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Trichomonas vaginalis and HIV co-infection among women under community supervision: A call for expanded *T. vaginalis* screening

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Abstract

Background—The United States has a large community supervision population, a growing number of whom are women. *Trichomonas vaginalis* infection is strongly associated with an increased risk of HIV acquisition and transmission, particularly among women, but there is a paucity of research on HIV and *T. vaginalis* co-infection among women under community supervision.

Methods—This paper examines the prevalence of *T. vaginalis* infection and *T. vaginalis* and HIV co-infection at baseline among women under community supervision in New York City. It also examines the 12-month outcomes of women treated for *T. vaginalis*. Women received biological tests for HIV and *T. vaginalis* at baseline and 12 months follow-up.

Results—Of the 333 women tested for sexually transmitted infections, 77 women (23.1%) tested positive for *T. vaginalis* at baseline and 44 (13.3%) were HIV positive. HIV-positive women had significantly higher rates of *T. vaginalis* infection than HIV-negative women (36.4% vs. 21.3%, $p \leq 0.05$). Sixteen women (4.8%) were co-infected with *T. vaginalis* and HIV. Of the 77 women who were positive for *T. vaginalis* infection at baseline, 58 (75.3%) received treatment by a healthcare provider. Of those who received treatment, 17 (29.3%) tested positive for *T. vaginalis* at the 12 month follow-up.

Conclusions—Given the high prevalence of *T. vaginalis* among this sample of women, particularly among HIV positive women, and high levels of reinfection or persistent infection, screening for *T. vaginalis* among women under community supervision may have a substantial impact on reducing HIV acquisition and transmission among this high risk population.

Short Summary

A study of women under community supervision found higher rates of *T. vaginalis* infection among HIV-positive women than among HIV-negative women.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest exist.

Keywords

T. vaginalis; HIV; women; community supervision; trichomoniasis

INTRODUCTION

In 2014, an estimated 4.7 million adults (or about 1 in 52 US adult residents) were under community supervision (which can include individuals on probation or parole, in community courts, or in alternative to incarceration programs) and approximately 25% of individuals under community supervision were female, up from 22% in 2000.[1] Women under community supervision are disproportionately black and socioeconomically disadvantaged[2] and bear a disproportionately high HIV and STI burden.[3] They are at increased risk for HIV and STI acquisition, as they have been found to engage in higher levels of injection drug use and unprotected sex than men under community supervision.[4] Despite their increased risk, they are rarely tested for HIV or STIs. It is estimated that only 18% of individuals in the U.S. community corrections system receive HIV screening and just 0.02% receive STI testing.[5] Furthermore, few studies have examined rates of HIV and STIs among this large high-risk population, and many used less-reliable data measures, such as self-reported survey data rather than biological testing.[2] Given the sheer number of women under community supervision and their elevated risk for HIV and STIs, this lack of data represents a substantial gap in public health knowledge.

Women are often more adversely affected by STIs than men and are particularly in need of STI screening. For example, chronic genital chlamydia infection in women can lead to pelvic inflammatory disease (PID), infertility and ectopic pregnancy, but reproductive outcomes in men are comparatively minor.[6] Human papillomavirus (HPV) can result in cancer, particularly cervical cancer in women, but the occurrence of HPV-related cancers in men is much less frequent.[7] Likewise, prolonged *T. vaginalis* infection in women can result in PID, pre-term delivery, and low birth weight, but men rarely experience consequences of infection.[8]

T. vaginalis infection is the most prevalent curable STI in the United States and the world (affecting approximately 276 million people a year), with prevalence rates higher than both *C. trachomatis* and *N. gonorrheae* combined.[9] Unlike infections with *C. trachomatis* and *N. gonorrheae,* however, trichomoniasis is not classified as a notifiable disease in the United States and receives little public health attention. Though often discounted as an infection with few consequences, if left untreated, *T. vaginalis* infection can result in a host of adverse reproductive health outcomes, such as pregnancy complications and PID.[10,11] Furthermore, it is also associated with increased risk for HIV transmission and acquisition.[12,13] Quinlivan et al. estimated that 23% of HIV transmission events from HIV-infected women may be attributable to *T. vaginalis* infection when 22% of women are co-infected with *T. vaginalis* (a rate not uncommon among high-risk populations), thus suggesting the importance of *T. vaginalis* control among HIV positive women.[14] Another study found that, in the US, 747 new HIV cases in women a year are a result of the facilitative effects of *T. vaginalis* infection on the transmission of HIV.[15] Although research has indicated that effective *T.*

vaginalis control may reduce HIV transmission and acquisition,[16] the infection is asymptomatic in the majority of cases,[17] so it is rarely screened for and often remains untreated.[18]

