Published in final edited form as:
J Acquir Immune Defic Syndr. 2013 June 1; 63(2): 239–244. doi:10.1097/QAI.0b013e31828ded1a.

Feasibility of identifying a cohort of US women at high risk for HIV infection for HIV vaccine efficacy trials: Longitudinal results of HVTN 906

Beryl A. Koblin, PhD[1], **Barbara Metch, MA, MS**[2], **Richard M. Novak, MD**[3], **Cecilia Morgan, PhD**[2], **Debbie Lucy, MS**[1], **Debora Dunbar, MSN**[4], **Parrie Graham, MSPH**[3], **Edith Swann, PhD, RN**[5], **Tamra Madenwald, MA, MPH**[2], **Gina Escamilia, MS**[2], and **Ian Frank, MD**[4,6] **on behalf of the HVTN 906 study team**

[1]Laboratory of Infectious Disease Prevention, New York Blood Center, New York, NY

[2]Vaccine and Infectious Disease Division, Fred Hutchinson Cancer Research Center, Seattle, WA

[3]Section of Infectious Diseases, University of Illinois at Chicago, Chicago, IL

[4]HIV Prevention Division, University of Pennsylvania, Philadelphia, PA

[5]Division of AIDS, National Institute of Allergy and Infectious Diseases, NIH, Bethesda, MD

[6]Infectious Diseases Division, University of Pennsylvania, Philadelphia, PA

Abstract

Background—Identifying cohorts of US women with HIV infection rates sufficient for inclusion in vaccine efficacy trials has been challenging. Using geography and sexual network characteristics to inform recruitment strategies, HVTN 906 determined the feasibility of recruiting a cohort of women at high risk for HIV acquisition.

Methods—HIV uninfected women who reported unprotected sex in the prior six months, resided or engaged in risk behavior in local geographical high-risk pockets and/or had a male partner who had been incarcerated, injected drugs or had concurrent partners were eligible. Behavioral risk assessment, HIV counseling and testing and pregnancy testing were done at baseline, 6, 12 and 18 months.

Results—Among 799 women, 71% were from local high-risk pockets and had high-risk male partners. Median age was 37 years; 79% were Black; 15% Latina. Over half (55%) reported a new partner in the prior six months, 57% reported a male partner who had concurrent female sexual partners and 37% reported a male partner who had been incarcerated. Retention at 18 months was 79.5%. Annual pregnancy incidence was 12%. Annual HIV incidence was 0.31% (95% CI: 0.06, 0.91). Risk behaviors decreased between screening and six months with smaller changes thereafter.

Correspondence and reprints: Beryl A. Koblin, PhD Laboratory of Infectious Disease Prevention New York Blood Center 310 E. 67th Street New York, NY 10065 Telephone: 212-570-3105 Fax: 212-861-5873 bkoblin@nybloodcenter.org.

Presented in part at AIDS Vaccine 2012, Boston, MA September 9-12, 2012
Conflicts of Interest: No conflicts were declared.

Discussion—This cohort of women recruited using new strategies based on geography and sexual network characteristics did not have an HIV incidence high enough for HIV vaccine efficacy trials, despite high baseline levels of risk and a high pregnancy rate. New strategies to identify cohorts of US women for efficacy trials are needed.

Keywords

HIV vaccine trials; United States women; heterosexual transmission

INTRODUCTION

Trials of biomedical interventions to prevent HIV infection, including microbicides, antiretrovirals for prevention and vaccines, require study participants at high risk of HIV infection, who adhere to study product and complete study follow-up visits to ensure adequate assessment of efficacy[1;2]. Women continue to be an important population in the United States (US) for participation in clinical trials of biomedical HIV prevention strategies. In 2010, women accounted for 21% of all new HIV diagnoses[3]. Eighty-six percent of infections among women were acquired through heterosexual contact. African American and Latina women comprised 62% and 18% of new HIV diagnoses among women, while comprising 13% and 17% of the US women, respectively[3]. Inclusion of women in HIV biomedical intervention trials also is important since efficacy of some biomedical interventions has differed by population, possibly due to biologic differences, route of exposure (e.g. vaginal vs. anal intercourse) or differences in adherence to use of study product, as observed in recent pre-exposure prophylaxis studies[4-9].

