

Anal Sex, Vaginal Practices, and HIV Incidence in Female Sex Workers in Urban Kenya: Implications for the Development of Intravaginal HIV Prevention Methods

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Abstract

Multiple intravaginal HIV prevention methods, including microbicide gels, barriers, and intravaginal rings, are in clinical development in Africa. Development of intravaginal HIV prevention products requires an understanding of sexual behavior, sexually transmitted infection (STI), and vaginitis prevalences, and sexual and vaginal practices in potential target populations. We assessed these factors in a cohort of Kenyan female sex workers (FSW). Women who reported exchanging sex for money/gifts at least three times in the past month and who were HIV uninfected were enrolled and followed for 6 months. STI prevalence and HIV incidence were analyzed by multivariate logistic regression analysis, controlling for demographic and behavioral factors. Thirty-seven percent (74/200) reported having had anal sex. Frequency of anal sex was higher with regular and casual partners than with primary partners. Women were less likely to use condoms for anal sex than for vaginal sex with regular or casual partners. Vaginal washing was universal (100%). HIV incidence was 5.6 per 100 person-years (95% CI 1.62, 11.67). HIV incidence was not associated with any demographic or risk behavior. The relatively high rate of anal sex and universal vaginal washing may complicate both safety and efficacy evaluation of intravaginal products and should be taken into account in trial design. This FSW population had significant HIV incidence and needs continued HIV prevention interventions.

Introduction

OF 2.7 MILLION NEW ADULT HIV-1 infections in 2008, nearly half were in women. Women now account for 47% of adult infections worldwide and 60% of adult infections in sub-Saharan Africa.¹ As HIV increasingly affects women, a safe, effective, acceptable, female-controlled method of HIV prevention is urgently needed to decrease heterosexual HIV transmission. Recently, an antiretroviral-based gel showed significant efficacy in preventing HIV among women in South Africa, spurring clinical testing of related products.² Potential female-controlled methods currently under investigation include microbicides formulated as vaginal gels, creams, films or suppositories, intravaginal rings, vaccines, and antiretrovirals administered as oral preexposure prophylaxis.³ Development of intravaginal products in particular requires an understanding of sexually transmitted infection (STI) and

vaginitis prevalences, specific sexual behaviors, and vaginal practices in potential target populations. Concurrent STIs may enhance toxicity of an intravaginal product or susceptibility to HIV infection.⁴⁻⁶ Practices such as vaginal washing may introduce local toxicity and/or interact with an intravaginal product.⁷⁻⁹ And high rates of unprotected anal intercourse may diminish the measured effectiveness of intravaginal products in preventing HIV infection.¹⁰⁻¹²

In preparation for future studies of intravaginal HIV prevention methods, we assessed HIV risk behavior, HIV incidence, prevalence of STIs and vaginitis, vaginal practices, and retention in a newly described cohort of HIV-uninfected female sex workers (FSW) in urban Kenya. HIV prevalence from 30% to 67% has been documented in Kenyan FSW cohorts,^{13,14} however recent attempts to identify HIV-uninfected FSW cohorts with incidence sufficient for HIV prevention trials have been difficult.¹⁵

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Materials and Methods

Study population

The study was designed and implemented with the Kenya AIDS Vaccine Initiative, a local research organization providing HIV prevention and care activities targeting FSW and other HIV at-risk populations in Nairobi. For FSW, these activities include HIV prevention education in locales frequented by FSW and their clients, HIV voluntary counseling and testing, free male and female condom distribution, providing material support to local clinics serving FSW, and implementing FSW social empowerment groups. Women who attended education sessions for FSW in the Mukuru neighborhood of Nairobi were offered HIV testing and if HIV uninfected, were recruited for the study. Mukuru is a slum area located on the city outskirts that has previously not been targeted for HIV prevention research. Women age 18–60, HIV negative, not pregnant, and who reported exchanging sex for money or gifts at least three times in the past month were eligible to enroll. Women who were pregnant or HIV infected were counseled and referred for medical care but excluded from the study. Ethics approval for the study was obtained from the Kenyatta National Hospital Ethics and Emory University Institutional Review Board. Written informed consent was obtained from all participants prior to any study procedures.

