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Performance and comparison of self-reported STI symptoms among high-risk populations – MSM, sex workers, persons living with HIV/AIDS – in El Salvador

Neha S Shah[1], **Evelyn Kim**[1], **Flor de Maria Hernández Ayala**[2], **Maria Elena Guardado Escobar**[3], **Ana Isabel Nieto**[3], **Andrea A Kim**[1], and **Gabriela Paz-Bailey**[2,4]

[1]Centers for Disease Control and Prevention, Atlanta, GA, USA

[2]Training Programs in Epidemiology and Public Health Interventions Network, Atlanta, GA, USA

[3]Ministry of Public Health, San Salvador, El Salvador

[4]Universidad de Valle de Guatemala, Guatemala City, Guatemala

Abstract

Background—Resource-limited countries have limited laboratory capability and rely on syndromic management to diagnose sexually transmitted infections (STI). We aimed to estimate the sensitivity, specificity and positive predictive value (PPV) of STI syndromic management when used as a screening method within a study setting.

Methods—Men who have sex with men (MSM), female sex workers (FSWs) and people living with HIV/AIDS (PLWHA) participated in a behavioural surveillance study. Data were obtained on demographics, sexual behaviours, STI history and service utilisation. Biological specimens were tested for genital inflammatory infections (*Neisseria gonorrhoeae* [GC], *Chlamydia trachomatis* [CT], *Mycoplasma genitalium* [MG], *Trichomonas vaginalis* [TV]) and genital ulcerative infection (syphilis and Herpes simplex virus-2).

Results—There was a high prevalence of Herpes simplex virus-2 (MSM 48.1%, FSW 82.0% and PLWHA 84.4%). Most participants reported no ulcerative symptoms and the majority of men reported no inflammatory symptoms. Sensitivity and PPV were poor for inflammatory infections among PLWHA and MSM. Sensitivity for FSWs inflammatory infections was 75%. For ulcerative infections, sensitivity was poor, but specificity and PPV were high.

Corresponding author: Neha S Shah, 850 Marina Bay Parkway, Building P, 2nd floor, Richmond, CA 94804, USA. nshah6@cdc.gov.

Author contributions

All authors were involved in the design of the analytical plan, interpretation of results and preparation of manuscript. GPB, MG, FH and AK were involved with the study design. NSS, EK, FH, MG and GPB were involved in data collection and NSS, EK and FH were involved in data analysis. All authors have approved the final version.

Conflict of interest

The authors declare no conflict of interest.

Conclusions—Reliance on self-reported symptoms may not be an effective screening strategy for these populations. STI prevention studies should focus on symptom recognition and consider routine screening and referral for high-risk populations.

Keywords

Diagnosis; high-risk behaviour; screening; sex workers; AIDS; syndromic

Introduction

Though controversy exists about the role of treating sexually transmitted infections (STI) as part of HIV prevention programming, in resource-limited countries with a concentrated HIV epidemic and where STI services are limited but where STI have a high prevalence, improved STI treatment can potentially reduce the incidence of HIV.[1–5] Additionally, STI themselves are a public health concern and cause significant morbidity, mortality and economic costs.[6] In countries with a generalised HIV epidemic and among population with high-risk behaviours, STI control can be cost-saving.[1] The World Health Organization (WHO) estimated that there are more than 340 million new cases of STIs globally among adults aged 15–49 years[7] with 50 million annually in the Americas.[8] With this renewed emphasis on the importance of STI control in the era of HIV, prompt diagnosis and treatment for STI are crucial.

More than 75% of the STI burden is in the developing world,[7] where laboratory diagnoses of STI are not always available or are costly. Recognising this challenge, the WHO developed guidelines for STI diagnosis and treatment in resource-constrained settings using syndromic management.[9] With the syndromic management approach, easily recognised signs and consistent groups of symptoms are identified as syndromes, which are then assigned treatment regimens that will address the majority of, or the most serious, organisms responsible for producing the respective syndrome.[9] Syndromic management relies on individuals recognising STI signs and symptoms, seeking healthcare and reporting symptoms to healthcare professionals. Numerous studies have been conducted to assess the effectiveness of STI syndromic management;[10–15] however, data outside a healthcare setting have shown conflicting results. In a HIV voluntary testing and counselling setting, syndromic management can lead to many missed diagnosis and 3.2% overtreatment, while in a pharmacy setting the majority of symptomatic individuals were seropositive for an STI.[16,17] Additionally, efficacy of these guidelines can vary by gender and disease type[10–15] as some STI can be asymptomatic[18,19] in which case syndromic management would have limited application and can lead to missed diagnoses.