Despite the relatively stable rate of new HIV diagnoses from 2007 to 2010 attributed to heterosexual contact in the US[10], longitudinal cohort studies and HIV vaccine efficacy trials have observed relatively low HIV incidence rates among enrolled women compared to men who have sex with men (MSM). For example, a vaccine preparedness study conducted in the 1990's found an annual HIV incidence rate of 1.2% among women compared to 1.6% among MSM[11]. Two more recent HIV vaccine efficacy trials including women in the US found even greater differences in annual incidence rates among women compared to MSM (VaxGen 004: 0.8% among women vs. 2.7% among MSM[12] and the Step Study: 0.6% among US women vs. 3.9% among US MSM) (unpublished data, SCHARP)[13]. In these trials, eligibility criteria for women were based predominately on individual-level risk behaviors, including injection drug use (IDU), crack cocaine use, exchanging sex for money or drugs, multiple partners or limited partner characteristics such as being HIV infected or an injection drug user. More recently, a better understanding of the HIV epidemic among women in the US has emerged with an emphasis on risk related to one's sexual networks, sexual partner concurrency and residence or engagement in risk activity within local high-risk geographic areas[14-17].

HVTN 906 was an observational cohort study designed to determine the feasibility of recruiting a high incidence cohort of US women for HIV vaccine efficacy trials using recruitment and eligibility criteria based on sexual networks, sexual concurrency and detailed geographic knowledge of high-risk pockets in three urban areas[18]. The baseline data from this cohort have been previously described[18]. Here, we present an analysis of retention, HIV and pregnancy incidence, and changes in sexual risk behaviors during follow-up.

METHODS

HVTN 906 was a prospective observational study conducted in Chicago, New York City (NYC) and Philadelphia. The protocol and informed consent documents were approved by

the Institutional Review Boards for each participating institution. Our approach was to recruit women who would be eligible for an HIV vaccine efficacy trial and who resided or engaged in risk behavior in local geographical high-risk pockets (i.e., areas of high HIV prevalence or incidence, commercial sex work, or drug use) and/or were partners of men who were from subgroups with a high HIV prevalence. Thus, HIV uninfected women were eligible if they were between the ages of 18 to 45, willing to receive HIV test results and risk reduction counseling, not pregnant with no intention to become pregnant for 18 months, met high-risk behavioral criteria, and provided informed consent. High-risk behavior was defined as self-report of unprotected vaginal or anal sex with a male partner in the prior six months and i) residing or engaging in risk behaviors (unprotected sex, exchange of sex, or crack cocaine use) within a site-specific geographic high-risk pocket; and/or ii) having a male partner who had either been incarcerated in the last year, injected drugs in the last year, or had concurrent sex with another partner in the last six months. In addition, sites could develop additional criteria that might identify an even higher risk cohort than from these common criteria. Chicago required that women be referred by HIV-positive female peers and self-report crack cocaine use. Midway through the enrollment period, NYC added a requirement that all women meet the high-risk male partner criterion.

Recruitment strategies used were previously published in detail[18]. In brief, each site identified neighborhoods with the highest rates of new HIV infections among women. By design, we allowed each site to use different recruitment strategies to provide data on the effect of different approaches on the profile of enrolled women at baseline[18].

Chicago focused on identifying and recruiting from sexual networks that included HIV positive members through street outreach and use of a modified respondent driven sampling scheme. HIV-positive women identified during screening were given coupons and asked to give these coupons to women they knew who smoked crack and who had sex with the same male partner(s).

NYC identified specific locations for potential recruitment and flyer placement based on local reports, interviews with community-based organization and brief street interviews. In addition, NYC recruited women at bus stops for visitor transportation to upstate prisons, and women in visitor waiting areas of jails and prisons. Finally, NYC recruited men in the identified risk pockets who reported being HIV-infected, an injection drug user, recently incarcerated or having concurrent partners and asked them to refer their female partners to the study.

