Sexual Risk Behaviors Among HIV-Positive Black Men Who Have Sex With Women, With Men, or With Men and Women: Implications for Intervention Development

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Epidemiological studies consistently show that Black men are disproportionately affected by HIV/AIDS.¹ Although non-Hispanic Black men composed approximately 6% of the US population, they accounted for 29.2% of the estimated number of adults and adolescents living with HIV/AIDS at the end of 2005.^{1,2} Surveillance data show that unprotected male-male sexual intercourse and injection drug use are the primary modes of HIV transmission among Black men. Behavioral studies examining sexual risk show that some HIV-positive persons, including HIV-positive Black men, continue to engage in unprotected sexual intercourse with male and female partners of negative and unknown HIV serostatus.3-8

Considerable research has examined sexual and drug risk behaviors, partner characteristics, and sociodemographics of HIV-positive men. Factors such as use of alcohol or drugs during last episode of sexual intercourse,⁹⁻¹² partnership status (steady or nonsteady),13,14 number of partners,15 partner's HIV status (negative, positive, or unknown),^{16–18} poverty,¹⁹ and sexual exchange (paying or receiving goods or money for sexual intercourse)^{20,21} have all been associated with high-risk sexual behaviors among HIVpositive persons. Many of these studies included relatively few Black men, or Black homosexual and bisexual men were combined into 1 group, or Black men were compared with high-risk men of other race/ethnicity. Although all of these studies have produced pieces of a puzzle for understanding issues associated with HIV transmission among Black men living with HIV/AIDS, they have not specifically focused on behaviorally different groups of HIV-positive Black men.

Rates of HIV seropositivity are high among Black men, and HIV infections are spreading *Objectives.* We compared demographics and sexual and drug risk behaviors among HIV-positive Black men who have sex with women only, with men only, or with men and women to assess differences among and between these groups.

Methods. We analyzed cross-sectional data from the Supplement to HIV and AIDS Surveillance Project for 2038 HIV-positive Black men who reported being sexually active. We classified the participants by their reported sexual behaviors in the past year: intercourse with women (n=1186), with men (n=741), or with men and women (n=111).

Results. Respondents whose sexual partners were both men and women reported more noninjection drug use, sexual exchange, and sexual partners than did the other 2 groups. Bisexual respondents were also more likely than were heterosexuals to report unprotected intercourse with a steady female partner and were more likely than were both other groups to report having steady partners of unknown HIV serostatus and using drugs during their last sexual episode.

Conclusions. HIV-positive Black men with both male and female sexual partners engaged in more sexual and drug risk behaviors than did their heter-osexual and homosexual peers. More information concerning the prevention needs of behaviorally bisexual HIV-positive Black men is needed. (*Am J Public Health.* 2009;99:1072–1078. doi:10.2105/AJPH.2008.144030)

throughout Black communities. We therefore sought to examine differences in self-reported sexual behavior between HIV-positive Black men who have sex with men (MSM), with women (MSW), or with men and women (MSMW) without regard to self-reported sexual orientation. In particular, we examined differences in sexual risk behavior between MSW and MSMW and between MSM and MSMW in the past year. Our data may identify factors contributing to the spread of HIV in Black communities, assist researchers to develop interventions to reduce and eliminate high-risk behaviors in these populations, and ultimately help reduce and prevent the transmission of HIV.

METHODS

Initiated in 1990 and ending in 2004, the Centers for Disease Control and Prevention Supplement to HIV and AIDS Surveillance Project was a cross-sectional multisite study to supplement information routinely collected in HIV/AIDS surveillance in the United States. For our analyses, we focused on the last 4 vears of data (2000-2004). Data were collected by 19 local and state health departments (Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Kansas, Maryland, Michigan, Minnesota, New Jersey, New Mexico, Pennsylvania, South Carolina, Texas, and Washington; 2 of the sites were in 1 state), with each representing a mixture of high-to-moderate HIV prevalence and incidence levels. Interviewers asked participants questions about sociodemographics, substance use, sexual behaviors, medical history, and service utilization. Details of the study's recruitment, methods, and questionnaire are reported elsewhere.²²

Participants and Measures

From June 2000 to January 2004, more than 8000 HIV-positive men and women aged 18 to 79 years were interviewed; our study focused on Black men (N=3047). Because we wanted to specifically focus on sexually active men, those who reported no sexual partners in the past year (n=1009; 33.1%) were excluded, leaving a total of 2038 for analysis.

