and associations with Amsel criteria may vary between populations. We assessed relationships between vaginal bacteria and Amsel criteria among two distinct cohorts.

Methods Kenyan participants from the placebo arm of the Preventing Vaginal Infections (PVI) trial and participants from a Seattle-based cross-sectional BV study were included. At PVI trial enrollment and bi-monthly follow-up visits and the Seattle study visit, Amsel criteria were recorded, and the vaginal microbiota was characterized using 16S rRNA gene sequencing. For each cohort, logistic regression models were fit to evaluate associations between vaginal bacterial relative abundance and each Amsel criterion (PVI cohort models used generalized estimating equations).

Results Among 84 PVI participants (contributing 496 observations), the prevalence of amine odor was 25%, clue cells 16%, vaginal discharge 10%, elevated vaginal pH 69%, and BV 13%. Among 220 Seattle participants, the prevalence of amine odor was 40%, clue cells 37%, vaginal discharge 52%, elevated vaginal pH 67%, and BV 44%. BV-associated bacterium 1 (BVAB1) was positively associated with each Amsel criterion in both cohorts. *Atopobium vaginae*, *Eggerthella* type 1, *Gardnerella*, *Sneathia amnii*, and *Sneathia sanguinegens* were positively associated with each criterion in the Seattle cohort, and all but discharge in the PVI cohort. *Prevotella amnii* was positively associated with each criterion except discharge in the PVI cohort. *Megasphaera* type 1 and *Prevotella timonensis* were positively associated with each criterion in the Seattle cohort. *Lactobacilli* were negatively associated with individual criteria in both cohorts.

Conclusions A set of core vaginal bacteria were positively associated with Amsel criteria in both cohorts, suggesting their importance in the manifestation of BV signs and symptoms, regardless of population differences. These results may have implications for future BV treatment studies.

Bacterial vaginosis

003.1 BACTERIAL VAGINOSIS AND BEHAVIORAL FACTORS ASSOCIATED WITH INCIDENT PELVIC INFLAMMATORY DISEASE IN THE LONGITUDINAL STUDY OF VAGINAL FLORA

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Background Pelvic inflammatory disease (PID) leads to long-term reproductive consequences for cisgender women. Bacterial vaginosis (BV) and behavioral factors may play a role in PID pathogenesis. We assessed associations between BV, behavioral factors and incident PID in a large prospective cohort.

Methods We analyzed data (n=2,956) from the NIH Longitudinal Study of Vaginal Flora, a cohort of non-pregnant cisgender women followed quarterly for 12 months. PID was defined by at least one of the following: cervical motion

tenderness, uterine tenderness, or adnexal tenderness (160 cases). We tested associations between BV (measured using Nugent's and Amsel's criteria) and PID at the subsequent visit using Cox proportional hazards models. Baseline socio-demographic factors (age, race, highest education level, marital status, monthly household income), time-varying sexual behaviors (condom use frequency, number of sexual partners, sexual partner concurrence), vaginal douching, and Chlamydia trachomatis (CT), untreated at baseline and concurrent with BV, were covariates. Adjusting for the few *Neisseria gonorrhea* and *Trichomonas vaginalis* cases did not alter results.

Results The 2,956 participants contributed a total 2516.2 person-years, with a median 349 days per participant. In multi-variable modeling, Nugent-BV (aHR=1.53, 95% CI:1.05–2.21), symptomatic Amsel-BV (aHR=2.15, 95% CI:1.23–3.75) and vaginal douching (aHR=1.47, 95% CI:1.03–2.09) were associated with greater risk of incident PID. Other factors associated with incident PID included baseline untreated CT, douching, and being married.

Conclusions BV was associated with incident PID in a large prospective cohort, controlling for behavioral factors and sexually transmitted infections (STIs). Larger studies on how BV, STIs, behaviors, and host responses interactively affect PID risk are needed.

003.2 THE SHORT-TERM IMMUNE IMPACT OF BACTERIAL VAGINOSIS TREATMENT IS UNRELATED TO LACTOBACILLUS SPP. ABUNDANCE

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Background Bacterial vaginosis (BV) induces genital inflammation and enhances HIV acquisition risk, while vaginal *Lactobacillus* predominance is associated with mucosal immune quiescence and reduced HIV risk. BV treatment reduces vaginal proinflammatory cytokines, but it is unclear whether this is due to reductions in BV-associated anaerobes or an increase in *Lactobacillus* spp. We investigated the short-term impact of BV treatment on the vaginal immune milieu and microbiome.

Methods Study participants comprised 48 women with BV, all of whom were treated with intravaginal metronidazole for 5 days before enrollment into a clinical trial of the live biotherapeutic LACTIN-V to prevent BV recurrence. Vaginal swabs were collected at baseline and within 48 hours of completing metronidazole treatment, prior to study product administration. Soluble immune factors were assayed from vaginal swabs by multiplex ELISA, relative bacterial abundance was assessed

by metagenomic sequencing (NovaSeq), and absolute abundance of key bacterial species was assessed by qPCR.

