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

doi:10.1136/sextrans-2011-050109.131

[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

doi:10.1136/sextrans-2011-050109.132

[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.

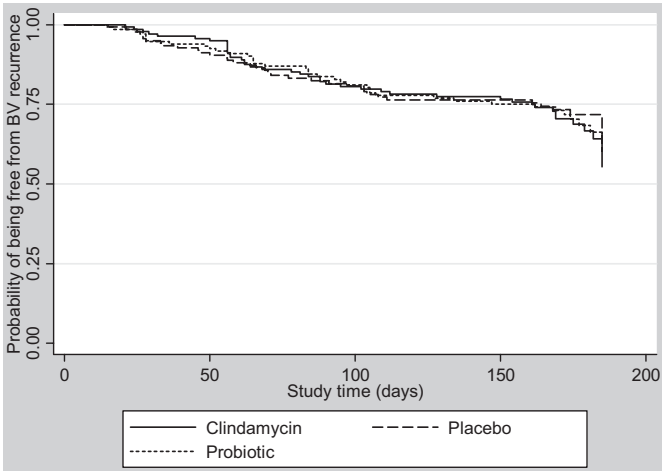
Methods Three arm randomised double-blind placebo controlled trial of 450 women (150 per arm): [MetPlac] oral metronidazole (7 days)/vaginal placebo (12 days), [MProb] oral metronidazole (7 days)/vaginal probiotic(12 days) and [MetClin] oral metronidazole (7 days)/vaginal clindamycin (1 g 2% nocte,7 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)

participant demographic or behavioural characteristics between arms. Adherence to study medication did not differ between arms: 382 (91%) took all or most oral metronidazole and 330 (80%) all or most vaginal therapy. Retention rates were high, with 77 (17%) lost to follow-up over 6 months, and did not differ between arms. Participants contributed 153.7 person years of follow-up to analyses. On exit survey 88% of participants did not know or correctly guess the vaginal therapy they had received. Six month cumulative BV recurrence rates did not differ between study arms by per protocol analysis: MetPlac (32%, 95% CI 24% to 41%) MetProb (33%, 25% to 42%) and MetClin (34%, 26% to 42%), p>0.05 (Abstract O3-S5.06 figure 1), or intention-to-treat analysis (noncompleter=recurrence) [recurrence range 44-9%].



Abstract O3-S5.06 Figure 1

Conclusions The addition of vaginal clindamycin or a vaginal probiotic to oral metronidazole does not improve 6 month BV recurrence rates. This is the first RCT to evaluate the efficacy of combination clindamycin/metronidazole for BV treatment, and has important implications for clinical practice. Combination therapy is often used in patients with recurrent BV, but evidence to support this practice has not been available.

Clinical sciences oral session 6—clinical advances in diagnosis & screening

O3-S6.01 IMPROVED DIAGNOSTICS OF BACTERIAL VAGINOSIS WITH MOLECULAR TECHNIQUES

doi:10.1136/sextrans-2011-050109.133

[1]A Speksnijder, [2]P Gruteke, [1]D Jonker, [1]H de Vries, [1]A van Dam. *[1]Health Service Amsterdam, Amsterdam, Netherlands; [2]Onze Lieve Vrouwe Gasthuis General Hospital, Amsterdam, Netherlands*

Background *Bacterial vaginosis* (BV) is a disturbance of the vaginal microflora. BV can cause discharge complaints and lead to pelvic inflammatory disease, ectopic pregnancy and premature birth. We evaluated a combination of PCR assay's and whole bacterial community analysis with the standard diagnostic algorithm to validate a molecular assay for the determination of BV.

Methods 160 women with vaginal discharge complaints were included. 80 women were classified as BV and 80 as non-BV according to Amsel criteria. Gram stains from vaginal smears were made for Nugent scoring. Vaginal swabs were tested with PCR assays for *Gardnerella vaginalis*, *Atopobium vaginae*, BV associated bacterium type 2 (BVAB2) and Megaspheara type 1 (MS1). Whole bacterial community analysis was performed by fluorescent Terminal Restriction Fragment Length polymorphism (TRFLP) of 16S-rDNA. TRFLP patterns and predictive fragments of a number of BV associated bacteria were analysed with Bionumerics software (Applied Maths, Belgium).