Participants were asked their gender, ethnicity, race, age, sexual orientation, years of education completed, household income, employment status, incarceration history, and date they tested positive for HIV. Participants' stage of infection at time of interview (HIV infection [not AIDS] or AIDS) were obtained from the national HIV/AIDS reporting system. They were also asked whether they had engaged in the following behaviors in the past year: using injection drugs, using noninjection drugs, receiving money or drugs in exchange for sexual intercourse, and paying money or drugs in exchange for sexual intercourse.

Sexually active participants were asked their number of sexual partners, by gender, in the past year. Men were asked about their most recent sexual partners (steady and nonsteady, by gender). A steady partner was defined as a sexual partner the participant felt committed to above anyone else. A nonsteady partner was defined as the most recent other sexual partner. For each partner type, participants reported whether they had engaged in any of the following behaviors during their last sexual episode: vaginal intercourse, anal intercourse (insertive or receptive), condom use during vaginal and anal intercourse, alcohol use (enough to become drunk or "buzzed"), and drug use. Participants were also asked whether each of their sexual partners had HIV.

Statistical Methods

We divided the sample into 3 groups (MSW, MSM, and MSMW) and compared sociodemographic characteristics, HIV-related information, and drug and sexual risk behaviors with the χ^2 analysis for categorical variables and analysis of variance for continuous variables. We tested for normality of continuous variables and for nonnormal variables; *P* values were calculated with the Kruskal–Wallis test. For significant overall comparisons, we conducted posthoc tests to assess pairwise differences.

Next, we conducted a χ^2 analysis to investigate differences between MSMW and MSW in sexual risk behaviors with female partners. We conducted separate analyses for steady female and nonsteady female partners. We conducted similar analyses to compare sexual behaviors of MSMW and MSM, looking separately at their steady male and nonsteady male partners. If the expected value of any sample size was less than 5, the Fisher exact test was used. We used SAS version 9.1 (SAS Institute, Cary, NC) to conduct all data analyses.

RESULTS

Descriptive data for the 3 subgroups of HIVpositive sexually active Black men are provided in Table 1. Approximately 58.2% of the participants reported sexual intercourse with women only in the past year. A little over 36% reported intercourse with men only, and 5.4% reported intercourse with both men and women. The mean age was 39.5 years (SD=8.9; median=40.0). By self-report, 57.3% identified as heterosexual, 28.2% as homosexual, and 12.7% as bisexual. We compared respondents' reported sexual behaviors with their sexual identity in the past year. For MSW, nearly 96% reported their sexual identity as heterosexual. We observed some discordance in the reporting of sexual identity and sexual behavior for MSM (76% homosexual and 18.5% bisexual) and MSMW (72% bisexual, 14% homosexual, and 10.3% heterosexual).

Slightly more than one quarter of respondents did not complete high school, nearly half were earning less than \$10000 annually, and 61.5% were unemployed. Nearly 59% of the men reported ever being in jail. Nearly 63% had an AIDS diagnosis, and the mean time since their HIV diagnosis was 57 months (SD=59; median=31 months). MSW were significantly more likely than were MSM to be older, have fewer years of education, earn less income, be unemployed, and have an incarceration history; they had also known their positive serostatus for a shorter time, on average.

Slightly more than 28% of participants reported engaging in unprotected sexual intercourse (Table 1). However, we found no significant differences among the 3 groups in reporting unprotected sexual intercourse. MSMW were significantly more likely than were MSM or MSW to report receiving payment or paying for sexual intercourse in the past year. Slightly more than 57% of respondents used noninjection drugs; MSMW reported this behavior significantly more often than did MSW or MSM.

Sexual Partnerships

Overall, 41.2% of the participants reported having only a steady partner in the past year. Nearly 40% reported having only nonsteady partners, and 18.9% reported having both steady and nonsteady partners (data not shown).

Men who have sex with women. The mean number of female partners among MSW in the past year was 3.0 (SD=8.4; median=1). Slightly more than 45% (n=536) reported having a steady female partner only, 32% reported having nonsteady female partners only, and nearly 21% (n=238) reported having both a steady and a nonsteady female partner.