The HIV prevalence in the general population in El Salvador is less than 1%. However, recent data have shown a high rate of STI and HIV among high-risk populations in El Salvador.[20–22] Among men who have sex with men (MSM) in San Salvador, HIV prevalence was 14.5%, Herpes simplex virus-2 (HSV-2) was 49.8%, syphilis was 14.1% and other STIs were 11.1%.[20] Among people living with HIV/AIDS (PLWHA) in San Salvador, STI prevalence was 18.6%.[21,23] According to a study among high-risk populations conducted in five Central American countries, MSM and female sex workers (FSWs) in El

Salvador had the highest rates of HIV (15.3% and 3.2%, respectively), syphilis (15% in FSWs), gonorrhoea (10.7% in FSWs), chlamydia (23.3% in FSWs) and HSV-2 (56.5% and 95.7%, respectively) seroprevalence compared with other countries (other prevalence data not specifically stated).[24] Given the high prevalence of STI in these populations, there is an urgent need to accurately identify and promptly treat STI in El Salvador.

The objectives of this analysis were to determine if self-reported STI symptoms were an accurate measure for STI positivity by comparing them to laboratory diagnoses for three high-risk populations: FSWs, MSM and PLWHA, and if PLWHA participants differentially reported STI compared to MSM and FSWs.

Methods

From March to September 2008, the El Salvador Ministry of Health conducted an integrated behavioural and biologic survey among MSM, FSW and PLWHA in San Salvador, Santa Ana, San Miguel and Sonsonate using methods described in detail elsewhere.[20,22,23] PLWHA were recruited from eight public hospitals from three cities that treat approximately 80% of all individuals with HIV infection in El Salvador. Participants were identified and sampled consecutively through HIV care and treatment programmes, HIV well-being programmes and HIV support groups. MSM and FSWs were recruited from March to September 2008 using respondent-driven sampling (RDS)[25,26] in San Salvador, San Miguel and Sonsonate. Study sites were chosen based on high HIV care reporting, estimated STI prevalence rates and convenience and accessibility to the target populations. The protocol was approved by the US Centers for Disease Control and Prevention and the Ethics Committee of Clinical Research of the National Hospital Rosales in El Salvador.

After written informed consent was obtained, participants completed both an audio computer-assisted survey instrument (ACASI) and face-to-face interview addressing demographic background, sexual behaviours, STI history and service utilisation. The face-to-face interview was conducted by trained study staff. STI symptoms questions included asking whether the participant experienced any of the following symptoms in the last 12 months: vaginal or penile discharge, dysuria, genital or anal ulcers or wounds, genital itching, bad odour and genital or anal warts. If a participant was not familiar with these terms, the study staff defined these symptoms for participants. Women were also asked if they had any lower abdominal pain in the last 12 months. Following the interview, individuals were provided STI counselling and biological specimens (blood, urine, vaginal swabs for women and anal swabs for men) were collected by a trained laboratory technician. Individuals could refuse to participate in any component of the study. Syphilis testing was conducted using the rapid plasma reagent (RPR) test (Macro-Vue RPR; Becton, Dickinson and Company, USA) and confirmed by the *Treponema pallidum* agglutination (TPPA) particles test (Fujirebio Diagnostics, USA). Syphilis positivity was defined as serum-positive results for both RPR (at one in eight dilutions) and TPPA tests. HSV-2 testing was conducted using HerpeSelect® (Herpes-Select; Focus Diagnostics, USA). HSV-2 seropositive was defined as having an index value of >1.1. Urine samples, vaginal swabs for women and anal swabs for men were tested using a multiplex real time polymerase chain reaction (PCR, Applied Biosystems GeneAmp; Life Technologies, USA) for *Neisseria*

