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Screening for genital and anorectal sexually transmitted infections in HIV prevention trials in Africa

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Abstract

Objectives: Our objectives were (1) to demonstrate the value of routine, basic sexually transmitted infection (STI) screening at enrolment into an HIV-1 vaccine feasibility cohort study; and (2) to highlight the importance of soliciting a history of receptive anal intercourse (RAI) in adults identified as 'high risk'.

Methods: Routine STI screening was offered to adults at high risk for HIV-1 upon enrolment into a cohort study in preparation for HIV-1 vaccine trials. Risk behaviors and STI prevalence were summarized, and the value of microscopy assessed. Associations between prevalent HIV-1 infection and RAI or prevalent STIs were evaluated with multiple logistic regression.

Results: Participants had a high burden of untreated STIs. Symptom-directed management would have missed 67% of urethritis cases in men and 59% of cervicitis cases in women. RAI was reported by 36% of male and 18% of female participants. RAI was strongly associated with HIV-1 in men (adjusted odds ratio [aOR] = 3.8, 95% CI 2.0 – 6.9), and independently associated with syphilis in women (aOR 12.9, 95% CI 3.4 – 48.7).

Conclusions: High-risk adults recruited for HIV-1 prevention trials carry a high STI burden. Symptom-directed treatment may miss many cases, and simple laboratory-based screening can be done with little cost. Risk assessment should include questions about anal intercourse and whether condoms were used. STI screening, including specific assessment for anorectal disease, should be offered in African research settings recruiting participants at high risk for HIV-1 acquisition.

Key words: sexually transmitted infections, HIV, receptive anal intercourse

Introduction

Sexually transmitted infections (STI), including infection with the human immunodeficiency virus (HIV), are a major cause of morbidity and mortality worldwide [1, 2]. STIs other than HIV have been implicated in the transmission and acquisition of HIV infection, and their treatment can play an important role in HIV prevention [3, 4]. Numerous large-scale, clinical trials are ongoing to test the efficacy of HIV-1 prevention interventions, including vaccines, microbicides, pre-exposure prophylaxis, and suppression of genital herpes simplex infection. Such trials typically aim to recruit persons at high risk for HIV-1 acquisition in order to acquire sufficient numbers of incident HIV-1 infections for adequate statistical power. While many trials have included expanded STI screening for either research or patient care purposes [5, 6], the incorporation of routine, basic STI services for study participants has not been uniformly adopted. Where protocols call for long-term follow-up of persons at high risk, we present the argument that offering syndromic treatment alone is insufficient, and should be supplemented with basic laboratory investigations and expanded risk assessment in the context of HIV-1 prevention trials.

We present our experience with a basic STI screening program in the context of an ongoing cohort study in preparation for HIV-1 vaccine trials based near Mombasa, Kenya. While the site has been participating in a multi-centre, multi-country effort to identify volunteers at high risk for HIV-1 infection in Africa, the addition of basic microscopy for STI screening programme was site-specific, as no such screening was available in the community. Our primary objective was to demonstrate the value of routine, basic STI screening at enrolment into an HIV-1 vaccine feasibility cohort study, with the simple hypothesis that STI screening at enrolment into the cohort would result in increased diagnosis and treatment of STIs among study participants. When several of our volunteers reported recent anal intercourse at enrolment, another site-specific element in our recruitment strategies became an expansion of the eligibility criteria to

include a self-report of recent anal sex. Therefore, another objective became highlighting the importance of soliciting a history of receptive anal intercourse (RAI) in adults identified as 'high risk'. We hypothesized that anal sex was not uncommon among high-risk adults and that participants with a history of recent RAI would be at increased risk for prevalent STIs, including proctitis.