Men who have sex with men. The mean number of male partners among MSM in the past year was 5.0 (SD=14.0; median=2). Nearly 38% (n=275) reported having a male steady partner only. Thirty-six percent (n=267) reported having a nonsteady male partner, and 25% (n=181) reported having both steady and nonsteady male partners.

Men who have sex with men and women. Participants were classified as MSMW if they reported sexual intercourse with at least 1 male and 1 female partner in the past year. The most common partnerships were (1) a nonsteady female and nonsteady male partner (n=37; 33.3%), (2) a steady male and nonsteady male and female partners (n=21; 18.9%), and (3) a steady male and nonsteady female partner (n=14; 12.6%).

Overall, MSMW reported a significantly higher mean number of partners (8.0 [SD=16]) than did MSW (P<.001) and MSM (P<.05) in the past year. However, we observed no significant differences in the number of female partners reported by MSMW and MSW or in the number of male partners reported by MSMW and MSM. Similarly to the other 2 groups, more than 60% of MSMW reported a

TABLE 1—Sociodemographic Characteristics and Sexual and Drug Risk Behaviors Among HIV-Positive, Sexually Active Black Men: Supplemental HIV and AIDS Surveillance Project, 19 US States, 2000–2004

	Total, No. (%) or Mean \pm SD	MSW, No. (%) or Mean $\pm{\rm SD}$	MSM, No. (%) or Mean $\pm{\rm SD}$	MSMW, No. (%) or Mean $\pm{\rm SD}$	P ^a
Total	2038 (100)	1186 (58.2)	741 (36.4)	111 (5.4)	
Age, ^{x,y} y	39.5 ± 8.9	41.6 ± 8.8	36.7 ± 8.3	35.8 ± 8.8	<.001
Sexual orientation ^{x,y,z}					<.001
Heterosexual	1159 (57.3)	1136 (95.9)	12 (1.7)	11 (10.3)	
Homosexual	570 (28.2)	1 (0.1)	554 (76.0)	15 (14.0)	
Bisexual	257 (12.7)	45 (3.8)	135 (18.5)	77 (72.0)	
Other	35 (1.7)	3 (0.2)	28 (3.8)	4 (3.7)	
Education, ^{x,y} y					<.001
<12	537 (26.3)	424 (35.8)	95 (12.8)	18 (16.2)	
12	799 (39.2)	495 (41.7)	257 (34.7)	47 (42.4)	
13-15	532 (26.1)	209 (17.6)	290 (39.1)	33 (29.7)	
≥16	170 (8.3)	58 (4.9)	99 (13.4)	13 (11.7)	
Income, ^x \$					<.001
<10000	919 (48.5)	582 (53.0)	291 (41.9)	46 (45.6)	
10 000-19 999	421 (22.2)	241 (21.9)	158 (22.7)	22 (21.8)	
20 000-29 999	289 (15.3)	152 (13.8)	121 (17.4)	16 (15.8)	
≥30000	266 (14.0)	124 (11.3)	125 (18.0)	17 (16.8)	
Employed ^x	785 (38.5)	433 (36.5)	307 (42.0)	42 (37.8)	.053
Ever incarcerated ^{x,z}	1200 (58.9)	789 (66.6)	346 (46.8)	65 (58.6)	<.001
HIV diagnosis ^{x,z}					<.001
AIDS	1262 (62.5)	739 (62.7)	470 (64.4)	53 (47.8)	
HIV (not AIDS)	757 (37.5)	439 (37.3)	260 (35.6)	58 (52.2)	
Time since learning HIV diagnosis, ^{x,z} mo	57.1 ± 59.4	49.2 ± 55.5	70.8 ± 63.5	$50.4\ \pm54.9$	<.001
Sexual and drug risk behaviors in past y					
Any unprotected intercourse	573 (28.1)	333 (28.1)	203 (27.4)	37 (33.3)	.43
Paid for intercourse ^{x,y,z}	260 (34.0)	163 (29.6)	61 (37.2)	36 (72.0)	<.001
Received payment for intercourse ^{x,y,z}	145 (27.2)	35 (15.0)	82 (32.7)	28 (56.0)	<.001
Noninjection drug use ^{x,y,z}	857 (57.1)	442 (50.9)	346 (64.0)	69 (75.0)	<.001
Injection drug use ^x	62 (15.5)	48 (14.9)	12 (20.0)	2 (11.8)	.79
Multiple sexual partners ^{x,y,z}	4 (11)	3 (8)	5 (14)	8 (16)	<.001

Note. MSW = men who have sex with women; MSM = men who have sex with men; MSMW = men who have sex with men and women.

