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# Update on Guidelines and Technology in the Diagnosis and Treatment of *Trichomonas vaginalis*

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## Introduction

The Centers for Disease Control and Prevention (CDC) published an update to the Sexually Transmitted Diseases Treatment Guidelines in June 2015. The update included specific changes related to the diagnosis and treatment of *Trichomonas vaginalis* infection.<sup>1,2</sup>

*T vaginalis* is a commonly occurring sexually transmitted infection, with an estimated 3.7 million infections among people in the United States.<sup>3</sup> Previous studies have shown this sexually transmitted infection is associated with premature membrane rupture, preterm labor, low birth weight, increased risk for pelvic inflammatory disease, and an increased risk for human immunodeficiency virus (HIV) transmission and acquisition in both men and women.<sup>4-12</sup> In fact, an estimated 700 new cases of HIV infections among US women could be attributed to infection with *T vaginalis* each year.<sup>6</sup> In light of this high prevalence, it is difficult to reconcile why trichomoniasis remains an often misunderstood sexually transmitted disease.

In this supplement, three articles address key aspects of the CDC update on trichomoniasis: "The End of the Wet Mount," by Sharon L. Hillier, PhD, and Claire Danby, MD, MSc; "Trichomoniasis and the 2015 CDC STD Treatment Guidelines: New Insights, New Urgency," by Paul Nyirjesy, MD; and "*Trichomonas vaginalis*: Ensuring Reimbursement in Clinical Practice," by Maria Trent, MD, MPH.

## References

1. Centers for Disease Control and Prevention. 2015 sexually transmitted diseases treatment guidelines. Available at: <http://www.cdc.gov/std/tg2015/>. Accessed January 12, 2016.
2. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases guidelines, 2015. *MMWR Recomm Rep*. 2015;64(RR-03):1-137.
3. Satterwhite CL, Torrone E, Meites E, et al. Sexually transmitted infections among US women and men: prevalence and incidence estimates, 2008. *Sex Transm Dis*. 2013;40(3):187-193.
4. Cotch MF, Pastorek JG 2nd, Nugent RP, et al. *Trichomonas vaginalis* associated with low birth weight and preterm delivery. The Vaginal Infections and Prematurity Study Group. *Sex Transm Dis*. 1997;24(6):353-360.
5. McClelland RS, Sangaré L, Hassan WM, et al. Infection with *Trichomonas vaginalis* increases the risk of HIV-1 acquisition. *J Infect Dis*. 2007;195(5):698-702.
6. Chesson HW, Blandford JM, Pinkerton SD. Estimates of the annual number and cost of new HIV infections among women attributable to trichomoniasis in the United States. *Sex Transm Dis*. 2004;31(9):547-551.
7. Minkoff H, Grunebaum AN, Schwarz RH, et al. Risk factors for prematurity and premature rupture of membranes: a prospective study of the vaginal flora in pregnancy. *Am J Obstet Gynecol*. 1984;150(8):965-972.
8. Pastorek JG 2nd, Cotch MF, Martin DH, Eschenbach DA. Clinical and microbiological correlates of vaginal trichomoniasis during pregnancy. The Vaginal Infections and Prematurity Study Group. *Clin Infect Dis*. 1996;23(5):1075-1080.
9. Van Der Pol B, Kwok C, Pierre-Louis B, et al. *Trichomonas vaginalis* infection and human immunodeficiency virus acquisition in African women. *J Infect Dis*. 2008;197(4):548-554.
10. Hughes JP, Baeten JM, Lingappa JR, et al; Partners in Prevention HSV/HIV Transmission Study Team. Determinants of per-coital-act HIV-1 infectivity among African HIV-1-serodiscordant couples. *J Infect Dis*. 2012;205(3):358-365.
11. Kissinger P, Adamski A. Trichomoniasis and HIV interactions: a review. *Sex Transm Infect*. 2013;89(6):426-433.
12. Moodley P, Wilkinson D, Connolly C, Moodley J, Sturm AW. *Trichomonas vaginalis* is associated with pelvic inflammatory disease in women infected with human immunodeficiency virus. *Clin Infect Dis*. 2002;34(4):519-522.

