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Reaching a Rapid Mycoplasma Genitalium Diagnosis

Announcer:
You're listening to Women's Health Update on ReachMD, sponsored by Hologic. Here's your host, Dr. Amy Mackey.

Dr. Mackey:
If I were to ask you to think of the most common infectious gynecologic conditions, what's the first thing that comes to mind? Maybe it's chlamydia or gonorrhea, but what about Mycoplasma genitalium? Also known as MGEN, Mycoplasma genitalium is often underdiagnosed and undertreated. And while molecular assays are quickly becoming the standard of care in the diagnosis of this and other infectious conditions, there's still much more to be shared and learned about how to more rapidly identify this infection.

Welcome to Women's Health Update on ReachMD. I'm Dr. Amy Mackey, and here to explain our current understanding of MGEN and how the community is looking to address it is Dr. Maria Trent. Dr. Trent is a Professor of Pediatrics in the Division of General Pediatrics and Adolescent Medicine at Johns Hopkins School of Medicine in Baltimore, Maryland.

Dr. Trent, welcome to the program.

Dr. Trent:
Thank you for having me on the show today.

Dr. Mackey:
So Dr. Trent, back in 2015 when the CDC guidelines were last issued, MGEN was identified as an "emerging issue," but the CDC was unable to make a more definitive link to its role in women. Can you explain more about that?

Dr. Trent:
Sure. I think at the time, there was emerging data that was demonstrating various clinical presentations in women, particularly with regard to diseases such as pelvic inflammatory disease. I think that the CDC also lacked population-based data, and they also did not have commercial testing available or sort-of population-based data on which to make recommendations in the last iteration of the CDC guidelines. I think since that time, data continued to be produced that really suggest that mycoplasma genitalium in many populations is really common, and at times may be more common than STDs that we think of, such as chlamydia trachomatis or Neisseria gonorrhoeae. I think another big challenge is that we also have to be careful about antibiotic prescribing. Many people at the Centers for Disease Control and Prevention have said that we are really running out of antibiotics, and so we want to be thoughtful about how we are treating women, and so without a test to recommend treatment, I think was really difficult. I think particularly in the setting of mycoplasma genitalium or MGen because of some of the data had emerged that antibiotic resistance is a significant problem, between 50% and 80% in some populations are resistant to macrolide antibiotics, and those are antibiotics like azithromycin, which we commonly use to treat chlamydia trachomatis, we really had to rethink. I think the CDC wanted to be careful about recommendations because I think they were unsure about making the diagnosis accurately and then the medication regimen that we could be using. I am certain it is an area of active research, and I think what our colleagues have really demonstrated is that there is value in understanding the role of resistance so that we can create an approach algorithm to help clinical providers on the ground. I think the most exciting thing now though is that there is a test available, a commercially available test, for mycoplasma genitalium that is now on the market and available for use in laboratories across the country. I think that what is also exciting is that there is ongoing research to determine whether or not available resistance testing will also be cleared by the FDA as well.

Dr. Mackey:
Great, so as far as diagnosis is concerned, we now have molecular assays, such as nucleic acid amplification testing, and how has that

changed the way we diagnose sexually transmitted infections?

Dr. Trent:
Sure, so nucleic acid amplification tests, or NAATs, really do identify small amounts of DNA or RNA in a biologic sample that you take from a patient, and it can identify a range of bacteria, viruses, other pathogens, but you really only need a very small amount of that pathogen in the sample. Basically, people identified the nucleic acid that they want to target, and a probe can be made for that. Then you can use chemical reactions to really amplify, to make multiple copies of that DNA or RNA so that you can amplify the amount of response in the sample. That means you are able to actually detect it easier with much more sensitivity and specificity, which is the real benefit of this type of testing. It also means, because of the way that the tests are run in the lab, it is superior to culture, and certainly it is superior to syndromic management, which is what people have been doing. Nucleic acid amplification is the new test, has improved for example how we test for gonorrhea, chlamydia, trichomonas, a variety of agents. Having a test for mycoplasma genitalium really puts us on par in terms of our ability to have an accurate test. I think the testing for mycoplasma genitalium is specifically a transcription-mediated amplification test. It reacts to the RNA of mycoplasma genitalium, so it is right there with the sort-of testing that I think most clinicians in the United States have really become accustomed to. What is exciting is, like gonorrhea, chlamydia, and trichomonas, there now is a new FDA test that was approved in 2019, a nucleic acid amplification test for mycoplasma genitalium, which will increase our ability to provide a precise diagnosis to patients who may have a mycoplasma genitalium infection.