gonorrhoeae (GC), *Chlamydia trachomatis* (CT), *Mycoplasma genitalium* (MG) and *Trichomonas vaginalis* (TV). For diagnosing bacterial vaginosis (BV) a Gram stain test was performed. After pre-test counselling, HIV testing for MSM and FSWs was performed at the study site using two rapid HIV tests (Determine® HIV-1/2; Abbott, USA and OraQuick® Advance Rapid HIV-1 Antibody Test; Orasure Technologies, USA). HIV results and post-test counselling were provided after 30 min. Serology tests were conducted at the Central Laboratory in El Salvador, and PCR and Gram stain tests were conducted at Gorgas Memorial Laboratory in Panama. PCR quality control was provided by the Centers for Disease Control Laboratory in Atlanta, USA. HIV-positive samples were sent to the National Reference Laboratory for confirmatory enzyme-linked immunosorbent assay (ELISA) testing. Participants were provided with a voucher with their study identification number to access their results at the study site after two weeks. If any test was positive, the participant was offered free treatment for diagnosed STI and given a voucher for free partner STI testing and partner treatment as needed. If a participant reported STI symptoms, treatment was provided based on El Salvador's syndromic management guidelines. HIV-positive individuals were referred to the closest HIV clinic and encouraged to refer their partners for HIV testing at the nearest HIV testing centre.

Data entry and analysis

Data from the different sites for MSM and FSW recruitment were combined for data analysis. Results for GC and CT from urine and vaginal swabs or anal swabs were also combined. Face-to-face interview data were double data-entered and SPSS (version 12.0, Chicago, SPSS Inc.) was used for data management and recoding. Data analyses were conducted in SPSS and SAS version 9.2 (Cary, NC: SAS Institute, Inc). Among female participants, sensitivity, specificity and positive predictive values (PPVs) of self-reported vaginal discharge symptoms (discharge, pain/odour, lower back pain, itching) and laboratory-confirmed diagnoses of (1) GC or CT; (2) BV, TV or MG and (3) GC, CT, BV, TV or MG were calculated. Among male participants, sensitivity, specificity and PPVs of self-reported penile discharge symptoms (discharge, pain/odour, lower back pain, itching) and laboratory-confirmed diagnoses of (1) GC or CT; (2) TV or MG and (3) GC, CT, TV or MG were calculated. For both men and women, the same measures of sensitivity, specificity and PPV were calculated for self-reported genital ulcer symptoms and laboratory-confirmed diagnoses of syphilis or HSV-2 infections. This analysis was conducted at the specimen level for all study sites combined and therefore not adjusted for sampling design.

Results

Demographic and laboratory-confirmed diagnoses

A sample of 807 MSM, 810 FSW, 411 male PLWHA and 397 female PLWHA were recruited for the study. After excluding individuals without laboratory results and those who did not answer STI symptom questions, the final analyses included 503 MSM, 518 FSW, 356 male PLWHA and 245 female PLWHA for genital inflammatory infection (GC, CT, BV [women only], TV and MG results) analysis and 703 MSM, 768 FSW, 366 male PLWHA and 366 female PLWHA for ulcerative infection (HSV-2 and syphilis results) analysis. Among the PLWHA participants, the majority (71.3%) were between 26 and 45

years of age, while 65.8% of MSM and 34.4% of FSW were between 18 and 25 years of age. Among MSM, 11.9% were positive for a genital inflammatory infection and 48.8% were positive for HSV-2 or syphilis infection. Among FSW, positivity for a genital inflammatory infection was 79.3% and 82.2% for a genital ulcer infection of PLWHA, 9.0% of men and 52.7% of women were positive for genital inflammatory infections. The positivity for a genital ulcer infection was 80.9% and 88.3% among male and female PLWHA participants, respectively (Table 1). Results for individual test results for each population have been previously published.[20,22,23]

Self-reported symptoms

Among MSM, 86.1% did not report any penile inflammatory symptoms and 91.6% did not report any ulcerative symptoms in the last 12 months. Of the FSWs, 75.1% and 3.3% reported vaginal inflammatory and ulcerative symptoms, respectively. Of the male PLWHA, over 82% did not report any penile inflammatory or ulcerative symptoms. Among female PLWHA, 52.7% and 18.0% reported vaginal inflammatory and ulcerative symptoms, respectively (Table 1).

