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Molecular-based Testing for Sexually Transmitted Infections Using Samples Previously Collected for Vaginitis Diagnosis

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Background. Vaginal symptoms are a leading cause of primary care visits for women. Individuals exhibiting symptoms often receive laboratory testing based on clinic-specific standards of care. Thus, women seen at a family practice clinic might only receive a vaginitis workup, whereas those seen at a sexually transmitted diseases clinic could be more likely to receive only sexually transmitted infection (STI) testing.

Methods. The likelihood of STIs was assessed in women from whom samples were tested for vaginitis using a molecular diagnostic assay. Positivity rates for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* DNA, detected using the BD MAX CT/GC/TV assay, were calculated. Concordance between the BD MAX Vaginal Panel and the BD MAX CT/GC/TV assay for detection of *T. vaginalis* was determined.

Results. Women with bacterial vaginosis alone or with concurrent *Candida* spp infections had high rates of coinfection with sexually transmitted infections (24.4%–25.7%); samples from women who were negative for vaginitis had significantly lower positivity rates (7.9%; $P < .001$). *Trichomonas vaginalis* results were concordant between the BD MAX Vaginal Panel and the BD MAX CT/GC/TV assay in 559 of 560 samples tested.

Conclusions. These data suggest, as have other studies, that women with vaginitis symptoms may be at risk for an STI. Molecular testing could provide broad diagnostic coverage for symptomatic women and improve patient management, regardless of the type of clinic in which patients are treated.

Keywords. vaginitis; sexually transmitted infection; coinfection; molecular test; diagnosis.

Vaginitis, which most often manifests clinically as abnormal discharge, dysuria, odor, or itching [1], is one of the most common causes of primary care office visits for women in the United States [2]. Women seek care from a variety of provider types or clinical settings including obstetrician/gynecologists (OB/GYN), family planning, family practice, internal medicine, and sexually transmitted disease (STD) clinics. For symptomatic women, diagnostic testing often depends on the clinic type, available diagnostic services, and provider assumptions about their clientele. These real-world factors could result in restricted diagnostic testing of some causes of vaginitis, to the exclusion of others. In addition, comprehensive diagnostic testing for women in primary care settings can be hampered by a reliance on clinical methods (eg, wet prep microscopy and visual assessment of discharge) that are subjective and/or require specialized equipment and training [3, 4]. In other cases, testing may carry stigma associated with sexually transmitted infections (STIs) [5]. As public funds continue to be withdrawn from STD-specific clinical services, primary care providers must take on the additional responsibility of providing these services for their clients. Making this type of testing both simple (eg, through use of a single sample) and normative (ie, it is provided for everyone with these symptoms) will both improve services for women and reduce the stigma associated with STI testing.

A distinction is often drawn by providers between vaginitis (which is generally not perceived as an STI) and STIs, which have a negative connotation associated with unsafe behavior. However, *Gardnerella vaginalis*, the predominate bacteria associated with bacterial vaginosis (BV), is considered by many to be associated with sexual activity, if not strictly an STI, and several studies have shown a correlation between sexual behaviors and risk for BV [6]. In addition, *Trichomonas vaginalis* (TV) was initially considered to be transmitted by fomites, but is now known to be transmitted almost exclusively through sexual contact [7]. TV is included in "vaginitis" guidelines because it is usually considered a vaginal infection and causes vaginal

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symptoms, whereas *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT) cause cervical infection and cervicitis [8]. Thus, many practitioners in non-STD clinical settings do not consider TV to be an STI, which largely restricts diagnostic coverage to vaginitis panels.

Coinfection with BV and TV, coupled with inaccurate clinical evaluation, renders the correct diagnosis of vaginal infection difficult [9]. Laboratory methods such as Gram stain and culture may be highly subjective to sampling, transport conditions, and technical proficiency, and may have prolonged turnaround times. The BD MAX Vaginal Panel (MVP; Becton, Dickinson and Company, BD Life Sciences–Diagnostic Systems) is a molecular-based assay that facilitates data analysis of target genomic sequences in BV, *Candida* spp, and TV following polymerase chain reaction–based detection [10] to provide vaginitis diagnostics. Another assay, the BD MAX CT/CG/TV panel (MCGT; Becton, Dickinson and Company, BD Life Sciences–Diagnostic Systems) [11], is an STI panel that detects CT, GC, and TV DNA. In this study, we assessed the utility of diagnostic testing for CT, GC, and TV from stored samples, originally collected for diagnosis of vaginitis. Because the TV DNA target is included in the MVP, we also assessed the concordance of results between the 2 panels for this pathogen.

