

# Prevalence of *Trichomonas vaginalis* and Coinfection with *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in the United States as Determined by the Aptima *Trichomonas vaginalis* Nucleic Acid Amplification Assay

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**Our aim was to determine *Trichomonas vaginalis* prevalence using the Aptima *Trichomonas vaginalis* assay (ATV; Gen-Probe) and the prevalence of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* coinfections in U.S. women undergoing screening for *C. trachomatis*/*N. gonorrhoeae*. Discarded urogenital samples from 7,593 women (18 to 89 years old) undergoing *C. trachomatis*/*N. gonorrhoeae* screening using the Aptima Combo 2 assay (Gen-Probe) in various clinical settings were tested with ATV. Overall, *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* prevalences were 8.7%, 6.7%, and 1.7%, respectively. *T. vaginalis* was more prevalent than *C. trachomatis* or *N. gonorrhoeae* in all age groups except the 18- to 19-year-old group. The highest *T. vaginalis* prevalence was in women  $\geq 40$  years old ( $> 11\%$ ), while the highest *C. trachomatis* prevalence (9.2%) and *N. gonorrhoeae* prevalence (2.2%) were in women  $< 30$  years old. Coinfection prevalences were 1.3% for *C. trachomatis*/*T. vaginalis*, 0.61% for *C. trachomatis*/*N. gonorrhoeae* and *N. gonorrhoeae*/*T. vaginalis*, and 0.24% for *C. trachomatis*/*N. gonorrhoeae*/*T. vaginalis* and highest in women  $< 30$  years old. *T. vaginalis* prevalence differed by race/ethnicity, with the highest prevalence in black women (20.2%). *T. vaginalis* prevalence ranged from 5.4% in family planning clinics to 22.3% in jails. Multivariate analysis determined that ages of  $\geq 40$  years, black race, and patient locations were significantly associated with *T. vaginalis* infection. *T. vaginalis* is the most common sexually transmitted infection (STI) in women of  $> 40$  years, while *C. trachomatis* and *N. gonorrhoeae* prevalence is lowest in that age group. Higher *T. vaginalis* prevalence in women of  $> 40$  years is probably attributed to the reason for testing, i.e., symptomatic status versus routine screening in younger women. Coinfections were relatively low. High *T. vaginalis* prevalence in all age groups suggests that women screened for *C. trachomatis*/*N. gonorrhoeae*, whether asymptomatic or symptomatic, should be screened for *T. vaginalis*.**

**T**richomoniasis, caused by the protozoan *Trichomonas vaginalis*, is a common sexually transmitted infection (STI) affecting men and women, with an estimated 7.4 million cases annually in the United States (2, 6, 35). Approximately 50 to 60% of *T. vaginalis* infections in women are asymptomatic (1). Available effective treatment makes *T. vaginalis* one of the most curable STIs (35). Untreated *T. vaginalis* infections may result in long-term sequelae, such as pelvic inflammatory disease, preterm births, or low-birth-weight infants (7, 8). Moreover, *T. vaginalis* infection has been shown to increase the risk of HIV sexual transmission (20, 22, 31). Thus, detection of *T. vaginalis* is key for treatment, reducing transmission, and preventing associated negative health outcomes.

Currently, the gold standard for detection of *T. vaginalis* infection in women is culture of vaginal specimens. However, culture is only moderately sensitive ( $\sim 75\%$ ) compared to nucleic acid amplification tests (NAATs), is costly, and takes 3 to 7 days to provide results, thus making it unsuitable for routine clinical use (18, 25). More-rapid techniques include microscopy ("wet mount") of vaginal fluid, the most commonly used test in the clinic, and antigen detection (OSOM *Trichomonas* rapid test; Genzyme Diagnostics). However, sensitivity is low ( $\sim 50\%$ ) for microscopy and only moderate (82%) for antigen tests (18, 25). These tests also

show poorer sensitivity in asymptomatic populations. Furthermore, by microscopy, it is difficult to differentiate *T. vaginalis* from *Pentatrichomonas hominis*, a nonpathogenic gastrointestinal commensal flagellate that can contaminate samples during collection. Another diagnostic option is the Affirm VP III DNA probe test (Becton, Dickinson, San Jose, CA), which has moderate sensitivity (64 to 80%) compared to wet mount and/or culture (3, 4). PCR has moderately high sensitivity for *T. vaginalis* detection in vaginal fluids (80% to 95%), but there is no U.S. Food and Drug Administration (FDA)-approved PCR test for diagnosis of *T. vaginalis* infection (14, 21, 25, 26, 34). The only FDA-cleared NAAT for *T. vaginalis* is the Aptima *Trichomonas vaginalis* assay (ATV; Gen-Probe Inc., San Diego, CA). Sample types include urine, clinician-collected vaginal swabs (CVS), endocervical

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swabs (ES), and PreservCyt solution (Hologic Incorporated, Bedford, MA) for liquid-based cytology (PCyt). A multicenter study that determined ATV performance for FDA clearance demonstrated that assay sensitivity ranged from 95.2% for urine to 100% for CVS, ES, and PCyt samples (28). ATV was highly specific for *T. vaginalis* ( $\geq 98.9\%$ ) (28). Additional U.S. studies demonstrated that ATV has the highest sensitivity ( $>95\%$ ) in vaginal fluid of the available assays, including PCR, and has similarly high sensitivity in other sample types (urine, ES, and PCyt) (3, 13, 16, 18, 25). Andrea and Chapin demonstrated that the sensitivity of Affirm was only 64% in a comparison with ATV (3).