# The End of the Wet Mount

**Sharon L. Hillier, PhD**

Professor  
Departments of Obstetrics, Gynecology and  
Reproductive Sciences and Microbiology  
and Molecular Genetics  
University of Pittsburgh School of Medicine  
Pittsburgh, Pennsylvania

**Claire Danby, MD, MSc**

Assistant Professor  
Tufts University School of Medicine  
Boston, Massachusetts  
Department of Obstetrics and Gynecology  
Maine Medical Center  
Portland, Maine

## Introduction

Why has there not been greater success in the control of *Trichomonas vaginalis*? Other sexually transmitted pathogens, such as *Neisseria gonorrhoeae* and *Chlamydia trachomatis*, have been controlled through a combination of targeted screening programs using highly sensitive and specific tests, effective treatments, and partner notification and treatment. However, for *T vaginalis*, we have relied on insensitive tests to evaluate women with symptoms and have largely failed to routinely screen women for this sexually transmitted pathogen in populations at highest risk.<sup>1</sup>

This has led to failure to (1) identify the majority of people with infections and (2) treat sexual partners, which in turn has led to persistent infection and continued spread of this pathogen.

## Diagnostic tests for trichomoniasis

**Wet mount.** Globally, the most commonly used diagnostic test for *T vaginalis* is the “wet mount,” which is usually performed only for women presenting with vaginal symptoms. Performing a wet mount involves directly identifying *T vaginalis* under the microscope. A primary advantage is that it can be performed as a point-of-care test quickly and at low cost. However, the most important drawback of this method is that it detects motile pathogens only when present in the vaginal fluid at high density. Therefore, not only is this method very insensitive, detecting only 50% to 65% of infections,<sup>2</sup> but it also requires immediate evaluation. There may be delays in performance of microscopic evaluation of wet mounts in clinical practice due the lack of availability of a microscope or other competing clinician responsibilities.

One study evaluated the duration of trichomonad motility in wet mount preparations and reported that 35% of 65 specimens positive for motile trichomonads had no motile forms identified in as little as 30 minutes after a sample was placed on a slide under a cover slip.<sup>3</sup> Although the wet mount has been an important tool for diagnosing trichomoniasis in women for the past century, the availability of more sensitive testing methods and the high

prevalence of asymptomatic infections suggest that we need to reevaluate our reliance on the wet mount.

**Alternative point-of-care tests.** Food and Drug Administration (FDA)-cleared point-of-care tests are available in some settings and can improve detection compared with the wet mount. The OSOM *Trichomonas* Rapid Test (Sekisui Diagnostics; Framingham, MA) relies on a dipstick technology and can be performed in clinical settings (it is a Clinical Laboratory Improvement Amendments [CLIA]-waived test). This test is 82% to 95% sensitive, and results are available in approximately 10 minutes.<sup>2</sup> The sensitivity of this test in asymptomatic women may be lower.

Another moderately rapid test is the Affirm VPIII Microbial Identification Test (Becton Dickinson; Sparks, MD), which relies on direct DNA hybridization. This test does not “amplify” the DNA present so it is not as sensitive as the newest types of diagnostic tests cleared by the FDA (see nucleic acid amplification tests [NAATs], below). The Affirm test requires a moderate complexity CLIA license and takes approximately 45 minutes.

**Culture.** For many years, broth culture was considered the “gold standard” for detection of *T vaginalis*. Many of the studies linking *T vaginalis* to complications in pregnancy were performed using these culture techniques.<sup>4,5</sup> Use of this method requires that vaginal swab samples be transported immediately to the laboratory, and the swab is used to inoculate liquid media, which is then evaluated microscopically over a period of five days to detect motile forms. Since NAATs for this pathogen have become available, most research laboratories have discontinued use of culture as its sensitivity is less than that of the amplified tests (75% to 96%).<sup>2</sup>

**NAATs.** The Centers for Disease Control and Prevention (CDC) Sexually Transmitted Diseases Treatment Guidelines, 2015, recommend that diagnostic testing for *T vaginalis* be performed for women presenting with symptoms of vaginal discharge.<sup>2</sup> Given the poor performance of the wet mount, it is not surprising that the CDC 2015 guidelines also recommend the use of highly sensitive and specific tests for the detection of *T vaginalis*.<sup>2</sup>

Currently, 3 NAATs are FDA-cleared for detection of *T vaginalis* in vaginal, cervical, and urine samples obtained from women. The Aptima *T vaginalis* assay (Hologic

**Disclosures:** Dr. Hillier reports that she is a consultant to Perrigo and Symbio-mix and has an ongoing relationship with Becton Dickinson, Cepheid, and Hologic. Dr. Danby reports no financial relationships relevant to this article.