^aFor categorical values, *P* values were derived from the χ^2 test. For continuous variables, all data were nonnormal, and *P* values were derived from the Kruskal-Wallis test.

^xSignificant difference between MSM and MSW.

^ySignificant difference between MSW and MSMW.

^zSignificant difference between MSM and MSMW.

steady partner (36%, steady male only; 17.1%, steady female only; and 8%, steady male and female).

Sexual Risk Among Men Who Have Sex With Women and Both Men and Women

Steady female partner. MSMW were significantly less likely than were MSW to report having a steady female partner (25.2% vs 65.3%; P<.001). Nearly all of the participants reported engaging in vaginal sexual intercourse with their steady female partner (Table 2). However, MSMW were significantly more likely than were MSW to report engaging in unprotected vaginal intercourse and anal intercourse. Differences in use of alcohol and drugs in the context of most-recent sexual intercourse approached significance, with MSMW being more likely than MSW to report these behaviors. In addition, a substantial majority of both groups (68.6% of MSW and 85.7% of MSMW) reported their steady female partner's HIV status as negative or unknown, with MSMW being significantly more likely to report a steady partner of unknown serostatus than MSW.

Nonsteady female partner. MSMW were more likely to report having a nonsteady female partner than were MSW (77.5% vs 52.1%; P<.001). Table 2 summarizes past-year differences between the 2 groups. MSMW were significantly less likely than were MSW to report engaging in vaginal intercourse but

TABLE 2—Self-Reported Risk Behaviors During Last Sexual Episode Among HIV-Positive, Sexually Active Black MSW or MSMW, by Female Partners Status: Supplemental HIV and AIDS Surveillance Project, 19 US States, 2000–2004

	Stea	Steady Female Partner			Nonsteady Female Partner			
	MSW (n=774), No. (%)	MSMW (n=28), No. (%)	Р	MSW (n=618), No. (%)	MSMW (n=86), No. (%)	Р		
Reported sexual intercourse								
Vaginal intercourse	761 (98.3)	28 (100)	>.99	591 (95.6)	75 (87.2)	<.01		
Unprotected vaginal intercourse	210 (27.6)	13 (46.4)	.03	154 (26.1)	15 (20.0)	.25		
Anal intercourse	31 (4.0)	6 (21.4)	<.01	34 (5.5)	11 (12.8)	<.01		
Unprotected anal intercourse	19 (61.3)	3 (50.0)	.67	13 (38.2)	3 (27.3)	.72		
Substance use during last sexual episo	ode							
Alcohol use ^a	104 (13.4)	7 (25.0)	.09	153 (24.8)	24 (27.9)	.54		
Drug use	92 (11.9)	7 (25.0)	.07	151 (24.5)	37 (46.0)	<.01		
Partner serostatus								
HIV negative	421 (54.4)	12 (42.9)	.23	244 (39.6)	36 (41.9)	.69		
Unknown	110 (14.2)	12 (42.9)	<.01	286 (46.4)	38 (44.2)	.70		
HIV positive	243 (31.4)	4 (14.3)	.05	86 (14.0)	12 (14.0)	.99		

Note. MSW = men who have sex with women; MSMW = men who have sex with men and women.

^aEnough to become drunk or "buzzed."

more likely to report anal intercourse and drug use at last sexual episode with their nonsteady female partner. There were no significant differences between the 2 groups in engaging in unprotected vaginal or anal intercourse and being drunk at last sexual episode. Each group reported that 86% of their nonsteady female partners were HIV negative or of unknown status.

