Vibramycin (doxycycline hyclate capsule) 100 mg orally twice daily for 7 days for the treatment of uncomplicated urogenital chlamydia was evaluated in a randomised, double-blind, double-dummy, active-controlled, multicenter study. Males and nonpregnant females ages 19–45 with a confirmed diagnosis of urogenital chlamydia <14 days prior to enrolment or with a sexual partner with chlamydia were eligible. The study consisted of three visits: baseline, day 8 (end-of-treatment), and day 28 (test-of-cure [TOC]). The primary outcome was microbiological cure at TOC, defined as a negative result for *Chlamydia trachomatis* by the Gen-Probe (GP) Aptima Combo (AC) 2 assay (on urine in males and vaginal swab in females). The mITT population consisted of treated subjects with a GP AC2 positive for *C. trachomatis* at baseline. Non-inferiority of WC2031 was inferred if the lower limit of the 95% CI of the difference in cure rates was >–10%. Safety was studied through clinical evaluation and laboratory tests.

Results 495 subjects were randomised at 41 study sites. The mITT population with evaluable efficacy consisted of 323 (65%) subjects (156 in the WC 2031 group and 167 in the Vibramycin group). Baseline characteristics did not differ by group: median age 23, 61% female, 58% African American vs 36% Caucasian vs 7% other race, and 21% Hispanic ethnicity. The microbiological cure rate (95% CI) for the WC2031 group was 95.5% (92.3 to 98.8) vs 95.2% (92.0 to 98.4) for the Vibramycin group; the 95% CI for the difference in cure rates between treatments was (–4.3% to 4.9%). Types of adverse events were comparable between treatment groups. The WC 2031 group had less nausea and vomiting (13% vs 21% and 8% vs 12%).

Conclusions WC2031 was non-inferior to Vibramycin for treatment of uncomplicated urogenital chlamydia, was better tolerated, and demonstrated comparable safety. The once daily dosing of WC2031 may improve treatment adherence compared with twice daily doxycycline.

03-S4.04 TIME TO CURE CHLAMYDIA: PROSPECTIVE STUDY ON DETECTION OF ANORECTAL AND CERVICOVAGINAL CHLAMYDIA AFTER DIRECTLY OBSERVED TREATMENT WITH AZITHROMYCIN

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Background When a person, diagnosed with *Chlamydia trachomatis* (Ct), is being treated for Ct, STI Centres generally advise a short period of sexual abstinence; in most cases no test of cure is performed. These are considered best practices to cure Ct and prevent further spread, assuming high antibiotic efficacy. However, in about 5% of treated patients symptoms persist and among those retested 6–12 months later, 10% is Ct positive (again). Moreover, the efficacy of Azithromycin treatment for anorectal Ct is debated. The current study aims to increase understanding Ct treatment efficacy and to estimate time to cure cervicovaginal and anorectal Ct, using repeated measurements of laboratory, medical, and exposure parameters.

Methods Prospective study among 49 persons with cervicovaginal Ct (45 women) and/or anorectal Ct (four men, three women). After directly observed treatment with 1000 mg Azithromycin, each

participant provided during 2 months 18 time-sequential self-taken samples for testing for rRNA (TMA), Ct bacterial load (quantitative PCR; Ct plasmid DNA), and type Ct (serovar), and three time-sequential questionnaires on potential exposure (behaviour) and symptoms. Steady partners were treated as well. Here, we report on the 905 rRNA tests in 49 patients.

Results Of all women with cervicovaginal Ct, the proportion rRNA positive was 100% at treatment, 54% at day 7, 11% at day 12 and 17% 2 months after treatment. For anorectal Ct, these rates were 100%, 57%, 29%, and 50%. In total 45% of persons with cervicovaginal Ct and 57% with anorectal Ct had at least one positive rRNA sample in the period between 2 weeks and 2 months after treatment. Three cases of anorectal Ct (negative Lymphogranuloma venereum (LGV) PCR) remained rRNA positive during 2 months and tested Ct negative after administration of doxycycline (testing 2 months later).

Conclusions The proportion of Ct rRNA positivity during follow-up was much higher than expected in the light of assumed high effectiveness of Azithromycin treatment. Time to cure depends on the extent rRNA indicates clinically relevant or persistent Ct infection; this will be determined considering other markers (eg, Ct DNA) and symptoms as well (research ongoing). The persistent anorectal Ct cases that resolved after doxycycline treatment, contribute to the notion that this might be better treatment in anorectal Ct, after exclusion of LGV. Current study contributes to evidence based patient management and Ct transmission reduction.

03-S4.05 TREATMENT OF STUDENTS INFECTED WITH CHLAMYDIA AND GONORRHOEA IN A SCHOOL-WIDE SCREENING PROGRAM

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Background Providing treatment to individuals screened for a health condition is a key component of any health screening program. School-based screenings for sexually transmitted diseases (STD) offer the possibility of efficiently and promptly treating participants because students can be easily located after they have been tested. We describe treatment rates and time to treatment for students with *Chlamydia trachomatis* (CT) or *Neisseria gonorrhoeae* (NG) infection in a school-wide screening program.

Methods Between 1995 and 2005, 20 224 high school students were tested for CT and NG during annual screenings using urine specimens and commercial nucleic acid amplification tests. Test results were available approximately five working days after specimen collection. Students who tested positive were located at school during regular class hours for counselling and treatment by a school nurse, a clinic nurse, a public health nurse, or a physician. Treatment was with a single 1 gram oral dose of azithromycin for CT and 500 mg oral ciprofloxacin for NG, administered under direct observation. Before its removal from the market, cefixime 400 mg in single oral dose was used to treat NG. The names of infected students who could not be located in school were forwarded to a public health Disease Intervention Specialist (DIS) for follow-up. The DIS provided the program with an update on the follow-up status of each name referred.

Results During the 10-year period, 3422 infections (CT: 2746; NG: 304; CT and NG: 372) were identified. Treatment was documented for 2844 infections (83.1%). There were no significant differences in rates of treatment ($p>0.37$) by gender or by infection. The rates of treatment varied by school year from a low of 64.8% in 1996–1997