

tested positive for chlamydia compared to 8 in the Clinic Group, and the rate of reinfection was 12.9% in the Home Group and 14.6% in the Clinic Group ( $p=0.8$ ).

**Conclusions** Use of home-based, self-obtained vaginal swabs resulted in a significant increase in rescreening rates compared to rescreening in the clinic. Our findings indicate a role for home-based specimen collection as an alternative to clinic-based rescreening for chlamydia in women.

## Clinical sciences oral session 4: Treatment: Chlamydia, Gonorrhoea and related syndromes

### 03-S4.01 THE NEW SUPERBUG *NEISSERIA GONORRHOEA* MAKES GONORRHOEA UNTREATABLE?—FIRST HIGH-LEVEL CEFTRIAXONE RESISTANCE WORLDWIDE AND PUBLIC HEALTH IMPORTANCE

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**Background** The first *Neisseria gonorrhoeae* strain (H041) worldwide that is highly resistant to the extended-spectrum cephalosporin (ESC) ceftriaxone, which is the last remaining option for empirical treatment of gonorrhoea, has now been identified! This is a large public health problem and the era of untreatable gonorrhoea may now have been initiated. The present study completely characterised H041, phenotypically and genetically, to confirm the finding, comprehensively examine its antimicrobial resistance (AMR) and in detail elucidate the resistance mechanisms. Finally, public health actions for preventing and/or detaining global spread of ceftriaxone-resistant and untreatable gonorrhoea will be discussed.

**Methods** H041 was examined using seven species-confirmatory tests, antibiograms (30 antimicrobials) with Etest and agar dilution (only for ESCs), porB sequencing, *N. gonorrhoeae* multi-antigen sequence typing (NG-MAST), multilocus sequence typing (MLST) and sequencing of ESC resistance determinants (penA, mtrR, penB, ponA and pilQ). Transformation, using appropriate recipient strains, was performed to confirm the ESC resistance determinants.

**Results** H041 was assigned serovar Bpyust, MLST ST7363 and the new NG-MAST ST4220. H041 proved highly resistant to ceftriaxone (2–4 mg/l, which is 4–8-fold higher than any previously described isolate) and all other cephalosporins, as well as most other antimicrobials tested. A new penA mosaic allele, containing only four not previously described amino acid alterations, caused the ceftriaxone resistance, which was all proven using several transformation experiments.

**Conclusions** The new superbug *N. gonorrhoeae* has now developed also ceftriaxone resistance and an era of untreatable gonorrhoea may have been initiated. A reduction in global gonorrhoea burden by enhanced disease control activities combined with wider strategies for general AMR control and enhanced understanding of mechanisms of emergence and spread of AMR, which need to be monitored globally, is crucial. Furthermore, a public health response plan (including sustainable clinical, microbiological and epidemiological components) for a global perspective is essential. Ultimately, new drugs are essential to develop for efficacious gonorrhoea treatment.

### 03-S4.02 IS SINGLE DOSE AZITHROMYCIN ADEQUATE FOR ASYMPTOMATIC RECTAL CHLAMYDIA?

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**Background** Azithromycin is the recommended first-line therapy for asymptomatic rectal chlamydia. However a recent European study reported significant numbers of treatment failures, with higher failure rates in HIV positive men. In 2009, the Sydney Sexual Health Centre instituted a 6 week re-test policy for all cases of asymptomatic rectal chlamydia to assess the extent of azithromycin treatment failures.

**Methods** We conducted a retrospective audit of all men who have sex with men (MSM) diagnosed with asymptomatic rectal chlamydia in 2009. MSM with anal symptoms were excluded from this analysis, due to the possibility of lymphogranuloma venereum. We then categorised the infections present at re-testing as probable re-infections (men reported ongoing sexual activity with an untreated partner) or probable treatment failures (men did not have any obvious ongoing exposure, either because they did not report any further anal sex with any existing partners or because condoms were used consistently with all partners).

**Results** In the 12-month period there were 116 asymptomatic MSM treated for rectal chlamydia with 1 gram azithromycin as a single dose. Fourteen (12%) of the men were HIV positive. The median age was 33 years (range 20–64 years). Of the 116 men, 85 (73%) returned at varying times; median time of 10 weeks (78 days, range 21–372 days). Of the 85 men who returned, 11 (13%) were persistently positive and the median time to re-test was 11 weeks (78 days, range 47–209 days). Six of the 11 men were classified as probable re-infection and five as probable treatment failures, equating to an efficacy of 94%. None of the men classified as probable treatment failures were HIV positive.

**Conclusions** Interpreted conservatively, the azithromycin treatment failure rate could have been as high as 13% in our study. However most of these cases could be explained by re-infection suggesting an actual treatment failure rate of 6%. There was no evidence azithromycin is an ineffective first-line therapy for asymptomatic rectal chlamydia in MSM, but prospective studies would be welcome.

### 03-S4.03 SAFETY AND EFFICACY OF WC2031 VS VIBRAMYCIN FOR THE TREATMENT OF UNCOMPLICATED UROGENITAL CHLAMYDIA TRACHOMATIS INFECTION

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**Background** Recent studies report that treatment failure rates for single-dose azithromycin for urogenital chlamydia in females may be as high as 8%. There has been sparse research investigating new antibiotics for chlamydia, especially those that may reduce adherence difficulties with the CDC recommended doxycycline regimen (100 mg orally twice daily for 7 days).

**Methods** The safety and efficacy of WC2031 (doxycycline hyclate delayed-release 200 mg tablet) orally once daily for 7 days vs

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