In Philadelphia, local ethnographers identified street locations where drugs were sold or exchanged for sex, and where at-risk women could be approached for pre-screening evaluation. All pre-screening, screening, and follow-up evaluations were conducted on a mobile assessment unit parked within neighborhood risk pockets. Some women reporting high-risk behaviors at prescreening referred their women friends. In addition, men with a history of HIV infection, IDU, recent incarceration, or having sex with men were identified and asked to refer their female sexual partners for pre-screening.

Study visits

Potential study participants were prescreened in the field or over the telephone to determine preliminary eligibility, and eligible women were scheduled for a screening visit. At the screening visit, the women had a prescreening reassessment to confirm eligibility based on self-report and then completed an interviewer-administered questionnaire on demographics, behavioral risks, pregnancy history, and current contraception use. Pregnancy and HIV antibody tests were administered along with risk reduction counseling. Sites followed their

own HIV antibody testing procedures using FDA approved tests for initial and confirmatory testing on separate samples.

Enrollment of HIV uninfected, women who were not pregnant took place 7-28 days after the screening visit. Follow-up visits were scheduled every six months for 18 months to collect questionnaire data and to conduct HIV and pregnancy counseling and testing. Women were compensated $25 for the screening visit, $25 (Chicago and Philadelphia) or $30 (NYC) for the enrollment visits, and $25 (Chicago and Philadelphia) or $30 (NYC) for each follow-up visit.

Measures

Risk behaviors in the previous six months were assessed by a standardized interviewer-administered questionnaire at the screening, 6-, 12- and 18-month visits. For sexual risk behaviors, participants were asked about their total number of male sexual partners and how many they knew were HIV-infected, not HIV-infected or not sure whether or not they were HIV-infected. Questions were asked separately for a main partner (a man to whom you are legally married, living with as married, or a man who is closest to you in your heart, even if you do not live with him) and any other partners. Data were collected on the occurrence of each type of sexual behavior and condom use with the main partner. For all other partners, the data were collected on the number of men with whom each type of sexual behavior and condom use occurred. The sexual behaviors included vaginal sex, anal sex, vaginal or anal sex while the participant or partner was drunk/buzzed on alcohol or high on drugs, and vaginal or anal sex for money, gifts, drugs, goods, shelter, or services. Male partner characteristics collected included whether a partner was a new partner (first sex within last six months), age, recent incarceration, injection drug use, exchange of sex for money/drugs and services with other women, partner concurrency, and sex with men.

Questions on substance use included the frequency and amount of alcohol use; occurrence of injection drug use; and frequency of marijuana, crack cocaine, powder cocaine, amphetamine, heroin, and hallucinogen use from “never” to “daily” on a 6-point response scale[19]. Finally, diagnosis or treatment for a sexually transmitted infection (defined as chlamydia, gonorrhea, syphilis, genital or rectal herpes, genital or rectal warts, or pelvic inflammatory disease) was obtained by self-report, as well as, unusual vaginal discharge, and sore/ulcer in genital or rectal area.

Statistical analysis

The aim of the study with regard to HIV incidence was to rule out, with high probability, that the incidence rate was less than 1%. With a sample size of 800, if 18 or more infections were observed, then we would conclude with 97.5% confidence that the true incidence was at least 1.0% per year (lower bound of 95% CI for 18 infections). If the observed number of infections was 8 or fewer, then we would conclude with 97.5% confidence that the true incidence was no more than 1.5% per year (upper bound of 95% for 8 infections). The 18-month follow-up rate was chosen since previous studies suggested that HIV infections were occurring after one year of follow-up (STEP unpublished data, SCHARP).