Methods

Study population and data collection. In a clinic near Mombasa, Kenya, prospective volunteers at risk for HIV infection were identified and recruited into a cohort study in preparation for HIV-1 vaccine trials, starting in July 2005. Recruitment was aimed at high-risk groups such as female sex workers (FSWs), persons with a recent STI or multiple partners, HIV-1 serodiscordant couples, or any other person who in the opinion of the investigator was at higher risk for HIV-1 infection. When a number of men and women recruited reported practicing anal sex, inclusion criteria were modified to add any person reporting anal sex in the previous three months, and recruitment of men who have sex with men (MSM) and women practicing anal sex was intensified by peer educators. The National Ethical Review Committee of the Kenya Medical Research Institute approved this study. All participants provided written, informed consent.

Screening procedures at enrolment. A standardized, detailed socio-demographic and sexual behavior history was completed through a face-to-face interview with a counselor. When anal sex was practiced, information on whether the participant took an insertive and receptive role (for men) was obtained. Subsequently, study physicians obtained a brief medical history and performed a physical examination, including a genital examination. A bimanual and speculum-aided pelvic examination was performed for women, during which vaginal and endocervical swabs were systematically collected for microscopic examination. Urethral swabs were collected for symptomatic men or if urethral discharge was present on examination. The

presence of genital ulcers was recorded. Venous blood samples were collected for HIV-1 and syphilis serology.

From September 2006, male and female participants who reported RAI in the previous three months upon enrolment screening were asked about symptoms of anorectal pain, rectal discharge or bleeding, pain during sex, pain with defecation, or perianal ulcers or warts during the same period. Proctoscopy was offered to all participants reporting recent RAI to evaluate the STI burden of anal intercourse, and included inspection for perianal ulcers or condylomata, mucosa erythema or ulcerations, and mucopurulent rectal discharge, as well as collection of swabs of rectal secretions for Gram staining.

All participants received comprehensive risk reduction counseling, free male or female condoms and water-based lubricants, and treatment of STIs in accordance with WHO treatment guidelines [7]. Symptomatic vaginitis and urethritis were treated at the enrolment visit. Women were provided with treatment for cervicitis if mucopurulent discharge was seen. Results of laboratory testing were available 10 days after each visit. Participants were asked to return for results, and laboratory-confirmed STIs were treated at this time. Tracing was initiated if a participant with an STI diagnosis failed to return for results. Participants who were HIV-1 positive at screening were offered either referral to a collaborating point of care or enrollment into a parallel HIV-1-positive cohort in which they received comprehensive HIV care and periodic STI screening. Follow up of HIV-1 positive participants in a cohort with a similar appointment scheme has helped in retaining populations particularly vulnerable to HIV-1 infection while maintaining confidentiality about HIV-1 serostatus [8]. Volunteers received a small reimbursement for travel expenses.

Laboratory procedures. *Trichomonas vaginalis* was diagnosed by identification of motile trichomonads on a saline wet preparation of vaginal secretions. Vaginal candidiasis was defined as identification of organisms consistent with *Candida* species on a 10% potassium hydroxide slide. BV was diagnosed by microscopic analysis of a Gram-stained vaginal smear; a Nugent's score ≥ 7 was considered positive for BV [9]. Cervicitis was defined as the presence of ≥ 30 polymorphonuclear leukocytes per high power field on a cervical Gram stain. Urethritis was defined as the presence of ≥ 5 polymorphonuclear cells per high power field on a Gram-stained urethral smear. Due to limited resources, *Trichomonas vaginalis* and other pathogens were not tested specifically in men. The detection of Gram-negative, intracellular diplococci consistent with *N. gonorrhoeae* was used to define gonococcal infection. Proctitis was defined as the presence of ≥ 5 polymorphonuclear cells per high power field on a rectal Gram stain [10]. Laboratory technicians underwent training in the University of Washington's Mombasa-based research laboratory, with periodic quality control of readings. Quality assurance of the STI-screening programme was locally supported, and not part of the multi-centre study procedures.