MATERIALS AND METHODS

Population and Samples

The Standards for Reporting Diagnostic Accuracy (STARD) statement was used to ensure accurate reporting in this article [12]. The study design was a nonmatched, retrospective assessment using de-identified residual specimens from the MVP clinical study. Vaginal swab samples were collected during the MVP study as previously described [10]. The MVP study was a diagnostic accuracy, prospective cross-sectional study. All women enrolled in the study presented with at least 1 of the following symptoms of vaginitis or BV: abnormal vaginal discharge; vaginal itching; painful or frequent urination, irritation, or burning; painful or uncomfortable intercourse; and/or vaginal odor. All vaginitis results were known for samples prior to selection for MCGT testing.

In the parent clinical study for the MVP assay, 1740 women were enrolled [10]. From that pool, 1701 self-collected specimens were obtained that yielded reportable (positive or negative) results from the MVP. Within these specimens, 667 were positive for BV, 305 were positive for *Candida* spp, 303 were positive for BV and *Candida* spp, and 426 were negative for a vaginitis cause (Supplementary Table 1). A total of 1223 self-collected specimens were identified that produced results in the parent study for all the MVP targets. Within this group, 17 were excluded due to missing consent for use of remnant specimen and 64 specimens were excluded due to inclusion into another study. From the remaining 1142 specimens, 68 were identified as positive for TV and were included in this analysis. Following identification of the TV-positive samples, samples for analysis from vaginitis categories (BV, *Candida* spp, and vaginitis negative) were selected from the remaining 1074 specimens to match, as closely as possible, the positivity rates reported in the BD MAX parent study (Supplementary Table 1) [10]. The selection for BV, *Candida* spp, and vaginitis-negative specimens was performed in a blinded fashion (all demographic or other information unknown) using a code that randomly chose specimens based on vaginitis status. Overall, 1120 specimens were excluded and 581 specimens were included for testing with the MCGT assay.

MVP is an automated, in vitro diagnostic test on the BD MAX System. This US Food and Drug Administration–authorized molecular diagnostic assay provides qualitative (positive/negative) results for BV, *Candida* group (consisting of *C. albicans*, *C. tropicalis*, *C. parapilosis*, and *C. dubliniensis* [plus *C. glabrata* and *C. krusei* separately due to potential antifungal resistance]) and TV. MVP directly detects DNA targets from pathogens associated with *Candida* spp and TV, and determines BV diagnosis through a bioinformatic algorithm, which detects the presence, absence, and relative load of BV markers (*Lactobacillus* spp [*L. crispatus* and *L. jensenii*], *Gardnerella vaginalis*, *Atopobium vaginae*, *Megasphaera*-1, and BV-associated bacterium 2) [10].

Samples used in this study were previously stored at –20°C prior to shipment to test sites. Testing was performed at the University of Alabama at Birmingham and at the BD diagnostics facility in Québec City, Canada. Samples were allowed to come to room temperature, preheated according to the instrument parameters, and loaded onto the BD MAX instrument. The assay requires approximately 15 minutes of hands-on time for a run of 24 samples, and results are available in approximately 3.5 hours. All processes, including DNA extraction, reagent rehydration, amplification, and detection of target nucleic acid sequences, were handled automatically by the BD MAX instrument.

Samples were identified only with the study identification number that had been assigned during the MVP study, and no patient-specific information was provided to the testing laboratories. Institutional review board approval was obtained for this project and informed consent was performed during the MVP study with permission to use residual samples in future research [10].

