**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.1,2

*T vaginalis* is a commonly occurring sexually transmitted infection, with an estimated 3.7 million infections among people in the United States.3 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.4-12 In fact, an estimated 700 new cases of HIV infections among US women could be attributed to infection with *T vaginalis* each year.6 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; “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**


prévalence 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. 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. 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%).

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. 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*.

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

**Disclosure**

Dr. Hillier reports that she is a consultant to Perrigo and Symbo-mix and has an ongoing relationship with Becton Dickinson, Cepheid, and Hologic. Dr. Danby reports no financial relationships relevant to this article.
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. 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. 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%. 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. Women previously diagnosed with *T. vaginalis* should also be evaluated since reinfection is common.

The case study that appeared on page 53 better demonstrates the emergence and importance of NAAT technology in the detection and management of *T. vaginalis* infection.

**References**


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

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**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. 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.

**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. 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. Furthermore, there was high

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Disclosures: Dr. Nyirjesy reports that he is a consultant to Hologic and has received a research grant from Becton Dickinson.
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%. 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 VP III 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%; 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.

**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%. 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.

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.

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. 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). 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 systematically 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


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

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**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. 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. Effective integra-
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.3

**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.4 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.5

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.6 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
GUIDELINES AND TECHNOLOGY IN THE DIAGNOSIS AND TREATMENT OF TRICHOMONAS VAGINALIS

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

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

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 polices, 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**