T. vaginalis infection has a much higher prevalence among black women than women of other racial and ethnic backgrounds.[13] In the United States, a population-based study revealed an overall prevalence of 3.1% among women aged 14–49 years, with rates as high as 13.3% among black women.[17] A study in Baltimore showed that 1 in 7 black women were found to be infected with *T. vaginalis* (estimated prevalence 14.2%).[19] Another study found that black women had *T. vaginalis* rates that were ten times higher than white women, constituting a significant health disparity.[17] Unlike other STIs, *T. vaginalis* infection disproportionately affects older women,[18] who are also overrepresented in the criminal justice system. A national profile shows that women in the criminal justice system are typically in their early to mid-thirties.[20] Given the adverse reproductive effects of this parasite and its ability to facilitate the acquisition and transmission of HIV, it is imperative that this major health disparity gap for a population as high-risk as older black women under community supervision be addressed. *T. vaginalis* infection can be screened for outside of clinical settings (such as at a community supervision facility) by nucleic acid amplification testing from a self-collected vaginal swab and it is easily treated (often with only a single dose of metronidazole). Thus, providing regular screenings and adequate treatment among women under community supervision may be a relatively simple public health solution that could greatly reduce the morbidity of this infection.

This paper (1) assesses HIV and *T. vaginalis* prevalence and co-infection using biological data among women under community supervision in New York City, and (2) examines treatment outcomes at the 12 month follow-up among women who were positive for *T. vaginalis* at baseline.

MATERIALS AND METHODS

Design and Study Population

We used data from a randomized controlled trial testing the efficacy of a behavioral HIV/STI intervention (WORTH) among drug-involved women in the community corrections system.[21] Women were randomized into three arms: two intervention arms and a control arm. We used biological STI data from the baseline assessment and the 12 month follow-up interview. A total of 1,104 women were screened from community courts and probation sites in New York City. Of these, 337 women completed informed consent and baseline interviews, 306 were randomized into the study arms, and 278 women completed the 12 month assessment. To be eligible for inclusion, women had to be 1) 18 years of age or older, 2) under community supervision in a community or criminal court, on probation or parole, under drug treatment court supervision or another alternative to incarceration program (such as family court programs) within the past 90 days, 3) report one or more incidents of illicit drug use within six months, 4) have one or more incidents of unprotected vaginal or anal intercourse within the past 90 days, and 5) be HIV positive or at risk for HIV/STIs. Data were collected at community supervision sites throughout New York City. Trained staff administered surveys at baseline, and three month, six month and 12 month follow-up

periods. Biological HIV and STI tests were completed at baseline and 12 month follow-up. Participants were reimbursed for completing assessments and intervention sessions, up to a maximum of $265 for the completion of all assessments, intervention sessions, and testing. All participants provided written informed consent to participate in the study. This study was approved by institutional review boards at Columbia University and the Center for Court Innovation.

Measures

At baseline and during each of the follow-up periods, women completed a computer-assisted self-administered interview (CASI) approximately an hour and a half in length. This interview elicited detailed information on sociodemographic characteristics (age, ethnicity, marital status, education level, employment status, monthly income, and location of residency), incarceration history, alcohol and substance use history, sexual behaviors, and sexual partner characteristics.

Diagnosis of HIV and STIs, treatment, and follow-up

HIV biological testing—Oral swabs were collected from participants at baseline and 12 month follow-up to test for the presence of HIV-1 and HIV-2 antibodies using the OraQuick ADVANCE Rapid HIV Test.

