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TRANSCRIPT

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Her Diagnosis Matters: What Can You Do to Prevent Misdiagnosis of Vaginitis?

Narrator:
Welcome to ReachMD. This program Her Diagnosis Matters: What Can You Do to Prevent Misdiagnosis of Vaginitis? is sponsored by BD: Advancing the world of health.

Dr. Birnholz:
Misdiagnosis of vaginal infections can lead to inappropriate treatment of vaginal infections, prolonged symptoms, and increase in affected women's risk of developing serious complications. Clinical procedures and traditional diagnostic techniques are insufficient to accurately diagnose the most common types of vaginal infections. On this program, we'll focus on a validated in vitro diagnostic molecular solution designed to simplify, standardize, and improve the accuracy of vaginal infection diagnosis.

I am your host, Dr. Matt Birnholz, and I would like to welcome Dr. Charlotte A. Gaydos to the program. Dr. Gaydos is Professor of the Division of Infectious Diseases at Johns Hopkins University School of Medicine in Baltimore, Maryland. She is lead investigator for the multisite clinical trial for the BD MAX Vaginal Panel, and joins us, to talk about vaginitis and vaginosis in women's healthcare, and how molecular testing will provide improved treatment options for patients. This assay is run on the BD MAX

system, an automated, real-time PCR platform. Dr. Gaydos, welcome to the program.

Dr. Gaydos:
Thank you very much. I'm delighted to be here to speak with you today.

Dr. Birnholz:
Let's start by providing some background for our listeners. How burdensome is vaginitis and vaginosis in the women's healthcare practice, and what are the current traditional diagnostic methods being used today?

Dr. Gaydos:
Vaginitis is one of the most common problems worldwide. It accounts for virtually millions of office visits every year. Most women are at risk of developing vaginitis. It's not thought to be sexually transmitted. It can be caused by one of three different kinds of organisms. It can be caused by a yeast candidiasis, by Trichomonas vaginalis, and by a syndrome called bacterial vaginosis, commonly called BV. Some of the traditional methods to diagnose vaginitis by a clinician today, in their office, includes obtaining a vaginal swab, doing a pH determination, and then doing a visual exam for any kind of discharge. Then the clinician would place the swab in saline, which is called a wet preparation, and examine it under a microscope. They would look for yeast cells, clue cells indicative of BV, and motile trichomonads. There is also a test that they can do by placing a drop of potassium hydroxide on the wet mount, and determining whether or not there is a fishy odor which can be attributed to basic amines. Sometimes that is noted for bacterial vaginosis.

Dr. Birnholz:
What are the downstream effects of misdiagnosing vaginitis and vaginosis? And who is most at risk?

Dr. Gaydos:
One of the downstream unfortunate effects of misdiagnosing bacterial vaginosis is the fact that it has been associated, not only with acquiring HIV, but it also has been shown in many studies to be associated with adverse birth outcomes. It causes premature rupture of membranes and low birth weight, and actually, really, is heavily associated with the adverse events of pregnancy. So, that's something that we don't want to happen.

Dr. Birnholz:
In your publication, you evaluated a new diagnostic method for vaginitis that has been FDA-market authorized. Can you provide some background on the product and the data generated?

Dr. Gaydos:
Sure. This multiplex vaginal panel includes, as I mentioned, the ability to diagnose with one swab and

one test, Trichomoniasis, BV, and also the different Candida species. It can differentiate the ones that cause more severe cases and are harder to treat. So, they have a call-out to determine whether or not it's a Candida group, which includes many of the common causes of candidiasis, but they also have a call-out for Candida krusei, and Candida glabrata. So, the objectives of the perspective clinical trial and the study that we published was to evaluate the performance of this molecular panel, or this multiplex panel, a new diagnostic system.

Dr. Birnholz:
How does the new product improve diagnostic accuracy and initial selection of effective treatments?

Dr. Gaydos:
Well, it improves the capability, as I mentioned, that the physician or the clinician can actually diagnose with one swab and one test. It can detect co-infections which is important, because perhaps this would prevent the doctor from just treating for yeast, if there were yeast and BV present, or if there were one of the more difficult-to-treat Candida species, such as krusei or glabrata, then they would know to use a different kind of treatment, different antibiotic, rather than what they would normally use to treat a common Candida species.

Dr. Birnholz:
Can you speak a bit about the unique design of the assay in detecting bacterial vaginosis and why this is important?