**TABLE** Performance of diagnostic testing methods for *Trichomonas vaginalis*

Method	Commercial test	Sensitivity	Specificity
Wet mount	N/A	51%–65%	100%
Culture	N/A	75%–96%	100%
Antigen detection	OSOM® Trichomonas Rapid Test	82%–95%	97%–100%
Nonamplification DNA hybridization	Affirm™ VPIII Microbial Identification Test	63%	99.9%
Nucleic acid amplification tests	Aptima® <i>T vaginalis</i> assay	95%–100%	95%–100%
	BD ProbeTec <i>T vaginalis</i> Qx Amplified DNA Assay	96%–98%	98%–99%
	Xpert® TV test	96%–99%	99%

N/A, not applicable.

Gen-Probe; San Diego, CA) detects RNA in the sample by transcription mediated amplification. As shown in the **TABLE**, the sensitivity and specificity of the Aptima test in clinical studies have been greater than 95%. The BD ProbeTec *T vaginalis* Qx Amplified DNA Assay (Becton Dickinson; Franklin Lakes, NJ) is also approved for detection of *T vaginalis*, and it relies on amplification of DNA rather than RNA. According to the package insert for this system, this type of amplification test is 96% to 98% sensitive and 98% to 99% specific for detection of this pathogen. One study showed that the test system worked as well when women self-collected their samples.<sup>6</sup> The most recent FDA-cleared test is the Xpert TV test (Cepheid; Sunnyvale, CA), which relies on amplification of microbial DNA. This test system, which provides results in 45 minutes, also has excellent sensitivity and specificity according to information in its package insert.

There are no published data directly comparing the sensitivity of RNA- and DNA-based NAATs for

*T vaginalis*. Head-to-head studies of these systems are needed to evaluate whether there are meaningful differences in the sensitivity of RNA- vs DNA-based NAATs for the detection of *T vaginalis*.

### Why has identifying infected women been difficult?

Most of the women infected with *T vaginalis* worldwide are simply never tested or treated, and partner treatment is even more unlikely to occur. Most women infected with *T vaginalis* are either asymptomatic or have minimal symptoms.<sup>2</sup> Therefore, testing for *T vaginalis* only in women presenting with genital symptoms will fail to detect the large reservoir of infection among asymptomatic women.

Women aged 14 to 49 years who participated in the National Health and Examination Survey cycles for 2001–2004 provided self-collected vaginal swab specimens for detection of *T vaginalis*. The vaginal

### CASE STUDY

A 29-year-old divorced, nonpregnant white woman visits her gynecologist due to symptoms of abnormal discharge and malodor. She has a levonorgestrel-releasing intrauterine device (IUD) for contraception and reports having a single male sexual partner for the past year. She denies any past sexually transmitted diseases, including gonorrhea, chlamydia, or herpes, and reports that she never uses condoms with her current partner. She has had symptoms of malodorous discharge for more than three months, and she has sought health care three times with other providers for these symptoms. She has been treated twice with oral metronidazole for bacterial vaginosis.

Examination reveals a normal vulva without redness. Her cervix has no mucopus. Vaginal examination reveals moderate, thin, homogenous discharge with a fishy odor. Vaginal pH is five, and microscopic evaluation of vaginal fluid reveals clue cells but no motile trichomonads or yeast pseudohyphae or buds. White cells are not visible in the wet mount. Screening tests for sexually transmitted infections are ordered for *N gonorrhoeae*, *Chlamydia trachomatis*, and *T vaginalis*. Based on the clinical evaluation, the patient is diagnosed with bacterial vaginosis and is given a prescription

for topical metronidazole gel once daily for five days, since she had already been treated twice with oral metronidazole.

Two days later the laboratory test results are returned and the patient is found to have *T vaginalis* based on NAAT. The patient is advised that she and her partner need to receive oral metronidazole. (She receives a seven-day course of oral metronidazole to treat both the bacterial vaginosis and trichomoniasis while he receives a single 2-g dose of oral metronidazole.) They are advised that they should use condoms during sex during their treatment.

### Discussion

This patient likely has had trichomonads present at low density since she was infected months or years earlier. Such low-density infections are not apparent on wet mount but can cause chronic or recurring symptoms. Although oral metronidazole treatment should have eradicated the concurrent trichomoniasis when the patient received treatment for recurrent bacterial vaginosis, failure to treat the male partner likely led to reinfection and the recurrence of symptoms, especially since she reported never using condoms. Women having persistent or recurrent symptoms should be evaluated using sensitive tests to rule out trichomoniasis.

fluids extracted from these swabs were evaluated for the presence of *T vaginalis* by NAAT. The prevalence of *T vaginalis* infection in these 3754 US women was 3.1% overall, but there were large disparities in infection by race and ethnicity: for non-Hispanic white women, it was 1.3%; for Mexican American women, 1.8%; and for non-Hispanic black women, 13.3%.<sup>7</sup> Factors associated with increased likelihood of *T vaginalis* infection in multivariate analyses included non-Hispanic black race/ethnicity, a greater number of lifetime sex partners, increasing age, lower educational level, poverty, and douching.