The 2001 to 2004 National Health and Nutrition Examination Surveys (NHANES) used PCR testing to determine the first national *T. vaginalis* infection prevalence ( $\sim 3.2\%$ ) in American women 14 to 49 years old (1, 29). *T. vaginalis* infection was more prevalent than *Chlamydia trachomatis* (2.2%) and *Neisseria gonorrhoeae* (0.24%) infections combined among women 14 to 39 years old (9). The National Longitudinal Study of Adolescent Health, a prospective cohort study, used PCR testing and determined that the estimated *T. vaginalis* prevalence in young women was 2.8% (23). Using 1,525 home-collected mailed vaginal swabs and ATV, a recent report detected a *T. vaginalis* prevalence of 10% (11). The 7.4 million incident *T. vaginalis* infections per year makes *T. vaginalis* the most prevalent nonviral and treatable STI in the United States (2, 33). Despite high prevalence, *T. vaginalis* infections are currently not required to be reported to the U.S. Centers for Disease Control and Prevention (CDC; Atlanta, GA).

The goal of this study was to determine *T. vaginalis* prevalence by using the highly sensitive ATV assay in a large sample of women aged 18 or older that were undergoing *C. trachomatis*/*N. gonorrhoeae* screening in a wide geographical area and by comparing *T. vaginalis* prevalence to *C. trachomatis* and *N. gonorrhoeae* prevalence in the same samples.

(This work has been presented in part as an oral presentation at the International Society for Sexually Transmitted Disease Research [ISSTD] Meeting, Quebec, Canada, July 2011.)

## MATERIALS AND METHODS

**Overall study design.** Discarded, deidentified clinical specimens, collected July through November 2010 from women for *C. trachomatis*/*N. gonorrhoeae* testing with the Aptima Combo 2 assay (AC2; Gen-Probe Inc., San Diego, CA) on the Tigris DTS instrumentation system (Tigris; Gen-Probe) were used. AC2 is a NAAT that utilizes target capture specimen processing, transcription-mediated amplification (TMA), chemiluminescent probe hybridization, and the automated Tigris system to detect *C. trachomatis* and *N. gonorrhoeae* ribosomal RNAs (rRNAs) in urogenital samples. Samples from each participating laboratory were tested with the research-use-only ATV kit on the Tigris system. Each laboratory reported AC2 and ATV results and available deidentified demographic data to a centralized database. Prevalence for *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* and coinfection rates were determined.

**Study population and sites.** The study population included women 18 to 89 years old from 21 states who were with or without symptoms of STIs. Due to the use of discarded, deidentified samples, information on symptoms, sexual history, or STI history was not available. Therefore, based on current CDC *C. trachomatis*/*N. gonorrhoeae* screening recommendations (5, 35), samples collected from younger patients ( $<26$  years) were probably more heavily weighted for routine screening (asymptomatic) than samples collected from older women which were probably more associated with clinical symptoms. Collection sites included patients treated in a hospital setting (emergency departments [ED] or hospitalized), obstetric/gynecologic (OB/GYN) practices, family planning clinics,

family practices, sexually transmitted disease (STD) clinics, or other clinics performing tests for STIs. Eighteen laboratories throughout the United States using AC2 participated. Ethical approval was obtained at each site in accordance with institutional review board policies to release deidentified results and demographic information to Gen-Probe.

**Clinical specimens.** A total of 7,593 specimens, including self- or physician-collected vaginal swabs (CVS;  $n = 791$ ), ES ( $n = 3,912$ ), urine ( $n = 1,945$ ), and ES specimens collected in PCyt (PCyt;  $n = 940$ ), were obtained and tested for *C. trachomatis*/*N. gonorrhoeae* and *T. vaginalis*. Only one specimen per patient, independent of specimen type, was tested. All specimens were placed into the appropriate Aptima transport tubes before being shipped to the testing sites. CVS and ES specimens were added directly into transport buffer tubes upon collection. Urine samples were aliquoted at the collection site into Aptima urine specimen transport tubes, and for PCyt samples, a 1-ml portion was transferred into a specimen transfer kit. Each site collected a minimum of 350 patient specimens. Specimens were stored at 2 to 30°C and tested with ATV within 30 days of collection or up to 60 days after collection if using ES or CVS. This is the current time frame for testing *C. trachomatis*/*N. gonorrhoeae* from these sample types for the Aptima Combo 2 assay. In-house data (Gen-Probe, Inc.) have shown no loss of or decrease in ability to detect the *T. vaginalis* target for the sample types listed under the conditions described for collection and storage that are currently published in the package insert for the Aptima *T. vaginalis* product.

**ATV assay and sample testing.** ATV is a NAAT that utilizes the same technology and instrumentation as AC2 to detect *T. vaginalis* rRNA in urogenital samples. Consecutive female samples meeting study entry criteria were tested in accordance with ATV instructions on the Tigris instrument.

**Data collection and statistical analysis.** ATV results were transmitted electronically to a central database. Associated *C. trachomatis*/*N. gonorrhoeae* results and deidentified demographic data (age, sex, race, clinic type, and location [identified by the first 3 digits of the zip code]) were entered into an electronic report form and sent for statistical analysis performed primarily with PC SAS version 9.2 or higher (Cary, NC). For categorical variables, summary statistics included the number of subjects and percentage for each category. For continuous variables, summary statistics included the number of observations and the mean, standard deviation, median, minimum, and maximum values. Age-adjusted odds ratios (ORs) were calculated via a multivariable logistic regression model controlling for age in categories ( $<20$ , 20 to 29, 30 to 39, and  $\geq 40$  years), whereas multivariable ORs further controlled for collection site, race, and geographical regions determined as Northeast (Delaware, Maryland, Rhode Island, Connecticut, New Jersey, New York, Pennsylvania), Southeast (Louisiana, Florida, Georgia, Kansas, Kentucky, Tennessee, Virginia), Southwest (California, Texas, New Mexico, Arizona, Colorado, Nevada, Utah), and Midwest (Indiana, Michigan, Minnesota, Ohio, Illinois, Missouri, Wisconsin). No patient specimens were collected from the Northwest region.

