Accuracy of the Clinical Diagnosis of Vaginitis Compared With a DNA Probe Laboratory Standard

Nancy K. Lowe, CNM, PhD, Jeremy L. Neal, CNM, PhD, and Nancy A. Ryan-Wenger, CPNP, PhD

OBJECTIVE: To estimate the accuracy of the clinical diagnosis of the three most common causes of acute vulvovaginal symptoms (bacterial vaginosis, candidiasis vaginitis, and trichomoniasis vaginalis) using a traditional, standardized clinical diagnostic protocol compared with a DNA probe laboratory standard.

METHODS: This prospective clinical comparative study had a sample of 535 active-duty United States military women presenting with vulvovaginal symptoms. Clinical diagnoses were made by research staff using a standardized protocol of history, physical examination including pelvic examination, determination of vaginal pH, vaginal fluid amines test, and wet-prep microscopy. Vaginal fluid samples were obtained for DNA analysis. The research clinicians were blinded to the DNA results.

RESULTS: The participants described a presenting symptom of abnormal discharge (50%), itching/irritation (33%), malodor (10%), burning (4%), or others such as vulvar pain and vaginal discomfort. According to laboratory standard, there were 225 cases (42%) of bacterial vaginosis, 76 cases (14%) of candidiasis vaginitis, 8 cases (1.5%) of trichomoniasis vaginalis, 87 cases of mixed infections (16%), and 139 negative cases (26%). For each single infection, the clinical diagnosis had a sensitivity and specificity of 80.8% and 70.0% for bacterial vaginosis, 83.8% and 84.8% for candidiasis vaginitis, and 84.6% and 99.6% for trichomoniasis vaginalis when compared with the DNA probe standard.

CONCLUSION: Compared with a DNA probe standard, clinical diagnosis is 81–85% sensitive and 70–99% specific for bacterial vaginosis, *Candida* vaginitis, and trichomoniasis. Even under research conditions that provided clinicians with sufficient time and materials to conduct a thorough and standardized clinical evaluation, the diagnosis and, therefore, subsequent treatment of these common vaginal problems remains difficult.

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LEVEL OF EVIDENCE: II

Symptoms of acute vulvovaginitis are one of the most common reasons for women's health care visits, with annual estimates of 6 to 10 million visits in the United States.[1,2] Despite technologic advances in point-of-care testing options, expert recommendations continue to describe a standard of clinical diagnosis by history and physical examination, pH determination, amine (whiff) test, and wet-prep microscopy for these common women's health complaints, partially due to concerns about increased costs associated with newer options.[1,3] In a review of studies published between 1966 and 2003, the diagnosis of bacterial vaginosis was made in 22–50% of symptomatic women, candidiasis vaginitis in 17–39%, and trichomoniasis vaginalis in 4–35%. Approximately 30% of symptomatic women remained undiagnosed after clinical evaluation.[4]

Several investigators have highlighted inaccuracies in the clinical diagnosis of these common clinical problems when compared with traditional criterion standards for both symptomatic and asymptomatic women.[5–7] In addition, concerns have been raised about the infrequency with which the recommended clinical diagnostic tools of microscopic assessment of

From the Division of Women, Children and Family Health, University of Colorado Denver College of Nursing, Aurora, Colorado; and Ohio State University College of Nursing, Columbus, Ohio.

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Corresponding author: Nancy K. Lowe, CNM, PhD, FACNM, FAAN, University of Colorado Denver, College of Nursing, 13120 East 19th Avenue, Room 4235, Mail Stop C288-18, PO Box 6511, Aurora, CO 80045; e-mail: nancy.lowe@ucdenver.edu.

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vaginal fluid, pH determination, and amine testing is actually performed in routine clinical practice.[8,9] Whether declines in use of the traditional diagnostic tools are due to training failure resulting in poor skills, the imposition of Clinical Laboratory Improvement Amendment regulations causing abandonment of previously performed microscopic examinations,[10] a decrease in time available per patient to maintain productivity, or other factors is unclear.

