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Improving M. gen Diagnosis with NAAT Technology

Announcer:
Welcome to ReachMD.

This medical industry feature, titled, “Improving M. Gen Diagnosis with NAAT Technology” is sponsored by Hologic.

Here’s your host, Dr. Jennifer Caudle.

Dr. Caudle:
Mycoplasma genitalium is an STI that shares similar health consequences to chlamydia and gonorrhea, but you may not be familiar with it. Until recently, there has been little guidance on how to manage this new pathogen. But with the release of a 2021 STI treatment guidelines, the CDC now recommends testing all women with recurrent cervicitis. And testing should be considered in women with PID.

This is ReachMD, and I'm your host Dr. Jennifer Caudle. And joining me to discuss challenges and approaches to diagnosing mycoplasma genitalium, or Mgen, is Dr. Eric Munson. Dr. Munson, Ph.D is an Assistant Professor of Clinical Laboratory Science at Marquette University.

Dr. Munson, thanks for being here today.

Dr. Munson:
Oh, thank you very much for the invitation to have this conversation. I appreciate it.

Dr. Caudle:
Dr. Munson, I understand you're going to be talking to us today about mycoplasma genitalium. For those of us that don't know, could you give us some background on exactly what mycoplasma genitalium is, and its effect on patients?

Dr. Munson:
Absolutely mycoplasma genitalium, otherwise known as Mgen, is a prevalent, often misdiagnosed, sexually transmitted infection, or STI, that was discovered in the early 1980s. It is more common than gonorrhea and has similar prevalence rates to chlamydia, with about 10% of women and men in the United States being infected. Mgen, is also an STI that shares similar clinical presentation to chlamydia, gonorrhea, and trichomoniasis. However, not all Mgen infections appear with symptoms. When patients do experience symptoms, they are similar to those associated with other urogenital tract bacterial infections.

Dr. Caudle:
And what can you tell us about these urogenital tract bacterial infections and risk of coinfection?

Dr. Munson:
Well, Mgen has been detected in about 10 to 30% of women with clinical cervicitis and has been identified in up to about a quarter of pelvic inflammatory disease, or PID cases. And unfortunately, untreated PID can lead to adverse pregnancy outcomes such as infertility and ectopic pregnancy. Men, however, are more likely than females to exhibit symptoms of an Mgen infection. And in fact, Mgen is responsible for about 30% of persistent or recurrent urethritis cases in men.

Dr. Caudle:
And with that background in mind, let's discuss diagnosis. What are some challenges clinicians typically encounter when testing for this STI?

Dr. Munson:

Well, the challenges for diagnosing Mgen have been multifactorial. When patients have symptoms, they can overlap, and are often indistinguishable from other infections like chlamydia, gonorrhea, or trichomoniasis. Mgen detection can be difficult because the bacterial organism burden is much lower when compared to other STIs commonly tested for. Traditional testing methods are not practical in the detection of Mgen. Microscopy, such as gram stain, is an ineffective testing method, as Mgen actually lacks a cell wall and, therefore, cannot be visualized under the microscope. Culture is also not clinically feasible, as the organism is so small that it can take up to six months to grow or culture in the laboratory. Because of this, the recommendation from the CDC is to test for Mgen with a highly sensitive NAAT test.

Dr. Caudle:
For those of you who are just joining us, this is ReachMD. I'm your host, Dr. Jennifer Caudle, and today I'm speaking with Dr. Eric Munson. We spoke a bit earlier about the background of mycoplasma genitalium. But now, let's dive into the new guidance from the CDC.

Dr. Munson, the 2021 CDC guidelines recently came out, can you share with us the new guidance for testing patients for Mgen?

Dr. Munson:
Absolutely. Until recently, it has been unclear which patients should be tested for Mgen. But with the release of the new guidelines from the CDC, it is now recommended to test women with recurrent cervicitis. And testing should also be considered in women with PID. For men, it is recommended to test patients with recurrent urethritis.

Dr. Caudle:
Dr. Munson, now that we know which patients should be tested, can you explain NAAT technology for us and why it's needed to detect Mgen?

Dr. Munson:
Absolutely, this is very important. So largely because of this COVID-19 pandemic, we've obviously heard of the term NAAT, and have used it a lot in the media lately. So NAAT, actually stands for nucleic acid amplification testing. It's a molecular-based testing methodology that detects a very specific nucleic acid sequence of a particular organism, often a viral or a bacterial pathogen. So, NAAT testing in general has higher accuracy rates or sensitivity perhaps, when compared to other nonmolecular testing methods. More specifically, when ribosomal RNA, or rRNA, is used as a target for NAAT testing as compared to DNA they have shown to have sensitivities up to 100%. There is only one copy of DNA per organism, but there are thousands of ribosomal RNA transcripts present per organism. As a result, NAAT technology targeting ribosomal RNA versus DNA improves clinical accuracy for this pathogen. And indeed, studies have found that using ribosomal RNA NAAT test can identify the 40% of patients missed by DNA-based testing.