## RESULTS

**Overall prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections.** Overall prevalences of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections were 8.7%, 6.7%, and 1.7%, respectively (Table 1). Rates of coinfection were low ( $\leq 1.3\%$ ): 1.3% of subjects were coinfecting with *T. vaginalis* and *C. trachomatis*, 0.61% were coinfecting with *T. vaginalis* and *N. gonorrhoeae*, 0.61% were coinfecting with *C. trachomatis* and *N. gonorrhoeae*, and 0.24% of subjects had a triple coinfection (*T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae*).

**Prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections by age.** Of the three STIs surveyed, *T. vaginalis* was the most prevalent in all age groups except the 18- to 19-year-old group, for which *C. trachomatis* was the most prevalent (*C.*

TABLE 1 Prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections by age, race, and collection site

Characteristic or prevalence category <sup>a</sup>	<i>n</i>	Prevalence (%) <sup>b</sup>						
		<i>T. vaginalis</i>	<i>C. trachomatis</i>	<i>N. gonorrhoeae</i>	<i>C. trachomatis</i> / <i>N. gonorrhoeae</i> / <i>T. vaginalis</i>	<i>C. trachomatis</i> / <i>T. vaginalis</i>	<i>C. trachomatis</i> / <i>N. gonorrhoeae</i>	<i>N. gonorrhoeae</i> / <i>T. vaginalis</i>
Overall prevalence (no. infected/total no. of samples)	7,593	8.7 (663/7,593)	6.7 (508/7,588)	1.7 (129/7,579)	0.24 (18/7,577)	1.3 (97/7,588)	0.61 (46/7,577)	0.61 (46/7,579)
Mean age (yr) (SD)		29.82 (10.62)	23.4 (6.0)	24.0 (6.9)	22.00 (2.35)	23.41 (5.49)	21.89 (3.78)	23.15 (5.53)
Median age (yr) (minimum-maximum)		26.0 (18–82)	22.0 (18–65)	22.0 (18–53)	21.5 (18–26)	22 (18–46)	21 (18–37)	21.5 (18–50)
Age								
≥18 and <20	907	8.5	14.4	3.3	0.2	2.1	1.3	0.9
≥20 and <30	3,975	8.3	8.0	2.0	0.4	1.7	0.8	0.9
≥30 and <40	1,667	7.9	2.5	0.8	0.0	0.4	0.1	0.2
≥40	1,044	11.8	1.7	0.5	0.0	0.3	0.0	0.1
Race								
White	1,668	5.7	5.7	1.6	0.1	0.6	0.4	0.5
Black	1,385	20.2	12.1	4.0	0.7	3.6	1.7	1.7
Hispanic/Latino	718	5.0	5.9	0.7	0.0	0.6	0.0	0.1
All others/unknown <sup>c</sup>	3,822	6.6	5.3	1.1	0.2	0.9	0.5	0.3
Collection site								
Family planning	784	5.4	10.4	1.5	0.0	1.4	0.5	0.1
Hospital <sup>d</sup>	493	16.6	7.3	2.2	1.0	3.0	1.0	1.6
Family practice, internal medicine	817	6.1	7.8	1.2	0.0	0.4	0.4	0.0
OB/GYN	2,059	7.3	4.4	0.8	0.2	0.9	0.3	0.3
Jail, STD clinic	1,304	16.4	10.5	3.5	0.5	2.5	1.3	1.5
Other/unknown	2,136	5.9	4.6	1.6	0.2	0.8	0.5	0.6

<sup>a</sup> SD, standard deviation.

<sup>b</sup> In the calculations of prevalence, the denominator may be less than the number shown for *n* due to missing or invalid assay data. Values are the prevalence unless otherwise indicated in the stub entry for that row (i.e., mean and median age). Values given in parentheses are identified by the information in parentheses in the stub entry for that row.

<sup>c</sup> "Other" races include American Indian, Native Alaskan, Asian, and Native Hawaiian/Pacific Islander.

<sup>d</sup> Consists of patients seen in an emergency department and/or hospitalized.

*trachomatis*, 14.4%; *T. vaginalis*, 8.5%; *N. gonorrhoeae*, 3.3%) (Table 1 and Fig. 1). *T. vaginalis* prevalence was lowest in women <40 years old (range, 7.9% to 8.5%) and highest in women ≥40 years old (11.3% in women 40 to 49 years old, 13.0% in women ≥50 years old). In contrast, *C. trachomatis* and *N. gonorrhoeae* prevalence was lowest in women ≥40 years old (<2%) and highest in women <30 years old (ranges, 8.0% to 14.4% for *C. trachomatis* and 2.0% to 3.3% for *N. gonorrhoeae*). Double and triple coinfections were more common in women <30 years old than in women ≥30 years old (Table 1). Univariate and multivariate analyses (Table 2) revealed a significant association between *T. vaginalis* infections and women aged ≥40 years.