The criterion standards to which symptoms and clinical diagnoses primarily have been compared are culture in Diamond's media for trichomoniasis vaginalis, Gram stain using Nugent's criteria for bacterial vaginosis, and agar culture for candidiasis vaginitis. These methods are not immediately available in many clinical settings, are individually time-consuming, and do not provide timely results. A DNA probe analysis of vaginal fluid for *Gardnerella vaginalis*, candida species, and *Trichomonas vaginalis* (Affirm VPIII, BD Diagnostics, Sparks, MD)[11] provides a point-of-care testing option for these three common causes of acute vulvovaginal symptoms. The purpose of this study was to estimate the accuracy of clinicians' diagnoses for military women experiencing symptoms suggestive of vulvovaginitis compared with the DNA probe standard.

MATERIALS AND METHODS

This was a prospective, clinical comparative study in which clinicians conducted standardized clinical examinations for women presenting with vulvovaginal symptoms. Active-duty military women who presented for health care with vulvovaginal or urinary symptoms at one of four troop medical clinics in the U.S. Army or Navy between November 2002 and July 2006 were invited to participate in the parent study. The total sample was 715 women, 547 of whom were experiencing vulvovaginal symptoms and are the focus of this report (Fig. 1). Sample size was calculated for the primary aim of the parent study using the approach of the prevalence of the condition (a population proportion) and the desired levels of accuracy of the diagnostic test.[12] Using criteria of 95% positive predictive values, 95% negative predictive values, and precision of plus or minus 3% with a 38% prevalence of bacterial vaginosis/trichomoniasis vaginalis and 45% candidiasis vaginitis from our previous clinical study of civilian women,[13] we needed at least 534 participants with vaginal symptoms. The study protocol was approved by The Ohio State University, Oregon Health & Science University, the U.S. Army, and the U.S. Navy institutional review boards for human subject research.

The clinicians in this study were nurse practitioner (NP) research staff for the parent project with the primary aim of testing the accuracy of women's self-diagnosis of vulvovaginal symptoms compared with the DNA probe analysis of vaginal secretions for bacterial vaginosis, trichomoniasis vaginalis, or candidiasis vaginitis. One component of the research