Screening can be considered for populations of women at high risk for *T vaginalis*, and evaluation of local prevalence may be important in deciding whether broader screening is advised. In addition, experts recommend annual routine screening for HIV-infected pregnant and nonpregnant women.<sup>8</sup> Women previously diagnosed with *T vaginalis* should also be evaluated since reinfection is common.

The case study that appeared on page S3 better demonstrates the emergence and importance of NAAT technology in the detection and management of *T vaginalis* infection.

## References

1. Hillier SL. Prevalent, treatable and significant: barriers to the control of *Trichomonas vaginalis* in women. *Sex Transm Infect.* 2013;89(6):415.
2. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases guidelines, 2015. *MMWR Recomm Rep.* 2015;64(RR-03):1-137.
3. Stoner KA, Rabe LK, Meyn LA, Hillier SL. Survival of *Trichomonas vaginalis* in wet preparation and on wet mount. *Sex Transm Infect.* 2013;89(6):485-488.
4. Cotch MF, Pastorek JG 2nd, Nugent RP, et al. *Trichomonas vaginalis* associated with low birth weight and preterm delivery. The Vaginal Infections and Prematurity Study Group. *Sex Transm Dis.* 1997;24(6):353-360.
5. Pastorek JG 2nd, Cotch MF, Martin DH, Eschenbach DA. Clinical and microbiological correlates of vaginal trichomoniasis during pregnancy. The Vaginal Infections and Prematurity Study Group. *Clin Infect Dis.* 1996;23(5):1075-1080.
6. Van Der Pol B, Williams JA, Taylor SN, et al. Detection of *Trichomonas vaginalis* DNA by use of self-obtained vaginal swabs with the BD ProbeTec Qx assay on the BD Viper system. *J Clin Microbiol.* 2014;52(3):885-889.
7. Sutton M, Sternberg M, Koumans EH, McQuillan G, Berman S, Markowitz L. The prevalence of *Trichomonas vaginalis* infection among reproductive-age women in the United States, 2001-2004. *Clin Infect Dis.* 2007;45(10):1319-1326.
8. Meites E, Gaydos CA, Hobbs MM, et al. A review of evidence-based care of symptomatic trichomoniasis and asymptomatic *Trichomonas vaginalis* infections. *Clin Infect Dis.* 2015;61(suppl 8):S837-S848.

# Trichomoniasis and the 2015 CDC STD Treatment Guidelines: New Insights, New Urgency

Paul Nyirjesy, MD

Professor

Departments of Obstetrics and Gynecology and Medicine  
Director, Drexel Vaginitis Center  
Drexel University College of Medicine  
Philadelphia, Pennsylvania

## Introduction

Diagnosing vaginal infections is often fraught with error. In the case of *Trichomonas vaginalis* infection, providers have traditionally relied on saline microscopy for diagnosis, as trichomonads are easy to recognize. However, relying solely on microscopy, even for symptomatic cases, still results in many *T vaginalis* cases being missed. Our clinical experience with trichomoniasis confirms the poor sensitivity of microscopy, in which only 35% of 60 newly diagnosed cases were identified with our use of microscopy.<sup>1</sup> Fortunately, the Centers for Disease Control and Prevention (CDC) 2015 Sexually Transmitted Diseases Treatment Guidelines shed new light and urgency on

trichomoniasis and offer guidance for achieving a more accurate and sensitive diagnosis of *T vaginalis* infection.<sup>2,3</sup>

## Diagnosing trichomoniasis

In the CDC 2015 guidelines, a nucleic acid amplification test (NAAT) in the form of the Aptima *T vaginalis* assay (Hologic Gen-Probe; San Diego, CA) is identified as a test cleared by the Food and Drug Administration (FDA) for the detection of *T vaginalis*, detecting 3- to 5-fold more *T vaginalis* infections than wet mount microscopy.<sup>2-5</sup> In a prospective study of 933 evaluable women, the Aptima test detected trichomonas RNA by transcription-mediated amplification with a clinical sensitivity of 95.3% to 100% and specificity of 95.2% to 100% in a variety of specimens, including vaginal, urine, endocervical, and ThinPrep Pap™ samples.<sup>6</sup> Furthermore, there was high

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concordance between different types of specimens. These compared favorably to results with culture, which has a sensitivity of 89.2% and a specificity of 100%.<sup>7</sup> The test can be performed on the same swab used for testing of gonorrhea and chlamydia, giving it the added advantages of being readily available and easily performed.