STI biological testing—Women obtained a self-collected vaginal swab during their visit at both the baseline and 12-month follow-up sessions to test for *T. vaginalis, C. trachomatis,* and *N. gonorrhoeae*. Specimens were collected Monday through Thursday and shipped twice weekly (on Tuesdays and Thursdays). After the specimens were collected, they were logged and refrigerated immediately. Specimens were then packaged for shipment and transported on ice packs to the clinical laboratory at Emory University via FedEx priority overnight, morning delivery, where they were immediately incubated and refrigerated at 2–8°C. Lab tests were conducted sometime between the same day of arrival up to five days after arrival. Specimens were tested for *T. vaginalis* using the Taq-Man PCR assay, developed and validated by the Caliendo Laboratory at Emory University.[22] The limit of detection for this assay is <0.2 organisms per reaction or 40 copies per ml. The sensitivity and specificity of the TV assay is 100% and 99.6%.[22] *C. trachomatis* and *N. gonorrhea* were tested for using the Becton Dickinson Probe ET Amplified DNA Assay (Becton, Dickinson and Co, Sparks, Maryland).

Participants with positive HIV/STI test results received risk-reduction counseling from the Clinical Research Coordinator (CRC) and were encouraged to inform their partners and have their partner treated simultaneously. All women who tested positive for an STI were referred by the CRC to a physician for the appropriate treatment and provided the CRC with forms completed by their medical providers to verify treatment. All women were retested for STIs at the 12 month follow-up assessment and all HIV-negative women were retested for HIV.

T. vaginalis treatment outcomes at 12 months—We followed all women who were infected with *T. vaginalis* infection at baseline and determined 1) whether they received treatment for *T. vaginalis* infection or not, 2) whether they tested positive for *T. vaginalis*

infection at the 12 month follow-up assessment, and 3) the incident infections of *T. vaginalis* at the 12 month follow-up assessment. Treatment costs were covered by the participants' insurance or by study funds for participants who had no insurance.

Statistical analysis

Descriptive statistics were used to describe the sample. We used chi-square tests to compare significant differences in STIs between HIV positive and HIV negative individuals. Individuals who had missing data were excluded from the analysis. Out of 337 women who completed baseline interviews, four were excluded because they did not provide vaginal swabs for STI testing, so 333 women were retained for analysis in this paper. In the chi-square test examining *T. vaginalis* among HIV positive and negative individuals, an additional two women were excluded because they refused an HIV test. Descriptive statistics were conducted to illustrate treatment outcomes of *T. vaginalis* infection. All analyses were conducted using SPSS 23 (Durham, NC).

RESULTS

Sociodemographic characteristics

Table 1 provides information on the main demographic characteristics of the sample. The mean age was 41.3 years, with participants ranging in age from 18–62 years (interquartile range, 33–49 years). Almost three-quarters of women identified as black or African American (71.2%). Most women were unemployed (91.0%) and had a high school education or less (73.6%). The majority of women were highly impoverished. Over half (57.2%) of the women surveyed made less than $400 a month and over a quarter (29.4%) made between $401-$850 a month. The majority of women were single (67.0%). Women who were black/African American were significantly more likely to be infected with *T. vaginalis* than women who were not black/African American ($p \leq 0.05$). There were no other sociodemographic differences between women who were infected with *T. vaginalis* and women who were not.

HIV/STI prevalence and co-infections

Baseline prevalence of STI infections are shown in Table 2. The rate of *C. trachomatis* infection was 3.0% (n=10) and *N. gonorrheae* was 1.2% (n=4). Nearly a quarter of participants tested positive for *T. vaginalis* infection (23.1%, n=77). Of the 331 women tested both for STIs and HIV, 44 (13.3%) were HIV positive. Sixteen women (4.8%) were co-infected with *T. vaginalis* and HIV. Rates of *T. vaginalis* infection were found to be significantly higher among HIV positive women than among HIV negative women (36.4% vs. 21.3%, $p \leq 0.05$). Other co-infections included one participant diagnosed with both *T. vaginalis* and *N. gonorrheae* (0.3%) and one participant diagnosed with both *C. trachomatis* and *N. gonorrheae* (0.3%). No HIV positive participants were diagnosed with *C. trachomatis* or *N. gonorrheae*. Among the 77 women who tested positive for *T. vaginalis* infection at baseline, only two (2.6%) had been previously tested in the past 90 days.