Analyses

Although TV is a target in MVP, this pathogen is strictly transmitted through sexual contact. In the analyses presented here, "vaginitis" will be used as a term to describe the presence of BV and/or *Candida* spp, excluding TV. Thus, "BV only," "*Candida* only," "BV and *Candida*," or "no vaginitis" represent 4, mutually exclusive categories in which TV may or may not be present. All TV infections are described as STI. Demographic data, including age and symptoms reported, were analyzed in the context of infection variables to characteristics of patients with infections.

Positivity rates of CT, GC, and TV were calculated based on the MCGT results. Odds ratios (ORs) were determined along with their asymptotic confidence intervals (CIs). Fisher exact test was used to generate *P* values. The statistical difference for overall percentage agreement values was performed with the determination of the Cohen κ coefficient. The Wald CIs [13] are provided for the κ statistic. A κ statistic of > 0.90 indicates almost perfect agreement between the 2 populations being studied (beyond chance) [14]. Adjusted positivity rates within MVP-tested samples were generated using weighted values. Weighted values were calculated by using the ratio of the vaginitis positivity rates in the parent study [10] to the rates in this study and using that correction factor to estimate the STI positivity rates accordingly for BV only, BV/TV, *Candida* spp only, *Candida* spp/TV, BV/Candida spp, BV/*Candida* spp/TV, TV only, and MVP-negative specimens. *P* values for adjusted positivity rates were calculated using bootstrapping. Results were considered significant at the level of $\alpha \leq .05$.

RESULTS

Testing was performed on 581 specimens from women who had provided specimens for the MVP study [10]. TV results were obtained from 560 of 581 (96.4%). Twenty-one specimens were removed as they did not generate reportable results from the MCGT assay. This was due either to instrumental failure or an internal control failure. The cumulative positivity rate (70.2%; Table 1) for BV and *Candida* spp combined was similar to the rate reported in the parent study (74.2%) [10]. This suggests that the randomization of sample selection was effective.

As shown in Table 1, the mean age for women who provided samples in this study was 28.2 years. The median age in this study was 27 years (range, 18–72 years). The mean age for the BV or *Candida* spp–positive group and the BV and *Candida* spp–negative group was 31.1 years and 29.1 years, respectively. Fifty-eight percent of the women were black, with white participants comprising 23.9% of the study population. Most of the samples were collected at family planning clinics (68.8%), whereas fewer were collected at STD/human immunodeficiency virus clinics and OB/GYN clinics (17.0% and 14.3%, respectively). In the BV and/or *Candida* spp–positive group, 22.4% of women were coinfected with an STI, whereas 9.0% of women who were negative for both BV and *Candida* spp were positive for an STI. For individual STIs, TV had a positivity rate in women with BV and/or *Candida* spp of 15.0%, whereas TV was present in only 6.0% of women who were negative for both

Table 1. Summary of Demographic Information

Characteristic	Total (N = 560)		BV or *Candida* Species Positive (n = 393 [70.2%])		BV or *Candida* Species Negative (n = 167 [29.8%])	
Mean age, y	28.2	…	31.1	…	29.1	…
Median age, y (range)	27 (18–72)	…	26 (18–70)	…	29 (18–72)	…
Race						
Black/African American	58 (325)	…	65.4 (257)	…	40.7 (68)	…
White	23.9 (134)	…	19.3 (76)	…	34.7 (58)	…
Other	18.0 (101)	…	15.3 (60)	…	24.6 (41)	…
Ethnicity						
Hispanic/Latino	8.2 (46)	…	6.9 (27)	…	11.4 (19)	…
Non-Hispanic	91.8 (514)	…	93.1 (366)	…	88.6 (148)	…
Clinic type						
STD/HIV	17.0 (95)	…	18.6 (73)	…	13.2 (22)	…
Family planning	68.8 (385)	…	73.0 (287)	…	58.7 (98)	…
OB/GYN	14.3 (80)	…	8.4 (33)	…	28.1 (47)	…
Symptoms						
Abnormal vaginal discharge	75.9 (425)	…	79.1 (311)	…	68.3 (114)	…
Painful/frequent urination	11.6 (65)	…	9.4 (37)	…	16.8 (28)	…
Vaginal itching/burning/irritation	48.2 (270)	…	46.1 (181)	…	53.3 (89)	…
Painful/uncomfortable intercourse	10.21 (57)	…	8.1 (32)	…	15.0 (25)	…
Vaginal odor	48.9 (274)	…	57.5 (226)	…	28.7 (48)	…
STI result	Observed	Adjusted, %	Observed	Adjusted, %	Observed	Adjusted, %
Any STI positive	18.4 (103)	14.9	22.4 (88)	16.2	9.0 (15)	10.9
CT positive	6.1 (34)	6.1	7.9 (31)	7.6	1.8 (3)	1.8
GC positive	1.8 (10)	1.7	2.0 (8)	1.9	1.2 (2)	1.2
TV positive	12.3 (69)	8.3	15.0 (59)	8.4	6.0 (10)	8.3