Study procedures

At study entry, medical history and detailed sexual and vaginal hygiene behavioral data were collected during face-to-face interviews by female nurses in the local languages. A physical examination including speculum and bimanual pelvic examination was performed by a gynecologist. Anal specimens were not collected. Participants were followed every 3 months to collect interim medical history and behavioral assessment and were provided with HIV testing, risk reduction counseling, syndromic screening, and treatment for STIs following Kenyan national STI treatment guidelines, free male and female condoms, pregnancy testing, and family planning counseling. In addition, at month 6, the physical examination and STI testing were repeated. Women with pregnancy detected during the study were counseled and referred for prenatal care. Women diagnosed with HIV infection during the study were counseled and referred to the nearest free HIV treatment clinic and provided free transportation to the HIV clinic for the duration of the study. Participants were compensated for their time and transportation for each visit.

Laboratory procedures

Blood was tested for syphilis using rapid plasma reagin with confirmation by a *Treponema pallidum* hemagglutination assay, HSV-2 IgG antibody (Captia EIA, Trinity Biotech, USA), and HIV antibodies (Unigold, Trinity Biotech, Ireland; Determine, Abbott Laboratories USA; Vironostika). Urine was tested for human chorionic gonadotropin to detect pregnancy. Vaginal secretions were tested for *N. gonorrhoea* and *C. trachomatis* (Amplicor CT/NG, Roche, USA), *Trichomonas vaginalis* (InPouch TV, BioMed Diagnostics, USA), bacterial vaginosis, and candida (Gram stain of vaginal smear). Bacterial vaginosis was diagnosed if Nugent's score of

the Gram stain was 7 or greater.¹⁶ A diagnosis of candidiasis was made if the Gram stain showed candida and the participant had vaginal pruritis, discharge, or dysuria consistent with candidiasis. Laboratory testing was conducted by the Kenya AIDS Vaccine Initiative Laboratory and University of Nairobi Microbiology Annex laboratory, both of which participate in local quality assurance programs.

Statistical analysis

Data were analyzed using SAS 9.1. Proportions were calculated and 95% confidence intervals were determined using exact binomial estimates for proportions and using a Poisson distribution for incidence. HIV incidence was calculated as the number of HIV seroconversions divided by the total person years (PY) of follow-up and expressed as the number of events per 100 PY. Associations between STI diagnoses and sex worker characteristics were analyzed with unadjusted odds ratios. Associations between incident HIV and potential risk factors, sex worker characteristics, and STI diagnoses were analyzed using incidence rate ratios and 95% CI assuming a Poisson distribution. Variables associated with the outcome at a level of $p < 0.20$ were included in a backward stepwise multivariate regression model to determine adjusted odds ratios and rate ratios. Factors remaining significant at $p < 0.10$ and those that changed the unadjusted ORs by more than 10% were retained in the final model.

Results

From March to October 2008, 214 women were screened and 200 enrolled. Pregnancy was the primary reason for ineligibility. Table 1 shows the baseline sociodemographic and HIV risk behaviors of the cohort.

Almost all participants self-identified as commercial sex workers and were unmarried, with primary school or less education. Women reported an average of 2.4 regular paying sex partners per day (sex on a regular basis, i.e., weekly) and 1.9 casual sex partners per day (one-time or anonymous partner). Only 3% of women knew the HIV status of their sexual partners. Reported condom use during vaginal sex, sometimes or always, in the past month with regular or casual partners was high, 90% and 88%, but less common with primary partners (boyfriend or husband), 41%, $p < 0.0001$. Anal sex was reported by 37% of women. Frequency of anal sex in the past month varied significantly by partner type, being most common with regular partners and casual partners and less common with primary partners, 35% and 29% vs. 9%, $p < 0.001$. Despite the relatively high frequency of anal sex with regular or casual partners, condoms were less likely to have been used for anal sex than for vaginal sex: 24% and 21% of women reported "never" using condoms for anal sex with regular or casual partners, respectively, compared to 9% and 10% for vaginal sex, $p = 0.0009$. Almost half of the women reported being paid more for sex without a condom. Having sex under the influence of drugs or alcohol and physical or sexual assault related to sex work in the past month occurred in one-third and one-fifth of women, respectively.

Female condom use was low, with only 11% of women reporting regular use; 28% had never used female condoms. Of the 27% (53/200) who disliked female condoms, the major reasons were cost and difficulty accessing (42%), dislodging during intercourse (25%), and overall cumbersomeness (17%).