Multivariate logistic models were used to assess predictors of retention and pregnancy. A predictor was considered statistically significant if the Wald p-value was < 0.05 or the confidence interval for the odds ratio excluded 1. Predictors assessed were: site, recruitment source, eligible based on risk pocket, eligible based on high-risk partner, age, race, education, employment, income, health care, housing situation, living with a main partner, moved in the year prior to screening, spent at least one night at no address or one night in jail in the six months prior to screening, and sexual risk behaviors and drug and alcohol use

reported at the screening visit. Additional predictors assessed for retention were perceived personal benefit from an HIV vaccine and whether the woman thought it possible that she would become HIV infected within five years after enrollment. Retained was defined as having the 18 month visit or becoming HIV infected. The pregnancy modeling was limited to women who reported not being sterilized at enrollment.

Rates and 95% Poisson confidence intervals for HIV infection and pregnancies among non-sterilized women were calculated. For HIV infection, person-years were calculated as time from enrollment to first positive HIV test for infected women or to the last negative test date for non-infected women. For pregnancy rates, person-years were calculated from enrollment to last pregnancy test with time while pregnant (measured from estimated conception to outcome date) subtracted.

Generalized estimating equation (GEE) models were used to assess changes in the average number of partners and percentages of women reporting risk behaviors over time, adjusting for predictors of drop-out. GEE modeling was selected since it accounts for the within subject correlation between assessment times in reporting a behavior. For number of partners, data were log-transformed and the identity link function used (linear regression). For the other binary behaviors, a logit link was used (logistic regression). Changes between baseline and 18 months and between six and 18 months with score test p-values < 0.05 were considered statistically significant.

RESULTS

Study sample

Between January 2009 and May 2010, 799 women were enrolled. The median age of the women was 37 years and most (79.1%) were African American (Table 1). About half (49.3%) had less than a high school degree, 84.7% were unemployed and 79.1% had an annual income of less than $10,000. Over one-third (37.5%) lived with a main partner, 14.9% had been homeless in the prior six months and 17.3% had been in jail in the prior six months. The majority (71.3%) lived or engaged in risky behavior within a site-identified high-risk pocket and had a high-risk partner; 18.3% met only the risk pocket criteria, and 10.4% met only partner criteria.

With regard to male partner characteristics and sexual risk behaviors in the six months before baseline, the median number of male partners was 3, with most partners of unknown HIV status and few women reporting a known HIV-infected partner (Table 2). Over three-quarters (78.0%) of the women reported having a main partner and 54.7% reported having a new partner in the prior six months. Over half (57.3%) of the women reported a male partner who had concurrent female sexual partners, 37.0% reported having a male partner who had been incarcerated in the past six months and 4.0% reported a male partner who had sex with men. Over half (52.3%) of the women reported exchanging sex for money, drugs, goods or other services at baseline (Table 3) and 73.4% reported having unprotected sex while drunk or high, and 72.2% while their partner was drunk or high. Approximately half (49.4%) of the women used crack cocaine in the prior six months, 31.0% were heavy alcohol users and 26.7% used heroin.

Retention

Of the 799 women, 686 (85.9%) completed the 6-month visit, 663 (83.0%) completed the 12-month visit and 635 (79.5%) completed the 18-month visit. The median follow-up time was 16.5 months (IQR 16.4-16.8 months). Of the 164 women who did not complete the study, 82.9% were unable to be contacted or adhere to the visit schedule and 6.1% were incarcerated.

Using baseline data in a multivariate analysis of predictors of retention, women who did not complete their 18-month visit were more likely to have moved in the year prior to baseline (OR=1.8; 95% CI: 1.3, 2.7) and have a male partner who was incarcerated in the six months prior to baseline (OR=1.6; 95% CI: 1.1, 2.2). Older women (OR=0.98 per year increase in age; 95% CI: 0.96, 1.00) and African American women (OR=0.5; 95% CI: 0.3, 0.7) were less likely to miss their 18-month visit. No sexual risk behaviors were significantly associated with loss-to-follow-up in multivariate analysis.

