(14%) of women diagnosed as having VVC alone. Of the 471 women diagnosed as having co-BV/VVC based on clinical criteria, only 191 (41%) had culture confirmation of yeast plus a Nugent score of ≥7. Of the remaining women, 105 (22%) had BV alone, 126 (27%) had yeast alone, and 49 (10%) had neither BV nor yeast. Intermediate Nugent scores of 4-6 were noted in 109 (23%) of women diagnosed with co-BV/VVC.

CONCLUSION: In this large multicenter study employing standard clinical diagnostic algorithms for BV, VVC, and co-BV/VVC, possible mixed infection occurred in 14-20% of women diagnosed as having a single condition, while clinical diagnosis of co-BV/VVC was lab confirmed in fewer than half. Reliance on clinical criteria for diagnosis of BV and/or VVC can lead to misdiagnosis.

LEARNING OBJECTIVES: Describe the limitations of clinical criteria for diagnosis of bacterial vaginosis and vulvovaginal candidiasis, especially when present as co-infections.

16 Elevated risk of bacterial vaginosis among copper intrauterine device users: a prospective cohort analysis

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OBJECTIVES: To evaluate the association between copper IUD (Cu-IUD) use and bacterial vaginosis (BV) incidence among women enrolled in the MTN-020/ASPIRE trial.

METHODS: This secondary analysis includes 2,614 HIV-negative women ages 18-45 from Malawi, South Africa, Uganda and Zimbabwe. Women reported use of Cu-IUD, injectable contraceptives (DMPA, NET-EN), oral contraceptives (OC), implants containing etonogestrel or levonorgestrel, or none/other non-hormonal contraception at monthly visits. BV was evaluated by Nugent score at 6-monthly intervals. We used Andersen-Gill proportional hazards models to evaluate the association between contraceptive method and BV. Among new Cu-IUD users, we used generalized estimating equations to test changes in incidence following initiation and subsequent discontinuation of Cu-IUD. All models were adjusted for potential confounders, including number of sexual partners, condom use, partner circumcision status, intravaginal practices, and study site.

RESULTS: Throughout follow-up, DMPA was the most commonly used contraceptive (47%), followed by implant (32%), Cu-IUD (24%), OC (21%), NET-EN (19%), and none/other non-hormonal contraception (15%). Relative to women using none/other non-hormonal contraception, women using Cu-IUD had higher BV incidence (138 cases per 100 person-years [95% CI: 130, 147] vs. 112 [95% CI: 98, 127]; HR: 1.27, 95% CI: 1.10, 1.46). Results were similar when comparing BV incidence among Cu-IUD users to OC and implant users. Among 304 women who initiated Cu-IUD during follow-up, BV incidence increased nearly two-fold in the 6 months following initiation relative to the 6 months prior to initiation (RR: 1.91, 95% CI: 1.46, 2.50). Seventy-four (24%) women subsequently discontinued Cu-IUD use; BV incidence remained elevated in the 6 months following discontinuation (RR: 1.58, 95% CI: 1.10, 2.27), then was similar to pre-initiation rates within one year (RR: 1.13, 95% CI: 0.71, 1.81).

CONCLUSION: These data add to the growing body of evidence that Cu-IUD users have an elevated risk of BV, and further suggests that Cu-IUD discontinuation is associated with decreased risk within a year. Women and their providers may wish to consider BV risk when discussing contraceptive options. Future research should investigate the mechanism(s) by which Cu-IUD use increases BV risk, as well as a potential mediating role of BV in increasing HIV risk among Cu-IUD users in settings with high HIV incidence.

LEARNING OBJECTIVES: Learners will be able to describe the association between Cu-IUD use and incident bacterial vaginosis.

17 Results of a phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of astodrimer gel for prevention of recurrent bacterial vaginosis

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OBJECTIVES: To determine the efficacy and safety of Astodrimer Gel in reducing recurrent BV in women with a history of recurrent BV.

