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### Burdensome Vaginal Infections: Best Diagnostic Practices for Driving Better Patient Outcomes

Narrator:

Welcome to CME on ReachMD and the Omnia Education Activity entitled: Burdensome Vaginal Infections, Best Diagnostic Practices for Driving Better Patient Outcomes. Your host is Dr. Patrice Basanta-Henry. Dr. Basanta-Henry will speak with Dr. Neil Silverman who is a Clinical Professor in the Department of Obstetrics and Gynecology and Division of Maternal-Fetal Medicine at the David Geffen School of Medicine at UCLA in Los Angeles, California.

Dr. Silverman has nothing to disclose. This CME activity is supported by an independent medical educational grant from BD Life Sciences.

Dr. Basanta-Henry:

This is ReachMD and I am Dr. Patrice Basanta-Henry. Joining me today to discuss diagnostic and treatment approaches to the patient presenting with vaginitis is Dr. Neil Silverman from the David Geffen School of Medicine at UCLA. Dr. Silverman, welcome to the program.

Dr. Silverman:

Thank you, Dr. Henry.

Dr. Basanta-Henry:

So, to start things off, how much of an issue is vaginitis in a women's healthcare provider's practice?

Dr. Silverman:

Actually, this is an extraordinarily common issue for practitioners who care for women's health issues and the presentation of vaginitis is actually the most common gynecologic condition that women will seek care for, so that it is an issue with a high patient burden as well as a high economic burden in terms of diagnostic and treatment. Most women will have a vaginal infection characterized by discharge, or itching, or odor, at some point during their lifetime. From a problematic point of view, with the availability of complementary and alternative therapies and over-the-counter medications for some disorders, particularly candidiasis, many symptomatic women will actually seek out these products before or in addition to an evaluation by a medical provider, so that issues of self-diagnosis and self-treatment, which would represent poor management, are a common issue that providers confront. A study published about 10 years ago demonstrated that among women who self-diagnose vulvovaginal candidiasis, for example, only about 30% of them had an accurate diagnosis when they ultimately went to a medical provider, and that women who had had clinically proven candidiasis in the past, were actually not more accurate in self-diagnosing vulvovaginal candidiasis than women who hadn't had a diagnosis before. So, this is an issue for providers dealing with women who try, and frequently are unsuccessful at, self-diagnosis and self-treatment, as well as for women who request telephone diagnosis and treatment over the telephone which would be another instance of suboptimal management.

Dr. Basanta-Henry:

What would you say are the most common causes of an abnormal vaginal discharge?

Dr. Silverman:

Women will have a normal vaginal discharge and the typical normal vaginal discharge is clear-to-white, and odorless, and high

viscosity, and if you would evaluate normal vaginal secretions, it would be dominated by lactobacilli, although other pathogens can be present. These lactobacilli produce lactic acid which helps to maintain a normal vaginal pH of 3.8 to 4.2, and typically this acidic environment and other host immune factors inhibit overgrowth of bacteria. Some of these lactobacilli also produce hydrogen peroxide which is a microbicide. So vaginitis is typically characterized by vaginal discharge, vulvar itching, irritation, and odor, or any combination of those. The most common documented etiologies of vaginitis are bacterial vaginosis which represents about 40 to 45% of diagnosed infections, vulvovaginal candidiasis another 20 to 25%, and trichomoniasis about 15 to 20%, and then a smaller proportion will be mixed diagnoses. It's also important for providers to realize that even after they have done an appropriate evaluation and laboratory testing regimen that some women will have symptoms in the absence of an identifiable pathogen. And then, the possibility of mechanical or chemical, allergic, or noninfectious causes of vulvovaginal symptoms needs to be explored.

Dr. Basanta-Henry:

Can you describe for us a practical clinical approach to a woman who presents with a chief complaint of an abnormal vaginal discharge?