HIV and pregnancy incidence

A total of 3 new infections were detected over 959 person years of follow-up for an annualized HIV incidence of 0.31% (95% CI: 0.06, 0.91). Two infections were detected at the 6- month visit and 1 at the 12-month visit. A total of 595 (74.5%) of the women were not sterilized, and the incidence of pregnancy in this group was 12.0% (95% CI: 9.5%, 15.0%) with 78 pregnancies occurring among 68 women. Almost half (48.5%) of first pregnancies occurred during the first six months of follow-up. In multivariate analysis, women who became pregnant while on-study were likely to be younger (OR=0.9 for 1 year increase; 95% CI: 0.87, 0.93), have moved in the year before baseline (OR=1.9; 95% CI: 1.1, 3.4), be living with a main partner (OR=1.8; 95% CI 1.0, 3.1), have had a pregnancy prior to baseline (OR=3.2, 95% CI 1.1, 9.8), have had more partners whose HIV status was unknown (OR=1.01 for 5 partner increase; 95% CI 1.00, 1.01), be enrolled in Philadelphia (OR=2.0; 95% CI 1.1, 3.8) and met the high risk partner criteria (OR=2.8; 95% CI: 1.1, 7.0).

Risk behaviors over time

Overall, reported sexual risk behaviors declined significantly from baseline to the first follow-up visit at six months, with a much lower rate of change thereafter (Table 3). Some behaviors did not continue to decline after the 6-month visit, specifically unprotected sex while a partner was either drunk or high, crack use, heavy alcohol consumption, and having an IDU partner, as well as, STD diagnosis/treatment or symptoms.

DISCUSSION

The HIV epidemic among women in the US remains a significant public health issue, with one in five new diagnoses occurring among women[10]. African American and Latina women are affected at greatly disproportionate rates, with rates 15 and 4 times greater than white women, respectively[20]. Despite new recruitment strategies based on geography and sexual network characteristics, high baseline levels of risk behaviors and HIV prevalence[18] and a high incidence of pregnancies, the annual HIV incidence (0.31%) and retention rate among women in HVTN 906 were not at a sufficient level to practically support an efficacy trial with an HIV infection outcome. Similar results with a risk-pocket-based approach was seen in another study conducted during the same time period (HPTN 064) with a similar annual HIV incidence of 0.32% (95% CI: 0.14 to 0.74)[21].

A number of factors could explain these findings. The follow-up time of 18 months may have been too short. It is possible that HIV infections could have occurred later if women were in serial relationships with partners of different risk profiles. However, the percent of women with new partners declined and the three infections occurred by 12 months of follow-up. Thus, extending follow-up may not address the issue and is not necessarily practical for efficacy trials. Higher risk women may have been among those lost to follow-up, underestimating HIV incidence in the cohort. However, retention was not associated with baseline sexual risk behaviors except for having a partner who had been incarcerated. Although a high proportion of women reported unprotected sex throughout follow-up, and close to three-quarters were recruited from high-risk pockets and had a high-risk male

partner, it is possible that the unprotected sex was not occurring in high prevalence sexual networks, that the number of male partners was not high enough, or that HIV-infected male partners were on antiretroviral treatment with suppressed viral loads, leading to a low rate of HIV infection transmission[22].

Finally, analysis of sexual risk behaviors in this cohort suggests that risk among the women declined during follow-up, a phenomenon that has been observed in many longitudinal cohorts of groups at risk[2;11]. The women may have demonstrated "regression to the mean" with regard to behavior change[23] as part of the selection criteria for the study was sexual risk. The women may also have reported higher risk at baseline to enroll and less risk during follow-up to interviewers due to socially desirable responding. However, the low HIV incidence may also indicate that risk reduction did occur, potentially as a result of study participation and HIV counseling and testing.