HIV-1 was tested on site by two rapid test kits (*Determine*, Abbot Laboratories, USA; *Unigold*, Trinity Biotech, PLC, Ireland). Discrepant rapid HIV-1 test results were resolved using a 4th-generation HIV antigen/antibody assay performed at the Kenya AIDS Vaccine Initiative laboratories in Nairobi [11]. Screening for syphilis was performed at the KEMRI laboratories in Kilifi using rapid plasma reagin, with positive samples confirmed by a *Treponema pallidum* haemagglutination assay.

Data analysis. Data were analyzed using Stata 9.2, and were summarized using frequencies for categorical variables and medians with inter-quartile ranges for continuous variables. Sensitivity, specificity, and predictive values of symptoms for the diagnosis of various genital tract infections were calculated according to standard formulae, and 95% confidence intervals were calculated

using exact binomial estimation. Missing data (e.g., from participants who refused a genital examination, or from visits prior to the addition of questions on anorectal symptoms in September 2006) were excluded from the analysis. Associations between reported recent sexual behaviour, prevalent genital tract infection, and HIV-1 or syphilis were evaluated using multivariate logistic regression for records with complete clinical and laboratory data. A forward stepwise model was created, retaining variables in association with the outcome ($p < 0.2$) or resulting in a $>10\%$ change in the unadjusted odds ratio. P -values were two-tailed unless otherwise noted, with values <0.05 considered statistically significant.

Results

Characteristics and STI prevalence of study population. A total of 897 participants at risk for HIV-1 infection were enrolled in the study cohort between July 2005 and June 2007. Three-hundred and four (34%) study volunteers self-identified at enrolment as commercial sex workers, 316 (35%) as men who have sex with men (MSM), 169 (19%) as having multiple recent sexual partners, 58 (7%) as having STI symptoms, 28 (3%) as having an HIV-1 seropositive partner, and 22 (2%) were peer leaders who helped with recruitment, but were at slightly lower risk. Sociodemographic and sexual behavior characteristics of this cohort, including use of condoms and family planning methods, are presented in table 1; in this table, “regular” partners are those identified as persons with whom there is an ongoing relationship, while “casual” partners are persons with whom there is no expectation of a continuing relationship. The overall prevalence of STI symptoms and signs, as well as laboratory-diagnosed STIs in men and women at cohort enrollment is presented in table 2. For the analysis of symptoms and signs, 22 women and 36 men had incomplete data and were excluded. For the analysis of laboratory-confirmed STIs, 37 women and 50 men were excluded due to incomplete data.

Value of microscopy. Of the 32 women diagnosed with trichomoniasis, 20 (62%) had not complained of vaginal discharge. Of the 34 women diagnosed with cervicitis, 20 (59%) reported no vaginal discharge and 29 (81%) had no cervical mucopus on speculum exam. Pelvic inflammatory disease was diagnosed clinically and treated in 13 women, of whom 3 reported no vaginal discharge. Of the 27 cases of laboratory-diagnosed urethritis, 18 (67%) had no compatible symptoms. The sensitivity, specificity, and predictive values of genital tract symptoms for laboratory diagnosis of an STI at enrolment is presented in Table 3.

Receptive anal intercourse. RAI in the previous 3 months was reported by a total of 191 men (36%) and 64 women (18%); 57 (89%) of the women reporting recent RAI identified themselves as FSWs. From September 2006, clinicians documented anorectal symptoms and offered proctoscopy to all participants engaging in RAI to screen for rectal STIs. Anorectal symptoms including pain and bleeding were common among persons reporting RAI (reported by 33%); rectal discharge was less common (reported by 10% of men and 2% of women). Participants reporting anorectal symptoms were more likely to agree to undergo proctoscopy (61%) compared to those who were asymptomatic (30%, $p < 0.001$). Men were more likely to accept proctoscopy than women, irrespective of symptoms (45% versus 26%, respectively, $p = 0.024$). Among the 69 participants who had a complete anorectal exam by proctoscopy, mucoid or mucopurulent discharge was seen in 14 (20%) participants, mucosal erythema in 21 (30%), and ulcerations in 5 (7%). No anal ulcers were seen in persons diagnosed with syphilis, although only two such persons underwent proctoscopy. Proctitis was diagnosed by Gram stain in 4 (7%) participants, all of whom were men; 3 were symptomatic.

