O06.2 *IN VITRO* COMBINATION TESTING AND SELECTION OF RESISTANCE TO ZOLIFLODACIN COMBINED WITH SIX ANTIMICROBIALS FOR *N. GONORRHOEAE*

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Background Resistance in *Neisseria gonorrhoeae* to all therapeutic antimicrobials for gonorrhoea has emerged. Novel antimicrobials for treatment are imperative and the first-in-class spiropyrimidinetrione zoliflodacin appears promising. Zoliflodacin could be introduced in dual antimicrobial therapies to prevent the emergence and/or spread of resistance. We investigated the *in vitro* activity and induction/selection of resistance to zoliflodacin alone and in combination with six novel, currently or previously used therapeutic antimicrobials against *N. gonorrhoeae*.

Methods The international gonococcal reference strains examined were WHO F (wild-type), and WHO O, WHO V, and WHO X (strains with different AMR profiles). Zoliflodacin was evaluated alone or in combination with ceftriaxone, spectinomycin, gentamicin, tetracycline, cethromycin, and sitafloxacin in checkerboard assays, time-kill curve analysis, and induction/selection of resistance studies.

Results Zoliflodacin alone or in combination with all six antimicrobials showed rapid rates of *in vitro* bacterial killing against all examined strains in time-kill studies. Tetracycline or cethromycin combined with zoliflodacin decreased the rate of zoliflodacin growth inhibition, while ceftriaxone or gentamicin increased the rate of cell killing. The frequency of induced/selected zoliflodacin resistance mutations was low for zoliflodacin and further reduced for all antimicrobial combinations. All resistant mutants contained the GyrB mutations D429N, K450T or K450N, resulting in zoliflodacin MICs of 0.5–4 mg/L consistent with previous results.

Conclusion Zoliflodacin, alone or in combination with STI therapeutic antimicrobials has a rapid and high *in vitro* efficacy against gonococci with low resistance emergence. Zoliflodacin remains a promising novel oral therapeutic for gonorrhoea monotherapy and as part of dual antimicrobial therapy with low resistance emergence potential. A phase III clinical trial evaluating efficacy and safety of zoliflodacin for uncomplicated gonorrhoea treatment is planned in 2019.

Disclosure No significant relationships.

O06.3 EFFICACY OF RESISTANCE GUIDED THERAPY FOR *MYCOPLASMA GENITALIUM* USING DOXYCYCLINE FOLLOWED BY AZITHROMYCIN OR MOXIFLOXACIN

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Background Macrolide-resistance in *Mycoplasma genitalium* (MG) exceeds 50% in many nations and increasing quinolone-resistance is reported. Recent data showed resistance-guided therapy (RGT) using doxycycline then sitafloxacin for macrolide-resistant MG cured 92% of infections and doxycycline-azithromycin for macrolide-susceptible MG cured 95%. As sitafloxacin is not widely available, we undertook a study of RGT to evaluate the efficacy of moxifloxacin in RGT to provide data that is relevant to international guidelines and to assess the efficacy of this alternative approach in a population with 15–20% quinolone-resistance (ParC mutations).

Methods Patients attending Melbourne Sexual Health Centre between April 2017-June 2018 with urethritis, cervicitis or proctitis were treated with doxycycline (7 days)and recalled if positive for MG. Macrolide-susceptible cases received azithromycin (1g, then 500 mg daily 3 days)and resistant-cases received moxifloxacin (400 mg daily, 7 days). Patients attended for test of cure (TOC) following treatment. Adherence and side effects were recorded. Patients were included in the efficacy analysis if they were treated in accordance with RGT protocol, were not at high risk of reinfection and had a 14–90 day TOC.

Results 382 participants (80 female/106 heterosexual male/196 MSM) were included: 109 (28.5%) had macrolide-susceptible MG and 273(71.5%) macrolide-resistant MG. Doxycycline-azithromycin cure was 95.4% (95%CI 89.7–98%) and doxycycline-moxifloxacin cure was 91.9% (95%CI 88.1–94.6%). Median time to TOC was 27 days (IQR=22–35). Doxycycline-azithromycin data was combined with our prior RGT study and the pooled estimate of cure (n=186) was 95.2% (95%CI 91.1–97.4%). Analysis of selected macrolide resistance is underway but will not exceed 4.3% (95%CI 2.2–8.6%).

Conclusion Despite 15–20% quinolone resistance in Melbourne the sequential strategy of doxycycline-moxifloxacin achieved unexpectedly high cure (92%), and did not differ to doxycycline-sitafloxacin, a more effective quinolone, suggesting preceding doxycycline may improve cure through reducing pre-treatment load. Doxycycline followed by azithromycin for susceptible infections consistently achieves 95% cure and low levels of selected resistance (<5%).

Disclosure No significant relationships.

O06.4 EFFICACY AND COST-EFFECTIVENESS OF QHPV VACCINE WITH IMIQUIMOD OR PODOPHYLLOTOXIN FOR PATIENTS WITH ANOGENITAL WARTS (HIPVAC)

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Background The comparative efficacy, and cost-effectiveness, of imiquimod (IMIQ) or podophyllotoxin (PDX) cream, either alone or in combination with the quadrivalent HPV vaccine (Gardasil®, Merck) in the treatment and prevention of recurrence of anogenital warts is unknown.