TABLE 1. BASELINE SOCIODEMOGRAPHIC AND HIV RISK BEHAVIORS (PAST MONTH), N=200

Age in years, mean (range)	28 (18–55)
Education	
None	83/200 (41.5%)
≤8 years	99/200 (49.5%)
>8 years	18/200 (9.0%)
Marital status	
Never married	98/200 (49.0%)
Married	1/200 (0.5%)
Separated/divorced/widowed	101/200 (50.5%)
Religion	
Christian	180/200 (90%)
Muslim	3/200 (2%)
Other/none	17/200 (8%)
Employment status	
Commercial sex worker	192/200 (96.0%)
Casual worker	8/200 (4.0%)
Daily income, mean (range)	US \$2 (0.26–13)
Number of dependents, mean (range)	2.1 (0–6)
Age at first intercourse, mean	16 (8–26)
Have primary partner ^a	64/200 (32.0%)
Sometimes or always use condom during vaginal sex with primary partner	26/63 (41.3%)
Sometimes or always have anal sex with primary partner	6/64 (9.4%)
Sometimes or always use condoms during anal sex with primary partner	2/7 (29.0%)
Number of regular partners ^b per day, mean (range)	2.4 (0–7)
Sometimes or always use condom during vaginal sex with regular partners	171/190 (90.0%)
Sometimes or always have anal sex with regular partners	68/192 (35.4%)
Sometimes or always use condoms during anal sex with regular partners	52/71 (73.2%)
Number of casual partners ^c per day, mean (range)	1.9 (0–5)
Sometimes or always use condom during vaginal sex with casual partners	164/187 (87.7%)
Sometimes or always have anal sex with casual partners	54/188 (28.7%)
Sometimes or always use condoms during anal sex with casual partners	41/56 (73.2%)
No knowledge of partner's HIV status	194/200 (97.0%)
Sometimes or always was paid more for sex without a condom	58/200 (29.0%)
Drinks alcohol ≥3 drinks at a time	59/200 (25.2%)
Uses illicit drugs	44/200 (21.5%)
Sometimes or always has sex under the influence of drugs or alcohol	63/200 (31.5%)
Experienced sexual or physical assault related to sex work in the past 1 month	39/200 (19.5%)

^aPrimary partner is the main sexual partner, i.e., boyfriend or husband.

^bRegular partner pays with money or goods for sex on a regular basis.

^cCasual partner pays with money or goods for sex on a one-time or anonymous basis.

Use of modern contraceptive methods was high in this population with 52% using nonbarrier methods and 17.5% using male or female condoms (Table 2). Only 25% of women reported regular monthly menses, perhaps related to the relatively high proportion of women on hormonal contraception, either injectable (37%) or oral contraceptives (12%).

Vaginal washing after sex was common with 73% of the women reporting vaginal washing after each sex act and 100% washing at least once daily. Soap and water were most commonly used, but lemon and salt/salt water were also mentioned along with a variety of other agents such as tea leaves, soda, and herbs. Cleaning and preparing for the next client were the most common reason for vaginal washing, however, astringents such as lemon and salt were felt to dry and tighten the vagina as well as kill germs. Lubricant use during sex was reported by about one-third of participants. All lubricant products mentioned contained mineral oil or other products known to degrade latex condoms.

Several HIV risk behaviors declined significantly during the 6-month follow-up period, including the average number of

TABLE 2. BASELINE CONTRACEPTION AND VAGINAL PRACTICES, N=200

Current contraceptive method	
Nonbarrier method	104 (52.0%)
Injectable	74 (37.0%)
Oral contraceptive	23 (11.5%)
Norplant	4 (2.0%)
IUD	2 (1.0%)
Tubal ligation	2 (1.0%)
Condom	35 (17.5%)
Male condom	31 (15.5%)
Female condom	4 (2.0%)
Nonbarrier method and condom	3 (1.5%)
None	58 (29.0%)
Number of pregnancies, mean (range)	2.7 (0–13)
Douche or wash genitals at least once daily	200 (100.0%)
Douche or wash genitals after every sex act	146 (73.0%)
Products used for douching/washing ^a	
Soap and water	169 (84.5%)
Fingers/cloth	54 (27.0%)
Lemon	23 (11.5%)
Salt/salt water	22 (11.0%)
Water	19 (9.5%)
Other (soda, herbs, tea leaves)	3 (2.0%)
Reasons for douching ^a	
Prepare for next client	30 (15.0%)
Clean/prevent smell	159 (79.5%)
Prevent infections	23 (11.5%)
Dry and tighten	27 (13.5%)
Relieve itching/irritation	6 (3.0%)
Other	1 (0.5%)
Use lubricant during sex	65 (32.5%)
Types of lubricants used ^a	
Body oil (mineral oil)	44 (22.0%)
Vaseline (petroleum jelly)	25 (12.5%)
Other	4 (2.0%)
Types of health care providers used for STI or vaginitis symptoms ^a	
Medical clinic	114 (57.0%)
Pharmacist	80 (40.0%)
Traditional healer	8 (4.0%)

^aMore than one answer is possible.