Dr. Silverman:

Even though studies have demonstrated that a medical history alone is insufficient for an accurate diagnosis of vaginitis, after all if it were we all could diagnose this over the telephone, an appropriate and careful history is a critical component of a full evaluation of a woman presenting with vaginal symptoms. The history needs to be done in concert with a thorough examination and appropriate laboratory testing, to try to determine an identifiable etiology of the vaginal symptoms. In terms of the history, it's important to explore sexual behaviors and practices, gender of sex partners, menstrual history, vaginal hygiene practices, and among vaginal hygiene practices vaginal douching is a very important issue to explore, because douching has actually been shown to increase the risk of some vaginal infections, particularly bacterial vaginosis and *Trichomonas*. In addition, a history of self-treatment with medication should be elicited. So, after a history is taken, and an examination is undertaken looking at the vulva, looking at the vagina, evaluating the cervix, a variety of diagnostic methods are available. Traditionally, microscopy has been used as a primary form of evaluating a patient presenting with symptoms suggestive of vaginitis and microscopy allows for evaluation for trichomonads under the microscope, or for yeast forms to look for candidiasis, or to look for clue cells which are the typical cell forms associated with bacterial vaginosis. However, more and more clinical settings no longer have microscopy available to them, and microbiologic testing is now a primary role of evaluating women presenting with vaginal symptomatology. The CDC has recognized this and they specifically say that in settings where microscopy and pH paper are not available, or where clinical personnel are not trained in the use of them, that nucleic acid testing, using molecular technologies to identify agents, is now an appropriate first-line method of evaluating women with vaginal symptoms, and these are specifically used for the diagnosis of bacterial vaginosis and trichomoniasis.

Dr. Basanta-Henry:

Dr. Silverman, let's talk about the guidelines for screening and testing from various sources such as the CDC, WHO, and ACOG, among others. How familiar are clinicians with these guidelines and are they actually compliant in following them?

Dr. Silverman:

All of the agencies that you mentioned put a great deal of work and use the experience of many clinical experts to try to come up with practical clinical useful guidelines for a variety of settings. Unfortunately, we know that, not just in the area of vaginitis, but in a number of clinical settings, while guidelines do exist, clinicians are not always aware of the most recent iterations, the most current evolution of guidelines, and that is unfortunate, but our societies do try to make these very readily available to practitioners. ACOG has Practice Bulletins and Committee Opinions available for members on their website and the CDC makes its current guidelines available to all readers on their website, CDC.gov.

Dr. Basanta-Henry:

If you are just tuning in, you are listening to CME on ReachMD. I am your host, Dr. Patrice Basanta-Henry, and today I'm speaking with Dr. Neil Silverman. We're speaking about best clinical practices for patients presenting with vaginitis.

Let's focus on screening methods for vulvovaginal candidiasis, trichomoniasis, and bacterial vaginosis. And can you please explain the steps you take to rule out or rule in these various possible infections?

Dr. Silverman:

Starting with vulvovaginal candidiasis, this is typically caused by *Candida albicans*, although it can be caused by other *Candida* species. And the typical symptoms of vulvovaginal candidiasis include: pruritus, vaginal soreness, dyspareunia, external dysuria, and even, and abnormal vaginal discharge. However, none of these symptoms is specific for vulvovaginal candidiasis and it's been estimated that almost 75% of women will have at least one episode of vulvovaginal candidiasis over their lifetime and almost half of them will have two or more episodes. So, the types of candidiasis that we deal with are either uncomplicated or complicated. Uncomplicated is a single episode which is easily identified and treated. Complicated becomes when people have recurrent or severe symptoms, or vaginitis

caused by a non-albicans species of candidiasis, or there's an underlying medical issue in the woman such as diabetes, or immunosuppression, or some other chronic debilitation. So, when a woman presents with symptoms suggestive of vulvovaginal candidiasis, it's important to do an examination to look for things like vulvar edema or fissures or excoriations and, typically, a discharge with vulvovaginal candidiasis is thick and curdy. So, traditionally, this can be evaluated microscopically, so you can do a wet prep, mixing some of the discharge from a swab on a slide using either saline or 10% potassium hydroxide. A Gram stain of vaginal discharge can also be done, but from a point-of-care method in the clinic, microscopy still tends to be a fairly straightforward way of evaluating this. Candida vaginitis is typically associated with a normal vaginal pH, so less than 4.5, and our current guidelines state that, if possible, examination of a wet mount microscopically with potassium hydroxide preparation should be performed for all women with signs or symptoms suggestive of Candida. For those women who have negative microscopic evaluations, but clearly have signs or symptoms that raise suspicion, vaginal cultures for Candida should be considered. And this needs to be discussed with a practitioner-specific lab to know the type of swab that should be sent and if Candida cultures can't be performed for these women, then empiric treatment can be considered for a first episode. But, identification of Candida by culture, if someone doesn't have symptoms, is an indication for treatment because about 10 to 20% of women will actually have colonization with Candida in the absence of symptoms, so that this is not something that should be done as a screening test, but only in a woman who presents symptomatically. So, the majority of women in whom a suspicion is raised and a culture is performed will have a diagnosis of Candida albicans vaginitis and this can then be treated, either with an intravaginal agent or with an oral agent like fluconazole.

