

LEARNING OBJECTIVES: Learners will be able to characterize the effectiveness of CMV HIG at prevention of congenital CMV infection among women with primary CMV in early pregnancy

13 Real-world outcomes associated with nucleic acid amplified versus direct DNA probe testing for vaginitis

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OBJECTIVES: To address the ongoing discussion related to the costs of diagnosing vaginitis the study compared the impact of diagnoses using nucleic acid amplified testing (NAAT) with direct DNA probe (DP). Real-world outcomes using commercial medical claims data compared the diagnostic and therapeutic costs among vaginitis patients between a general population of women and women with diabetes.

METHODS: The IBM Watson Health MarketScan® Commercial database was used to identify women aged 18 to 64 years with evidence of a new diagnosis of vaginitis that occurred between 2012 and 2017. Patients were stratified by type of testing used to determine the vaginitis diagnosis. All-cause healthcare expenditures were measured during 6-month and 12-month follow-up periods. Outcomes were described by testing cohort (NAAT, DP) and patient type: general and diabetic (Type I, II).

RESULTS: In total, 207,113 women with commercial insurance met the inclusion and exclusion criteria (NAAT cohort, N=108,559; DP cohort, N = 98,554) a sub-cohort of 12,522 women with diabetes (NAAT cohort, N=6,463; DP cohort, N = 6,059) was analyzed separately. Overall healthcare costs among all patients were higher in the DP cohort in the 6-month follow-up period (\$5,042 DP vs \$4,872 NAAT, p=.0025) and 12-month follow-up period (\$9,366 DP vs \$8,938 NAAT, p<.0001). In the cohort of women with diabetes, the NAAT group trended lower in both the 6 months (\$9,344 DP vs \$8,972 NAAT) and in the 12 months following the diagnosis (\$17,715 vs \$17,083 NAAT) although not statistically significant.

CONCLUSION: NAAT testing for vaginitis reduces healthcare costs compared to DP in the general population. While managing vaginitis among women with diabetes presents challenges for the clinician, more information will be helpful to understand how a NAAT test may provide improved outcomes and impact patient management decisions.

LEARNING OBJECTIVES: Learners will be able to describe the healthcare resource utilization and costs of vaginitis diagnosis associated with use of NAAT and DP tests.

14 Characterizing the vaginal microbiome in women with recurrent bacterial vaginosis and treatment implications

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OBJECTIVES: We aimed to characterize the vaginal microbiome in women with recurrent bacterial vaginosis (BV) compared to women without infection, and to describe the effect of oral metronidazole treatment on the microbiome of recurrent BV.

METHODS: Women aged 18-40 years, with recurrent BV, were prospectively enrolled. Vaginal samples (lavage) were collected at baseline (D0), at 7-10 days (D7) and 30-40 days (D30) after initiation of oral metronidazole treatment (500mg BID, 7 days). DNA was extracted, amplified using primers targeting the V3-V4 region of the

16srRNA, and then sequenced and processed through a hybrid Qiime MICCA bioinformatics pipeline.

RESULTS: Sixty-three participants, 17 recurrent BV patients and 46 controls, were enrolled. Beta diversity (p=0.045), but not alpha diversity (p=0.076) differed significantly between recurrent BV and control groups. The genera *Gardnerella* and *Prevotella* were relatively more abundant, while *Lactobacillus* was relatively less abundant in recurrent BV vs. control groups. Alpha diversity decreased (p=0.0049) after treatment with oral metronidazole, but increased (p=0.0062) to near baseline by D30. Metronidazole treatment resulted in an increase in *Lactobacillus* and decrease in *Gardnerella* that was not maintained after 30 days. Of the 10 recurrent BV patients with data for all three time points, 4 relapsed by D30. Beta diversity (p=0.044), but not alpha-diversity (p=0.07), differed significantly between patients that relapsed and those that did not.

CONCLUSION: Recurrent BV patients have significantly different beta diversity, less *Lactobacillus* and more *Gardnerella* and *Prevotella*, when compared to control patients. Oral metronidazole is associated with a decrease in alpha diversity, increased levels of *Lactobacillus* and decreased amounts of *Gardnerella*.

LEARNING OBJECTIVES: Learners will be able to describe (1) the composition of the vaginal microbiome in women with recurrent BV and how it differs from that of controls (2) how the vaginal microbiome of women with recurrent BV changes with metronidazole treatment.

15 Diagnostic accuracy of clinical criteria for bacterial vaginosis, vulvovaginal candidiasis and BV/VVC co-infections

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OBJECTIVES: Approximately 8-18% of women having vaginal symptoms have been reported to have concurrent BV and VVC. The objective of this study was to assess the agreement between laboratory and clinical diagnosis of BV alone, VVC alone and BV/VVC co-infections when standardized criteria were employed in the context of a clinical treatment trial.

METHODS: Between 6/5/15 and 5/31/18, 1315 women were screened for a clinical trial evaluating treatment of vaginal infections at 51 sites in the US. Clinical diagnosis of BV was based on four Amsel criteria (discharge, vaginal pH >4.5, positive whiff test, ≥ 20% clue cells). Diagnosis of VVC was based on composite signs and symptoms score ≥2 (itching, burning, irritation, edema, erythema, excoriation) plus hyphae/pseudohyphae or yeast buds in vaginal fluid. Women having clinically documented co-BV/VVC had to meet the criteria for both conditions. Vaginal smears for diagnosis of BV using the Nugent criteria and vaginal swab samples were shipped overnight to a centralized laboratory for cultivation of yeast on Sabouraud's agar. A total of 891 women were randomized to treatment; Gram stains, vaginal yeast cultures or both were missing for 19 women leaving an evaluable population of 872 women..

RESULTS: The study population had a median age of 29 (range 17-66) and was 33.7% white, 62.7% black and 3.6% other self-reported race. Of the 194 women diagnosed with BV alone, 156 (80%) had a Nugent score ≥7, but 42 (22%) also had yeast detected by culture, with 33 (20%) women having both BV and yeast based on lab testing. Among 207 women diagnosed with VVC alone, only 147 (71%) had a positive yeast culture and 34 (16%) had a Nugent score ≥7. Based on lab testing, both BV and yeast were present in 29