Other tests mentioned in the CDC guidelines include the BD ProbeTec *T vaginalis* Qx Amplified DNA Assay (Becton Dickinson; Franklin Lakes, NJ), the OSOM Trichomonas Rapid Test (Sekisui Diagnostics; Framingham, MA), and the BD Affirm VPIII Microbial Identification Test (Becton Dickinson; Franklin Lakes, NJ), a DNA hybridization probe test.

As mentioned, and apart from testing symptomatic women with vaginal discharge, CDC guidance also encourages testing women who are at higher risk for having a sexually transmitted infection in general and *T vaginalis* infection in particular. These populations include high-prevalence settings. For example, in sexually transmitted disease clinics the prevalence of trichomoniasis was 16.2% by wet mount but 28.7% by vaginal swab Aptima *T vaginalis* assay. It should be noted that a Pap smear, which may occasionally report *T vaginalis* infection, has a sensitivity similar to that of wet mount but also a false-positive rate of 4% to 8%<sup>8</sup>; thus, patients with a Pap smear positive for trichomoniasis should obtain a more accurate test. Many laboratories will offer the Aptima *T vaginalis* assay as a reflex test off a liquid cytology sample that reads positive for *T vaginalis*.

Mention must also be made related to the testing of asymptomatic women for potential *T vaginalis* infection. The CDC 2015 guidelines on trichomoniasis state that "although data are lacking on whether screening and treatment for asymptomatic trichomoniasis in high-prevalence settings or persons at high risk can reduce any adverse health events and health disparities or reduce community burden of infection...decisions about screening [asymptomatic women] might be informed by local epidemiology of *T vaginalis* infection."

Finally, the CDC also suggests that, when highly sensitive testing (such as NAAT) on a specimen is not feasible, a testing algorithm be employed in which wet mount is used first, followed by NAAT if negative, as a means to improve diagnostic sensitivity.<sup>2,3,7</sup>

### CDC treatment recommendations for trichomoniasis

Nitroimidazoles, primarily metronidazole, have been the mainstay of treatment for decades. Metronidazole, given as a single oral 2-g dose, is associated with low cost, high compliance, and cure rates of 84% to 98%.<sup>2,3</sup> Tinidazole, 2-g as a single oral dose, has been a recommended therapy since 2006. The potential benefits of tinidazole are a longer half-life, higher levels in serum and genitourinary secretions, possibly greater efficacy, and fewer gastrointestinal side effects, but they may be outweighed by

the significantly higher cost. A seven-day course of oral metronidazole 500 mg twice a day is accepted as an alternative treatment regimen. For pregnant women, a single 2-g dose of metronidazole is recommended, and the guidelines reassure providers that treating trichomoniasis in pregnancy is not associated with any adverse pregnancy outcomes. The seven-day regimen is recommended as it results in higher cure rates than the single-dose regimen (91.5% vs 83.2%) in women infected with HIV.<sup>9</sup>

Although metronidazole allergy is rare, severe reactions, ranging from skin rash to angioedema and anaphylactic shock, have been described. Tinidazole, the only other recommended drug for trichomoniasis, is closely related to metronidazole, and there are essentially no data on cross-reactivity. Thus, for patients who are allergic to metronidazole, CDC guidelines recommend desensitization and management with a specialist. Both oral and intravenous regimens exist. In a small case series collected by the CDC, 15 women with trichomoniasis and metronidazole allergy were all successfully desensitized and treated.<sup>10</sup>

Since *T vaginalis* is sexually transmitted, partner treatment is recommended. Because *T vaginalis* in men can be found in semen, urine, or under the coronal sulcus, excluding male infection can be difficult. Thus, even if asymptomatic, presumptive therapy for male partners to avoid reinfection is indicated. Patient-delivered partner therapy may be one option for treatment; however, certain states prohibit prescribing medications to partners if there is no provider-patient relationship. Providers can consult the CDC website (<http://www.cdc.gov/std/ept/legal>) to determine if it is legal for them to do so in their locale. As noted previously, and similar to what is recommended for gonorrhea and chlamydia infection, retesting the patient after treatment is essential, even if she believes her partner has been treated, as early as two weeks but within three months of treatment. This (1) ensures she is cured and (2) assesses for possible reinfection (critical with reinfection rates up to 17%).