IUD, intrauterine device; STI, sexually transmitted infection.

regular partners, 6 vs. 5, $p < 0.01$, the average number of casual partners, 5 vs. 4, $p < 0.01$, and alcohol use 55% (94/71) vs. 49% (86/171), $p < 0.05$. However, the proportion of volunteers reporting unprotected vaginal and anal sex did not change.

Vaginal discharge and abdominal pain were reported by about half of the women at baseline. Clinical pelvic inflammatory disease, defined as lower abdominal tenderness on palpation, cervical motion tenderness, and adnexal tenderness on examination with no other established cause, was diagnosed in 7.2% of women. Table 3 shows the prevalence of common STI, vaginitis, and genital symptoms at enrollment and month 6. As expected, vaginitis was common, with 38.0% of women diagnosed with bacterial vaginosis, 9.0% with trichomoniasis, and 7.0% with vaginal candidiasis. Gonorrhea and chlamydia diagnoses were lower than expected, 6.0% and 5.5%. Active genital ulcer disease was uncommon despite an HSV-2 seroprevalence of 72%. All STI and vaginitis rates declined on follow-up at month 6.

In multivariate analyses, diagnosis of chlamydia, gonorrhea, trichomoniasis, or syphilis at baseline was strongly associated with alcohol use (aOR=3.35, 95% CI 1.56, 7.23, $p=0.002$) and reporting never having anal sex with casual partners (aOR=3.32, 95% CI 1.29–8.55, $p=0.013$). Chlamydia was strongly associated with age ≤ 22 (aOR=7.75, 95% CI 1.94–30.88, $p=0.004$) and any lubricant use (aOR=3.6, 95% CI 0.96–13.14, $p=0.057$). Trichomoniasis was associated with having more than two dependents (aOR=2.90, 95% CI 1.05–8.00, $p=0.04$) and reporting never using a condom for vaginal sex with a casual partner (aOR=4.84, 95% CI 1.45–16.15, $p=0.01$). Reduced risk for HSV-2 Ab seropositivity was associated with age ≤ 22 (aOR=0.49, 95% CI 0.24–1.0, $p=0.05$). Reduced risk for bacterial vaginosis was associated with having anal sex with regular partners (aOR=0.53, 95% CI 0.28–0.99, $p=0.045$). No significant associations were found for gonorrhea or syphilis.

Five new HIV infections occurred during follow-up (89.3 person years of follow-up). HIV incidence was calculated at 5.6 per 100 person-years (95% CI 1.62, 11.67). HIV incidence was not clearly associated with any demographic, genital behavior, or risk behavior in univariate or multivariate analyses (Table 4).

Retention was 93% at 1 month and 86% after 6 months of follow-up. Seasonal migration back to rural hometowns and pregnancy accounted for the majority of loss to follow-up.

Thirteen pregnancies occurred during follow-up for an annual pregnancy rate of 14.2 per 1000 women.

Discussion

Our findings on partner-specific condom use, frequency of anal sex, vaginal washing practices, STI prevalence, and HIV incidence in this cohort of Kenyan female sex workers highlight many issues relevant for the development of HIV prevention methods, particularly intravaginal methods. First, reported condom use with regular or casual partners was high, reflecting significant knowledge of HIV risk associated with sex work in this urban slum FSW population. However, reported condom use was significantly lower with primary partners even though women were unlikely to know any partners' HIV status, suggesting that FSW were still unable to negotiate condom use with long-term partners or did not want to use condoms perhaps because these partners are considered less risky.¹⁷ Such partner-specific condom use has been seen in other FSW and female cohorts in a variety of settings^{18–20} and supports the concept that HIV prevention methods that are controlled by or can be detected by male partners may not be feasible for women in primary partnerships. Completely discrete intravaginal products, oral pre-exposure prophylaxis, or vaccines may be the only types of methods that can overcome this barrier.