Table 4 presents associations between prevalent HIV infection and either recent RAI or prevalent STIs at enrolment among men and women in the cohort. RAI was strongly associated with HIV-1 in men (aOR 3.8, 95% CI 2.0 – 6.9), but this association did not reach significance in

women (aOR 1.2, 95% CI 0.5 – 2.5). Prevalent HIV-1 infection was significantly associated with anogenital ulcers, anogenital condylomata, and confirmed urethritis in men. In women, prevalent HIV-1 infection was significantly associated with anogenital condylomata and pelvic inflammatory disease; associations with vaginal trichomoniasis and syphilis were of borderline significance. Of note, two-thirds of the women with active syphilis on enrollment reported recent RAI. In a separate multivariate analysis of factors associated with syphilis in women, recent RAI remained significantly associated with prevalent syphilis on enrolment (aOR 12.9, 95% CI 3.4 – 48.7, full analysis not included).

Discussion

This study was conducted in a group of high-risk young adults recruited into a cohort study in preparation for HIV-1 vaccine trials and therefore selected on the basis of their high-risk behaviors, including commercial sex work. In this population, the burden of untreated STIs identified at enrolment was relatively high, even with the use of limited screening methods. Not surprisingly, basic microscopic examination of vaginal, cervical, urethral and rectal secretions identified a large number of STIs in persons not complaining of discharge, who would not normally have been treated using a syndromic approach. Limitations of the syndromic approach are widely recognized [7, 12-14], especially for the detection of cervicitis, which is often asymptomatic in women [15]. We found that both vaginal trichomoniasis and urethritis would also have been frequently missed if symptoms alone were used to identify STIs in our cohort. Microscopy also allowed us to avoid treating all women with vaginal discharge and a positive STI risk assessment for cervicitis, as recommended by WHO syndromic treatment guidelines in the absence of microscopy [7]. This practice leads to increased cost and the potential for adverse effects and drug resistance [12]. Therefore, we conclude that the addition of basic microscopy can be a valuable intervention in adults who are identified for cohort recruitment based on their presumed higher risk for HIV-1 infection.

Clearly, additional cases of STI would have been identified by expanded screening, including culture for *T. vaginalis* and *N. gonorrhoeae* or nucleic acid amplification testing (NAAT) for *N. gonorrhoeae* and *C. trachomatis*. For example, the prevalence of gonococcal cervicitis was 5% at enrolment into a Mombasa-based female sex worker cohort in which culture has been routinely available [16]. Using only microscopy in our cohort, we found no cases of gonococcal cervicitis by Gram stain alone. In a recent circumcision trial of mostly heterosexual Kenyan men, NAAT testing identified gonococcal urethritis in 2% of participants, and *C. trachomatis* in 5%; *T. vaginalis* was detected by culture in 2% [6]. We found a 1% prevalence of gonococcal urethritis by Gram stain alone, and were unable to identify *C. trachomatis* or *T. vaginalis* infections. Because herpes simplex infection is an important cause of GUD and increases the risk of HIV-1 transmission [17], specific testing for HSV-2 infections would also be valuable for counseling and patient management purposes. While our data demonstrate that even low-cost microscopy can have considerable value in high-risk populations, expanded screening would be needed to estimate the prevalence of specific infectious etiologies and further reduce the STI burden in our study population.