As retesting after treatment for *T vaginalis* infection becomes more common, providers will increasingly encounter positive follow-up tests. These positive tests may represent noncompliance with treatment, reinfection from either the same or a new partner, or treatment failure related to a resistant organism. Since the first two possibilities can only be determined from a patient's history, the provider needs to assess treatment compliance for both the patient and her partner, validate there was no sexual activity while one of the partners had not been treated, and collect an interim sexual history. Should noncompliance or reinfection seem likely, the patient can be retreated.

Metronidazole and tinidazole resistance, unfortunately, does occur, at rates estimated at 4% to 10% and 1%, respectively.<sup>2,3</sup> Because nitroimidazoles represent

the mainstay of therapy, patients with clinically defined resistance should be treated initially with a higher dose of metronidazole (500 mg twice a day for seven days). Should this option fail, higher doses of metronidazole or tinidazole are recommended—2 g daily for seven days of either drug. Since tinidazole is more active against *T vaginalis*, in my practice I tend to use tinidazole. For subsequent treatment failures, sending the isolate to the CDC for susceptibility testing is recommended, as is using even higher doses of tinidazole (2 g to 3 g for 14 days in combination with intravaginal tinidazole 500 mg twice a day).<sup>11</sup> For the rare patient who either requires high-dose tinidazole or fails with treatment, referral to a specialist is recommended since alternative regimens have not been systemically evaluated.

### Conclusion

*T vaginalis* is now receiving more attention and, with the advent of highly sensitive testing modalities such as NAAT, a new era for screening can result in *T vaginalis*-infected women receiving a more accurate diagnosis and, subsequently, more effective treatment. For uncommon, more complicated cases in which patients have metronidazole allergy or resistance, the CDC 2015 guidelines provide excellent recommendations for treatment and follow-up. Review of these guidelines is highly encouraged.

### References

1. Keating MA, Nyirjesy P. *Trichomonas vaginalis* infection in a tertiary care vaginitis center. *Sex Transm Dis*. 2015;42(9):482-485.
2. Centers for Disease Control and Prevention. 2015 Sexually transmitted diseases treatment guidelines. Available at: <http://www.cdc.gov/std/tg2015/trichomoniasis.htm>. Accessed January 16, 2016.
3. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep*. 2015;64(RR-03):1-137.
4. Hollman D, Coupey SM, Fox AS, Herold BC. Screening for *Trichomonas vaginalis* in high-risk adolescent females with a new transcription-mediated nucleic acid amplification test (NAAT): associations with ethnicity, symptoms, and prior and current STIs. *J Pediatr Adolesc Gynecol*. 2010;23(5):312-316.
5. Roth AM, Williams JA, Ly R, et al. Changing sexually transmitted infection screening protocol will result in improved case finding for *Trichomonas vaginalis* among high-risk female populations. *Sex Transm Dis*. 2011;38(5):398-400.
6. Schwebke JR, Hobbs MM, Taylor SN, et al. Molecular testing for *Trichomonas vaginalis* in women: results from a prospective US clinical trial. *J Clin Microbiol*. 2011;49(12):4106-4111.
7. Nye MB, Schwebke JR, Body BA. Comparison of APTIMA *Trichomonas vaginalis* transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. *Am J Obstet Gynecol*. 2009;200(2):188.e1-188.e7.
8. ACOG Committee on Practice Bulletins—Gynecology. ACOG Practice Bulletin. Clinical management guidelines for obstetricians-gynecologists, Number 72, May 2006: vaginitis. *Obstet Gynecol*. 2006;107(5):1195-1206.
9. Kissinger P, Mena L, Levison J, et al. A randomized treatment trial: single versus 7-day dose of metronidazole for the treatment of *Trichomonas vaginalis* among HIV-infected women. *J Acquir Immune Defic Syndr*. 2010;55(5):565-571.
10. Helms DJ, Mosure DJ, Secor WE, Workowski KA. Management of *Trichomonas vaginalis* in women with suspected metronidazole hypersensitivity. *Am J Obstet Gynecol*. 2008;198(4):370.e1-7.
11. Sobel JD, Nyirjesy P, Brown W. Tinidazole therapy for metronidazole-resistant vaginal trichomoniasis. *Clin Infect Dis*. 2001;33(8):1341-1346.