Performance of self-reported symptoms and laboratory results

Results for the sensitivity, specificity and PPV of self-reported symptoms compared with laboratory-diagnosed STI among FSWs and female PLWHA are presented in Table 2. Among FSWs, sensitivity was between 74% and 75%, specificity ranged from 22% to 25% and PPV ranged from 13% to 79% for any self-reported vaginal inflammatory symptoms compared with laboratory-diagnosed STI. The sensitivity, specificity and PPV of genital ulcerative symptoms among FSWs compared with laboratory-diagnosed syphilis or HSV-2 infections were 3%, 96% and 80%, respectively. Among female PLWHA, sensitivity ranged from 25% to 52%, specificity was 47% and PPV from 1% to 52% for any self-reported vaginal inflammatory symptoms compared with laboratory-diagnosed STI. Sensitivity, specificity and PPV of genital ulcer symptoms among female PLWHA for laboratory-diagnosed syphilis or HSV-2 diagnoses were 19%, 88% and 92%, respectively. For inflammatory infections, FSWs had a higher sensitivity and PPV when compared to female PLWHA. For ulcerative infections, female PLWHA had a higher sensitivity than FSWs.

Table 3 presents the results for the sensitivity, specificity and PPV of self-reported symptoms compared with laboratory-confirmed STI diagnosis among MSM and male PLWHA. Among MSM, sensitivity ranged from 12% to 17%, specificity was 86% and PPV ranged from 3% to 14% for any self-reported penile inflammatory symptoms compared with laboratory-diagnosed STI. The sensitivity, specificity and PPV of genital ulcerative symptoms compared with laboratory-confirmed syphilis or HSV-2 infections were 11%, 94% and 63%, respectively. Among male PLWHA, there were no laboratory-confirmed diagnoses of GC or CT. The sensitivity for TV or MG among male PLWHA was 28%, the specificity 84% and the PPV 15%. The sensitivity, specificity and PPV of genital ulcerative symptoms compared with laboratory-confirmed syphilis or HSV-2 infections were 19%, 90% and 89%, respectively. When comparing ulcerative symptoms, male PLWHA had a higher sensitivity and PPV than MSM.

Discussion

The high prevalence of laboratory-diagnosed STI in these high-risk populations is concerning, especially among individuals infected with HIV, given the association between STI and HIV transmission.[27] Though high rates of STI positivity were observed in these populations, the majority of men and high percentage of women living with HIV were asymptomatic. These findings are consistent with previous studies[11,19,28] and suggest that self-reported symptoms in the last 12 months may not be reliable for detecting STI. Outreach programmes for high-risk populations should thus consider an integrated approach of better recognition of STI signs and symptoms recognition, mobile-team outreach, presumptive treatment, condom promotion, routine or periodic STI screening and risk factors associated with STI including partner STI status.[29–31]

Similar to previous results,[14,15,19,32,33] the sensitivity, specificity and PPV analyses showed that STI screening, referral and treatment based solely on self-recognised and reported symptoms may not be an effective strategy for the high-risk populations in this study. Among female PLWHA, syndromic screening would have missed the majority of the GC or CT infections and about half of BV, TV or MG cases. Among all men, almost 80% of genital inflammatory infections would have been missed. These results were similar to those seen among high-risk men in previous studies.[19,34] Though self-report of genital ulcerative infections had a high specificity, the majority of ulcerative cases in this study population would be missed if STI screening and referral was dependent on self-recognising and reporting of STI symptoms in the last 12 months. The addition of a physical examination, including a speculum examination for women and anoscopy for men, would likely improve these measures.[14]

Sensitivity, specificity and PPV results for self-reported genital inflammatory infections were different when comparing men and women. This may be attributable to more men reporting no STI symptoms. These data suggest that routine screening may be useful even in the absence of self-reported symptoms in high-risk populations.[29–31] In contrast, sensitivity of self-recognition and report of genital inflammatory infections were higher among FSWs. The discrepancy seen in FSWs may be influenced by current programmes for FSWs in El Salvador that encourage FSWs to receive free HIV screening through the use of mobile units.[35] In 2007, the Ministry of Health published guidelines for physicians who work with FSWs regarding STI symptom recognition, risk factors, management and STI education for FSWs.[36] These interventions may be increasing STI awareness and symptom recognition by FSWs and may account for the increased sensitivity, specificity and PPV seen in this study within this population.