Dr. Gaydos:
Yes. The assay has a unique design for bacterial vaginosis. BV is difficult to diagnose accurately. There are two commonly accepted methods which are very subjective on the part of the clinician. Most clinicians will use the Amsel criteria where they will look for a gray discharge, a high pH, clue cells seen on the wet prep, and then the whiff test or the fishy odor caused by the basic amines when they add the KOH. This is a method that most clinicians use. In the scoring of the assay, the company also used the Nugent score which is a research tool. And this involves a Gram stain of a vaginal swab where the reader would view for the presence or absence of lactobacilli. Lactobacilli are considered good. And then, they also would look for the presence of tiny curved Gram-negative or Gram-variable bacteria which are indicative of many of these difficult-to-grow, unusual organisms. So what's unique about this platform is that the platform really looks for the presence of lactobacilli as indicative of a healthy vagina. And it looks particularly for two common lactobacilli that had been noted to be associated with health, and that's Lactobacillus crispatus and Lactobacillus jensenii and they don't look for Lactobacillus iners which is not associated with a healthy vagina. And then, they also go on and use an algorithm to show that if the lactobacilli are not present, that they look for the molecular detection of certain of these

unusual organisms, which are indicative of BV, and these would include Gardnerella vaginalis, Atopobium vaginae, Megasphaera 1, and what we call BVAB2 which is bacterial vaginosis-associated bacilli. And so, being able to look for these unusual organisms, as well as the presence of lactobacilli, make this unique design not subjective at all, and it is a very molecular and straightforward way to diagnose bacterial vaginosis.

Dr. Birnholz:
And how do you think this new diagnostic method will decrease reoccurring vaginitis and vaginosis in patients, and why is this important?

Dr. Gaydos:
Well, I think that it gives the clinician a tool, so that they would be able to detect co-infections, and also whether or not there is a more resistant Candida there. Some of the methodology that is used by many clinicians, such as wet prep, is only about 50% sensitive. One of the big advantages is in the field of bacterial vaginosis in that many of the organisms that are associated with this syndrome are non-cultivable, or else difficult to culture. And so, there is no way, right now, for clinicians in their standard diagnostic methods to be able to look at some of these newer organisms. There's been a lot of research the last 10 to 15 years using some molecular sequencing to show that some of these unusual organisms are associated with bacterial vaginosis. So, this assay has the ability to, for BV, to do two things. We know that there are certain lactobacilli that are associated with a healthy vagina. And so this assay actually looks for those two types of lactobacilli that are associated with a good, healthy vagina, and then it also looks, secondly, for the presence of some of these unusual organisms that are associated with having BV, or what we call an unhealthy vagina.

Dr. Birnholz:
Before we wrap up, are there any additional thoughts you want to share or reiterate for our audience?

Dr. Gaydos:
So, I'd like to emphasize a little bit about the population that was studied. It was a very wide, broad look at women across the United States. There were 10 clinical centers and then there were three centers that actually tested samples from these 10 centers and actually ran the new diagnostic platform. So, the IRB was approved for all of these centers and then consent from each woman was also provided. So, there were about, the demographics included 686 women, and about 70% of these were either from the eastern or the south central U.S., but basically all areas of the country were covered. And about 66% are from family planning clinics. Others were STD clinics, family and other types of general practice clinics. The most common age group, even though it went from 18 to above 40, was the 18 to 29-year-old age group and this composed 63% of the population. As far as race, 53% of the population

were black, and about 25% were white, with the difference from the other races. About 75, 74% of these women had a vaginal discharge and they either had itching, burning, or irritation in the other 71%. So these were symptomatic women and often there was more than one symptom that was present.

I would like to discuss some of the results of the investigational tests. For BV, the sensitivity was about 90.5%. For the Candida group, the common variety Candida, was 90.9%. For glabrata it was 75%. There were very few of these that were determined in this study. And there were actually no krusei, no Candida krusei, that were found. The Trichomonas assay was about 93% sensitive.

I would like to also indicate some of the results of the single and the co-infections. So, actually, in all of these 1471 women who had complete information for either the reference tests and the new diagnostic test, there were 36% that had BV only. But then, there were 24% who had no pathogen or no syndrome diagnosed. In other words, they didn't have Trichomonas, they didn't have Candida, and they didn't have BV, which leads us to think that probably there are some other causes of symptoms of vaginitis that we don't even know about yet. The Candida group, there were about 16% that had just the Candida group organisms. And then, there were lots of co-infections, and interestingly, the most common co-infection was between BV and the Candida group, and 14% of the population had this. There were only a few that had BV, Candida group, and Trichomonas; only actually 21 people, not very many. And there were very few that had only Trichomonas. There were only 23 people, or like about 1%, that had Trichomonas only. So, we'd like to say that overall there is an improvement in the diagnostic accuracy in that looking at the different Candida species, looking at the different unusual organisms that can't be grown that cause BV, and also being able to call-out which of the Candida organisms that are more resistant to therapy, provide an increase, I think, in the diagnostic accuracy of this molecular assay.

Dr. Birnholz:
Well, with that, I want to thank Dr. Gaydos for joining me today to talk about Diagnostic and Treatment Updates for Vaginitis and Vaginosis, and the newly emerging assay for detecting this condition. Dr. Gaydos, it was great having you on the program.

Dr. Gaydos:
Thank you very much. I enjoyed speaking with you.

Narrator:
The preceding program was brought to you by BD: Advancing the world of health. Thank you for watching. This is ReachMD, be part of the knowledge.