Data are presented as % (No.) unless otherwise indicated.

Abbreviations: BV, bacterial vaginosis; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae* (gonococcus); GYN, gynecology; HIV, human immunodeficiency virus; OB, obstetrics; STD, sexually transmitted disease; STI, sexually transmitted infection; TV, *Trichomonas vaginalis*.

vaginitis causes. CT had positivity rates of 7.9% and 1.8%, and GC had positivity rates of 2.0% and 1.2%, in women with or without a vaginitis diagnosis, respectively.

Of the 560 specimens with TV reportable results, 557 had reportable results for all 3 targets on the MCGT assay. Of those 557 specimens, 39.7% (221/557) tested positive for BV only, 11.8% (66/557) tested positive for *Candida* spp only, 18.9% (105/557) tested positive for both BV and *Candida* spp, and 29.6% (165/557) specimens tested negative (Table 2). Overall, MCGT positivity was 6.1%, 1.8%, and 11.8% for CT, GC, and TV, respectively, among all the 557 specimens (Figure 1). The MCGT assay detected STI (any cause) in 24.4% of BV-only cases ($P < .0001$; BV vs no vaginitis), 9.1% of *Candida* spp cases ($P = .7929$; *Candida* spp vs no vaginitis), and in 25.7% of BV and *Candida* spp–positive cases ($P < .0001$; BV and *Candida* spp vs no vaginitis) (Figure 1). Only 7.9% of the specimens that were negative for any BV or *Candida* spp had any STI detected. Overall, 87% (87/100) of specimens positive for any STI were also positive for BV and/or *Candida* spp.

For the 557 specimens that provided reportable results for all the targets, results were stratified by presence of BV and by presence of *Candida* spp (Table 3). Women with BV, with or without *Candida* spp, were significantly more likely to have a CT infection (OR, 2.9 [95% CI, 1.2–6.8]; $P = .0114$), a TV infection (OR, 5.2 [95% CI, 2.5–10.8]; $P < .0001$), or any STI infection (OR, 3.7 [95% CI, 2.2–6.3]; $P < .0001$). Women with *Candida* spp were significantly more likely to have a CT infection (OR, 2.4 [95% CI, 1.2–4.8]; $P = .0197$).

Because of the selection algorithm for TV-positive specimens (ie, all available TV-positive samples were chosen for analysis), weighted positivity rates for STI causes were generated within the vaginitis sample population. Weighted positivity rates were similar to the unweighted positivity rates for CT and GC as causes of STI within the BV, BV/*Candida* spp, and no vaginitis populations (Table 2). When using the weighted positivity rates, CT remained significantly more common among women with BV (with or without *Candida* spp) compared to women with no vaginitis with *P* values <.5. This held true for the comparison of any STI among women with BV (with or without *Candida* spp) compared to women without vaginitis with *P* values <.5. However, for TV as a cause of STI, the weighted positivity rates were no longer statistically different for women with BV (with or without *Candid* spp.) compared to those with no vaginitis (Table 2).

Because TV infections can be detected by either the MVP or the MCGT assay, we wanted to assess the comparability of the test results across platforms. From the 560 specimens that provided a reportable result for TV by both assays, only 1 discrepant result (positive on the MCGT assay and negative on MVP) was identified (Supplementary Table 2). The percentage agreement among the 2 assays was 99.8% (95% CI, 99.0%–100%), with a κ score of 0.99 (95% CI, 0.98–1.00).