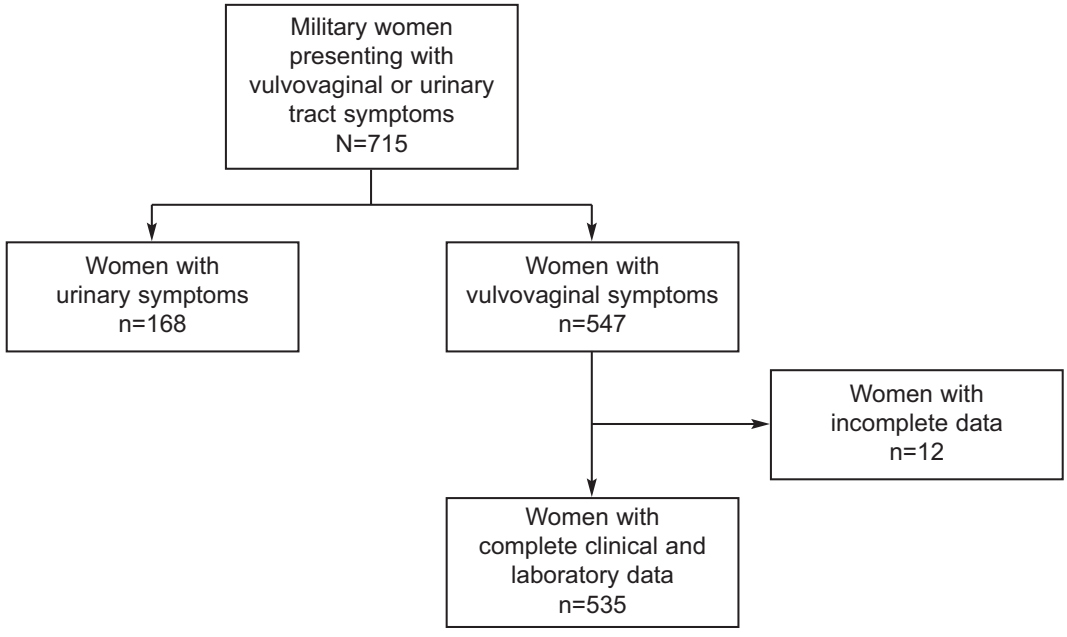

Fig. 1. Number of participants at each stage of the study.
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protocol was a clinical diagnosis and treatment plan by the research staff. The four research clinicians were masters-prepared, nationally certified, women's health nurse practitioners with 6 to 11 years of experience in the role. Two of the NPs were also certified as family or adult nurse practitioners. Three of the NPs had served from 4 to 21 active duty years in the U.S. Air Force or Navy, with one of these a current reservist.

After informed consent and completion of the self-diagnosis portion of the parent study, participants were interviewed and examined by the research NPs according to a standard clinical protocol for the diagnosis and management of vulvovaginal symptoms. Women were excluded from participation if they were menstruating or had coitus within the last 24 hours. The NPs were blinded to the participants' self-diagnoses throughout the data collection procedures.

The research interview protocol included behavioral risk factors and prior occurrence of and treatment for genitourinary infection, as well as a standard clinical history, including chief complaint, current symptoms, and self-care for symptoms. The clinical examination included a speculum examination for observation of mucopurulent cervicitis and evaluation of secretions for color, viscosity, and homogeneity. Vaginal specimens were collected for wet-prep microscopy (normal saline and 10% potassium hydroxide slides), whiff (amines) test using 10% potassium hydroxide added to the vaginal secretions, and determination of vaginal secretion pH (Phenazine Paper, Decon Laboratories, Inc., King of Prussia, PA). Vaginal fluid samples were collected for DNA probe analysis (Affirm VPIII, BD Diagnostics) for *G vaginalis*, *T vaginalis*, and candida species and from the endocervix for DNA probe analysis (Gen-Probe Incorporated, San Diego, CA) for *Chlamydia trachomatis* and *Neisseria gonorrhea*.

The DNA probe uses nucleic acid hybridization (two distinct single-stranded probes for each organism and a color development probe) to detect and identify *G vaginalis, T vaginalis*, and candida fungal species. Although *G vaginalis* is not the only bacterium associated with the polymicrobial disruption of bacterial vaginosis, it is the sentinel organism.[14] A test swab used to obtain a sample of vaginal fluid can be held at room temperature for up to 1 hour or up to 4 hours at 2–8°C. Study swabs were tested by trained military laboratory technicians in each clinical laboratory according to the manufacturer's directions for the BD MicroProbe Processor (BD Diagnostics). The DNA probe test readers were blind to the clinical findings, including the clinicians' diagnoses. Test results are not adversely affected by variables that make visual identification of microbial agents difficult, such as vaginal lubricants, douches, menses, or spermicides.[15]

Reported respective sensitivities and specificities of the DNA probe compared with conventional criterion standards of Gram stain/Nugent's criteria and/or culture for identifying G vaginalis (bacterial vaginosis) are 88–98% and 81–97%[14–16]; for *Trichomonas* (trichomoniasis vaginalis) 83–100% and 98–100%[14]; and for *Candida* (candidiasis vaginitis) 82% and 94%.[17] In two other studies, the identification of organisms associated with bacterial vaginosis, trichomoniasis vaginalis, and candidiasis vaginitis was consistently greater using the DNA probe than by Amsel criteria or by wet mount alone.[18,19]

The NPs made their clinical diagnoses and treatment decisions on the basis of the clinical data without knowledge of the DNA probe results. Because of the protocol of the parent study, the NPs remained blinded to the DNA probe results for *G vaginalis*, *T vaginalis*, and candida fungal species throughout the study but treated *C trachomatis* and/or *N gonorrhea* as indicated on the basis of the laboratory results for these organisms. The study protocol also included an in-person or telephone follow-up visit from 2 to 5 days after the initial enrollment visit. During this follow-up, data were systematically collected about the resolution of clinical symptoms, the timing of symptom resolution, satisfaction with the treatment prescribed, occurrence of treatment side effects, and other self-treatment approaches used.