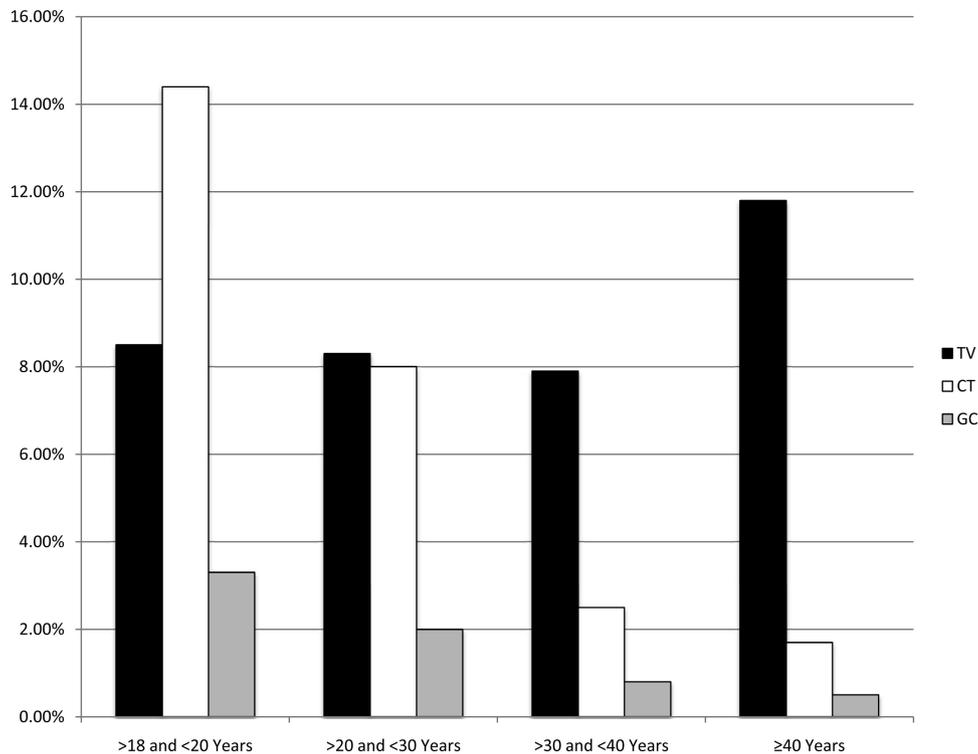
**Prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections by race.** STI prevalence varied greatly by race/ethnicity. For racial groups with >100 subjects, *T. vaginalis* prevalence was highest for blacks (20.2%), followed by whites (5.7%) and Hispanics/Latinos (5.0%) (Table 1 and Fig. 2). *C. trachomatis* prevalence was highest for blacks (12.1%), followed by Hispanics/Latinos (5.9%) and whites (5.7%) (Table 1). *N. gonorrhoeae* prevalence was highest for blacks (4.0%), followed by whites (1.6%) and Hispanics/Latinos (0.7%) (Table 1). Blacks had relatively higher rates of coinfection (*T. vaginalis* and *C. trachomatis*, 3.6%; *C. trachomatis* and *N. gonorrhoeae*, 1.7%; *T. vaginalis* and *N. gonorrhoeae*, 1.7%) than other ethnicities (<1%). Included in the unknown/other category were subsets of ethnic groups, including American Indians/Alaskan Natives (10.5%) and Native Hawaiians/Pacific Islanders (7.1%), with high *T. vaginalis* prevalence. *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* prevalence rates in the subset of Asian women were 3.8%, 9.9%, and 2.3%, respec-

tively. Univariate and multivariate analyses (Table 2) revealed a significant association between *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections and black women.

**Prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections by testing site and geographical location.** *T. vaginalis* prevalence varied greatly by sample collection site (Table 1 and Fig. 3) and geographical location (Fig. 4). *T. vaginalis* prevalence was highest among hospital-associated patients (16.6%) and jail inmates/STD clinic patients (16.4%), followed by OB/GYN practices (7.3%) and family practice/internal medicine practices (6.1%), and lowest in family planning centers (5.4%). *C. trachomatis* prevalence was highest among jail inmates/STD clinic patients (10.5%) and family planning centers (10.4%), followed by family practice/internal medicine practices (7.8%) and ED (7.3%), and lowest in OB/GYN practices (4.4%). *N. gonorrhoeae* prevalence was highest in jail inmates/STD clinic patients (3.5%), followed by hospital-associated patients (2.2%), family planning centers (1.5%), and family practice/internal medicine practices (1.2%), and lowest in OB/GYN practices (0.78%).

The subset of jail inmates had the overall highest rate of *T. vaginalis* (22.3%) and *C. trachomatis* (10.9%) infections, and the subset of inpatients had the highest overall rates of *N. gonorrhoeae* infections (4.0%). Univariate and multivariate analyses (Table 2) determined that *T. vaginalis* and *N. gonorrhoeae* infections were significantly associated with jail inmates/STD clinic attendees, while only *T. vaginalis* infections were significantly associated with women treated in hospital settings.

The highest U.S. rates for *T. vaginalis*, *C. trachomatis*, and *N.*



**FIG 1** Prevalence rates by age. TV, *Trichomonas vaginalis*; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*. Prevalence rates for women of younger ages (<30 years) are biased toward an asymptomatic population per CDC screening guidelines. Higher prevalence rates in older women are biased toward a symptomatic population.