Anal sex was not uncommon in this population, with 37% of women reporting ever having anal sex. Anal sex has been documented in other FSW cohorts in Kenya with prevalences of 14–40%.^{14,21,22} The relatively high prevalence of heterosexual anal sex is relevant for the development of intravaginal products, as these products are unlikely to extend protection to the rectum. During clinical trials of intravaginal products, even modest rates of anal sex in a population may allow for HIV transmission and, if not accounted for, may mask the true effectiveness of a product.^{11,12} Furthermore, anal sex was associated with lower reported rates of condom use, highlighting the importance of this sexual behavior even among heterosexual women. Current plans for clinical development of rectal microbicides include trials in women.¹⁰ FSW may benefit from rectal microbicides if they are shown to be effective.

The higher rates of anal sex with regular or casual partners than with primary partners seen in our study may reflect the taboo nature of anal sex, where anal sex may be available as a

TABLE 3. PREVALENCE OF STIs, VAGINITIS, AND GENITAL SYMPTOMS AT BASELINE AND MONTH 6

Diagnosis	Baseline (N=200)			Month 6 (N=171)		
	n	%	95% CI	n	%	95% CI
Bacterial vaginosis	76	38.0	31.2–45.1	37	21.6	15.7–28.6
Trichomoniasis	18	9.0	5.4–13.9	10	5.9	2.8–10.5
Vaginal candidiasis	14	7.0	3.9–11.5	7	4.1	1.7–8.3
Gonorrhea	12	6.0	3.1–10.3	4	2.3	0.6–5.9
Chlamydia	11	5.5	2.8–9.6	5	2.9	1.0–6.7
Syphilis	5	2.5	0.8–5.7	5	2.9	1.0–6.7
Genital condyloma	2	1.0	0.1–3.6	0		
Genital ulcer disease	2	1.0	0.1–3.6	0		
HSV-2 antibody	144	72.0	65.2–78.1	NA		
Vaginal discharge	53	26.5	20.5–33.2	43	25.2	18.8–32.3
Lower abdominal pain	50	25	19.2–31.6	13	7.6	4.1–12.7

TABLE 4. ASSOCIATION BETWEEN INCIDENT HIV AND DEMOGRAPHIC/BEHAVIORAL CHARACTERISTICS OR PREVALENT STI/VAGINITIS

Characteristic	Incident HIV	
	OR (95% CI)	p value
Age (≤ 22 , > 22)	1.83 (0.30, 11.28)	0.508
Income (≤ 200 KSh, > 200)	3.98 (0.64, 24.87)	0.114
Ever married vs. never married	1.45 (0.24, 8.90)	0.684
Dependents (> 2 , ≤ 2)	1.14 (0.19, 6.98)	0.888
Age at first intercourse (≤ 16 , > 16)	0.45 (0.7, 2.78)	0.383
Regular partners/week (> 4 , ≤ 4)	0.24 (0.04, 1.45)	0.093
Casual partners/week (> 4 , ≤ 4)	0.22 (0.02, 1.99)	0.142
Any condom use during vaginal sex with regular partners	0.36 (0.04, 3.39)	0.352
Any condom use during vaginal sex with casual partners	0.38 (0.04, 3.61)	0.385
Any anal sex with regular partners vs. no anal sex with regular partners	0.45 (0.05, 4.07)	0.464
Any anal sex with casual partners vs. no anal sex with casual partners	0.64 (0.07, 5.82)	0.687
Any condom use during anal sex with regular partners	0.36 (0.04, 3.39)	0.352
Any condom use during anal sex with casual partners	0.24 (0.02, 2.32)	0.183
Vaginal washing (> 1 daily, ≤ 1 daily)	2.35 (0.13, 43.50) ^a	0.307
Any lubricant use vs. none	0.51 (0.06, 4.67)	0.547
Any alcohol use vs. none	0.20 (0.02, 1.83)	0.118
Candidiasis	1.61 (0.08, 31.03) ^a	0.604
Bacterial vaginosis	0.41 (0.04, 3.73)	0.414
Chlamydia	1.46 (0.08, 28.03) ^a	0.586
Gonorrhea	1.33 (0.07, 25.53) ^a	0.568
Trichomoniasis	0.87 (0.05, 16.41) ^a	0.478
Syphilis	3.15 (0.15, 64.30) ^a	0.718
HSV-2 Ab ⁺	0.60 (0.20–3.71)	0.584
PID	0.41 (0.02–7.60) ^a	0.298

^aLogit estimate used as some cells equal zero.