For all analyses, laboratory diagnosis by DNA probe was considered the diagnostic standard for comparison. The data were analyzed with SPSS 16.0 (SPSS Inc., Chicago, IL). Descriptive statistics, cross tabulations, and 2×2 contingency tables were used to calculate sensitivity, specificity, positive predictive value, and negative predictive value with a 95% confidence interval. Absolute clinical diagnostic accuracy was mathematically defined as the number of matches between the clinical diagnoses and the DNA probe results, divided by the total number of DNA probe diagnoses in each category. Kappa coefficients (κ) were calculated as a measure of agreement that corrects for chance agreement between two raters,[20] or in this case, between the clinician and the DNA probe result.

RESULTS

The sample was 547 active duty U.S. military women (43% Army, 54% Navy, and 3% other branches) who presented for health care with vulvovaginal symptoms. The presenting symptom was abnormal dis-

Table 1. Demographic Characteristics of Sample (n=535)

Characteristic	n (%)
Age (y)	25.7±5.8 (18–50)*
Ethnicity/race	
African American	230 (43.0)
Hispanic/Latina	97 (18.1)
White	168 1 (3.4)
Other or not reported	40 (7.5)
Education	
High school graduate or GED	123 (23.0)
Some college	305 (57.0)
Associate degree	40 (7.5)
College degree	47 (8.8)
Postgraduate	17 (3.2)
Not reported	3 (0.6)
Marital status	
Single	212 (39.6)
Married/living with significant other	213 (39.8)
Divorced/widowed/separated	104 (19.4)
Other/not reported	6 (1.1)
Branch of military service	
Army	232 (43.4)
Navy	288 (53.8)
Air Force/Marines/Coast Guard	14 (2.6)
Not reported	1 (0.2)
Military rank	
Enlisted (E1–E3)	142 (26.5)
NCO (E4–E9)	350 (65.4)
Junior officer (O1–O3)	37 (6.9)
Senior officer (O4–O6)	3 (0.6)
Not reported	3 (0.6)

GED, general equivalency degree; NCO, noncommissioned officer.
* Mean±standard deviation (range).

charge of a wide range of descriptions (278, 50.8%), itching/irritation (182, 33.3%), malodor (57, 10.4%), vulvar burning (23, 4.2%), and miscellaneous others (7, 1.3%), including vulvar pain and vaginal discomfort. Of this sample, 535 participants had complete data sets for the relevant clinical and DNA probe laboratory standard tests and were the sample for this report. As summarized in Table 1, these participants had a mean age of 25.7 years and were predominantly African American or white enlisted personnel, with a high school or some college education.

The clinical diagnoses and the DNA probe laboratory standard diagnoses by vaginal organism type are summarized descriptively and cross-tabulated by all categories of diagnosis, including mixed vaginal infections, in Table 2. Overall, there was no evidence of trichomoniasis vaginalis, bacterial vaginosis, or candidiasis vaginitis in 17% of the women by clinical diagnosis and more than 25% by laboratory standard. The clinical diagnosis for these three most common causes of vaginitis had a 64.5% overall absolute accuracy, with the highest level of accuracy for the diagnosis of bacterial vaginosis or candidiasis vaginitis alone (77.3% and 76.3%, respectively). The lowest levels of absolute clinical diagnosis accuracy for these symptomatic women were for the absence of vaginitis (ie, normal or noninfectious vaginitis), trichomoniasis vaginalis alone, or mixed infections.

