women were invited to continue follow-up in an open cohort study. These post-trial data were analysed to test the hypothesis that the treatment effect would persist in the absence of PPT.

Methods Data were obtained from women who completed all 12 RCT visits and attended ≥1 cohort study visit within 120 days of their final RCT visit. We used Andersen-Gill proportional hazards models to estimate the post-trial effect of the intervention vs placebo on the incidence of BV by Gram stain (Nugent score ≥7) and Lactobacillus species by culture on Rogosa agar.

Results The RCT enrolled 310 subjects (155 per arm), of whom 165 (83 active and 82 placebo) were included in this analysis. Included subjects were slightly older (median (IQR): 33 years (29–39) vs 30 years (26–35); p<0.001) and reported a longer duration of sex work (median (IQR): 6 years (2–11) vs 3 years (1–6); p<0.001) compared to those excluded. At the final RCT visit, which represented the baseline visit for this analysis, demographic and behavioural characteristics were similar by arm. The prevalence of BV at the final RCT visit was 16% in the active arm and 43% in the placebo arm (p<0.001). The post-trial incidence of BV was 260/100 person-years (p-yrs) in the active arm vs 358/100 p-yrs in the placebo arm (HR=0.76; 95% CI: 0.51% to 1.12%). The prevalence of Lactobacillus colonisation at the final RCT visit was 17% in the active arm and 18% in the placebo arm (p=0.81). The post-trial incidence of Lactobacillus colonisation was 180/100 p-yrs in the active arm vs 127/100 p-yrs in the placebo arm (HR=1.42; 95% CI: 0.85% to 2.71%).

Conclusions Despite a decrease in BV and an increase in Lactobacillus colonisation during the RCT, the effect of PPT was not sustained during the 120 days following cessation of the intervention. New interventions that reduce BV recurrence and promote long-term Lactobacillus colonisation without the need for ongoing PPT or suppressive therapy are needed.

O3-S5.05 RPR TITRE VARIATION FOLLOWING EARLY SYPHILIS THERAPY: A POTENTIAL CONFOUNDER OF TREATMENT OUTCOME ASSESSMENT

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[1]K Holman, [2]M Wolff, [3]A Seña, [4]D Martin, [3]F Behets, [5]K Van Damme, [3]P Leone, [6]L McNeil, [2]J Winestone, [1]E Hook III. *[1]University of Alabama at Birmingham, Birmingham, USA; [2]Emmes Corporation, Rockville, USA; [3]University of North Carolina at Chapel Hill, Chapel Hill, USA; [4]Louisiana State University, Baton Rouge, USA; [5]University of North Carolina at Madagascar, Madagascar; [6]Family Health International Research, USA*

Objective Serologic tests for syphilis (STS) results at the time of diagnosis are the basis for evaluating response to syphilis therapy. Following treatment, however, STS titres may continue to increase for several weeks. In a recent study comparing azithromycin to penicillin or doxycycline for early syphilis treatment, patients had RPR titres measured initially, at 7 and at 14 days following treatment. We evaluated variation in RPR titres over the 14 days following therapy, hypothesising that RPR titre changes would vary with stage and initial titre.

Methods Prospectively identified HIV-seronegative participants at five North American and three Madagascar sites with primary, secondary or early latent syphilis were randomly assigned to penicillin, doxycycline (in the case of penicillin allergy) or azithromycin treatment. Blood for RPR analysis was drawn at days 0, 7, and 14 post-treatment. All RPR titres were determined simultaneously at a central laboratory. Analysis was done using SAS 9.2.

Results 465 patients had data available for at least 2 of 3 RPR measurements. Median RPR at diagnosis by stage was Primary 1:16, Secondary 1:64, Early Latent 1:32. Overall, 20% of patients showed a titre increase of at least one dilution in the 14 days following therapy. Of this group, 88.2% demonstrated an increase of 1 dilution, while 11.8% demonstrated an increase of ≥2 dilutions. The greatest proportion of titre increases following therapy was seen in patients with primary syphilis.

Conclusions Given the reliance upon changes in RPR titres for evaluating response to therapy, these changes in titre following therapy could affect whether a response is classified as treatment success/failure or serofast status. Further analyses will evaluate factors associated with increasing RPR titres following therapy, as well as the effect of these changes in titre on evaluation of response to therapy.

O3-S5.06 DOUBLE-BLIND RANDOMISED PLACEBO CONTROLLED TRIAL OF ORAL METRONIDAZOLE IN COMBINATION WITH EITHER VAGINAL CLINDAMYCIN OR AN OESTROGEN-CONTAINING VAGINAL PROBIOTIC FOR THE TREATMENT OF BACTERIAL VAGINOSIS

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[1]C Bradshaw, [2]M Pirotta, [2]J Hocking, [3]S Garland, [2]D de Guigand, [4]G Fehler, [2]A Morrow, [2]S Walker, [2]L Vodstrcil, [5]C Fairley. *[1]Melbourne Sexual Health Centre, University of Melbourne, Melbourne, Australia; [2]University of Melbourne, Australia; [3]Royal women's hospital, Australia; [4]Melbourne sexual health centre, Australia; [5]University of Melbourne, Melbourne sexual health centre, Australia*

Background To determine if addition of vaginal clindamycin or an oestrogen-containing vaginal probiotic, to current recommended therapy for bacterial vaginosis (BV), oral metronidazole for 7 days, reduces 6 month recurrence rates.

Methods Three arm randomised double-blind placebo controlled trial of 450 women (150 per arm): [MetPlac] oral metronidazole (7 days)/vaginal placebo (12 days), [MProb] oral metronidazole (7 days)/vaginal probiotic(12 days) and [MetClin] oral metronidazole (7 days)/vaginal clindamycin (1 g 2% nocte,7 days). Symptomatic 18–50-year-old females with BV on vaginal swab by the Nugent method were enrolled at Melbourne Sexual Health Centre, Australia. Participants underwent initial examination & STI screen and completed a detailed behavioural questionnaire at 0, 1, 2, 3 & 6 months. At each interval participants were posted a kit containing swabs and a slide for self-collection and a questionnaire. Principle study outcome: Nugent score of 7–10. Cumulative BV recurrence rates were calculated and compared using χ^2 and survival analyses using SPSS and STATA.

Results 450 women with BV were recruited from December 2007 to May 2010. Median age was 27 years (range 18–49), 210 (48%) reported a past history of BV; there were no significant differences in

Abstract O3-S5.05 Table 1

Stage	N	Median RPR at diagnosis	% With increased titres within 14 days following treatment (95% CI)	% With titres increased by one dilution following therapy (95% CI)	% With titres increased by ≥2 dilutions following therapy (95% CI)
Primary	115	1:16	30.4 (22.2 to 39.7)	80.0 (63.1 to 91.6)	20.0 (8.4 to 36.9)
Secondary	218	1:64	17.0 (12.2 to 22.6)	97.3 (85.8 to 99.9)	2.70 (0.1 to 14.2)
Early latent	132	1:32	15.9 (10.1 to 23.3)	85.7 (63.7 to 97.0)	14.3 (3.0 to 36.3)
Total	465	1:64	20.0 (16.5 to 23.9)	88.2 (79.8 to 93.9)	11.8 (6.1 to 20.2)