(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 ≥ 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 4th 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 gonorrhoeae* 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

9 evaluable 1000 mg patients enrolled to date, gonococcal eradication rates have been 100% (9/9) for urethral/cervical, pharyngeal (2/2), and rectal (1/1) infections. Susceptibility data from 25 isolates show the median MIC (range) for solithromycin was 0.06 μg/mL (0.015–0.125) and for azithromycin was 0.125 μg/mL (0.06–0.5).

Solithromycin was generally well-tolerated with mild dose-related gastrointestinal AEs (68%; 28/41). The most common AE was mild diarrhoea, occurring in 61% (17/28) of patients receiving the 1200 mg dose and 15% (2/13) of patients receiving the 1000 mg dose.

Conclusions A single dose of 1200 or 1000 mg solithromycin appears to be well-tolerated and effective in eradicating *N. gonorrhoeae.*

O02.6 AZITHROMYCIN VERSUS DOXYCYCLINE FOR THE TREATMENT OF GENITAL CHLAMYDIA INFECTION - A META-ANALYSIS OF RANDOMISED CONTROLLED TRIALS

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Introduction There has been considerable debate questioning the efficacy of azithromycin for the treatment of genital chlamydia. We conducted a meta-analysis to compare the efficacy of 1 gramme azithromycin with 100mg doxycycline twice daily for seven days for the treatment of genital chlamydia infection.

Methods Medline, PubMed, Embase and the Cochrane Controlled Trials Register were searched till end 2012. Inclusion criteria included (1) randomised controlled trial of azithromycin versus doxycycline for the treatment of urethral or cervical chlamydia, and; (2) evaluation of microbial cure within 3 months of treatment. Type of diagnostic test, duration of follow up, gender, patient status (all symptomatic versus both symptomatic/asymptomatic) and microbial cure were extracted. The primary outcome was difference in efficacy (doxycycline efficacy minus azithromycin efficacy) at final follow up. Meta-analysis calculated a pooled efficacy for each treatment and the difference in efficacy between treatments.

Results Of 692 references identified, 23 trials met the inclusion criteria. 1065 individuals were treated with azithromycin and 850 with doxycycline; all studies reported efficacy within 6 weeks follow-up. Pooled cure rates were 96.2%(95% CI: 94.2%, 98.3%) for azithromycin and 98.1%(95% CI: 96.6%, 99.7%) for doxycycline. The pooled efficacy difference was 1.9%(95% CI: 0.4%, 3.4%) showing a small but significant difference in favour of doxycycline; there was negligible heterogeneity between studies ($I2 = 1.9\%$, $p = 0.44$). There was no difference in efficacy in men (3.8%; 95% CI:–1.2%, 8.8%) or women (–0.9%; 95% CI: –5.3%, 3.6%). When stratified by type of test, efficacy was significantly higher for doxycycline in culture-based studies (1.8%; 95% CI: 0.4%, 3.3%), but not in NAAT-based studies (5.5%; 95% CI: –2.1%, 13.1%). Efficacy was higher for doxycycline in symptomatic men (6.3%; 95% CI: 3.0%, 12.3%), but not in symptomatic women (–4.5%; 95% CI: –14.9%, 5.9%).

Conclusion These results suggest that doxycycline may be more effective than azithromycin for the treatment of urethral or cervical chlamydia infection, especially in symptomatic men.

O.03 - Neisseria gonorrhoeae resistance: Superbug ante portas?

O03.1 RISK FACTORS FOR ANTIMICROBIAL RESISTANT *NEISSERIA GONORRHOEAE* IN EUROPE

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Introduction The European Centre for Disease Prevention and Control is responsible for the enhanced surveillance of sexually transmitted infections and co-ordinates the European gonococcal antimicrobial surveillance programme (Euro-GASP) in the European Union and the European Economic Area. Linked patient and antimicrobial susceptibility data from Euro-GASP allows those at risk of acquiring antimicrobial resistant *Neisseria gonorrhoeae* to be identified.

Methods Seventeen countries in 2009 and 21 countries in 2010 and 2011 submitted gonococcal isolates to Euro-GASP, which were tested by Etest or agar dilution for cefixime, ceftriaxone, ciprofloxacin, azithromycin, spectinomycin and gentamicin. Additional patient data linked to the gonococcal isolates susceptibility profiles was collected. All three years antimicrobial susceptibility data and linked patient data were combined. Patient variables associated with resistance were established using a univariate and multivariable analyses of odds ratios. Geometric means for ceftriaxone and cefixime MICs were calculated.

Results A total of 5034 gonococcal isolates were tested in Euro-GASP from 2009 to 2011. In the multivariable analysis heterosexuals (males only for ciprofloxacin), older patients and those without a concurrent chlamydia infection remained significantly more likely to be infected with isolates displaying cefixime decreased susceptibility and ciprofloxacin resistance. The geometric mean of cefixime and ceftriaxone MICs decreased from 2009 to 2011, most significantly for MSM; MSM had lower geometric means than heterosexuals in 2011. A bimodal MIC distribution of a 'more susceptible' and 'less susceptible' gonococcal population appears to be emerging alongside this geometric mean decrease.

Conclusion This Euro-GASP data suggests that the burden of gonococcal antimicrobial resistance is more prevalent among heterosexuals and decreasing in MSM. This study shows the importance of collecting and analysing patient data along with susceptibility data, however improved data numbers and representativeness is required before any focused treatments or public health intervention strategies are initiated.

Abstract O03.1 Table 1 Patient risk factors for antimicrobial resistance (OR, 95% CI from multivariable analysis)

	Cefixime decreased susceptibility	Ciprofloxacin resistance
MSM	1	1
Male heterosexuals	2.39 (1.58–3.61)*	1.49 (1.21–1.83)*
Female	2.75 (1.68–4.5)*	1.04 (0.8–1.34)
< 25 years	1	1
≥ 25 years	2.07 (1.36–3.13)*	1.67 (1.37–2.05)*
Chlamydia - yes	1	1
Chlamydia - no	1.87(1.1–3.16)*	2.2 (1.74–2.8)*

*P value < 0.05 (from the Pearson Chi^2-test)

O03.2 ANTIMICROBIAL RESISTANCE OF NEISSERIA GONORRHOEAE IN THE EUROPEAN UNION: RESPONSE TO THE THREAT OF MULTIDRUG RESISTANT GONORRHOEA

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