These results highlight the challenges for evaluation of HIV vaccines among US women in the future. Clearly, new strategies are needed to identify women at high risk. A report from New York City found that respondent-driven sampling within specific high-risk areas with recruitment by a previous participant who resided in a high-risk area was successful in identifying a sample with an HIV incidence of 2.6% among women[24]. This approach, while promising, was based on one city's experience and the HIV incidence was based on the detuned assay from a cross-sectional sample which may have overestimated incident infections. It is unclear whether such an approach would yield high incidence cohorts in other cities. Given the decrease in reporting of sexual risk behaviors between baseline and the first follow-up visit, future studies might consider multiple visits occurring between pre-screening and enrollment to ensure enrollment of higher risk participants. Another issue is the need to address the incidence of pregnancy in such studies. While the pregnancy rate in this study was not particularly different than the rates among US African American and Latina women in 2008 (14.4% and 13.7%, respectively)[25], female participants in HIV vaccine trials are asked to agree to consistent effective contraception use. The pregnancy incidence observed in the VaxGen 004 trial was lower than in this cohort (4.6 per 100 person-years) suggesting that once women enroll in an actual trial, the rate of pregnancy is lower. However, pregnancy incidence needs to be considered in study design as well as consideration of provision of contraceptive support or active referrals by study sites[26;27]. Finally, enhanced retention strategies and pregnancy prevention for women who are mobile and younger are needed to ensure inclusion of a wide range of women at risk.

Acknowledgments

The HVTN 906 study team would like to thank the study participants, community advisory board members, and the study site staff for their commitment to this study.

Source of Funding: This research was funded by the Division of AIDS, National Institute of Allergy and Infectious Disease, National Institutes of Health, grants 1UM1AI068614, 1UM1A1069470, 1UM1A1069554, 1UM1A1069534, 1UM1AI068635 and P30AI045008.

Reference List

1. Djomand G, Metch B, Zorrilla CD, et al. The HVTN protocol 903 vaccine preparedness study: lessons learned in preparation for HIV vaccine efficacy trials. J Acquir Immune Defic Syndr. 2008; 48(1):82–89. [PubMed: 18391750]
2. Koblin BA, Taylor PE, Avrett S, Stevens CE. The feasibility of HIV-1 vaccine efficacy trials among gay/bisexual men in New York City: Project ACHIEVE. AIDS Community Health Initiative Enroute to the Vaccine EFfort. AIDS. 1996; 10(13):1555–1561. [PubMed: 8931792]