Methods A randomised, controlled, multi-centre, partially-blinded factorial trial with an economic evaluation. Participants had new or recurrent warts; not treated within 3 months; no qHPV-vaccination. Randomisation, stratified by gender,

previous warts, HIV status to IMIQ 5% (16W), or PDX 0.15% cream (4W, extended to 16W if warts persist). Simultaneous blinded randomisation to Gardasil® or saline control (0–2–6 months). Composite primary outcome of wart clearance at 16W and remaining clear to 48W; analysis by logistic regression with multiple imputation for missing follow-up values. Economic evaluation considered the costs per quality-adjusted life year (QALY) for the National Health Service in England.

Results 503 participants enrolled; mean age 31 years; 66% male (20% of males MSM); 50% previous warts; 2% known HIV+. Adjusted OR (95%CI) for IMIQ relative to PDX 0.81 (0.54, 1.23); vaccine relative to placebo 1.46 (0.97, 2.20). aOR for primary outcome components (same comparators) of wart-free at W16 0.77 (0.52,1.14) and 1.30 (0.89,1.91) and remaining wart-free at 48W (in those wart-free at W16) 0.98 (0.54,1.78) and 1.39 (0.73,2.63) respectively. PDX without qHPV vaccine had the highest probability of being cost-effective across willingness-to-pay thresholds of GBP0–50,000/QALY. Adding qHPV vaccine to PDX exceeded GBP80,000/QALY.

Conclusion Though the effect of vaccine was not statistically significant, the odds of clearance at 16W+48W (primary outcome) were 46% higher with vaccine, consistent with the effects seen in component outcomes, wart-free at 16W, and 48W. IMIQ and PDX had similar efficacy; there was no evidence of a lower recurrence with IMIQ. PDX without qHPV vaccine is likely most cost-effective at the current qHPV price, but addition of qHPV may become cost-effective with reduced pricing.

Disclosure No significant relationships.

O06.5 DO TREATMENT RATES SUFFER IN A LOW-TOUCH SCREENING MODEL? NEW YORK CITY SEXUAL HEALTH CLINICS, 2017–2018

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Background Low-touch (i.e. limited staff interaction) models for asymptomatic STI screening have been widely adopted in sexual health clinics (SHCs) and can improve clinic flow and patients' experience. In New York City SHCs, asymptomatic patients who do not report contact to STI screen for urogenital and extragenital bacterial STI using self-collected specimens without a medical encounter. We evaluated treatment rates for Neisseria gonorrhea (GC) cases detected by this low-touch, self-screening model.

Methods We identified men-who-have-sex-with-men (MSM) who tested GC-positive by urogenital or extragenital nucleic acid amplification testing at any visit type (self-screening or standard clinician) during 01/2017–06/2018. Among GC cases that had not been presumptively treated, we assessed the number and percent of asymptomatic cases that returned for treatment within 30 days, and HIV pre-exposure prophylaxis (PrEP) use. We used Kaplan-Meier methods to examine time-to-treatment by visit type.

Results Of 3,944 GC cases, 2,268 were presumptively treated and 1,676 needed to return for treatment. Among returning patients, median time-to-treatment was 6 days (IQR: 4–8). Cases detected at self-screening visits had shorter time-to-treatment than those detected at standard visits (p=0.008). Among GC cases detected at self-screening visits, 85% (454/534) were treated ≤14 days, and 90% (480/534) ≤30 days, compared to 80% (917/1,142) of standard cases treated ≤14 days, and 87% (991/1,142) ≤30 days after the visit. HIV-negative men with rectal GC had shorter time-to-treatment following self-screening versus standard visits (p=0.007), and fewer remained untreated by 30 days (self-screening: 7% versus standard: 13%; p=0.02). Of 76 HIV-negative men with rectal GC who were lost to follow-up, 22 (29%) were documented to be taking HIV PrEP at time of testing/screening.

Conclusion Among HIV-negative MSM with rectal GC, a group for whom delayed treatment may increase risk for HIV acquisition, a low-touch/self-screening model results in overall treatment rates and times-to-treatment that compare favorably to a standard clinician model.

Disclosure No significant relationships.

O06.6 REDUCTION IN ADHERENCE TO ANTIRETROVIRAL THERAPY DURING POSTPARTUM: FINDINGS FROM A PROSPECTIVE COHORT STUDY

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Background The WHO recommended breastfeeding as the best feeding option for women with HIV in sub-Saharan Africa. Adherence to anteretroviral therapy is important for breastfeeding mothers to prevent vertical transmission of HIV. There is evidence that pregnancy tends to drive adhrence of antiretroviral therapy among women living with HIV, however it is unclear whether they main the level of adherence at pregnancy during the postpartum period.This study assesses the rate of drop-off in adherence in the post-partum period from the prospective cohort study of mother-infant pairs in Eastern Cape, South Africa.

Methods We conducted a follow up study on 485 mothers with HIV at 18 months post delivery to elucidate on their adherence to ART during their postpartum period. We obtained relevant items on demographic, lifestyle and self-reported adherence to ART. Adherence was measured using 7-items questions to probe adherence to ART since birth of their child to the previous night of the survey. Logistic regression (model) analysis was fitted to determine the predictors of good adherence in the cohort.

Results The mean age of the participants was 32.91 years (Standard Deviation 5.74). About 64% of the women reported complete adherence to ART representing a 5% percentage drop-off in adherence compared to the rate recorded during pregnancy. In the adjusted model, alcohol use in the last 12