Results Immediately following treatment, there was a marked drop in the vaginal level of proinflammatory cytokines (IL-1a, IL-6), chemokines (IL-8, MIP-1b, MIP-3a) and a marker of epithelial barrier disruption (sE-cad; all $p < 0.01$). The vaginal microbiome was generally shifted from BV to community state types (CSTs) dominated by *L. iners* (49%) or *L. jensenii* (31%). However, these CST shifts were driven by a dramatic (7–12-fold) reduction in the absolute abundance of BV-associated Gram negative anaerobes (*Prevotella* spp., *Gardnerella vaginalis*, *Atopobium vaginae*, and *Megasphaera*; all $p < 0.001$), while there were minor or no increases in the absolute abundance of *L. jensenii* (2.9-fold increase, $p = 0.006$) or *L. iners* (0.6-fold reduction, $p = 0.245$).

Conclusions Standard BV therapy reduced inflammatory cytokines/chemokines and enhanced epithelial integrity in the short term. Despite a shift to CSTs dominated by lactobacilli, these immune changes were linked to reductions in the absolute abundance of BV-associated anaerobes rather than to increased *Lactobacillus* abundance.

003.3 INTRAVAGINAL LACTIC ACID GEL VERSUS ORAL METRONIDAZOLE FOR TREATING WOMEN WITH RECURRENT BACTERIAL VAGINOSIS: THE VITA RANDOMISED CONTROLLED TRIAL

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Background Bacterial vaginosis (BV) is a common, embarrassing and distressing condition, with serious comorbidities. The VITA trial assessed the effectiveness of intravaginal lactic acid gel versus oral metronidazole for treating recurrent BV.

Methods Open-label, multicentre, parallel group, randomised controlled trial. Women aged ≥ 16 years with history of BV within the past 2 years and current symptoms were recruited at one GP practice and 19 sexual health centres in the UK. Participants were randomised to 5ml intravaginal lactic acid gel or oral 400mg twice daily metronidazole tablets, for 7 days. The primary outcome was participant reported resolution of BV symptoms by the end of Week 2, with subsequent follow up over 6 months. Semi-structured interviews explored tolerability and acceptability of the study treatments.

Results 518 participants were randomised (259 to metronidazole, 259 to lactic acid gel). Primary outcome data were available for 204 (79%) participants allocated to metronidazole and 205 (79%) allocated to lactic acid gel. Resolution of BV at Week 2 occurred in 143 (70%) participants in the metronidazole arm versus 97 (47%) participants in the lactic acid gel arm (adjusted risk difference -23.2% (95% CI -32.3 to -14.0%). Symptom resolution with no subsequent recurrences over 6 months occurred in 23% of those who took metronidazole and 16% of those using lactic acid gel. Side effects were more common following metronidazole compared to lactic acid gel. Interviews revealed that many women preferred lactic acid gel despite perceiving antibiotics to be more effective.

Conclusion Metronidazole is more effective than lactic acid gel in achieving short term resolution of BV symptoms but recurrence is common following both treatments. Lactic acid is associated with fewer reported side effects and is preferred by many women despite its lower efficacy.

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Trial Registration ISRCTN14161293

003.4 THE VAGINAL MICROBIOME AND DEVELOPMENT OF PELVIC INFLAMMATORY DISEASE: A PROSPECTIVE STUDY USING 16S RRNA LONG-READ SEQUENCING

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Background A low diversity vaginal microbiome dominated by *Lactobacilli*, may be associated with lower risk of pelvic inflammatory disease (PID). However, disruption to this balance through an increase in diversity, particularly dominated by *Gardnerella vaginalis*, may lead to increased susceptibility. Not all *Lactobacilli* are equally protective, species that produce higher proportions of D(-) isomer lactic acid (*L. crispatus*, *L. jensenii*, and *L. gasseri*) have proven protection against *Chlamydia trachomatis* (CT) infection, an important cause of PID, however *Lactobacillus iners*, which produces predominantly L (+) isomer lactic acid, may be less protective. We investigated the relationship between 'baseline' microbiome and the subsequent risk of acquiring PID, using stored vaginal samples from participants in the Prevention of Pelvic Infection chlamydia screening trials.

Methods 16S rRNA long-read nanopore sequencing was carried out on vaginal samples from 37 women who subsequently developed clinically defined PID during 12 months of follow-up, and 111 frequency-matched controls who did not. Samples were matched on age, ethnicity, CT status at baseline and number of sexual partners.

Results Three main taxonomic clusters were identified which were dominated by *L. iners*, *L. crispatus*, and *G. vaginalis*. Microbiomes dominated by *G. vaginalis* were associated with black ethnicity ($p = 0.002$), age ≥ 20 ($p = 0.048$) and bacterial vaginosis ($p < 0.0001$), but not with subsequent development of PID or CT infection at baseline. Lower rates of D(-) isomer lactic acid producing *Lactobacilli* were not associated with PID ($p = 0.53$) or concurrent CT ($p = 0.38$) infection, but were associated with bacterial vaginosis, as expected ($p < 0.0001$).

Conclusion We found no association between baseline vaginal microbiome composition and subsequent development of PID, nor between quantities of D(-) isomer lactic acid producing *Lactobacilli* and concurrent CT infection.

003.5 PID TREATMENT AND MYCOPLASMA GENITALIUM (MG): THE IMPACT OF VAGINAL DYSBIOSIS

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