METHODS: A total of 864 women aged 18-45 were enrolled at 67 centers in the US, Canada, Mexico and Puerto Rico. The target population was women with a history of recurrent BV (episodes in the past year), and a current diagnosis of BV by 3/4 Amsel criteria and Nugent score (NS) 4. Women received a 7-day course of oral metronidazole (500mg BID) for their BV. Subjects successfully treated (no symptoms, Amsel criteria for discharge, whiff test and clue cells all negative) were randomized 1:1 to receive 5g of Astodrimer 1% Gel (N=295) or placebo (N=291), vaginally, QOD for 16 weeks. Women were evaluated every 4 weeks for BV recurrence. Those who remained recurrence-free through 16 weeks were followed for up to 12-weeks off-therapy. The primary efficacy endpoint was BV recurrence, defined as 3 Amsel criteria, at or by Week 16 in the mITT population. Secondary analyses included time to recurrence, and recurrence of symptoms, individual Amsel criteria and NS 7-10.

RESULTS: Astodrimer Gel was superior to placebo for the primary and most secondary efficacy measures. BV recurrence rate at or by Week 16 was 44.2% (130/294) vs 54.3% (158/291); P=.015. The time to BV recurrence, as assessed by difference in survival curves, was significantly longer for Astodrimer Gel vs placebo; P=.007. Recurrence of BV symptoms (vaginal odor and/or discharge) at or by Week 16 was less frequent in the Astodrimer group (27.9%; P=.002) vs placebo (40.6%). The rate of recurrence of individual Amsel criteria, except pH, was also lower in the Astodrimer group. The recurrence of BV defined as NS 7-10 or by composite of NS

7-10 and Amsel criteria was also significantly lower for Astodrimer Gel vs placebo. Efficacy results during follow-up were in line with those for the 16-week treatment phase. Incidence of AEs was similar between groups. During treatment, potentially related AEs occurred in 12.2% (Astodrimer) vs 11% (placebo) (genitourinary AEs: 11.6% vs 10%). The rate of candidiasis was 14.6% for Astodrimer vs 8.9% for placebo during treatment, and 4.1% vs 5.8% in follow-up.

CONCLUSION: This study demonstrated Astodrimer 1% Gel is safe and effective for prevention of recurrent BV, a condition for which there is no approved therapy in the US. There was low potential for development of vulvovaginal candidiasis, which is a very common side effect of antibiotic therapies.

LEARNING OBJECTIVES: Learners will be informed that Astodrimer Gel has potential as a safe and effective novel, non antibiotic therapy for reducing recurrent BV, being associated with very low rates of vulvovaginal candidiasis, and thereby constituting an alternative to off-label therapeutic strategies based on conventional antibiotics.

18 A phase 2b, dose-selection study evaluating the efficacy and safety of oral ibrexafungerp vs fluconazole in vulvovaginal candidiasis (DOVE)

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OBJECTIVES: Ibrexafungerp (formerly SCY-078) is a novel IV/oral antifungal currently in development for the treatment of invasive and mucocutaneous fungal infections. Ibrexafungerp has broad activity against Candida spp., including azole-resistant strains. A phase 2b, dose-finding study was conducted to evaluate the safety and efficacy of oral ibrexafungerp in subjects with moderate to severe vulvovaginal candidiasis (VVC). We present the results of this phase 2b study here with focus on clinical response at Day-25 (secondary endpoint). Currently, oral ibrexafungerp is being tested in 2 pivotal phase 3 studies for patients with acute VVC.

METHODS: Randomized, double-blind, double-dummy study including 5 oral ibrexafungerp treatment groups (750mg-QD 1 day, 300mg-BID 1 day, 450mg-BID 1 day, 150mg-BID for 3 days, and 300-BID for 3 days) and an active comparator (oral fluconazole [FLU] 150mg single dose). Subjects were evaluated at Day-10 and Day-25 for clinical cure and mycological eradication.