3. Centers for Disease Control and Prevention. HIV Surveillance - Epidemiology of HIV Infection (through 2010). 2012. http://www.cdc.gov/hiv/topics/surveillance/resources/slides/general/index.htm8-8-2012
4. Sterling TR, Vlahov D, Astemborski J, et al. Initial plasma HIV-1 RNA levels and progression to AIDS in women and men. N Engl J Med. 2001; 344(10):720–725. [PubMed: 11236775]
5. Stanberry LR, Spruance SL, Cunningham AL, et al. Glycoprotein-D-adjuvant vaccine to prevent genital herpes. N Engl J Med. 2002; 347(21):1652–1661. [PubMed: 12444179]
6. Gandhi M, Bacchetti P, Miotti P, et al. Does patient sex affect human immunodeficiency virus levels? Clin Infect Dis. 2002; 35(3):313–322. [PubMed: 12115098]
7. Van Damme L, Corneli A, Ahmed K, et al. Preexposure Prophylaxis for HIV Infection among African Women. N Engl J Med. 2012
8. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. N Engl J Med. 2010; 363(27):2587–2599. [PubMed: 21091279]
9. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med. 2012; 367(5):399–410. [PubMed: 22784037]
10. CDC. HIV in the United States. 2011. www.cdc.gov6-14-2011
11. Seage GR III, Holte SE, Metzger D, et al. Are US populations appropriate for trials of human immunodeficiency virus vaccine? The HIVNET Vaccine Preparedness Study. Am J Epidemiol. 2001; 153(7):619–627. [PubMed: 11282787]
12. Flynn NM, Forthal DN, Harro CD, et al. Placebo-controlled phase 3 trial of a recombinant glycoprotein 120 vaccine to prevent HIV-1 infection. J Infect Dis. 2005; 191(5):654–665. [PubMed: 15688278]
13. Buchbinder SP, Mehrotra DV, Duerr A, et al. Efficacy assessment of a cell-mediated immunity HIV-1 vaccine (the Step Study): a double-blind, randomised, placebo-controlled, test-of-concept trial. Lancet. 2008; 372(9653):1881–1893. [PubMed: 19012954]
14. Adimora AA, Schoenbach VJ, Doherty IA. Concurrent sexual partnerships among men in the United States. Am J Public Health. 2007; 97(12):2230–2237. [PubMed: 17971556]
15. Adimora AA, Schoenbach VJ, Floris-Moore MA. Ending the epidemic of heterosexual HIV transmission among African Americans. Am J Prev Med. 2009; 37(5):468–471. [PubMed: 19840704]
16. Grinstead OA, Faigeles B, Comfort M, et al. HIV, STD, and hepatitis risk to primary female partners of men being released from prison. Women Health. 2005; 41(2):63–80. [PubMed: 16219588]
17. CDC. Characteristics associated with HIV infection among heterosexuals in urban areas with high AIDS prevalence --- 24 cities, United States, 2006-2007. MMWR Morb Mortal Wkly Rep. 2011; 60(31):1045–1049. [PubMed: 21832975]
18. Metch B, Frank I, Novak R, et al. Recruitment of Urban US Women at Risk for HIV Infection and Willingness to Participate in Future HIV Vaccine Trials. AIDS Behav. 2013; 17(2):760–772. [PubMed: 23090677]
19. HIVNET D01: Vaccine Preparedness Study/Uninfected Protocol Cohort. 2013. http://www.hptn.org/network_information/Public_Data_Sets/VPS_UPCdataFiles/VPS_UPC.pdf2-4-2013
20. Prejean J, Song R, Hernandez A, et al. Estimated HIV incidence in the United States, 2006-2009. PLoS One. 2011; 6(8):e17502. [PubMed: 21826193]
21. Hodder SL, Justman J, Hughes JP, et al. HIV Acquisition Among Women From Selected Areas of the United States: A Cohort Study. Ann Intern Med. 2013; 158(1):10–18. [PubMed: 23277896]
22. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med. 2011; 365(6):493–505. [PubMed: 21767103]
23. Cunningham JA. Regression to the mean: what does it mean? Alcohol Alcohol. 2006; 41(5):580. [PubMed: 16751218]
24. Jenness SM, Neaigus A, Murrill CS, et al. Estimated HIV incidence among high-risk heterosexuals in New York City, 2007. J Acquir Immune Defic Syndr. 2011; 56(2):193–197. [PubMed: 21233639]

25. Ventura, SJ.; Curtin, SC.; Abma, JC.; Henshaw, SK. Estimated pregnancy rates and rates of pregnancy outcomes for the United States, 1990-2008. Vol. Vol 60. National Center for Health Statistics. National vital statistics reports; Hyattsville, MD: 2012.

26. Brown-Peterside P, Ren L, Hirsch A, Drucker M, Koblin BA. Pregnancies among high-risk women in the first ever HIV vaccine efficacy trial. AIDS. 2003; 17(5):787–788. [PubMed: 12646816]

27. Latka MH, Fielding K, Gray GE, et al. Pregnancy incidence and correlates during the HVTN 503 Phambili HIV vaccine trial conducted among South African women. PLoS One. 2012; 7(4):e31387. [PubMed: 22532824]

Table 1

Baseline characteristics of women enrolled in HVTN 906 (n=799)

	N	%
Age		
18 - 20 years	61	7.6
21 - 30 years	169	21.2
31 - 40 years	313	39.2
41 – 45 years	256	32.0
Median (25th, 75th %tile)	37	28, 42
Race/ethnicity		
Black, non-Hispanic	632	79.1
Hispanic	122	15.3
Other	45	5.6
Education		
8th grade or less	35	4.4
9th-12th grade	359	44.9
HS grad or equivalent	255	31.9
Some college or graduate	150	18.8
Employed, other than sex work	122	15.3
Household income		
Less than $10,000	632	79.1
$10,000-$19,999	96	12.0
$20,000 or greater	56	7.0
Don’t know	14	1.8
Has public or private health insurance	527	66.0
Current living situation		
Own house/apartment	308	38.5
Family member house/apt.	220	27.5
Someone else’s house/apt.	146	18.3
Other	125	15.6
Lives with a main partner	300	37.5
Moved in last year	455	56.9
Homeless in last 6 months	119	14.9
Jail/prison in last 6 months	138	17.3
Pregnancy prior to enrollment	732	91.6
Eligibility criteria met		
Risk pocket + high risk partner	570	71.3
Risk pocket only	146	18.3
High risk partner only	83	10.4