Sexual Risk Among Men Who Have Sex With Men and Both Men and Women

Steady male partner. MSMW were significantly less likely than were MSM to report having a steady male partner (44.1% vs 61.7%; P<.001). MSMW were significantly more likely than were MSM to report being drunk or using drugs the last time they had sexual intercourse with their steady male partner (Table 3). Significantly more MSMW than MSM reported their steady male partner's serostatus

TABLE 3—Self-Reported Risk Behaviors During Last Sexual Episode by HIV-Positive, Sexually Active Black MSM or MSMW, by Male Partner Status: Supplemental HIV and AIDS Surveillance Project, 19 US States, 2000–2004

	Steady Male Partner			Nonsteady Male Partner		
	MSM (n=457), No. (%)	MSMW (n=49), No. (%)	Р	MSM (n=449), No. (%)	MSMW (n=87), No. (%)	Р
Reported sexual intercourse						
Insertive anal intercourse	236 (51.6)	31 (63.3)	0.13	177 (39.4)	58 (66.7)	<.01
Unprotected insertive anal intercourse	83 (35.2)	10 (32.3)	0.74	47 (26.6)	17 (29.3)	0.70
Receptive anal intercourse	273 (59.7)	25 (51.0)	0.30	248 (55.2)	36 (41.4)	<.01
Unprotected receptive anal intercourse	98 (35.9)	9 (36.0)	0.90	73 (29.4)	15 (41.7)	0.15
Substance use during last sexual episode						
Alcohol use ^a	57 (12.5)	12 (24.5)	0.02	79 (17.6)	21 (24.1)	0.15
Drug use	60 (13.2)	13 (26.5)	0.01	101(22.5)	31 (35.6)	<.01
Partner serostatus						
HIV negative	152 (33.3)	24 (49.0)	0.03	146 (32.6)	23 (26.4)	0.26
Unknown	69 (15.1)	13 (26.5)	0.04	188 (42.0)	46 (56.0)	0.06
HIV positive	235 (51.5)	12 (24.5)	<.01	115 (25.4)	18 (20.7)	0.35

Note. MSM = men who have sex with men; MSMW = men who have sex with men and women.

^aEnough to become drunk or "buzzed."

as HIV negative or unknown. MSMW were also significantly less likely to report having an HIV-positive steady male partner.

Nonsteady male partner. MSMW were more likely than were MSM to report having a nonsteady male partner (78.4% vs 60.6%; P<.001). In addition, MSMW were significantly more likely than were MSM to report insertive anal intercourse and use of drugs at last episode of intercourse but were less likely to report engaging in receptive anal intercourse with a nonsteady male partner (Table 3). Both groups reported that more than 70% of these partners were HIV negative or of unknown status.

DISCUSSION

Few studies have examined the sociodemographic characteristics and the sexual and drug risk behaviors among subgroups of HIVpositive Black men. We compared MSMW with MSW, and MSMW with MSM in this population. Of all Black HIV-positive men participating in the Supplement to HIV and AIDS Surveillance Project, approximately one third reported sexual abstinence in the past year, suggesting that they were eliminating or decreasing their risk for sexual transmission and that prevention resources should be targeted to sexually active men and men who may relapse to risk. Approximately 72% of sexually active participants reported using condoms with their most recent partners.

Although high-risk behaviors—unprotected intercourse, sexual exchange, noninjection drug use, large number of partners, alcohol or drug use at last episode of intercourse, intercourse with partners of negative or unknown HIV status—were reported across all 3 groups, HIV-positive Black MSMW reported more risk behaviors than did MSW and MSM. Interventions to reduce the high-risk behaviors of HIVpositive Black men who report intercourse with both men and women are urgently needed.

Higher HIV prevalence levels within Black communities and greater incidence of unprotected intercourse with multiple concurrent partners may be contributing to new infections and fueling the epidemic within these communities.^{1,23} Sexual risk behavior among HIVpositive Black men, such as engaging in unprotected intercourse and sexual exchange with other high-risk men and women, may be helping to sustain the epidemic in some communities.^{3,24,25} Therefore, interventions should be targeted to men reporting sexual exchange, particularly MSMW. Research exploring how contextual issues such as poverty, incarceration, mental health, and childhood sexual abuse influence sexual risk behaviors are needed.^{8,25–27}

Both MSW and MSMW reported unprotected vaginal intercourse with female partners; this type of risk behavior was more common among MSMW. Previous research with HIV-positive Black men reporting steady female partners found that fear of having their faithfulness challenged, potential disclosure of their HIV status, and negative beliefs about condom use correlated with inconsistent use or nonuse of condoms.^{28–30} Prevention efforts are needed to change norms and beliefs and to enhance risk reduction skills among HIV-positive Black men to prevent the further transmission of HIV to female sexual partners.