Several reports have shown that anal intercourse in both men and women may be more common than was previously thought in sub-Saharan Africa [18-20]. Despite strong local convictions that MSM behaviour, in particular, is incompatible with traditional African culture, recent studies in Senegal and Kenya have proven otherwise [8, 21, 22]. Ferguson and Morris have stressed the importance of specific, carefully worded questions to assess the occurrence of anal intercourse in women [23]. Both recall and social desirability bias may influence responses; in a South African coital diary study, FSWs reported a total of 5 anal sex acts per week compared to only 1 anal act per week when responding to a recall questionnaire [24]. Despite increasing evidence that anal intercourse is an important and not uncommon risk factor

for HIV/AIDS, questions on RAI initially included in the recently conducted national AIDS indicator survey in Kenya were rejected as being too offensive to ask (Larry Marum, personal communication). Unfortunately data on the general population practice of anal sex in Kenya remains elusive. In our high-risk cohort, we found that men and women frequently reported RAI in the previous three months. Frequency of condom use was lower for anal intercourse than for vaginal intercourse, as reported in previous African studies [22, 25]. The majority of women reporting RAI were sex workers, but other women did report this practice. Sex workers report receiving higher payment for RAI versus vaginal intercourse (unpublished observation); in addition, some women may use RAI as a form of birth control or to avoid vaginal sex during menstruation. Given that anal sex is not uncommon among high-risk adults, we recommend that STI screening include questions on RAI and the diagnosis of proctitis when symptoms are present; this is particularly important in research settings and programs aiming to reduce the risk of HIV-1 acquisition.

Unprotected RAI is reported to be the most efficient mode of sexual transmission of HIV among both MSM and heterosexual couples [26, 27], and increasing attention has recently been drawn to the role anal intercourse plays in HIV-1 transmission in sub-Saharan Africa [8, 22, 25, 28, 29]. We have, like others, presented evidence that African MSM are at higher risk of HIV-1 infection [8, 30, 31]. In our cohort men who practiced RAI had a higher HIV-1 prevalence risk than those practicing only insertive anal intercourse [8]. Among women in our cohort, RAI was not associated with prevalent HIV-1 infection, but women practicing RAI were more likely to have syphilis. It is not clear why this difference was found, although possibilities include differences in syphilis or HIV-1 prevalence among insertive partners, differences in condom use or sexual practices not captured by our questionnaires, or different biologic susceptibilities between men and women. Questions about RAI have not been routinely included in studies of syphilis risk

factors in African women [32, 33], and our research suggests that such questions are an important component of a sexual risk assessment in general.

Our STI screening program was conducted in the context of a large, multicenter HIV-1 cohort study aiming to recruit high-risk adults in preparation for HIV-1 vaccine trials. Study findings challenge general approaches to recruiting at-risk adults. First, to identify volunteers at the highest risk for HIV-1 infection, it may be preferable to inquire about specific sexual behaviour rather than rely on transactional sex, numbers of partners, and condom use as the sole indicators. Second, volunteers reporting recent anal sex may harbor anal infections that should be managed appropriately for public health reasons. Recent guidelines on the management of proctitis recommend proctoscopy and collection of Gram stain for all people reporting anal receptive intercourse [34, 35]. Third, HIV-1 prevention studies will target vulnerable and socially isolated people who lack access to appropriate health care. Since STI treatment can reduce both the risk of HIV-1 acquisition and transmission [36, 37], the incorporation of STI screening into prevention studies not only provides benefit to research participants, but also to the communities at large. Lastly, populations at higher risk of HIV-1 infection are increasingly more difficult to identify and retain, especially in areas in Africa where general population HIV-1 prevalence and incidence are declining [1]. STI screening and treatment may aid in the retention of volunteers — the crux of any intervention study. We have not presented data on incident STI in this paper, nor have we been able to assess the optimal period for repeat STI screening in this population. Further research into optimal STI screening procedures, in particular for screening of persons practicing RAI, is clearly needed.

In conclusion, adults with high-risk sexual behavior are at increased risk of both HIV-1 and other STIs, and may have a substantial burden of untreated STI upon entry into research studies. Basic microscopy is a valuable, low-cost component of STI screening that can identify

asymptomatic infections and avoid overtreatment of STIs based on non-specific symptoms. Soliciting a history of RAI in high-risk persons is important to identify persons in need of intensified risk reduction counseling. Further research into appropriate methods for proctitis screening in developing countries would add to the value of such screening. We believe that improving STI screening should be integrated into HIV-1 prevention research targeting high-risk populations, as an important service to participants and their communities.