Dr. Mackey:
So, with this improved diagnosis, and our ability to improve diagnosis, is there an opportunity for better patient management? And I want to include our males patients in this too, so what should clinicians be mindful about in either patient case?

Dr. Trent:
So, I think right now the recommendations have really been around patients who have had persistent disease. That is really the recommendation. Most in our research and what most people have found is that in studies where they include patients who do not have symptoms is certainly that many patients can be asymptomatic when they present, but I think this testing can be particularly valuable in settings where you have patients who have persistent symptoms in determining why they actually have disease. It could be a male patient who has urethritis and has persistent urethral discharge and has been unable to clear that despite having negative tests for gonorrhea, chlamydia, and so is trying to figure out why do I still have symptoms. How can I resume my normal life? Is there something else I should be doing? I think this test could be very useful in helping them. I think the great thing about the nucleic acid amplification test is that you can use a variety of specimen types to test patients ranging from endocervical vaginal specimens in women to urine specimens for men and women, and so it is really important to know that regardless of the patient's biology that this test could be used to screen them for infection.

Dr. Mackey:
For those just tuning in, you're listening to Women's Health Update on ReachMD. I'm Dr. Amy Mackey and I'm speaking with Dr. Maria Trent about how we can more rapidly diagnose Mycoplasma genitalium, or MGEN.

So Dr. Trent, now that we've talked about how we can be more aware of this infection in both our female and male patients, do you have a patient case you can share with us that will paint the pictures of what this looks like?

Dr. Trent:
Sure. Certainly. I totally confess that most of our research has been done with women. We have been collecting data over the last seven or eight years on over 800 women, many of them who are asymptomatic, just taking routine gynecologic services to determine the impact of this infection on their wellbeing. But we also have been testing women who have pelvic inflammatory disease. What we have found is that there are a section of clinical presentations for women who have mycoplasma genitalium, a good portion of those women will be asymptomatic, but we have also seen women who have severe disease and pelvic inflammatory disease, which is an upper reproductive tract disorder that has significant reproductive sequelae, is certainly within the realm of possibilities for presentation of mycoplasma. We have tried to parse out women who have mycoplasma alone vs mycoplasma coinfection, and so far, we have not been able to really distinguish those women, which is part of the reason why I think all the more research is needed to look at the clinical correlates not only in nonpregnant women but also in pregnant women. I think right now, I think part of the struggle that the clinician has, is do I need to do this in my asymptomatic patients, and the current recommendation is no. Although that may change over time, the recommendation is no. For symptomatic patients, when do I use this new mycoplasma testing? I think what we have seen certainly in patients who are symptomatic given the commonality of the disorder is certainly may be a course that could be recommended. Certainly, in our PID patients, we have seen rates of mycoplasma that are on par with our chlamydia rates in this population. I think for male patients, again I am reminded of the male patient who has simply been unable to clear his urethral discharge. I think that we provide a lot of reproductive care to women, but those of us who also provide care to men can see how distressing and concerning it is to them. It can have a significant impact on their health-related quality of life. I think those are the scenarios that you will often see in practice,

ranging from no symptoms at all to patients who really have significant clinical symptoms on presentation. I think what we have to do is to really be very thoughtful of those patients with symptoms with an eye towards the future on what do we do for patients who do not have symptoms.

Dr. Mackey:
And before we wrap up today, Dr. Trent, what final points do you want to leave with our audience regarding MGEN diagnosis and next steps?

Dr. Trent:
I think overall this is a really exciting time in terms of thinking through sexually transmitted diseases for patients. I anticipate that the CDC guidelines will come out in the next year, year and a half, and what will be exciting will be to see how they specifically address mycoplasm genitalium, particularly now that a new nucleic acid amplification test is available for use across the country. I think that nucleic acid amplification test will revolutionize care and allow us to provide more precise diagnoses for patients and couples in terms of thinking through what infections people have from a public health control perspective. In terms of really the next steps, I think that resistance testing will be critically important for us to develop algorithms that allow us to remain good stewards of antibiotics. We are at a time when we do not have as many new antibiotics to choose from, and so our ability to use novel diagnostics to drive clinical decision making is critically important. I think it is an exciting time that we have the new test, but I think we still have work to do in order to improve the precision with which we care for patients not only with mycoplasma genitalium but with other sexually transmitted infections.

Dr Mackey:
Those are all great comments for us to think on as we come to the end of today's program, and I want to thank my guest, Dr. Maria Trent, for joining me in this discussion.

Dr. Trent:
Thanks, so much for having me. I really appreciate the opportunity to share my thoughts.

Announcer:
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