Dr. Caudle:
And, is there a NAAT test for Mgen currently available to patients?

Dr. Munson:
Indeed, there is. As of January 2019, the Aptima mycoplasma genitalium assay developed by Hologic Incorporated, became the first NAAT test to be FDA cleared for the qualitative detection of ribosomal RNA from mycoplasma genitalium, urogenital infections in female and male patients. So, it is currently FDA cleared for use with urine and urethral, penile meatal, endocervical, and vaginal swab samples.

The Aptima multi test swab, which is orange, is a collection device that is commonly found in many physician offices. In addition to Mgen, this orange multi test swab can be used to test for chlamydia, gonorrhea, trichomoniasis, the entity known as bacterial vaginosis, also a couple of yeast species, Candida species, and Candida glabrata. With a single swab, you can obviously test for more than one infection at one time, allowing you to get multiple results with a single swab with just one collection from your patient.

Dr. Caudle:
Now let's take a brief look at treatment. If a patient tests positive for Mgen, using that technology, how should clinicians approach treatment?

Dr. Munson:
Well, treatment for STI's in general is organism specific, so it's really important to have an accurate diagnosis so that the patient can be treated appropriately. Failure to differentiate between Mgen and other STI agents, can lead to patients coming back with unresolved symptoms from receiving an ineffective treatment, which can lead to antimicrobial resistance. So, there's great concern at the CDC about the rise of resistant infection, which do a number of things within a community, such as putting more people at risk for that infection, making the spread more difficult to identify and contain, and perhaps impacting patient outcomes.

And in fact, in 2019, the CDC created a new category within their Annual Antimicrobial Resistance Report called, the Watch List. And this contained threats that they believe have resistance that could become common. Mgen was ranked number two in this Watch List, and so Mgen treatment should be accompanied with resistance testing, if available.

Mgen therapy requires a two-stage approach. And let me try to outline those stages for you right now. And the stages are really based on whether or not Mgen resistance testing is available. So, stage one recommended regimens - and again, if the Mgen resistance testing result is available stage one therapy would ensue. So, if the Mgen is susceptible to macrolides, then therapy would involve doxycycline for the first seven days at a 100-milligram oral dose two times a day. This would be followed with azithromycin. The initial dose of azithromycin would be a 1-gram oral dose, followed by 500-milligram doses orally, one time per day for an additional three days, and this adds up to 2.5 grams total azithromycin after the initial week of doxycycline.

If resistance testing is available, and it is determined that the Mgen result is resistant to macrolides, the therapy would then also start out with doxycycline for seven days with a 100-milligram oral dose two times a day, but instead, this will be followed for seven days with moxifloxacin. So instead of using azithromycin as a follow-up regimen, moxifloxacin would be used for seven days at a 400-milligram dose orally one time per day.

Stage two recommendations for therapy. If the Mgen testing result is not available, then the recommended regimen starts out again with doxycycline 100-milligram dose orally two times per day. This would be followed with a moxifloxacin regimen for seven days at a 400-milligram dose orally one time per day.

So the stage two recommendation involves Mgen results for which a resistance testing result is not available. And this would involve 100 milligrams orally two times a day of doxycycline for seven days. This would be followed by 400 milligrams orally, one time a day for seven days of moxifloxacin.

Dr. Caudle:
And before we close, do you have any takeaways for our audience on diagnosing Mgen or incorporating NAAT technology?

Dr. Munson:
Sure. I think the large take-home points here, number one the symptoms, if they're present of Mgen, could mimic a variety of other STIs. So, it's quite important to have specific laboratory testing to determine exactly which agent should be treated. And you know, there have been limitations in the past with respect to Mgen and laboratory diagnosis largely related to, you know, culture systems that are not readily available or do not work that well or give a quick turnaround time for that result. So, with the advent of the FDA cleared assay, such as the Aptima mycoplasma genitalium assay, laboratories now have the ability to give a quick and accurate result because of the nucleic acid amplification technology, which according to the CDC, is now the preferred method for testing. So, the quick turnaround time, as well as the more accurate result should allow clinicians to better manage their patients with respect to Mgen infection.

Dr. Caudle:
And with those comments in mind, I'd like to thank my guest, Dr. Eric Munson, for helping us better understand mycoplasma genitalium and how we can better diagnose this emerging health concern using NAAT technology. Dr. Munson, it was great speaking with you today.

Dr. Munson:
Oh, the pleasure was all mine. Thank you very much.

Dr. Caudle:
I'm your host, Dr. Jennifer Caudle and thanks for listening.

Announcer:
This program was sponsored by Hologic. If you missed any part of this discussion or to find others in this series, visit ReachMD.com/IndustryFeature. This is ReachMD. Be part of the knowledge.

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