Table 2. Concomitant Sexually Transmitted Infection and Vaginitis Diagnoses

STI Panel Results	BV (n = 221)	Adjusted Prevalence, %	*Candida* Species (n = 66)	Adjusted Prevalence, %	BV and *Candida* Species (n = 105)	Adjusted Prevalence, %	No Vaginitis (n = 165)	Adjusted Prevalence, %	Overall (N = 557)	Adjusted Prevalence, %
CT positive	6.3[a] (3.8–10.4), n = 14	6.0[a]	6.1 (2.4–14.6), n = 4	6.1	12.4[b] (74–20.0), n = 13	12.8[b]	1.8 (.6–5.2), n = 3	1.8	6.1 (4.4–8.4), n = 34	6.2
GC positive	2.7 (1.3–5.8), n = 6	2.5	1.5 (.3–8.1), n = 1	1.5	1.0 (.2–5.2), n = 1	1.0	1.2 (.3–4.3), n = 2	1.2	1.8 (1.0–3.3), n = 10	1.7
TV positive	19.0[b] (14.4–24.7), n = 42	11.4	1.5 (.3–8.1), n = 1	1.6[a]	14.3[a] (8.9–22.2), n = 15	8.6	4.8 (2.5–9.3), n = 8	8.0	11.8 (9.4–14.8), n = 66	8.3
Any STI positive	24.4[b] (19.2–30.5), n = 54	17.4[a]	9.1 (4.2–18.4), n = 6	9.2	25.7[b] (18.3–34.8), n = 27	20.8[a]	7.9 (4.7–13.0), n = 13	10.9	18.0 (15.0–21.4), n = 100	14.9

Data are presented as % (95% confidence interval) unless otherwise indicated. For this analysis, TV was categorized as a sexually transmitted infection rather than a cause of vaginitis. Prevalences were adjusted by weighting to control for the inclusion of all *Trichomonas*-positive samples from the parent study.

Abbreviations: BV, bacterial vaginosis; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae* (gonococcus); STI, sexually transmitted infection; TV, *Trichomonas vaginalis*.

[a] $P < .05$.

[b] $P < .001$.

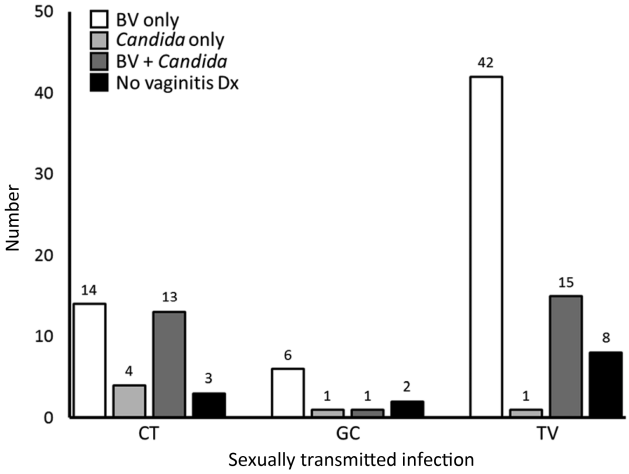

Figure 1. Distribution of sexually transmitted infections (STIs) among women with vaginitis. Groups that were either positive for bacterial vaginosis (BV) only, positive for *Candida* spp only, positive for both BV and *Candida* spp, or negative for both are shown. The number and type of STI in each vaginitis category are shown. In all groups except the *Candida* spp only, *Trichomonas vaginalis* represents the highest proportion of STI causes. *Chlamydia trachomatis* represent the second-highest cause (except in the *Candida* spp group), with *Neisseria gonorrhoeae* (gonococcus) being the least prevalent cause across all groups. Abbreviations: Dx, diagnosis; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*; TV, *Trichomonas vaginalis*.