## *Trichomonas vaginalis*: Ensuring Reimbursement in Clinical Practice

**Maria Trent, MD, MPH**

Associate Professor of Pediatrics  
Division of General Pediatrics and Adolescent Medicine  
Johns Hopkins School of Medicine  
Baltimore, Maryland

### Introduction

Epidemiologic data suggest a need for a public health control program for *Trichomonas vaginalis* in clinical practice. The United States Preventive Services Task Force (USPSTF), which evaluates the quality and strength of evidence to guide the use of available preventive services, does not currently evaluate the evidence to

support or refute the need for *T vaginalis* screening in primary care practice. Public and commercial payers of health services, however, use the USPSTF recommendations to guide healthcare policies adopted.<sup>1</sup> Fortunately, the CDC recommends appropriate testing for both symptomatic patients (diagnostic) and asymptomatic patients (screening) who reside in sexually transmitted infection (STI)-prevalent communities and or have other risk factors associated with increased infection, prior STI, or HIV infection.<sup>2</sup> Effective integra-

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tion of *T vaginalis* screening into practice is essential for reducing the disease burden and observed *T vaginalis*-related disease disparities in the United States.<sup>3</sup>

### Documentation

Proper documentation and coding to support compliant billing are necessary to sustain clinical practices offering evaluation, testing, and treatment for *T vaginalis*. A single clinical practice may accept payment from multiple payer sources; therefore, uniform and consistent strategies for documentation and coding that meet the Centers for Medicare and Medicaid Service (CMS) standards are recommended.<sup>4</sup> Health providers billing for clinical services must (1) document delivered services in the medical record; (2) accurately capture the services that were provided using Current Procedural Terminology (CPT) codes and/or Healthcare Common Procedure Coding System (HCPCS) codes; (3) capture the reasons for service provision; and (4) document any special circumstances involved in delivery of clinical services using modifiers. Services provided related to a CPT code include medical evaluations, procedures, and laboratory tests.

Evaluation and management (E/M) visits require the use of a CPT code that best represents the patient's status (new versus established), the setting of service delivery (e.g., outpatient, inpatient), and the level of service. Patients characterized as "new" should not have received any professional services from a health provider within the same specialty group within the last three years. STI testing is often performed in the context of problem-focused E/M visits, which are classified as either new patient visits (99201-99205) or established visits (99211-99215). The two methods used to calculate the E/M level is a composite of the three key elements: history, physical examination, and medical decision-making. When greater than 50% of the face-to-face time is spent counseling the patient, time can be used.<sup>5</sup>

Essentials for three-component documentation include (1) key historical elements (chief complaint, history of present illness, review of systems correlated with disease severity, and family and social history); (2) a physical examination; and (3) evidence of medical decision-making. The amount of documentation should reflect the number of diseases and management options considered, disease complexity, and the risk for complications. Time-based billing requires the inclusion of time spent with the patient and an attestation that over 50% of the visit was spent in counseling. In this instance, documentation should include the content of the discussion, including questions or issues raised by the patient, and provider recommendations for next steps. Health providers should code coexisting conditions at the time of the clinical encounter if they require treatment and patient management for the new diagnosis is affected by the condition.

The International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) is a set of codes for diseases, signs/symptoms, abnormal findings, and social circumstances that support the medical necessity of service provision by documentation in the medical record. ICD-10 also contains 68,000 different diagnostic codes with greater specificity about the diagnostic category, site, laterality, and details, such as the causative agent, that clarify the diagnosis (compared with 14,000 in ICD-9). The ICD-10 transition mandate applies to all parties covered by the Health Insurance Portability and Accountability Act (HIPAA), not just providers who bill Medicare or Medicaid.<sup>6</sup> Use of the appropriate ICD-10 coding with the required documentation elements in the medical record enhances the overall quality of medical reporting and support reimbursement for services rendered. Common causes for denial of medical claims include incorrect or duplicate coding, technical billing errors, and/or failure to file timely requests for reimbursement. The **TABLE** on page S8 outlines ICD-10 codes that may be useful for coding delivery of *T vaginalis*-related STI screening services.

### Additional policies for coverage

Commercial insurance plans may have additional policies that govern coverage of *T vaginalis* screening for asymptomatic patients in clinical practice as a medical necessity. These policies are often published online for access by patients and providers. Consider the case of a 19-year-old sexually active woman residing in a high *T vaginalis*-prevalent community who discloses a new sexual partner during a routine health maintenance visit. If she were symptomatic for vaginitis, diagnostic testing for *T vaginalis* would usually be covered as a medical necessity. If she were asymptomatic, however, additional coding and medical record documentation of risk factors, such as new or multiple sexual partners, prior STI history including HIV infection, and sex for money or drugs, may be required to document medical necessity. The same is true for the heterosexual male patient who presents for an acute visit for STI exposure. If the patient were symptomatic for *T vaginalis* urethritis, diagnostic testing for *T vaginalis* would be considered medically necessary. However, additional documentation of risk (e.g., exposure to *T vaginalis*) may be required to document medical necessity. Patients who have positive results with office-based testing (e.g., wet prep, DNA probe) would have definitive results for use of *T vaginalis*-specific ICD-10 codes with the E/M visit codes. Use of electronic health records allows for easy documentation of the core historical components and affiliation of laboratory orders to specific ICD-10 diagnoses that generate the billing codes for submission.

