(n=34), P timonensis (n=33), Anaerococcus tetradius (n=21), Finegoldia magna (n=20) and Peptoniphilus lacrimalis (n=20), whereas clindamycin resistance was detected among 74%, 42%, 19%, 30% and 30% of these anaerobes isolates, respectively. More than 90% of Prevotella amnii (n=33), Peptoniphilus harei (n=23) and Megasphaera-like bacteria (n=25) were susceptible to all three antibiotics. As expected, none of the Lactobacillus isolates were susceptible to metronidazole, whereas a majority were susceptible to both clindamycin and rifaximin in vitro.

**Conclusion** Rifaximin had MIC values for a range of microorganisms associated with BV which were superior or similar to the other two drugs approved for the treatment of this condition and deserves clinical evaluation as a new therapeutic agent for the treatment of BV.

002.3

## TREATMENT OUTCOMES FOR PERSISTENT MYCOPLASMA GENITALIUM-ASSOCIATED NGU: EVIDENCE OF MOXIFLOXACIN TREATMENT FAILURES

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**Background** Recent treatment trials have demonstrated low efficacy of doxycycline against *Mycoplasma genitalium* (MG) and increasing resistance to azithromycin. Treatment with azithromycin is recommended for persistent NGU if not used for the initial episode. We evaluated microbiologic cure rates for men with NGU and persistent detection of MG.

**Methods** English-speaking men aged 16 years attending the STD clinic in Seattle, WA with NGU (urethral discharge or urethral symptoms plus  $\geq$  5 PMNs/HPF) were enrolled in a randomised trial of NGU therapy between January 2007 and July 2011. Urine was tested for MG by PCR. Men received 1g azithromycin plus placebo doxycycline or doxycycline (100mg bid x 7d) plus placebo azithromycin. Treatment failures after 3 weeks received 'reverse therapy' (active doxycycline if they first received active azithromycin and vice versa). Persistent failures after 6 weeks received moxifloxacin (400mg x 7d). After September 2010, microbiologic failures at 3 weeks received moxifloxacin.

**Results** Of 606 enrolled men, 65 were positive for MG at enrollment and returned after 3 weeks. Microbiologic failure (positive MG test) occurred in 23/38 (60.5%) who received azithromycin and 19/27 (70.4%) who received doxycycline (p = 0.41). Of the 37 men with microbiologic treatment failure who received 'reverse therapy' and returned after 6 weeks, 19 (51.4%) had persistent detection of MG, including 14/20 (70.0%) retreated with doxycycline and 5/17 (29.4%) retreated with azithromycin (p = 0.02). All 19 men were prescribed moxifloxacin; 16 returned at 9 weeks and 2 (12.5%) had microbiologic failure, despite clinical cure. Four men received moxifloxacin after initial failure; 1 had microbiologic failure at 6 weeks, was retreated with moxifloxacin and microbiologically cured at 9 weeks.

**Conclusion** One half of MG-positive men retreated with a second standard NGU treatment regimen experienced microbiologic treatment failure. Moxifloxacin treatment failure, while not common, did occur, suggesting antimicrobial susceptibility in MG merits careful monitoring.

002.4

## PERSISTENT/RECURRENT CHLAMYDIAL INFECTION AMONG STD CLINIC PATIENTS TREATED WITH CDC-RECOMMENDED THERAPIES

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**Background** CDC guidelines recommend azithromycin or doxycycline as treatments for chlamydial infection. Recently, one randomised trial comparing these therapies suggested doxycycline was superior, while another found the two therapies were equivalent. We examined the risk of persistent/recurrent chlamydial infection among patients treated with doxycycline or azithromycin.

Methods We performed a secondary analysis of data from Project Aware, a randomised, controlled trial of a behavioural intervention. The trial enrolled patients aged ≥ 18 years without a prior HIV diagnosis in 9 U.S. STD clinics in 2010. At baseline, women with urogenital chlamydial infection and men with urethral and/or rectal chlamydial infections were treated with azithromycin or doxycycline, per clinic standard of care. Patients with a positive chlamydia test at 6-month follow-up were considered to have persistent/recurrent infection.

Results Of 5012 participants, 492 (9.8%) tested positive for C. trachomatis at baseline. Of these, 338 (69%) were treated with doxycycline or azithromycin without a second drug active against C. trachomatis; 92% (76 of 83) and 88% (225 of 255), respectively, were re-tested at 6 months. Comparing doxycycline and azithromycin, overall 7 (9.2%) and 26 (11.6%), respectively, had persistent/ recurrent infection (RR = 0.80, 95% CI = 0.36-1.76). Among persons with urogenital infections, 6 (10.0%) of 60 and 18 (10.1%) of 179 (RR = 0.99, 95% CI = 0.0.41-2.39), respectively had persistent/recurrent infection. Among men with rectal infections, 2 (9.5%) of 21 and 8 (16.3%) of 49 who received doxycycline and azithromycin, respectively, had persistent/recurrent infection (RR = 0.58, 95% CI = 0.14-2.52). On multivariate analysis, persistent/recurrent infection was significantly associated with black (vs. white) race (aRR = 4.29, 95% CI = 1.14-16.16) and rectal (vs. urogenital) infection (aRR = 5.42, 95% CI = 0.99-29.55), but not treatment regimen.

**Conclusion** There were no differences in persistent/recurrent urogenital chlamydia infections at six months by treatment type. Treatment failure of rectal infections among men may be more common with azithromycin and merits additional study.

002.5

## A PHASE II, DOSE RANGING STUDY TO EVALUATE THE EFFICACY AND SAFETY OF SINGLE-DOSE ORAL SOLITHROMYCIN (CEM-101) FOR TREATMENT OF PATIENTS WITH UNCOMPLICATED UROGENITAL GONORRHOEA

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**Objectives** Emerging resistance to available treatment creates an urgent need for new therapies for uncomplicated gonorrhoea. Solithromycin, a new 4<sup>th</sup> generation macrolide with 3 ribosomal targets, is highly active against most antibiotic-resistant strains of *Neisseria gonorrhoeae*. A Phase II, dose ranging study to evaluate the efficacy and safety of single-dose oral solithromycin for uncomplicated urogenital gonorrhoea was conducted.

**Methods** Consenting participants with suspected *Neisseria gonor-rhoeae* infection were cultured at the urethra/cervix, rectum, and pharynx at enrollment and Day 7. The primary outcome was bacterial eradication (conversion from positive baseline *N. gonorrhoeae* urethral/cervical culture to negative) at Day 7. Secondary outcomes included eradication of rectal or pharyngeal gonorrhoea and the eradication of gonococcal and chlamydial nucleic acids. Initially, eligible patients received a single 1200 mg oral dose of solithromycin; following demonstration of bacteriologic efficacy, a second cohort was treated with a single 1000 mg dose.

**Results** Of 41 (19 M, 22 F) participants enrolled, 28 were treated with a 1200 mg dose and, to date, 13 with 1000 mg. Gonococcal eradication rates in 22 evaluable 1200 mg patients were 100% (22/22) for urethral/cervical, pharyngeal (5/5), and rectal (2/2) infections. Of