Results from the MCGT and MVP assays were also analyzed according to clinic type in this study. We characterized the participating sites in this study as OB/GYN, family planning, or STD clinics. As shown above (Table 1), the majority of specimens were collected at family planning clinics. In the subset of samples used in this analysis, the proportion of participants originally recruited from STD (18.9%) and non-STD (81.1%) clinics was similar to the proportion in the parent study. For the current analysis involving MVP results, we found that a significantly higher proportion of BV-positive samples, compared to total results, were identified at STD (69.5%) clinics compared with non-STD (56.1%) clinics (P = .0166; Table 4). For *Candida* spp, no difference in the proportion of positive results was found based on clinic types at which the women were recruited. This distribution of causes of vaginitis across clinic types was similar to the distribution seen in the parent study as well. For STI results, a significantly higher proportion of CT results was obtained from STD clinics compared with non-STD clinics (11.6% vs 4.9%, respectively; P = .03). This was also the case for TV results (27.4% vs 9.2%; P < .001). While STI positivity was highest in the STD clinic population, the positivity rates of CT, GC, and TV (4.9%, 1.3%, and 9.2%, respectively) found among women attending non-STD clinics were higher than the national average prevalence rates [15].

DISCUSSION

The BD MAX system facilitates the detection of numerous vaginitis-causing pathogens, including BV, *Candida* spp, CT, GC, and TV, from 1 collected specimen. Here we show that a large percentage (>85%) of individuals positive for any STI were also positive for BV or *Candida* spp. Women who were positive for BV were significantly more likely to have a CT infection, a TV infection, or any STI, regardless of clinic type. This is important as non-STD clinic types had high positivity rates for STI. In addition, while BV positivity rates in the parent study were high in non-STD clinics (53.5%), the rates were even higher in STD clinics (74.5%). These current data, in combination with previous work [10, 16], suggest that it is common for women to have multiple pathogens that may play a role in vaginitis (including STI); therefore, accurate and comprehensive diagnostic testing is critical to ensure appropriate treatment of patients. Clinical diagnosis that determines only a single pathogen or syndrome is likely underdiagnosing STI infections that require different clinical management.

TV is a pathogen that is included in the MVP and is strongly associated with the presence of BV. Importantly, the MVP and MCGT assays have a high degree of concordance for the detection of TV, which should allow accurate and sensitive detection of this vaginitis-causing agent, regardless of the clinic type in which patients are seen. However, additional testing is warranted among women presenting with symptoms of vaginitis

Table 3. Likelihood of Sexually Transmitted Infections Among Women With Bacterial Vaginosis or *Candida* Species

	MVP							
	BV				*Candida* Species			
MCGT	Positive (n = 326)	Negative (n = 231)	OR (95% CI)	*P* Value	Positive (n = 171)	Negative (n = 386)	OR (95% CI)	*P* Value
CT positive	8.3 (27)	3.0 (7)	2.9 (1.2–6.8)	.0114	9.9 (17)	4.4 (17)	2.4 (1.2–4.8)	.0197
GC positive	2.1 (7)	1.3 (3)	1.7 (.4–6.5)	.5343	1.2 (2)	2.1 (8)	0.6 (.1–2.7)	.7311
TV positive	17.5 (57)	3.9 (9)	5.2 (2.5–10.8)	<.0001	9.4 (16)	13.0 (50)	0.7 (.4–1.3)	.2571
Any STI positive	24.8 (81)	8.2 (19)	3.7 (2.2–6.3)	<.0001	19.3 (33)	17.4 (67)	1.1 (.7–1.8)	.6323

Data are presented as % (No.) unless otherwise indicated.

Abbreviations: BV, bacterial vaginosis; CI, confidence interval; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae* (gonococcus); MCGT, BD MAX CT/CG/TV panel; MVP, BD Max Vaginal Panel; OR, odds ratio; STI, sexually transmitted infection; TV, *Trichomonas vaginalis*.