Table 2

Baseline partner characteristics in prior 6 months, HVTN 906

	N	%
Median no. of male partners (25th, 75th %tile)	3	2, 7
Median no. of male partners of unknown HIV status[a] (25th, 75th %tile)	2	0,5
Had an HIV positive partner [a]	17	2.1
Had a main partner	623	78.0
Had a new partner[b]	436	54.7
Had a male partner with concurrent female partners [a]		
Yes	457	57.3
No	87	10.9
Don't Know	254	31.8
Had a male partner who was incarcerated		
Yes	296	37.0
No	328	41.1
Don't Know	175	21.9
Had a male partner who injected drugs		
Yes	89	11.1
No	494	61.8
Don't Know	216	27.0
Had a male partner who had sex with men		
Yes	32	4.0
No	401	50.2
Don't Know	366	45.8

[a]One woman is missing data.

[b]Two women are missing data.

Table 3

Changes in sexual risk behaviors and male partner risk behaviors from baseline to 18 months, HVTN 906

	Baseline (n=799)	6-mos (n=686)	12-mos (n=661)	18-mos (n=632)	p-value[a] baseline to 18 mos	p-value[a] 6 to 18 mos
In past 6 months:	**%**	**%**	**%**	**%**		
Median no. of male partners (25th, 75th %tile)	3 (2,7)	2 (1,3)	1(1,3)	1(1,3)	<0.0001	0.001
Had a new partner	54.7	38.9	33.1	31.2	<0.0001	0.002
Had unprotected vaginal sex	99.6	81.8	79.0	76.1	<0.0001	0.006
Had unprotected anal sex	24.0	11.5	10.7	8.3	<0.0001	0.06
Had unprotected sex while drunk or high	73.4	59.5	56.4	53.3	<0.0001	0.009
Had unprotected sex while partner was drunk or high	72.2	53.7	53.4	50.4	<0.0001	Ns
Exchanged sex	52.3	37.0	35.6	33.1	<0.0001	0.02
Crack cocaine use	49.4	37.8	33.7	35.2	<0.0001	ns
Marijuana use	47.4	35.1	35.6	31.3	<0.0001	0.06
Heavy alcohol use[b]	31.0	20.7	20.6	19.5	<0.0001	ns
Heroin use	26.7	22.0	20.0	19.7	<0.0001	0.02
Cocaine use	11.6	6.0	3.3	3.8	<0.0001	0.04
Had a male partner who had concurrent female partners						
Yes	57.3	32.0	28.8	23.3	<0.0001	<0.0001
Don't Know	31.8	38.5	40.5	41.3		
Had a male partner who was incarcerated						
Yes	37.0	17.6	15.1	13.0	<0.0001	0.03
Don't Know	21.9	15.5	14.7	12.1		
Had a male partner who injected drugs						
Yes	11.1	3.6	3.5	3.5	<0.0001	ns
Don't Know	27.0	13.3	12.7	12.1		
Had a male partner who had sex with men						
Yes	4.0	1.5	1.4	1.4	ns	ns
Don't Know						
Diagnosed/treated for STI or symptoms	26.7	16.0	14.3	16.2	<0.0001	ns

[a] p-values were from score test statistics testing the null hypothesis that the behavior is the same at the two time points in the context of a GEE model using an exchangeable correlation structure and adjusted for predictors of drop-out (age, ethnicity/race, moved in the year prior to the screening visit, and at baseline reported a male partner who had been incarcerated). Male partner risk behaviors were categorized as yes vs no/don't know for statistical testing.

[b] Heavy alcohol use was defined as drinking 4 or more drinks every day or drinking 6 or more drinks on a typical day that the woman consumed alcohol.

ns= statistically non-significant (p-value > 0.05)