T. vaginalis treatment

Of the 77 women infected with *T. vaginalis* at baseline (see Figure 1), 5 (6.5%) women were not randomized into a study arm and did not continue with the study, 58 (75.3%) women received treatment for *T. vaginalis* infection, and 14 (18.2%) women did not receive treatment for *T. vaginalis* infection. Of those who were treated, over a quarter (29.3%) tested positive for *T. vaginalis* at the 12 month follow-up assessment. Of those who were not treated for *T. vaginalis* infection at baseline, nearly half (42.9%) tested positive for *T. vaginalis* at the 12 month follow-up. There were no significant differences in treatment outcomes between women who were HIV positive and those who were HIV negative. Among the 206 women not infected with *T. vaginalis* at baseline and retained through the 12 month follow-up period, 25 developed new *T. vaginalis* infections, with an overall incidence rate of 12.1 per 100 person-years. We did not find any significant differences in *T. vaginalis* prevalence or treatment outcomes between women in the three study arms.

DISCUSSION

Our findings showed a high rate of *T. vaginalis* infection among this sample of women under community supervision, particularly among HIV-positive women. At the baseline assessment, over a third of HIV-positive women were infected with *T. vaginalis*, as opposed to approximately a fifth of HIV-negative women. These results highlight the importance of effective *T. vaginalis* control among populations that also have a high prevalence of HIV infection, such as women under community supervision. Research has shown that *T. vaginalis* infection is associated with increased HIV acquisition and transmission.[13] In a longitudinal study among African women, Van Der Pol et. al found that the adjusted odds ratio for HIV acquisition was 2.74 for *T. vaginalis* positive cases.[12] Other studies have also indicated that *T. vaginalis* infection significantly contributes to HIV acquisition and transmission in the U.S.[14,15]

Though this paper was not designed to examine the contributing effects of *T. vaginalis* infection on HIV acquisition and transmission, these results illustrate the high burden of *T. vaginalis* infection among HIV-positive women under community supervision. Other studies among women involved in the criminal justice system have also found a high prevalence of *T. vaginalis* infection (26.0% in the Northeast/Midwest and 52.6% in Indianapolis),[23,24] indicating that targeted screening among this population would be beneficial. The vast majority of women in our study had not been previously screened for *T. vaginalis* infection and thus, had not been linked to treatment. Effective treatment of *T. vaginalis* has been shown to reduce HIV genital shedding beyond ART provision,[16] and therefore, may reduce HIV transmission. Furthermore, research indicates that annual *T. vaginalis* screening and treatment for HIV-positive women would result in a lifetime savings of $553 per woman in the prevention of new HIV infections to susceptible partners (approximately $159,264,000 total saved annually).[25] Thus, *T. vaginalis* screening and treatment programs among populations that bear a high burden of HIV and *T. vaginalis* infection, such as women under community supervision, may be a cost-effective way of reducing HIV transmission. Increased partnerships between public health and criminal justice systems may be one way to expand STI screening and treatment to better reach vulnerable populations. Though STI

testing in community supervision settings is not common, a study from Indianapolis indicated that community court-based STI screening programs can be an effective way to increase STI testing and linkage to care among individuals under community supervision.[26] The expansion of such programs into community supervision settings in NYC and other areas in the US could serve to increase the detection and treatment of *T. vaginalis* infection.

Consistent with other studies,[27,28] our findings indicated that untreated *T. vaginalis* infection may persist for extended periods of time (up to 12 months). Nearly half of participants in our study who did not receive treatment at baseline were infected with *T. vaginalis* at the 12 month follow-up assessment. The proportion of women who were positive at 12 months was not statistically significantly different among those who were and were not treated at baseline, indicating a need for regular *T. vaginalis* screenings and follow-up among both those who have and have not previously received treatment. Though we are unable to determine whether positive results at 12 months are persistent infections or reinfections, the outcomes of persistent or repeated *T. vaginalis* infection can be severe. Prolonged infection with *T. vaginalis* can result in a range of adverse reproductive health sequelae, including PID, preterm delivery, low birth weight, and, in rare instances, respiratory infections in neonates.[10,11,29] *T. vaginalis* infections are often asymptomatic,[30] and therefore, routine screening and timely linkage to effective treatment are needed to reduce negative outcomes. Targeted efforts to increase both may be warranted for this at-risk population.