To understand the pattern of diagnostic accuracy and inaccuracy, the clinical diagnosis for each single vaginal infection (trichomoniasis vaginalis, bacterial vaginosis, or candidiasis vaginitis) was determined (Table 3). In this analysis, mixed infections were assigned to their individual diagnostic categories so that a clinical diagnosis of bacterial vaginosis/trichomoniasis vaginalis was counted as one bacterial vaginosis diagnosis and one trichomoniasis vaginalis diagnosis. Therefore each row in Table 3 is an independent diagnostic accuracy evaluation for the

Table 2. Cross-Tabulation of Vaginitis Clinical Diagnosis and DNA Probe Laboratory Standard (n=535)

	DNA Probe Laboratory Standard							
Clinical Diagnosis	Negative	TV Only	BV Only	CV Only	BV/TV Mixed	BV/CV Mixed	BV/TV/CV Mixed	Row Total
Normal or other clinical diagnosis*	64	0	21	4	0	3	0	92 (17.2)
TV only	0	4	0	0	7	0	1	12 (2.2)
BV only	46	0	174	5	1	9	1	236 (44.1)
CV only	25	1	9	58	0	18	1	112 (20.9)
BV/TV	0	3	1	0	7	1	0	12 (2.2)
BV/CV	4	0	20	9	0	38	0	71 (13.2)
BV/TV/CV	0	0	0	0	0	0	0	0
Column total	139 (26.0)	8 (1.5)	225 (42.1)	76 (14.2)	15 (2.8)	69 (12.9)	3 (0.6)	535
Accuracy (%)	46.0	50.0	77.3	76.3	46.7	55.1	0	64.5

TV, trichomoniasis vaginalis; BV, bacterial vaginosis; CV, candida vaginitis.
Data are n (%) unless otherwise specified.
* This category also includes miscellaneous noninfectious clinical diagnoses such as contact dermatitis, herpes genitalis, condylomata, presumptive chlamydia or gonorrhea, traumatic injury, etc.

Table 3. Accuracy of Single Vaginitis Clinical Diagnosis and Treatment Implication for Each Infection Compared With DNA Probe Laboratory Standard (n=535)

	Accurate		Inaccurate		Accuracy Indices					
CD	+/+	–/–	+/–*	–/+†	Accuracy‡ (%)	Kappa§	Sensitivity	Specificity	PPV	NPV
TV	22	507	2	4	98.9	.87	84.6 (64.3–95.0)	99.6 (98.4–99.9)	91.7 (71.5–98.5)	99.2 (97.9–99.7)
BV	252	156	67	60	76.3	.51	80.8 (75.9–84.9)	70.0 (73.4–75.8)	79.0 (74.0–83.3)	72.2 (65.7–78.0)
CV	124	328	59	24	84.5	.64	83.8 (76.6–89.1)	84.8 (80.7–88.1)	67.8 (60.4–74.4)	93.2 (89.9–95.5)

CD, clinical diagnosis; +, CD or laboratory standard positive for that organism; −, CD or Laboratory negative for that organism; PPV, positive predictive values; NPV, negative predictive values; TV, trichomoniasis vaginalis; BV, bacterial vaginosis; CV, candidiasis vaginitis.

Data are n or % (95% confidence interval) unless otherwise specified.

* This inaccurate diagnosis would cause a commission treatment error, ie, prescribing a medication that is not indicated.

† This inaccurate diagnosis would cause an omission treatment error, ie, not prescribing a medication that is indicated.

‡ Number of accurate clinical diagnoses divided by the total number of clinical diagnoses (accurate and inaccurate).

§ Measure of agreement corrected for chance.

presence or absence of that specific diagnosis. Clinical diagnosis accuracy was highest for trichomoniasis vaginalis (98.9%) and lowest for bacterial vaginosis (76.3%). Sensitivities ranged from 80.8% (bacterial vaginosis) to 84.6% (trichomoniasis vaginalis); specificities, from 70.0% (bacterial vaginosis) to 99.6% (trichomoniasis vaginalis); positive predictive values, from 76.8% (candidiasis vaginitis) to 91.7% (trichomoniasis vaginalis); and negative predictive values, from 72.4% (bacterial vaginosis) to 99.2% (trichomoniasis vaginalis). The κ coefficients indicated excellent agreement between clinician and the DNA probe for trichomoniasis vaginalis, good agreement for candidiasis vaginitis, and fair agreement for bacterial vaginosis.