Our study had a number of limitations. The study was designed to assess behavioural risk factors. Further research should evaluate if similar results are found in a clinical setting. Questions regarding STI symptoms were included in the face-to-face questionnaire; thus, the data have been subject to underreporting due to social desirability bias. Respondents were asked about occurrence of symptoms over the 12 months prior to the study; however, STI can remain asymptomatic in individuals, especially for anorectal STI, for longer than 12 months. Therefore, both recall bias and potentially asymptomatic STI, could lead to an

underreporting of STI symptoms. In addition, not all participants in the survey responded to STI questions and agreed to STI testing. Therefore, our findings may not be generalisable to the population as a whole. Finally, the study is cross-sectional by design, and although the questionnaire asked about symptoms over the past 12 months, laboratory tests identified current infections and there were no data on whether participants sought treatment for the symptoms they reported. This would likely underestimate specificity and PPV; however, to what degree our findings may be affected is unknown.

To date, this is the first study to validate self-reported STI symptoms among FSWs, MSM and PLWHA in Central America. Our findings suggest that relying on self-reported STI symptoms may be a poor indicator of infection among high-risk groups in El Salvador as many infections are asymptomatic and can lead to missed diagnoses. In order to minimize missed diagnoses, especially in the setting of minimal STI laboratory capability and to reach high-risk populations, El Salvador should consider using creative methods including conducting risk assessment, STI symptom screening and physical examinations at research study sites. Additionally, encouraging referrals to clinics at study sites may aid in early identification and treatment of STI.[37] The high prevalence of STI positivity noted in this study, their associated morbidity and the high cost of treating sequelae of STI,[38] may justify the potential of overtreatment of patients using syndromic management. Further, because there is an increased risk of HIV transmission with STI and that there is minimal STI laboratory testing capability in El Salvador, syndromic management may be an acceptable and the only alternative for high-risk populations in low-resource settings especially for symptomatic individuals.[39] Nevertheless, the evolution of resistant GC reported in North America and recently in South America and the Caribbean, can lead to the development of resistance strains in El Salvador as well.[40,41] If possible, El Salvador should consider increasing their laboratory diagnostic capabilities to facilitate prompt STI diagnosis, appropriate treatment and to minimize development of resistant strains of STI due to the potential of misdiagnosis with syndromic management. With limited laboratory resources, to increase referrals to STI clinics and prompt diagnosis, El Salvador should consider increasing efforts to provide more education regarding STI, improving symptom recognition and risk factors for STI, and perhaps routine or periodic screening of high-risk individuals.

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Table 1

Age, self-reported prevalence of signs, or symptoms related to STI, and etiological prevalence of STIs among men who have sex with men, female sex workers, and persons living with HIV/AIDS (PLWHA) in San Miguel, San Salvador, and Sonsonate, El Salvador, 2008.

			PLWHA		
	MSM	**FSW**	**Male**	**Female**	**Total**
Age	*n* = 807	*n* = 810	*n* = 411	*n* = 397	*n* = 808
18–25	531 (65.8)	279 (34.4)	44 (10.7)	61 (15.4)	105 (13.0)
26–35	197 (24.4)	335 (41.4)	158 (38.4)	165 (42.6)	323 (40.0)
36–45	58 (7.2)	152 (18.8)	132 (32.1)	121 (30.5)	253 (31.3)
> 45	21 (2.6)	44 (5.4)	77 (18.7)	50 (12.6)	127 (15.7)
	n = 503	*n* = 518	*n* = 356	*n* = 245	*n* = 601
Self-reported genital inflammatory symptoms in the last 12 months					
Vaginal/penile discharge	15 (3.0)	327 (63.1)	12 (3.4)	103 (42.0)	115 (19.1)
Pain with urination	33 (6.6)	152 (29.3)	33 (9.3)	53 (21.6)	86 (14.3)
Itching around genital area	35 (7.0)	157 (30.3)	35 (9.8)	43 (17.6)	78 (13.8)
Pain in lower abdomen – women only		87 (16.8)		43 (17.6)	43 (17.6)
Any of the above vaginal or penile inflammatory symptoms	70 (13.9)	389 (75.1)	61 (17.1)	129 (52.7)	190 (31.6)
No genital inflammatory symptoms	433 (86.1)	129 (24.9)	295 (82.9)	116 (47.4)	411 (68.4)
Laboratory-confirmed inflammatory infection[a]	60 (11.9)	411 (79.3)	32 (9.0)	129 (52.7)	161 (26.8)
	n = 703	*n* = 768	*n* = 365	*n* = 366	*n* = 731
Self-reported genital ulcer symptoms in the last 12 months					
Genital or anal ulcer	37 (5.3)	17 (2.2)	48 (13.2)	51 (13.9)	99 (13.5)
Genital warts	23 (3.3)	11 (1.4)	27 (7.4)	24 (6.6)	51 (7.0)
Any ulcerative symptoms	59 (8.4)	25 (3.3)	63 (17.3)	66 (18.0)	129 (17.6)
No ulcerative symptoms	644 (91.6)	743 (96.7)	303 (83.0)	300 (82.0)	603 (82.4)
Laboratory-confirmed ulcerative infection	343 (48.8)	631 (82.2)			
HSV-2	338 (48.1)	630 (82.3)	294 (80.5)	323 (88.3)	617 (84.4)
Syphilis	31 (4.4)	17 (2.2)	20 (5.5)	2 (0.5)	22 (3.0)