Even after receiving treatment for *T. vaginalis* infection at baseline, nearly 30% of women in our study were found to be infected with *T. vaginalis* 12 months later. The source of these repeat infections is unclear. Possible sources of repeat positives after treatment are reinfection from an untreated baseline partner, infection from a new partner, or treatment failure. Though women were encouraged to have their partner screened and treated for *T. vaginalis*, we did not verify partner treatment. Partner referral methods for STI testing and treatment are limited in effectiveness,[18] and it is probable that few of these women's partners were actually screened and treated for *T. vaginalis* infection. It is also possible that some women may have been infected by a new partner. Over half of the women in our study had multiple sex partners. Treatment failure may be another cause of a repeat positive. Treatment of *T. vaginalis* with a single 2g dose of metronidazole is the standard of care for HIV negative women (500 mg twice a day for 7 days for HIV positive women),[28] but it is imperfect. Previous studies have found high repeat infection rates (8–20%) among women receiving a 2g dose of metronidazole, indicating that a single dose of metronidazole may be insufficient in some cases.[31–33] Regardless of the reason for a repeat positive, these findings highlight the need for regular rescreening, effective treatment regimens and partner treatment strategies.

The data have a number of limitations that should be considered. First, although we had participants return signed forms from the doctor stating that they were treated for *T. vaginalis* infection, we did not have them return the prescription bottles, so we cannot ensure that they actually received or took the prescription. Second, we did not re-test women treated for *T. vaginalis* infection immediately post-treatment; thus, we were unable to distinguish reinfection from persistent infection or treatment failure. Third, although we encouraged women to have their partners screened and treated for *T. vaginalis* infection, we did not

verify partner testing and treatment. Finally, these data were obtained from a convenience sample of drug using women under community supervision in New York City; thus, our findings may not be generalizable to broader populations or community supervision populations in other geographical settings.

T. vaginalis infection is an important STI that can result in severe reproductive health outcomes and has the potential to amplify the acquisition and transmission of HIV. *T. vaginalis* infection has been shown to disproportionately affect black women from low socioeconomic backgrounds, a demographic group that is also disproportionately represented in community supervision settings and has a high burden of HIV. Despite a growing body of research demonstrating its importance, *T. vaginalis* continues to be largely ignored in public health discourse, perhaps because of the demographic of individuals most affected by this pathogen. Targeted screening among high risk populations most affected by this infection, such as women in community supervision settings and their partners, may greatly improve *T. vaginalis* control. Without specific screening mandates and targeted funding, *T. vaginalis* infection will continue to place disadvantaged women at increased risk for adverse reproductive health outcomes and facilitate the acquisition and transmission of HIV infection.

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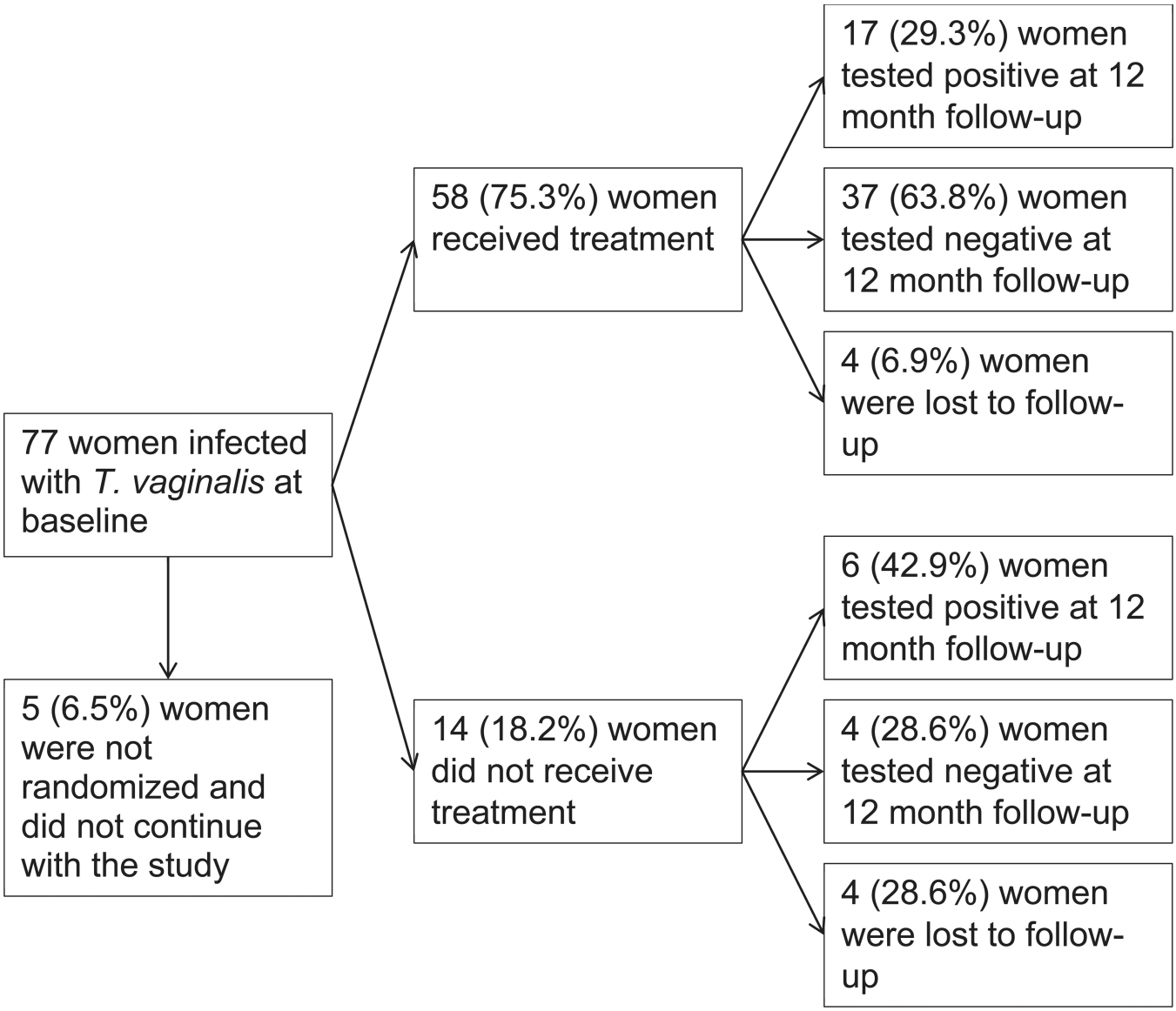