Table 4. Prevalence of Vaginitis Infections in Specimens Obtained at Sexually Transmitted Disease (STD) and Non-STD (Obstetrics and Gynecology, Family Practice) Clinics

Selected, Residual Samples Utilized in This Study (N = 560)			
Infection	Non-STD Clinic (n = 465)	STD Clinic (n = 95)	*P* Value
BV	56.1 (261)	69.5 (66)	.0166
Candida spp	29.5 (137)	35.8 (34)	.2239
CT	4.9 (23)	11.6 (11)	.0300
GC	1.3 (6)	4.2 (4)	.0719
TV	9.2 (43)	27.4 (26)	<.0001
Original Sample Group Obtained During the BD MAX Vaginal Panel Study (N = 1701) [10]			
Infection	Non-STD Clinic (n = 1395)	STD Clinic (n = 306)	*P* Value
BV	53.2 (742)	74.5 (228)	<.0001
Candida spp	36.0 (502)	34.6 (106)	.6566
TV	6.4 (89)	16.0 (49)	<.0001

Data are presented as % (No.) unless otherwise indicated.

Abbreviations: BD, Becton, Dickinson and Company; BV, bacterial vaginosis; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae* (gonococcus); STD, sexually transmitted disease; TV, *Trichomonas vaginalis*.

and testing positive for TV. Among the 68 women identified as positive for TV using the MVP assay, only 6 were coinfected with another STI (1 with GC, 4 with CT, and 1 with CT and GC; Supplementary Table 1). Therefore, use of a positive TV result to indicate the need for additional STI testing would have missed the remaining 29 CT and 8 GC infections identified through dual testing as these were from TV-uninfected women. Furthermore, given the significant association of a BV- and/or *Candida* spp–positive result with CT infection (compared to vaginitis-negative women), reflex testing for STI only in vaginitis-negative specimens would likely be an ineffective strategy for identifying all infections. These conclusions are clinically relevant given that different oral antibiotic treatment regimens exist for TV that may or may not effectively treat BV, and that CT and GC infections would not be covered by therapies commonly used to treat any of the MVP targets [17].

In the United States and many industrialized countries that collect surveillance data, the rates of all STIs continue to increase despite long-standing recommendations for annual screening among women <25 years of age [8]. The best measure of US screening rates is provided annually by the Health Education Data Information System. Available data indicate that only 50% of women in the recommended age range are screened each year [18]. Screening most often occurs at federally funded STD clinics, family planning clinics, and OB/GYN and primary care practices [19]. As federal funding for the first 2 clinic types decreases, the burden of testing is shifting to OB/GYN and primary care practices where women are more often assessed for vaginitis to the exclusion of STI screening. In this scenario, molecular testing represents an efficient, sensitive, accurate, and objective test that can be performed for all causes of vaginitis.

This study has limitations that should be noted. First, the MCGT assay was performed on frozen remnant specimens enrolled during the MVP study [10]; the specimens were tested beyond the 30-day stability period that is claimed by the BD MAX UVE Specimen Collection Kit. Second, the samples were chosen to include all available TV-positive specimens (as determined from the MVP study) to determine concordance between the MVP and MCGT assays. As a result, the distribution of TV in the study population (approximately 11%) is not truly representative of that previously published (8.3%) [10]. Indeed, adjustment for specimen collection procedures resulted in a reduced prevalence value for TV as an STI cause in the BV and BV/*Candida* spp vaginitis populations. Finally, the low numbers of GC-positive samples limited our statistical power for comparison of STI rates in vaginitis-positive and -negative groups for this pathogen.

CONCLUSIONS

As women are seen in different clinical settings for symptoms indicative of vaginitis, it is important for treating clinicians to be aware that women with symptoms of vaginitis could be at an increased risk for an STI. The increased risk of some STIs in women who are positive for BV or *Candida* spp provides a strong impetus for comprehensive testing for STI. Integration of molecular testing for vaginitis and STI would establish consistent, objective, and sensitive testing methods [10], regardless of clinic type, to accurately identify and treat patients for these conditions.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

Author contributions. All authors contributed to the interpretation of the data, critically revised the manuscript for important intellectual content, approved the final version to be published, and agree to be accountable for all aspects of the work. BD employees, who are also authors, played the following roles during the study and development of the paper: S. P. facilitated data acquisition and interpretation, drafting, and revision of the manuscript; S. K. facilitated conception and design of the study, data acquisition and interpretation, and drafting and revision of the manuscript; C. C. facilitated study conception and design, and manuscript revision. These 3 authors provided final approval of the manuscript and agree to be accountable for the accuracy and integrity of this work.

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