[a] *Neisseria gonorrhoeae, Chlamydia trachomatis, Mycoplasma genitalium, Trichomonas vaginalis*, and Bacterial vaginosis (for women only).

PLWHA: people living with HIV/AIDS; MSM: men who have sex with men; FSW: female sex workers; HSV-2: Herpes simplex virus-2

Table 2

Performance of various self-reported symptoms and laboratory test results among FSWs and women living with HIV/AIDS (PLWHA) in Sonsonate and San Salvador, El Salvador, 2008.

	Female sex workers					Female PLWHA				
	No. identified infected by lab tests	**No. reporting STI symptoms with positive lab**	**Sensitivity**	**Specificity**	**PPV**	**No. identified infected by lab tests**	**No. reporting STI symptoms with positive lab**	**Sensitivity**	**Specificity**	**PPV**
Reported any genital inflammatory symptoms for										
	n = 518					*n* = 245				
Gonorrhoea and/or chlamydia	70	52	0.74	0.25	0.13	4	1	0.25	0.47	0.08
Bacterial vaginosis and/or Trichomonas and/or *Mycoplasma genitalium*	404	300	0.74	0.22	0.77	128	67	0.52	0.47	0.52
Any genital inflammatory infection[a]	411	307	0.75	0.23	0.79	129	67	0.52	0.47	0.52
Reported any genital ulcerative symptoms for										
	n = 768					*n* = 366				
HSV-2	630	20	0.03	0.96	0.80	323	61	0.19	0.88	0.92
Syphilis	17	1	0.06	0.97	0.04	2	0	0.07	0.99	0.80

[a] *Neisseria gonorrhoeae, Chlamydia trachomatis, Mycoplasma genitalium, Trichomonas vaginalis*, and Bacterial vaginosis.

PLWHA: people living with HIV/AIDS; STI: sexually transmitted infection^; PPV: positive predictive value; HSV-2: Herpes simplex virus-2

Table 3

Performance of various self-reported symptoms and laboratory test results among MSM and men living with HIV/AIDS (PLWHA), in San Miguel and San Salvador, El Salvador, 2008.

	Men who have sex with men					Male PLWHA				
	No. identified infected by lab tests	**No. reporting STI symptoms with positive lab**	**Sensitivity**	**Specificity**	**PPV**	**No. identified infected by lab tests**	**No. reporting STI symptoms with positive lab**	**Sensitivity**	**Specificity**	**PPV**
Reported any genital inflammatory symptoms for										
	n = 503					*n* = 356				
Gonorrhoea and/or chlamydia	46	8	0.17	0.86	0.11	0	0	N/A	N/A	N/A
Trichomonas and/or *Mycoplasma genitalium*	17	2	0.12	0.86	0.03	32	9	0.28	0.84	0.15
Any of genital inflammatory infection[a]	60	10	0.17	0.86	0.14	32	9	0.28	0.84	0.15
Reported any genital ulcerative symptoms for										
	n = 703					*n* = 365				
HSV-2	338	37	0.11	0.94	0.63	294	55	0.89	0.21	0.19
Syphilis	31	2	0.06	0.92	0.03	20	5	0.08	0.95	0.25

[a] *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Mycoplasma genitalium*, and Trichomonas vaginalis.

PLWHA: people living with HIV/AIDS; STI: sexually transmitted infections; PPV: positive predictive value; HSV-2: Herpes simplex virus-2; N/A: not applicable