Black MSM have been disproportionately affected by the HIV epidemic.¹ Previous research indicates that some HIV-positive men select sexual partners for their matching serostatus-a practice known as serosorting-as a strategy to reduce HIV transmission.^{11,18} Our data suggested that some respondents used this strategy. In our sample, MSM were more likely than were MSMW to report that their steady male partners were HIV positive. One possible explanation is that HIV-positive MSM have more venues and social settings available to meet and socialize. Also, more MSW than MSMW reported having a steady HIV-positive female partner. Little research exists on the type and number of venues available for MSW and MSMW to find HIV-positive female partners. Additional research is needed on partner selection, including serostatus-based decisions, and venues in which HIV-positive Black men find partners.

Use of drugs and alcohol has been associated with increased odds of engaging in unprotected intercourse among HIV-positive persons.^{13,30} Substance use may make it more difficult to use condoms, possibly because of loss of inhibition and impaired judgment.³¹ We found that the prevalence of any alcohol or drug use at last episode of intercourse with any partner type was 28.3% for MSW, 26.7% for MSM, and 56.8% for MSMW (data not shown). With a variety of

partner types, MSMW tended to combine sexual intercourse and substance use more frequently than did the other 2 groups. Stigma attached to both serostatus and male–male sexual behavior may have been related to more substance use during last episode of sexual intercourse among MSMW. Comprehensive interventions addressing substance use and sexual risk, including stigma attached to male–male sexual behavior and being HIV positive, are needed for HIVpositive Black men. For the development of such interventions, additional information should be collected about stigma, disclosure, internalized homophobia, partner drug use, sexual exchange, addiction, and other factors.

Conditions associated with poverty (e.g., unemployment, incarceration, and low household income) were highly prevalent among our sample and have been associated with sexual risk in other studies of HIV-positive Black men.^{19,32,33} Given the structural barriers and challenges in the lives of Black men, interventions narrowly focused on reducing unsafe sexual behaviors may not be enough to curb the epidemic; structural and community interventions should be considered.^{34,35} For example, a job-training program coupled with a risk reduction intervention might assist some men to reduce risk.³⁴ Microenterprise programs have been considered for Black women in the United States and should also be explored for Black men.³⁶ Community-level interventions within Black communities that address stigma associated with same-gender sexual behaviors and being HIV-positive might also help HIV-positive men.³⁷

Our analysis benefited from acquiring data from a large and diverse group of HIVpositive Black men, but it also had some limitations. The Supplement to HIV and AIDS Surveillance Project was a cross-sectional survey in select localities in the United States, so causation could not be established. Our results may not be generalizable to all HIV-positive Black men, because the exclusion of certain localities could have biased the data. In addition, we analyzed self-reported responses about sexual risk behaviors collected during face-to-face interviews. Risk behaviors may have been underreported because respondents may have wanted to give socially desired responses regarding high-risk sexual practices.38

We did not conduct statistical tests to determine whether drug use or sexual behaviors

were independently associated with partner type or were the result of differences in participant demographics or partner's serostatus. In addition, we did not explore confounding factors or complex risk associations.

Surveillance data continue to indicate that Black men are at high risk for HIV infection, particularly men who have sex with men.³⁹ Few HIV interventions have been developed for HIV-negative or HIV-positive Black men. Recently, 4 interventions for HIV-positive persons were shown to reduce HIV transmission risk,⁴⁰ but none focused exclusively on Black men. Because of the high prevalence of HIV infection among Black men and in Black communities, there is an urgent need for prevention interventions for this population. Future research should focus on determining which interventions work for HIV-positive Black men in general and what specific components of these interventions may need to be tailored to specific subgroups within this population.

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Contributors

P.S. Spikes, D.W. Purcell, and K. Williams contributed to the study concept and design. Data analyses and interpretation were conducted by P.S. Spikes, D.W. Purcell, Y. Chin, and H. Ding. P.S. Spikes and D.W. Purcell drafted the article. D.W. Purcell, K. Williams, and P.S. Sullivan provided critical revision of the article for important intellectual content.

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Human Participant Protection

All instruments and procedures for the Supplement to HIV and AIDS Surveillance Project were reviewed and approved annually by local and Centers for Disease Control and Prevention institutional review boards.

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