*gonorrhoeae* were found in the Southeast (14.4%, 7.9%, and 2.5%, respectively), followed by the Southwest (9.5%, 7.8%, and 1.7%, respectively) and the Midwest (9.5%, 6.6%, and 2.2%, respectively). The Northeast had the lowest rates for all three STDs (*T. vaginalis*, 4.3%; *C. trachomatis*, 4.8%; *N. gonorrhoeae*, 0.9%). Univariate and multivariate analyses (Table 2) determined that the Southwest, Southeast, and Midwest were significantly associated with increased odds of *T. vaginalis* infections. The Southwest and Southeast were significantly associated with increased odds for *C. trachomatis* infections, and the Southeast and Midwest were significantly associated with increased odds for *N. gonorrhoeae* infections. By univariate analysis only, *C. trachomatis* infections were determined to be significantly associated with the Midwest and *N. gonorrhoeae* infections were determined to be significantly associated with the Southwest.

**Prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections by specimen type.** The prevalence of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections by specimen type is presented in Table 3. Since only one sample type per patient was tested in this study, a direct comparison of detection rates by sample type was not possible. However, the overall prevalence rates for *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis*, and coinfections were equivalent for CVS and urine. The prevalence rates for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* were slightly lower for endocervical swabs than for CVS and urine, but the rates for all samples were equivalent for coinfections. PCyt specimens had the lowest detection rates for *C. trachomatis*, *N. gonorrhoeae*, *T. vaginalis*, and coinfections.

## DISCUSSION

Prevalence of *T. vaginalis* is not well characterized primarily because *T. vaginalis* infections are not reportable to public health officials and are generally not part of routine screening. In addition, published studies that measured *T. vaginalis* prevalence generally used relatively insensitive methods. This study is the first to use the highly sensitive (>95%) ATV to determine *T. vaginalis* prevalence in a large number of U.S. women of all ages undergoing screening or diagnostic testing for *C. trachomatis*/*N. gonorrhoeae* infections. The use of remnant samples allowed the comparison of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* prevalences in various patient populations, clinical settings, and different geographical regions (21 states). Consecutive enrollment of all samples meeting inclusion criteria prevented sample selection bias.

Our study had several limitations that need to be considered when interpreting the data. The population is not nationally representative of the U.S. population in general, and no Pacific Northwest sites participated. Patient selection was biased (women were screened for *C. trachomatis*/*N. gonorrhoeae*), and the reasons for *C. trachomatis*/*N. gonorrhoeae* testing varied among age groups. Younger age groups (18 to <30 years old) were tested as part of routine screening (asymptomatic) or due to symptomatic complaints and therefore constituted a significant portion of the samples enrolled (4,882, versus 2,711 samples from women >30 years old). In contrast, women ≥50 years old were most likely symptomatic, as routine *C. trachomatis*/*N. gonorrhoeae* screening is not done in this age group. This study did not include sexually active women <18 years old. Studies by Goyal et al. determined

TABLE 2 Univariate and multivariate analyses of risk factors associated with *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* infections

Risk factor	Indicated values for each infection <sup>a</sup>								
	<i>T. vaginalis</i>			<i>C. trachomatis</i>			<i>N. gonorrhoeae</i>		
	Prevalence (%)	OR (95% CI)	Multivariate analysis OR estimate (95% CI)	Prevalence (%)	OR (95% CI) <sup>b</sup>	Multivariate analysis OR estimate (95% CI) <sup>b</sup>	Prevalence (%)	OR (95% CI) <sup>c</sup>	Multivariate analysis OR estimate (95% CI) <sup>c</sup>
Age (yr)									
≥18 and <20	8.49	1	1	14.35	1	1	3.31	1	1
≥20 and <30	8.33	0.98 (0.76–1.27)	1.03 (0.79–1.36)	8.03	0.52 (0.42–0.65)	0.53 (0.42–0.66)	2.04	0.61 (0.40–0.93)	0.66 (0.43–1.02)
≥30 and <40	7.92	0.93 (0.69–1.24)	1.03 (0.76–1.40)	2.52	0.15 (0.11–0.22)	0.17 (0.11–0.24)	0.78	0.23 (0.12–0.44)	0.27 (0.14–0.52)
≥40	11.78	1.44 (1.07–1.94)	1.51 (1.10–2.07)	1.63	0.10 (0.06–0.17)	0.09 (0.06–0.16)	0.48	0.14 (0.05–0.37)	0.14 (0.06–0.37)
Race									
White	5.70	1	1	5.70	1	1	1.56	1	1
Black	20.22	4.15 (3.25–5.31)	4.04 (3.12–5.22)	12.08	2.34 (1.80–3.06)	2.63 (1.99–3.49)	3.98	2.67 (1.66–4.29)	2.66 (1.61–4.41)
Hispanic/Latino	5.01	0.86 (0.58–1.27)	0.88 (0.58–1.32)	5.85	1.18 (0.80–1.72)	1.29 (0.87–1.94)	0.70	0.49 (0.19–1.29)	0.60 (0.22–1.64)
All others/unknown	6.59	1.15 (0.90–1.46)	0.92 (0.69–1.23)	5.34	1.07 (0.83–1.38)	1.54 (1.15–2.06)	1.13	0.80 (0.49–1.31)	0.71 (0.40–1.27)
Clinic type									
Family planning	5.36	1	1	10.36	1	1	1.54	1	1
Hospital	16.63	3.53 (2.38–5.21)	3.50 (2.30–5.32)	7.30	0.68 (0.45–1.03)	0.65 (0.42–1.00)	2.24	1.47 (0.64–3.35)	2.00 (0.83–4.82)
Family practice, internal medicine	6.12	1.15 (0.76–1.76)	1.27 (0.80–2.01)	7.83	0.74 (0.52–1.04)	0.87 (0.60–1.28)	1.23	0.80 (0.34–1.87)	1.62 (0.65–4.02)
OB/GYN	7.29	1.39 (0.98–1.98)	1.33 (0.90–1.98)	4.42	0.40 (0.29–0.55)	0.40 (0.28–0.57)	0.78	0.50 (0.24–1.07)	0.73 (0.32–1.70)
Jail, STD clinic	16.41	3.47 (2.46–4.89)	2.59 (1.77–3.80)	10.52	1.02 (0.76–1.36)	0.91 (0.65–1.26)	3.45	2.29 (1.21–4.36)	2.73 (1.32–5.65)
Other/unknown	5.85	1.10 (0.77–1.57)	1.67 (1.12–2.49)	4.64	0.42 (0.31–0.57)	0.47 (0.33–0.66)	1.64	1.07 (0.55–2.07)	2.36 (1.12–4.95)
Region									
Northeast	4.30	1	1	4.78	1	1	0.92	1	1
Southwest	9.51	2.35 (1.83–3.01)	1.88 (1.40–2.50)	7.76	1.82 (1.42–2.34)	1.51 (1.13–2.03)	1.68	1.94 (1.13–3.34)	1.64 (0.88–3.06)
Southeast	14.44	3.78 (2.87–4.98)	6.32 (4.62–8.63)	7.88	1.83 (1.34–2.50)	2.26 (1.60–3.19)	2.49	2.90 (1.59–5.31)	6.77 (3.45–13.29)
Midwest	9.48	2.35 (1.80–3.05)	2.00 (1.50–2.65)	6.64	1.39 (1.06–1.83)	1.16 (0.86–1.56)	2.20	2.38 (1.37–4.13)	2.33 (1.29–4.22)