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Author Contributions

MLG and SMG drafted the manuscript. MLG, EJS, and ADS conducted the analysis. EJS, RSM, and SMG established the STI screening for the cohort. MM, PG, SM, LW, HO, and MAP provided input into protocol development and valuable comments on the manuscript.

Conflict of Interest

The authors declare no conflict of interest. This study was funded by the International AIDS Vaccine Initiative (IAVI).

Key Messages

- Populations at high risk for HIV-1 infection in Africa carry a high burden of untreated sexually transmitted infections (STIs).
- Basic STI screening with microscopy can detect additional genital STIs and provide benefit to high-risk individuals and their sexual partners.
- STI screening, including specific assessment for anorectal disease, should be offered in African research settings recruiting participants at high risk for HIV-1 acquisition.

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Table 1. Sociodemographic characteristics and sexual risk behaviours at enrollment

		Men N = 536	Women N = 361
		median (IQR) or %	median (IQR) or %
<i>Sociodemographics</i>			
Age	in years	27 (24-33)	27 (23-32)
Level of education	in years	8 (7-12)	8 (7-12)
Employment	None	35.8	28.5
	Self	33.6	64.0
	Formal	30.6	7.5
Marital status	Single	78.0	64.8
	Married	13.8	14.4
	Separated or widowed	8.2	20.8
Circumcision status	Reported or observed*	89.7	4.4
Family planning	Non-barrier method**	—	23.0
	Non-barrier method** plus condom	—	3.9
	Condom alone	—	28.3
<i>Sexual partnerships</i>			
Number of different sexual partners (last month)	Regular	1 (0-1)	0 (0-1)
	Casual	2 (0-4)	1 (0-4)
Transactional, anal, group, and non-consensual sex (last 3 months)	Received money or goods for sex	57.1	72.6
	Paid another person for sex	43.1	2.2
	Engaged in receptive anal intercourse	35.6	17.7
	Participated in group sex †	11.4	7.5
	Forced to have sex	3.0	5.8
Condom use with regular partners (previous week)	Always used	25.2	23.6
	Never used	63.4	69.1
	<i>Persons active with regular partner</i>	<i>N = 262</i>	<i>N = 191</i>
Condom use with casual partners (previous week)	Always used	38.2	64.1
	Never used	41.3	17.4
	<i>Persons active with casual partner</i>	<i>N = 293</i>	<i>N = 167</i>
Condom use with receptive anal sex (previous 3 months)	Always used	18.9	23.8
	Never used	35.6	41.3
	<i>Persons reporting anal sex ‡</i>	<i>N = 191</i>	<i>N = 63</i>

IQR = inter-quartile range

* 12 men and 20 women had missing data on circumcision status

** Included oral contraceptive pills, depo-provera injections, implants, or bilateral tubal ligation

† 1 woman had missing data on participation in group sex

‡ 1 woman had missing data on condom use during anal sex

Table 2. Prevalence of sexually transmitted infections at enrollment

		N	%	95% CI
Genital tract symptoms and signs				
Women (n= 339)				
	Vaginal discharge	100	29.5	24.6 - 34.3
	Lower abdominal pain	65	19.2	15.0 - 23.4
	Genital ulceration	25	7.4	4.6 - 10.2
	Vaginal or vulval condylomata	8	2.4	0.7 - 4.0
Men (n= 500)				
	Urethral discharge	41	8.2	5.8 - 10.6
	Dysuria	57	11.4	8.6 - 14.2
	Genital ulceration	19	3.8	2.1 - 5.5
	Genital condylomata	9	1.8	0.6 - 3.0
Laboratory-confirmed infections*				
Women (n = 324)				
	Vaginitis			
	Any confirmed vaginitis	180	55.9	50.4 - 61.3
	<i>Trichomonas vaginalis</i> †	32	9.9	6.7 - 13.2
	<i>Candida albicans</i> †	82	25.5	20.7 - 30.2
	Bacterial vaginosis†	110	34.2	29.0 - 39.3
	Cervicitis			
	Non-specific cervicitis	34	10.6	7.2 - 13.9
	Gonococcal cervicitis	0	0	0 - 1.1‡
	HIV-1	103	32.0	26.9 - 37.1
	Syphilis	11	3.4	1.4 - 5.4
Men (n = 486)				
	Urethritis			
	Non-specific urethritis§	27	5.5	3.5 - 7.6
	Gonococcal urethritis	5	1.0	0.1 - 1.9
	HIV-1	102	21.0	17.4 - 24.6
	Syphilis	16	3.3	1.7 - 4.9