transaction and perhaps more acceptable to report in this setting, but is not commonly reported in noncommercial relationships. Unfortunately, the high rates of condom use for vaginal sex with regular and casual partners did not carry over to anal sex: condom use for anal sex was significantly lower. It is possible that women were not aware of the HIV risk from anal sex; however, another study found that Kenyan FSW rated anal sex as more risky than vaginal sex.²² Women in the current study may not have been able to negotiate condom use for anal sex with regular and casual partners, but given the high rates of condom use for vaginal sex this seems less likely. Condom use with anal sex may also have been less common if it was associated with forced sex or if women were paid more for anal sex without a condom. We did not collect data on these topics, but other studies in Kenya have shown these associations.^{21,22}

Vaginal washing was universal in this population; most women washed multiple times per day with at least a quarter using acidic and/or drying agents. Vaginal washing may complicate the evaluation of intravaginal products in several ways. Frequent vaginal washing soon after sex may dilute or remove a gel or cream product, limiting the duration of effect.²³ Intravaginal washing may cause direct irritation to the vaginal or cervical mucosa complicating the evaluation of product-related toxicity, or the cleaning agents could interact with the product leading to a new toxicity or enhancing an existing toxicity.²³ Some studies have associated vaginal washing with increased STI and HIV acquisition, although many have shown no clear association.^{24–26} We found no correlation between vaginal washing and prevalent STI or incident HIV infection. The potential effects of vaginal washing and related vaginal practices on intravaginal products, such as microbicide gels or intravaginal rings, need to be evaluated in a systematic manner as part of the product development process.²³

Although some expected sociodemographic and behavioral factors, such as age, alcohol use, and condom use were associated with prevalent STIs, we did not detect their association with incident HIV. The lack of clear correlates for incident HIV may be due to the small number of infections detected during follow-up. The relatively low rates of STIs, particularly chlamydia and gonorrhea, in this cohort suggest that the prevalence of these STIs among their partners is low and/or that vaginal sex is well protected. In contrast, the HIV estimate of 5.6 per 100 person years suggests that HIV is circulating widely within the population, perhaps through unprotected anal sex or in women with multiple cofactors.

Several FSW cohorts in both urban and rural Kenya have been well described, including aspects of our findings on anal sex, partner-specific condom use, and vaginal washing.^{14,20,22,24} However, the cohort described here is particularly relevant for biomedical HIV prevention trials because of the high HIV incidence observed. Recent studies of HIV incidence in FSW cohorts in other areas of Nairobi have found lower incidence rates that would not support participation in efficacy trials.¹⁵ Our data suggest that even in well-studied urban areas such as Nairobi, continued HIV transmission is occurring in previously undescribed FSW cohorts.

This study has several limitations. Self-reported vaginal practice and sexual activity data may be subject to social desirability bias, leading to underreporting of risk behavior. The number of women who reported using condoms as a form of contraception was much lower than the number reporting sometimes or always using condoms with various partners. Women may have interpreted condom use for contraception to mean consistent condom use with all partners resulting in lower reporting for this behavior. In some languages, anal sex can be confused with vaginal penetration from behind; however, anatomically correct Swahili words were used to describe anal sex to avoid this confusion. We did not collect data on anorectal STIs or anal hygiene. The period of follow-up limited our ability to determine a more precise estimate of HIV incidence and possibly also to determine cofactors for HIV acquisition. More details on how vaginal washing was conducted, the timing relative to sex, and the chemical composition of the products used could provide information relevant for the preclinical and clinical development of intravaginal prevention products. Although detailed quantitative vaginal

practice and sexual behavior data were collected, there may be other behaviors important to the development of biomedical HIV prevention methods and HIV risk that could be better identified through qualitative research.

The relatively high rate of anal sex and universal vaginal washing seen in this Kenyan FSW population may complicate both the safety and efficacy evaluation of intravaginal products. As testing of intravaginal HIV prevention methods accelerates, these findings should be taken into account in manufacturing, preclinical, and clinical development plans. This newly described FSW population in urban Kenya has significant HIV incidence, needs continued HIV prevention interventions, and would be appropriate for HIV prevention trials. Longer-term follow-up of this population is needed to better understand cofactors for HIV acquisition.

Acknowledgments

The authors acknowledge Alice Githae, Vera Etole, Carol Nasambu, Ruth Ndati, Linda Ostianda, Dr. Maurine Mutua, Samuel Kazungu, Prof. Omu Anzala and the study participants for their valuable contributions to the study. Funding was provided by the CDC Foundation and Emory Center for AIDS Research (NIH/NIAID Grant P30 AI050409).

Author Disclosure Statement

No competing financial interests exist.

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