RESULTS: 153 subjects with culture-confirmed VVC composed the primary population for analysis (mITT). The ibrexafungerp dose of 300mg BID for 1 day (600mg-dose) showed the best combination of clinical efficacy and tolerability. At Day-10, clinical cure, defined as complete resolution of all signs and symptoms (S&S), was observed in 14 of 27 (52%) subjects in the 600mg-dose arm and 14 of 24 (58%) subjects in the FLU arm. At Day-25, the clinical cure rate in the ibrexafungerp 600mg-dose arm increased to 70% vs. a decrease to 50% in the FLU arm. At Day-25 none of the subjects receiving the 600mg-dose had S&S >3 in contrast with 30% of subjects in the FLU group reporting S&S >3 and 17% reporting S&S ≥ 7. The most common AEs were mild nausea and diarrhea.

CONCLUSION: These results support the selection of ibrexafungerp 600mg-dose for Phase 3 registration studies in VVC and provide additional information on the efficacy and safety of ibrexafungerp in patients with VVC.

LEARNING OBJECTIVES: Learners will be able to evaluate the efficacy and safety of ibrexafungerp, a novel triterpenoid antifungal, in the treatment of vulvovaginal candidiasis as compared to standard of care, fluconazole. At the end of the presentation the learner will be aware of the potential of ibrexafungerp to treat VVC and the dose selected in this phase 2b study.

19 Physiologic parameters and sepsis bundle initiation among third trimester gravidas with influenza-like illness, 2017-2018 influenza season

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OBJECTIVES: To characterize maternal vital signs of third trimester gravidas with influenza-like illness during the 2017-2018 flu season in the context of a hospital-wide sepsis bundle initiative, triggered by any 2 abnormal vital signs defined as: temperature $<36°C$ or $>38°C$, heart rate >90/min, systolic blood pressure <90mmHg, and respiratory rate>20/min.

METHODS: This was a retrospective cohort study of third-trimester women presenting with influenza-like symptoms during the 2017-2018 influenza season, who subsequently delivered at our hospital. Influenza-like illness was defined as respiratory symptoms for which a provider ordered a rapid flu test. Women testing positive for RSV, diagnosed with pyelonephritis, and those admitted for non-influenza related indications were excluded. We compared minimum and maximum vital signs recorded within the first 4 hours of presentation among third trimester gravidas with positive versus negative rapid influenza tests. For women in the outpatient setting, missing values were assumed to be within normal parameters for categorical analysis. We compared odds of flu+ versus flu- gravidas qualifying for sepsis bundle initiation based on 2 vital signs outside specified parameters.

RESULTS: A total of 423 women were evaluated for influenza-like illness in the third trimester between September 1, 2017 and March 31, 2018. Of these, 85 (20%) were excluded. Of the remaining 338, 136(40%) tested positive for influenza A or B, and 202(60%) tested negative. Median gestational age at presentation was 34.7 ± 4 weeks for flu+ and 34.9 ± 4 weeks for flu- women ($p=0.63$). Compared with flu - women, flu+ women had higher maximum temperature (37.6 ± 0.7 vs 37.1 ± 0.6 °C, $p<0.001$) and heart rate (115 [100,125] vs 99 [88,112] beats/min,$p<0.001$) within 4 hours of initial presentation. In categorical analysis, flu+ women were 3.86 times more likely than flu- women to have fever $>38°C$ within 4 hours of presentation. Flu+ women had 4.00 higher odds (95%CI 2.17, 7.38) of maximum heart rate >90 beats per minute compared with flu- women. Sixty five percent of flu+ and 18% of flu- women met vital signs criteria for sepsis bundle initiation; flu+ women in the third trimester were 8.73 times more likely to meet criteria than flu- women (95% CI 5.27, 14.46). Despite this, only 2(1%) flu+ and 0 flu- women required ICU admission. Overall, one fifth of women delivered within 2 days of evaluation.

CONCLUSION: Flu+ women in the third trimester of pregnancy are more likely to present with fever and elevated heart rate than flu- women. Women with influenza-like illness in the third trimester of pregnancy frequently have vital signs meeting hospital criteria for initiation of sepsis bundle initiatives. Despite this, ICU admission is rare.

LEARNING OBJECTIVES: Learners will be able to characterize maternal vital signs of third trimester gravidas with influenza-like illness and recognize limitations of vital signs criteria for sepsis bundle initiation when applied to third trimester gravidas.