<sup>a</sup> Multivariate analysis odds ratio (OR) estimates were adjusted for age, race, clinic type, and region. CI, confidence interval.

<sup>b</sup> Five observations were deleted due to missing values for the response or explanatory variables.

<sup>c</sup> Fourteen observations were deleted due to missing values for the response or explanatory variables.

the *T. vaginalis* prevalence to be 9.9% in women 14 to 19 years old who presented to the ED with complaints suggestive of an STI (12). Another study by Huppert et al. found that the *T. vaginalis* prevalence was 18.5% in women 14 to 21 years old (18). Due to the use of deidentified, discarded clinical samples, patient clinical status (asymptomatic or symptomatic), history of sexual partners, and history of STIs could not be obtained, thereby limiting the interpretation of the data. Therefore, the age of the patient contributes to the bias in STI prevalence noted in this study, and

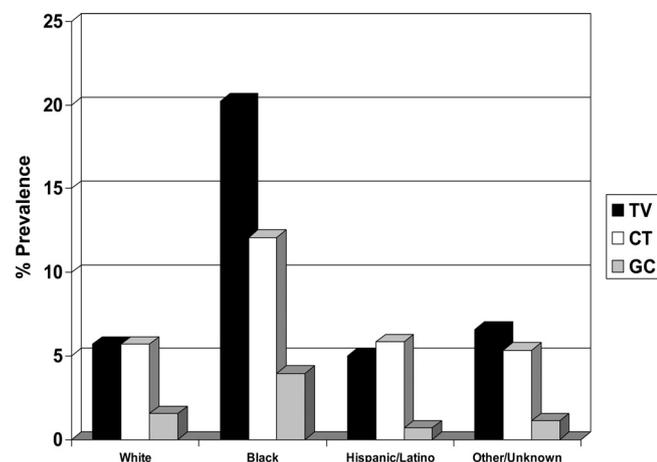


FIG 2 Prevalence rates by racial/ethnic group. TV, *Trichomonas vaginalis*; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*. The other/unknown group includes American Indians, Alaskan Natives, Native Hawaiians/Pacific Islanders, and Asians.

overall *T. vaginalis* rates may be underestimated by exclusion of certain populations. Finally, this study was not intended to compare the performances of the assays in the various specimen types, as multiple specimen types from each patient were not tested. However, overall, the detection rates for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* were highly comparable in CVS and urine specimens and only slightly lower for ES. These specimen types accounted for 86.7% of the types tested, and comparable *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* detection rates suggest that no major disparities in assay performance by specimen type biased the overall results. As expected, the lowest detection rates for *C. trachomatis*, *N. gonorrhoeae*, and *T. vaginalis* were for PCyt specimens, as PCyt is used primarily for cervical cancer screening and STI testing is generally performed as adjunctive routine screening.

Despite these limitations, the following observations are of clinical significance. Strengths of the study included a substantial sample size, the availability of *C. trachomatis*/*N. gonorrhoeae* infection status, and the use of highly sensitive NAATs for *T. vaginalis* and *C. trachomatis*/*N. gonorrhoeae* testing from the same sample.