### Summary

The CDC currently publishes evidence-based guidance for asymptomatic screening and diagnostic testing for

**TABLE** Commonly used ICD-10 codes for trichomonas-related STI visits

Category	ICD-10 code	Description
Disorders of genital area	L29.3	Vaginal itch
	N76.0	Vaginitis
	N89.8	Vaginal discharge
	N93.9	Vaginal bleeding
	R36.9	Urethral discharge
	N34.1	Unspecified urethritis
	N41.9	Inflammatory disease of the prostate, unspecified
	N45.1	Epididymitis
	N72	Cervical inflammation
N73.9	Pelvic inflammatory disease	
Factors influencing health status/rationale for contact with health services	Z11.3	Venereal disease screening
	Z11.8	Encounter for screening for other infectious and parasitic diseases, trichomonas screening
	Z11.9	Encounter for screening for other infectious and parasitic diseases, unspecified
	Z20.9	Contact with or exposure to communicable disease
	Z71.89	Counseling on other sexually transmitted diseases
	Z72.51	High-risk sexual behavior
Infectious diseases	A59.00	Trichomoniasis, urogenital
	A59.01	Trichomoniasis, vulvovaginal
	A59.02	Trichomoniasis, prostatitis
	A59.03	Trichomoniasis, cystitis and urethritis
	A59.9	Trichomoniasis
	A64	Unspecified sexually transmitted disease

STI, sexually transmitted infection.

*T vaginalis* in clinical practice. For effective billing and coding for *T vaginalis* screening associated with clinical care, providers must: (1) be knowledgeable about the local epidemiology of common STIs; (2) consistently collect sexual history data during routine and acute visits; (3) understand the indications for *T vaginalis* screening and treatment; (4) be familiar with the CPT, ICD-10 codes, insurer policies, and state regulations for appropriate billing and coding of services; (5) provide clinical assessment and laboratory testing consistent with optimal standards of care; (6) document provided services and medical necessity of screening tests in the medical record based on clinical symptoms and/or risk based on lifestyle (e.g., new or multiple partners), and/or situational issues (e.g., exposure to STI); and (7) document time spent with the patient if more than 50% is spent counseling the patient.

### Conclusion

In conclusion, Drs. Hillier and Danby reminded us that the wet mount is becoming obsolete with increasing availability of more sensitive laboratory tests; Dr. Nyirjesy stressed the relevance of the 2015 CDC recommendations on STI treatment; and Dr. Trent provided

insight to ensuring reimbursement for *Trichomonas vaginalis* testing. Taken together, these three articles provide new insights into the diagnosis and treatment of *Trichomonas vaginalis* directly relevant to today's clinical practice.

### References

1. Meyers D, Wolff T, Gregory K, et al. USPSTF recommendations for STI screening. *Am Fam Physician*. 2008(6);77:819-824.
2. Workowski KA, Bolan GA; Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep*. 2015;64(RR-03):1-137.
3. Secor WE, Meites E, Starr MC, Workowski KA. Neglected parasitic infections in the United States: trichomoniasis. *Am J Trop Med Hyg*. 2014;90(5):800-804.
4. Cavanaugh S. ICD-10 Blog Center for Medicare Services. <https://www.cms.gov/medicare/coding/icd10/index.html>. Accessed December 16, 2015.
5. Centers for Medicare and Medicaid Services. Evaluation and management services guide. 2014. [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/eval\\_mgmt\\_serv\\_guide-ICN006764.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/eval_mgmt_serv_guide-ICN006764.pdf). Accessed December 16, 2015.
6. Centers for Medicare and Medicaid Services. ICD-10-CM Official Guidelines for Coding and Reporting. 2014. [http://www.cdc.gov/nchs/data/icd/icd10cm\\_guidelines\\_2014.pdf](http://www.cdc.gov/nchs/data/icd/icd10cm_guidelines_2014.pdf). Accessed December 16, 2015.