Figure 1.
T. vaginalis treatment flowchart

Table 1

Sociodemographic characteristics of women under community supervision in New York City, 2009–2011 (N=333)

	Overall N=333	**Positive for *T. vaginalis* N=77**	**Negative for *T. vaginalis* N=256**	**P-value**
Age, *mean (SD)*	41.3 (10.5)	40.9 (9.56)	41.4 (10.76)	.707
Race/Ethnicity, *n (%)*				
Black/African American	237 (71.2%)	62 (80.5%)	175 (68.4%)	**.039**
Not black/African American	96 (28.8%)	15 (19.5%)	81 (31.6%)	
Education				
High school or less	245 (73.6%)	61 (79.2%)	184 (71.9%)	.200
Some college or more	88 (26.4%)	16 (20.8%)	72 (28.1%)	
Employment status				
Unemployed	303 (91.0%)	73 (94.8%)	230 (89.8%)	.324
Occasional or seasonal	6 (1.8%)	2 (2.6%)	4 (1.6%)	
Part-time	13 (3.9%)	1 (1.3%)	12 (4.7%)	
Full-time	11 (3.3%)	1 (1.3%)	10 (3.9%)	
Monthly income				
Less than $400 per month	192 (57.7%)	51 (66.2%)	141 (55.1%)	.156
$400–850 per month	98 (29.4%)	20 (26.0%)	78 (30.5%)	
$851 or higher per month	43 (12.9%)	6 (7.8%)	37 (14.5%)	
Marital Status				
Single, never married	223 (67.0%)	54 (70.1%)	169 (66.0%)	.796
Married	52 (15.6%)	11 (14.3%)	41 (16.0%)	
Divorced/Separated/Widowed	58 (17.4%)	12 (15.6%)	46 (18.0%)	

Table 2

Baseline prevalence of STIs and chi-square analysis among HIV positive and HIV negative women in the community corrections system in New York City, 2009–2011 (N=333 women with STI test results; N=331 women with both STI and HIV test results)

	Overall, N=333	**HIV positive, N=44**	**HIV negative, N=287**	**P-value**
C. trachomatis	10 (3.0%)	0 (0.0%)	10 (3.5%)	.370
N. gonorrhoeae	4 (1.2%)	0 (0.0%)	4 (1.4%)	1.00
T. vaginalis	77 (23.1%)	16 (36.4%)	61 (21.3%)	***.027***