All except nine of the participants had DNA probe results for *C trachomatis* and *N gonorrhoea* from samples taken at the time of data collection. Only 14 (2.6%) were positive for *C trachomatis* alone, 2 (0.4%) for *N gonorrhoea* alone, and 14 (2.6%) for both organisms. Of the 30 participants positive for *C trachomatis* and/or *N gonorrhoea*, 26 (86.7%) were also positive for bacterial vaginosis alone or in combination with trichomoniasis vaginalis and/or candidiasis vaginitis. Only one woman who was DNA probe negative for bacterial vaginosis, trichomoniasis vaginalis, or candidiasis vaginitis was positive for *C trachomatis* and/or *N gonorrhoea*, and she was positive for both organisms.

The protocol for the parent study called for a follow-up interview with the study participants, preferably in person or by telephone. Follow-up interviews were conducted with 474 (88.6%) of the participants at a mean of 7 and median of 5 days after the enrollment clinical visit. Ninety-three percent of these interviews occurred within 2 weeks, and 75.9% were conducted in person. Prolonged delays in follow-up and those lost to follow-up primarily occurred due to military responsibilities including deployments. Among the 446 (94.1%) women whose symptoms had been relieved, 60% of the clinical diagnoses, including the presence of mixed infections, were accurate when compared with the DNA probe.

Only 28 (5.9%) of the participants reported that their symptoms had not been relieved after their clinic visit. Of these 28 women, 57%[16] had identical diagnoses by clinical diagnosis and DNA probe (10 no infection, five bacterial vaginosis only, and one candidiasis vaginitis) and there were no cases of trichomoniasis vaginalis. Of the remaining 12 women, seven had bacterial vaginosis by DNA probe that was not identified by clinical diagnosis; four had no infection by DNA probe, of which two were given a clinical diagnosis of bacterial vaginosis and two, candidiasis vaginitis; and one had bacterial vaginosis/candidiasis vaginitis by DNA probe and candidiasis vaginitis only by clinical diagnosis. Because the research staff was blinded to the DNA probe results, clinical reevaluation was offered to those women who remained symptomatic.

As presented in Table 2, 139 (25.9%) of 535 women with both clinical diagnosis and laboratory results had no identifiable DNA for trichomoniasis vaginalis, bacterial vaginosis, or candidiasis vaginitis. Of these 139 women, three had no *C trachomatis* or *N gonorrhoea* results recorded, and one was positive for both organisms. Therefore, the remaining 135 symptomatic women were DNA probe laboratory negative for these five most common causes of vulvovaginal symptoms. Forty of these women (29.6%) were identified clinically as normal, 23 (17.0%) were diagnosed with other vulvovaginal problems, 44 (32.6%) with bacterial vaginosis, 24 (17.8%) with candidiasis vaginitis, and four (3.0%) with a mixed bacterial vaginosis/candidiasis vaginitis infection. The 23 "other" di-

agnoses were contact dermatitis (six), yeast vulvitis (six), traumatic injury including abrasions and minor lacerations (four), herpes genitalis (two), condylomata (one), presumptive *Chlamydia* (one), lichen sclerosis (one), atrophic vaginitis (one), and possible vulvar vestibular syndrome (one).

DISCUSSION

The distribution of vaginitis type detected by DNA probe or *N gonorrhea/Chlamydia* DNA probe among these predominantly young adult symptomatic military women was similar to that reported by Landers and colleagues[7] in a similarly aged and ethnic/racially distributed sample of symptomatic women using traditional laboratory standards. Notably, in our data and that of Landers, more than 26% and 21%, respectively, of the women were found to be free of any laboratory-identifiable bacterial vaginosis or infections despite the presence of clinical symptoms. These findings are also consistent with those of others who have reported normal flora by laboratory standard[21] and the absence of a diagnosis for a significant percentage (30–35%) of symptomatic women.[4] Laboratory findings in both the current study and that by Landers et al[7] showed the highest incidences for bacterial vaginosis (58.2% compared with 46%), followed by candidiasis vaginitis (27.6% compared with 29%), trichomoniasis vaginalis (4.8% compared with 12%), and GC/*Chlamydia* (5.7% compared with 11%). The incidence of sexually transmitted infections (trichomoniasis vaginalis, GC, or *Chlamydia*) was approximately 50% lower in our population of military women, although the numbers of these infections in both samples were small.