CI = confidence interval

* Defined in methods section

† 29 women had concurrent BV and candidiasis; 12 had concurrent BV and trichomoniasis; 4 had concurrent candidiasis and trichomoniasis

‡ One-sided p value (97.5)

§ 223 urethral smears were performed; 8 men with urethral discharge had a missing urethral smear

Table 3. Predictive values of clinical symptoms*

		Laboratory confirmed diagnosis			Diagnostic agreement % (95% confidence interval)			
		Yes (%)	No	Total	Sens	Spec	PPV	NPV
Women		<i>T. vaginalis vaginitis</i>						
	Yes	12 (13)	79	91	37.5 (21-56)	72.8 (67-78)	13.2 (7-22)	91.3 (87-95)
	No	20 (9)	211	231				
Vaginal discharge		<i>Cervicitis†</i>						
	Yes	14 (15)	77	91	41.2 (26-59)	73.3 (68-78)	15.4 (9-25)	91.3 (87-95)
	No	20 (9)	211	231				
Men		<i>Urethritis‡</i>						
Dysuria and/or Urethral discharge	Yes	9 (12)	65	74	33.3 (17-54)	85.8 (82-89)	12.2 (8-22)	95.6 (93-97)
	No	18 (4)	394	412				

Sens = Sensitivity, Spec = Specificity, PPV = Positive predictive value, NPV = Negative predictive value

* Based on subjects with complete data (322 women, 486 men)

† Includes gonococcal and non-specific cervicitis

‡ Includes gonococcal and non-specific urethritis

Table 4. Associations between prevalent HIV-1 infection and either RAI or prevalent STIs

	Women* N = 322			Men† N = 486		
	aOR	95% CI	P value	aOR	95% CI	P value
Receptive anal sex (within 3 months)	1.2	0.5 – 2.5	0.71	3.8	2.0 – 6.9	<0.001
Clinical anogenital ulcer disease	1.1	0.4 – 2.9	0.84	2.6	1.0 – 6.9	0.05
Clinical anogenital condylomata	3.9	1.0 – 14.5	0.04	4.0	1.4 – 11.7	0.01
Clinical pelvic inflammatory disease‡	3.0	1.0 – 8.7	0.04	—	—	—
Laboratory confirmed <i>T. Vaginalis</i> vaginitis	2.1	0.9 – 4.8	0.06	—	—	—
Laboratory confirmed cervicitis	0.6	0.3 – 1.5	0.32	—	—	—
Laboratory confirmed urethritis	—	—	—	3.3	1.3 – 8.7	0.02
Laboratory confirmed active or untreated syphilis	3.2	0.9 – 12.1	0.08	1.9	0.6 – 6.0	0.27

CI = confidence interval, aOR = adjusted odds ratio

* Model adjusted for age, transactional sex (3 months), partner count (1 month) and unprotected sex with casual partners & regular partners (1 week, y/n).

† Model adjusted for age, transactional sex (3 months), partner count (1 month), unprotected sex with casual partners & regular partners (1 week, y/n), reported sex with women (3 months), circumcision and reported insertive anal sex (3 months).

‡ Treated for clinically diagnosed pelvic inflammatory disease, based on complaint of abdominal pain, compatible history and exam findings, and no alternative diagnosis made.