New study shows substandard approaches to diagnosis and treatment for Vaginal Discharge Syndromes

Four of every ten women received inappropriate treatment

FRANKLIN LAKES, N.J., October 6, 2020 – BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, announced the publication of an investigator-initiated study funded by BD Life Sciences - Integrated Diagnostics Solutions in the journal, *Clinical Infectious Diseases (CID)*. The study was performed to assess how effectively women with vaginal discharge syndromes or vaginitis were being evaluated in community practice settings and to determine the appropriateness of the treatments prescribed for vaginitis.

Although vaginitis is a common condition, diagnosis of its usual causes[1,2] (bacterial vaginosis [BV], vulvovaginal candidiasis [VVC], or *Trichomonas vaginalis* [TV]) in women of reproductive age is not standardized. Approximately 75% of women will experience at least one episode of vaginitis that requires treatment during their lifetime[3].

Approximately 300 women in this study, presenting with vaginitis-consistent symptoms, were evaluated at community-based practices and had reference lab testing performed (reference lab testing was considered clinical "truth" for diagnostic purposes in this study). Based on the results from the reference lab testing, 47% of the 170 women with vaginitis received inappropriate treatment following their office-based visit. Overall, 40% of the 300 female participants were prescribed antifungals and/or antibiotics inappropriately.

Empiric treatment—a therapeutic approach based on clinical judgement with incomplete information on the patient's condition—is often considered harmless for a patient with these types of symptoms. However, this study found that one out of every five women that received a prescription based on clinical findings from their office visit, but did not have a reference lab-confirmed diagnosis of vaginitis, returned for repeat symptoms of vaginitis in the subsequent 90 days. The study concluded that diagnostic accuracy and appropriateness of treatment at community-based practices for women with symptoms of vaginitis could be improved.

Despite a broad knowledge of the conditions associated with vaginitis, clinical diagnosis remains a significant challenge, with many clinicians believing that vaginal infections can be diagnosed by patient history and symptoms alone[4]. As a result, research has shown that up to 40% of women are estimated to leave their initial physician visit without a proper vaginitis diagnosis[5].

"This study documents how infrequently CDC-recommended point of care testing such as assessment of vaginal pH, microscopic examination of vaginal fluid, or the "whiff" test are performed when women present with vaginal symptoms in primary women's health care settings," said Dr. Sharon Hillier of the University of Pittsburgh and Magee-Women's Research Institute and corresponding author of the study.

In a CID editorial commentary, Dr. Jack D. Sobel of Wayne State University School of Medicine, cites the recent publication as "a call to action" against the syndromic treatment of women with vulvovaginal symptoms in the United States[6]. The commentary pleads with the healthcare community to seek the correct diagnoses and avoid empiricism as it pertains addressing women presenting with vulvovaginal complaints, which were common in community practice.

"Women who seek care and treatment for vaginitis symptoms deserve the best care possible and that ultimately begins with improved diagnostic accuracy," concluded Molly Broache, BSN, MSN, WHNP, Medical Science Liaison with BD. "Overall, the research suggests that the current diagnostic approach for management of vaginal discharge syndromes provides insufficient care for a substantial proportion of women."

For independently-developed continuing medical education (CME) activities pertaining to this topic, please visit www.omniaeducation.com.

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The BD MAX Vaginal Panel was market authorized as an *in vitro* diagnostic in October 2016 and it is utilized on the BD MAX System. The assay detects microorganisms responsible for Bacterial Vaginosis (BV), Trichomoniasis (TV) and Vulvovaginal Candidiasis (VVC), also known as a yeast infection, which are the most common infectious causes of vaginitis.[1,2,3] The in vitro diagnostic (IVD) assay is the first multiplex, real-time polymerase chain reaction (PCR) assay authorized by FDA for the detection of microorganisms responsible for both vaginitis and vaginosis in women that exhibit symptoms of vaginal infections. BV diagnosis is challenging, as it is caused by bacterial imbalances in the vagina. To address this challenge, the BD MAX Vaginal Panel has a unique algorithm that determines the ratio of healthy versus unhealthy bacteria, improving BV diagnosis.

About the BD MAX™ System

The BD MAX System is a fully integrated, automated platform that performs nucleic acid extraction and real-time polymerase chain reaction (PCR), providing results for up to 24 samples across multiple syndromes in approximately three hours. The BD MAX System offers laboratories *in vitro* diagnostic assays that span women’s health and sexually transmitted infections, enteric infections, and healthcare-associated infections, along with an open-system capability and reagents.

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