Because the clinical diagnosis of trichomoniasis vaginalis relies on the microscopic visualization of the trichomonads (present or absent) and the clinical diagnosis of bacterial vaginosis relies on the multiple indicators of Amsel's criteria, it is not surprising that these two diagnoses were at opposite ends of the accuracy range for the clinical diagnosis of vaginitis in symptomatic women. However, our accuracy estimates for the clinical diagnosis of the three most common causes of vulvovaginal symptoms compare favorably with those of Landers et al[7] despite differences in the laboratory standard used for comparison. For candidiasis vaginitis alone, the clinical diagnosis of candidiasis vaginitis was made in 83.8% of women in our study who were positive for *Candida* by DNA probe, similar to 87.1% of 364 culture-positive women reported by Linhares et al[22] These similar findings support the conclusion that, regardless of the laboratory standard used, the clinical diagnosis of these common vaginal problems remains challenging even under conditions wherein the clinicians conducted a systematic clinical and microscopic evaluation as dictated by the research protocols. Because of reports suggesting that this systematic evaluation may be relatively uncommon in day-to-day clinical practice,[8,9] it is highly likely that most women experience a diagnostic accuracy that is significantly below these research findings. Perhaps as suggested by Fowler,[23] part of the apparently common clinical diagnosis inaccuracy is that our current vaginitis diagnostic classification system requires revision and expansion to accurately reflect the full spectrum of altered vaginal microflora and make use of newer point-of-care diagnostic options.

Clinically, the practical issues are the avoidance of inappropriate treatment that can be categorized as errors of commission (prescribing a drug in the absence of disease) or errors of omission (not prescribing a drug in the presence of disease), the resolution of symptoms, and patient satisfaction. Overall, of the symptomatic women in our study, 23.4% were prescribed a medication on the basis of clinical diagnosis not supported by the laboratory standard representing commission prescriptive errors. The clinical diagnosis led to 16.1% omission prescriptive errors in which women were not prescribed a medication indicated by the laboratory result. Despite these errors, the participants who were contacted for follow-up reported a high level of symptom resolution (more than 94%). It is unknown whether this apparent success of clinical management regardless of both commission and omission treatment errors would have been as high if information from those lost to follow-up (about 13%) was available. Further, it is unknown how many of the participants experienced recurrent symptoms and returned for additional evaluation outside of their research involvement or experienced symptom decline due to spontaneous remission of infections and microflora disruptions.

Limitations of our study include its observational nature, small subgroup size for trichomoniasis vaginalis, and the laboratory standard for bacterial vaginosis limited to a DNA probe for *G vaginalis* that ignores the polymicrobial nature of this disruption of the vaginal microflora. Despite these limitations, we found that under research conditions during which clinicians had sufficient time and materials to conduct a standardized clinical evaluation, including physical examination, determination of vaginal pH, an amines test, and wet-prep microscopy, the diagnosis and subsequent treatment of common vaginal infections remains problematic when compared with a labora-

tory standard provided by the DNA probe. However, despite the diagnostic and treatment inaccuracies, women in our study generally reported significant symptomatic relief on follow-up. The question remains whether the accumulation of data documenting the relative inaccuracy of clinical diagnosis for common causes of lower genital tract complaints even under the best of circumstances points to an unacceptably poor quality of women's health care. The availability of the DNA probe analysis for bacterial vaginosis, trichomoniasis vaginalis, and candidiasis vaginitis, as well as other newer specific point-of-care testing options, may provide the opportunity to significantly improve the accuracy of diagnosis and treatment for these common ambulatory problems.

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