Dr. Basanta-Henry:

Dr. Silverman, recently a PCR assay has been authorized by the FDA for diagnosis of both vaginitis and vaginosis. In a single test it can detect a variety of bacterial pathogens responsible for BV in addition to Candida species infection. Can you tell us more about the how the algorithm detects healthy from unhealthy bacteria in the vaginal microbiome, and how this improves diagnostic accuracy and initial selection of pharmacologic intervention?

Dr. Silverman:

This is a very important question and a very important issue for clinicians because bacterial vaginosis is the most common gynecologic infection that they encounter among women of reproductive age in the United States, and it's seen in up to 10 to 30% of heterosexual women in the developed nations, and in 20 to 50% of women who have sex with women. Traditionally, the method for diagnosis of bacterial vaginosis has been microscopic evaluation of a smear of vaginal secretions that is specifically stained, but this technique, although it has been validated in a number of studies, is fairly subjective, requires specialized training, and is not widely available to all clinicians and is not an office-based test. So, a highly accurate molecular assay for the diagnosis of bacterial vaginosis would be of great utility, both for clinicians and particularly for their patients.

So, there have been molecular probe assays that have been developed that have used real-time polymerase chain reaction assays looking at the ability to detect a variety of organisms that have been associated with vaginal health and disease, as well as having the ability to detect both beneficial and pathogenic strains of yeast, or candida. One particular assay was evaluated by a group out of Wayne State University last year and published in the Journal of Clinical Microbiology in 2016. As an example, this particular PCR-based probe was able to have very high sensitivity and specificity when compared to traditional gram-stained microscopy slides and also had very high positive and negative predictive values above 94 percent. These molecular-based tests are now becoming more clinically available to practitioners in their offices and hopefully will allow them to have greater access to precise diagnosis of bacterial vaginosis in women who present with symptoms. In addition, these assays, while adding significantly to the availability of precise diagnosis for symptomatic women in office settings, will also expand the availability of precise diagnosis in women who present on an emergent basis in the hospital setting to provide similar precise diagnoses for women who may have symptomatic vaginitis who require and deserve precise diagnosis.

Dr. Basanta-Henry:

As follow-up, with early and more accurate detection and more precision in selecting pharmacologic intervention, how do you think this newer approach will help decrease recurrent BV and thus diminish the burden of women affected by BV?

Dr. Silverman:

It's been very well studied that recurrent bacterial vaginosis or inaccurate diagnosis of bacterial vaginosis is a very important issue for women who are affected with this disorder.

Therefore, a precise diagnostic method for making an appropriate diagnosis in the first place can help women know what's going on, receive appropriate and targeted treatment rather than presumptive treatment, and in some cases allow them after treatment to adopt some lifestyle modifications that may help them prevent recurrences of what has finally been accurately diagnosed.

Dr. Basanta-Henry:

Dr. Silverman, we are reaching the end of our time together. Do you have any final thoughts you would like to share with our listening audience?

Dr. Silverman:

What I'd like our listening audience to appreciate is that while we frequently will see women with symptoms of vaginitis present as a chief complaint in our office, the approach can be sorted out in a methodical way with appropriate diagnostic techniques that include exam, history, and targeted diagnostic therapies. As we've talked about, for many of these women, microscopy is still an important adjunct to diagnosis, but it is not as sensitive as newer technologies that have become available. The CDC, for example, and many insurers, now recommend that for bacterial vaginosis and trichomoniasis, the newer molecular techniques are appropriate for first-line diagnostics. The advantage of the molecular techniques in addition, as it relates to trichomoniasis, is that either vaginal swabs or urine can be tested so that we can talk about less invasive ways of diagnosis of this common sexually transmitted infection.

Dr. Basanta-Henry:

Well, I very much want to thank Dr. Silverman for joining us to talk about updated clinical approaches to treating patients with vaginitis. Dr. Silverman, it was a pleasure speaking with you.

Dr. Silverman:

Thank you very much. It was a pleasure speaking with you, Dr. Henry.

Narrator:

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