*T. vaginalis* prevalence was 8.7% in the overall study population. This value is higher than the 3.2% value reported in the 2001 to 2004 NHANES, the most recent study reporting *T. vaginalis* prevalence in the general U.S. female population (1). The difference in prevalence between this study and NHANES may be attributed to various factors. First, it may be due to an increase in *T. vaginalis* prevalence in the last 6 to 9 years (NHANES utilized data from 2001 to 2004). Second, the higher sensitivity of ATV compared to that of the PCR used in NHANES allows the detection of

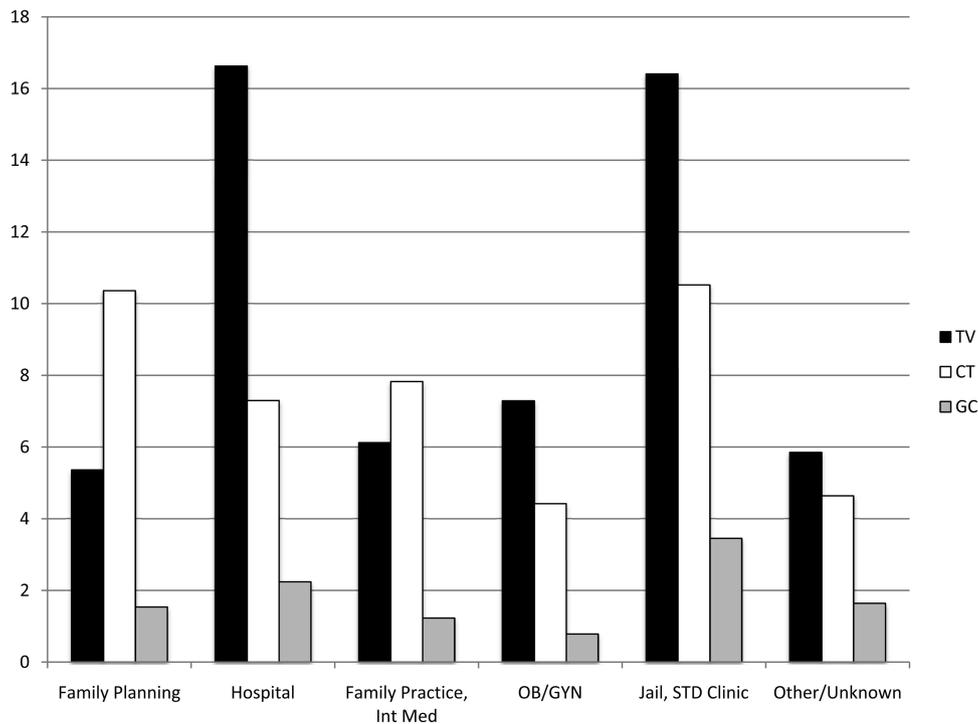


FIG 3 Prevalence rates by testing site. TV, *Trichomonas vaginalis*; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*; Int Med, internal medicine; STD, sexually transmitted disease.

a higher number of cases and therefore may have yielded a higher prevalence. Third, and most important, the populations analyzed in NHANES and the present study differed. The NHANES population consisted of noninstitutionalized civilians selected at random that represent the entire U.S. population because the data set was weighted based on U.S. Census data and was generally a low-risk population. In contrast, our study population was inherently at higher risk for STIs since the subjects were undergoing testing for *C. trachomatis*/*N. gonorrhoeae*. It is unknown what percentage of the patients were asymptomatic for *C. trachomatis*/*N. gonorrhoeae* and being screened according to current guidelines (5, 35) or were symptomatic for *C. trachomatis*/*N. gonorrhoeae* and being tested for diagnosis of *C. trachomatis*/*N. gonorrhoeae*. Regardless of the symptomatic status, this population can be considered po-

tentially high risk for STIs since the CDC and other guidelines recommend annual *C. trachomatis*/*N. gonorrhoeae* screening of sexually active women under 26 years or older women with risk factors, such as new sexual partners. In addition, our population was 18.2% black (which is larger than the national average of 12.8%) (30), a population known to have high *T. vaginalis* prevalence (13% to 14%) (1, 29).

Like NHANES, we found that *T. vaginalis* prevalence was higher than that for *C. trachomatis* and *N. gonorrhoeae* combined, even though *C. trachomatis* and *N. gonorrhoeae* prevalence in our population was higher than that reported in NHANES (2.2% for *C. trachomatis* and 0.24% for *N. gonorrhoeae*) (9). A recent prevalence study, in which home-collected mailed vaginal swabs were tested by ATV, reported a 10% prevalence of *T. vaginalis* in women (11). Unlike our study, that report did not find that age was significantly associated with *T. vaginalis* positivity. Like the present study, however, black race was highly associated with *T. vaginalis* infection (adjusted OR, 2.69; prevalence, 13.2%).

An analysis of *T. vaginalis* prevalence by age group revealed that *T. vaginalis* infection affects women of all ages and that *T. vaginalis* prevalence is highest in women >40 years old and lowest in women <40 years old. These findings are in agreement with NHANES (1, 29) and other studies (3, 10, 23, 27). This age distribution contrasts with that of *C. trachomatis* and *N. gonorrhoeae*, whose prevalence was highest in women <30 years old and lowest in women ≥40 years old (9). *T. vaginalis* prevalence remained higher than that of *C. trachomatis* and *N. gonorrhoeae* for all age groups except the youngest women (18 to 19 years), for whom *C. trachomatis* prevalence was highest. This trend agrees with a previous study that reported *C. trachomatis*, *T. vaginalis*, and *N. gonorrhoeae* prevalence rates of 10.1%, 6.0%, and 4.1%, respectively,

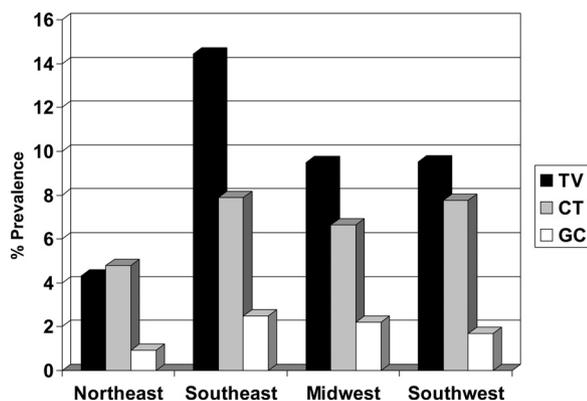


FIG 4 Prevalence rates by geographical region. TV, *Trichomonas vaginalis*; CT, *Chlamydia trachomatis*; GC, *Neisseria gonorrhoeae*.