Results Compared to Amsel criteria, the highest sensitivity of 100% was achieved with a duplex PCR for G. vaginalis and/or *A vaginae* and the highest specificity of 86% was found with a singleplex BVAB2 specific PCR. Best overall performance was shown using a duplex real time PCR for BVAB2 and/or MS1 with a sensitivity of 90% and a specificity of 78% with respect to Amsel criteria. Using Nugent criteria as a standard, this duplex PCR has a sensitivity of 84% and specificity of 86%. From TRFLP results, the presence of predictive fragments of *Prevotella, Aerococcus, Megaspheara, Mycoplasma, Peptostreptococcus, Leptotrichia, Eggerthella, Gardnerella, Atopobium* and *Dialister* was most associated with BV positive samples. Cluster analysis of microbial profiles revealed clear differences between BV and non-BV and indicated possible intermediate or transition stages.

Conclusions A combination of bacterial species are involved in BV. For molecular diagnostics a duplex PCR of Gardnerella en/of Atopobium can be used for initial screening confirmed by a BVAB2 specific PCR. A more effective alternative is a real time duplex PCR targeting BVAB2 and/or MS1. Microbial profiling supports most targets used in the PCR assays. Cluster analysis of microbial profiles can be used to interpret discordant validation results and possibly for diagnosis.

O3-S6.02 SCREENING FOR *MYCOPLASMA GENITALIUM*, *CHLAMYDIA TRACHOMATIS* AND *BACTERIAL VAGINOSIS* IN A PUBLIC HOSPITAL, PREGNANCY TERMINATION SERVICE

doi:10.1136/sextrans-2011-050109.134

[1]S Garland, [2]A Marceglia, [2]S Tabrizi, [2]A Maria Costa. *[1]The Royal Women's Hospital, Melbourne, Australia; [2]Royal Women's Hospital, Melbourne, Australia*

Garland SM1, Marceglia AH2, Tabrizi SN1Costa AM1 1 Microbiology Infectious Diseases, 2 Choices and Sexual Health Service, Royal Women's Hospital, Parkville, Victoria, Australia The Royal Women's Hospital is the largest public provider of therapeutic abortions in Victoria, Australia. Prior to their medical or surgical termination, all women presenting to the Pregnancy Advisory Service (PAS) have been screened for *Mycoplasma genitalium* utilising an in-house PCR assay 1 in addition to *Chlamydia trachomatis* using a commercial PCR and bacterial vaginosis (BV) by Gram stained smear of posterior fornix secretions. From August 2009 to December 2010, the prevalence for *M genitalium* was 4.6% (CI 3.5% to 5.6%), *C trachomatis* 5.3% (CI 4.2% to 6.4%) and BV 16.2% (CI 14.4% to 18.0%). Most women had a normal genital tract on clinical examination. Of the women infected with *C trachomatis* and *M genitalium*, 42% and 34% respectively had abnormal genital tract signs. The average age of women attending the PAS clinic was 26.4 years, with 45.3% of the women being under 25. The average age for women with *M genitalium* was 24.6 years, whilst for those with *C trachomatis* it was 22.4 years. The 50 test of cures completed after treatment for *M genitalium* to date have all been negative. This is in contrast to local treatment failure rates in similar aged males (symptomatic with nonspecific urethritis in a sexual health clinic) and females (screening within a general practitioner setting) of 28% and a population treatment failure rate of 12%. We are uncertain what role our direct observed patient treatment plays in this low failure rate. This presentation will report on the first 17 months of screening for *M genitalium* in the PAS clinic and its implications for service provision within The Women's. Given the role of *M genitalium* in cervicitis, and the increasing evidence for its role in upper