.0%)
Tested > 12 months	117/1296 (9.0%)
Tested < 12 months	1012/1296 (78.1%)
Tested, time unknown	12/1296 (0.9%)
restea, time anknown	12/1230 (0.370)

Table 2. Odds Ratio (OR) and 95% CI Obtained from Univariate Analysis that Predicts the Risk of Infrequent HIV Testing (Not having an HIV test in the Prior Year)

			Univariate Mo	Univariate Model	
Characteristics	Level	n (%)	OR (95% CI)	р	
Age	Older (>30)	186 (23.3%)	1.41 (1.06, 1.88)	0.0173	
	Younger (< 30)	86 (17.7%)			
Household income	< \$10,000	119 (24.8%)	1.43 (1.09, 1.88)	0.0101	
	> \$10,000	148 (18.7%)			
Education	high school graduate or less	155 (23.0%)	1.25 (0.96, 1.64)	0.1040	
	some college	117 (19.2%)			
Employment status	Unemployed	205 (24.1%)	1.74 (1.29, 2.36)	0.0003	
	Employed	67 (15.4%)	,		
Housing status	Unstable	38 (28.8%)	1.59 (1.06, 2.37)	0.0248	
	Stable	234 (20.3%)			
Health insurance	Uninsured	129 (24.2%)	1.35 (1.03, 1.77)	0.0281	
	Insured	143 (19.1%)			
Gay/homosexual	Yes	103 (18.6%)	0.76 (0.58, 1.00)	0.0481	
	No	169 (23.2%)			
Poppers use	Yes	19 (15.2%)	0.64 (0.39, 1.07)	0.0883	
	No	235 (21.8%)			
City	LA	47 (23.2%)	1.67 (1.00, 2.79)	0.0492	
	SF	43 (24.2%)	1.77 (1.05, 2.98)	0.0328	

	Atlanta	72 (28.5%)	2.21 (1.37, 3.57)	0.0012
	Boston	33 (16.6%)	1.10 (0.64, 1.90)	0.7223
	NY	48 (18.4%)	1.25 (0.76, 2.07)	0.3840
	DC	29 (15.3%)		
Depression	Yes	121 (23.4%)	1.28 (0.97, 1.69)	0.0862
	No	130 (19.3%)		
See health care	No	134 (26.0%)	1.60 (1.22, 2.10)	0.0006
provider in last 6				
months				
	Yes	138 (18.0%)		
Internalized	medium/high	129 (23.5%)	1.27 (0.96, 1.67)	0.0898
homophobia	(sum: 17-35)			
	low (sum: 7-16)	130 (19.5%)		<b>V</b>
HIV stigma	high (sum > 16)	106 (24.1%)	1.32 (0.99, 1.76)	0.0623
	low (sum < 15)	134 (19.5%)		

Table 3. Multivariate Analysis of the Probability of Infrequent HIV Testing
(No HIV test in the Prior Year)

**Univariate model** Multivariate model Characteristic N (%) OR (95% CI) OR (95% CI) RR (95% CI) Level р р S 0.0028 **Employment** Unemployed 205 (24.1%) 1.74 (1.29, 2.36) 0.0003 1.67 (1.19, 2.33) 1.04 (1.01, 1.07) status 1.52 (0.97, 2.40) 0.0692 1.04 (1.00, 1.08) Housing status Unstable 38 (28.8%) 1.59 (1.06, 2.37) 0.0248 Seen health care 134 (26.0%) 1.60 (1.22, 2.10) 0.0006 1.60 (1.19, 2.15) 0.0018 1.08 (1.03, 1.13) No provider in last 6 months 1.32 (0.99, 1.76) HIV stigma high (> 16) 106 (24.1%) 0.0623 1.40 (1.05, 1.89) 0.0242 1.03 (1.00, 1.05) City LA 47 (23.2%) 1.67 (1.00, 2.79) 0.0492 1.22 (0.70, 2.11) 0.6171 City SF 43 (24.2%) 1.77 (1.05, 2.98) 0.0328 1.35 (0.77, 2.39) 0.2904 City Atlanta 72 (28.5%) 2.21 (1.37, 3.57) 0.0012 1.57 (0.93, 2.63) 0.0220 City **Boston** 33 (16.6%) 1.10 (0.64, 1.90) 0.7223 0.80 (0.44, 1.45) 0.0748 NY 48 (18.4%) 1.25 (0.76, 2.07) 0.3840 0.98 (0.57, 1.68) 0.3728 City