TABLE 3 Overall prevalence of *T. vaginalis*, *C. trachomatis*, *N. gonorrhoeae*, and mixed infections by specimen type<sup>a</sup>

Specimen type	Prevalence (no. positive/no. tested [%]) of each infection						
	<i>C. trachomatis</i>	<i>N. gonorrhoeae</i>	<i>T. vaginalis</i>	<i>C. trachomatis/N. gonorrhoeae/T. vaginalis</i>	<i>C. trachomatis/T. vaginalis</i>	<i>C. trachomatis/N. gonorrhoeae</i>	<i>N. gonorrhoeae/T. vaginalis</i>
Endocervical swab	240/3,912 (6.13)	57/3,911 (1.46)	326/3,912 (8.33)	11/3,911 (0.28)	50/3,912 (1.28)	23/3,911 (0.59)	20/3,911 (0.51)
Liquid Pap transport	23/940 (2.45)	3/940 (0.32)	32/940 (3.40)	1/940 (0.11)	3/940 (0.32)	1/940 (0.11)	1/940 (0.11)
Urine	169/1,945 (8.69)	51/1,942 (2.63)	216/1,950 (11.08)	4/1,940 (0.21)	31/1,945 (1.59)	16/1,940 (0.82)	16/1,942 (0.82)
Vaginal swab	76/791 (9.61)	18/786 (2.29)	89/791 (11.25)	2/786 (0.25)	13/791 (1.64)	6/786 (0.76)	9/786 (1.15)

<sup>a</sup> Specimen type results are not directly comparable, as only one specimen type per patient was tested.

in women 14 to 17 years old (32) and with results from another study that showed prevalence rates of 11%, 6.3%, and 0%, respectively, in women 13 to 21 years old (16). Rates of *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* coinfection were low (<1.3%) in the whole population. Other studies reported coinfection rates in high-risk populations or reported *C. trachomatis* and *N. gonorrhoeae* prevalence in *T. vaginalis*-positive women (1, 24). *T. vaginalis/C. trachomatis* and *T. vaginalis/N. gonorrhoeae* coinfections were more common in women <30 years old, probably because *C. trachomatis* and *N. gonorrhoeae* infections are more prevalent in this age group.

An analysis of STI prevalence by ethnicity showed large disparities. *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* prevalences were highest in black populations, a trend documented in the U.S. population for *T. vaginalis* as well as for *C. trachomatis* and *N. gonorrhoeae* (1, 9, 11, 15, 17, 29). NHANES found the highest *T. vaginalis* rates in non-Hispanic black women (13.3%), and within this group, *T. vaginalis* rates increased from 8.3% (14 to 19 years) to almost 20% (40 to 49 years) (1). A significant association between black race and *T. vaginalis* prevalence was reported for high-risk adolescent females (16). Although other ethnic groups (American Indians/Alaskan Natives and Native Hawaiians/Pacific Islanders) had high *T. vaginalis* prevalence rates, due to low subject numbers, we cannot conclude that this prevalence is truly representative in these ethnic groups.

We found that *T. vaginalis* prevalence and, in some cases, *C. trachomatis* and *N. gonorrhoeae* prevalence were highest in women attending STD clinics, testing in a hospital setting, and incarcerated in jails. High *T. vaginalis* prevalence (32%) has been observed among women incarcerated in San Francisco county jail (10). Similar findings relating to *C. trachomatis* and *N. gonorrhoeae* infections were reported for black adolescents 18 to 19 years old who were incarcerated in adult correction facilities (19). Although women attending STD clinics are expected to have high *T. vaginalis*, *C. trachomatis*, and *N. gonorrhoeae* rates due to high-risk behavior and/or symptomatic status, providers should be aware of the high *T. vaginalis* rates in the hospital setting. Patients who are presenting with symptomatic vaginal complaints and using the ED as the primary source of health care may contribute to this high rate and will require further investigation. Interestingly, corresponding *C. trachomatis* and *N. gonorrhoeae* rates were not particularly high in this setting. This lower prevalence in OB/GYN, family practice/internal medicine, and family planning clinics might be expected since many of these women were probably being routinely screened according to *C. trachomatis/N. gonorrhoeae* testing guidelines and were <26 years old and/or pregnant. Interestingly, women in family planning and family practice groups had higher rates of *C. trachomatis* than *T. vaginalis*.

In summary, the availability of the FDA-cleared ATV, which can be run on the same fully automated system and with the same samples as AC2, provides a unique opportunity to screen women at risk for *Trichomonas vaginalis*, *Chlamydia trachomatis*, and *Neisseria gonorrhoeae* infections. High *T. vaginalis* prevalence in all age groups suggests that all women that are considered at high risk for STIs (multiple or new partners, non-barrier contraception, etc.), including women >40 years old, should be screened for *T. vaginalis* even if they are not being tested for *C. trachomatis/N. gonorrhoeae*. *T. vaginalis* screening can be performed when these women appear for routine adjunct human papillomavirus (HPV)/cytology screening since all testing can be done using the same PCyt sample or a separate swab sample. The high prevalence of *T. vaginalis* infection, particularly in asymptomatic women, emphasizes the need for *T. vaginalis* to be made a reportable disease by the CDC. Further studies using ATV are needed to estimate the true prevalence of *T. vaginalis* in adolescent females younger than 18 years of age.

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