006.2 A PILOT RANDOMISED CONTROLLED TRIAL OF HIGH-DOSE VITAMIN D SUPPLEMENTATION TO PREVENT RECURRENCE OF BACTERIAL VAGINOSIS

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[1]**A Norris Turner**, [1]P Carr Reese, [1]J Anderson, [2]K S Fields, [2]M Ervin, [3]M Klebanoff, [4]R Jackson. *[1]Division of Infectious Diseases, Ohio State University, Columbus, OH, United States; [2]Sexual Health Clinic, Columbus Public Health, Columbus, OH, United States; [3]The Research Institute, Nationwide Children's Hospital, Columbus, OH, United States; [4]Division of Endocrinology, Diabetes and Metabolism, Ohio State University, Columbus, OH, United States*

Background Bacterial vaginosis (BV) is the most common cause of vaginal infection worldwide and is associated with myriad negative reproductive health outcomes. Several cross-sectional studies indicate that women with low vitamin D levels have increased BV prevalence.

Methods This randomised, double-blinded, placebo-controlled trial started enrollment in September 2011 and concluded follow-up in January 2013. Women (n = 126) with symptomatic BV were enrolled from an urban STD clinic in the midwestern United States. All participants received standard metronidazole therapy. Intervention participants (n = 63) also received nine doses of 50,000 international units of cholecalciferol (vitamin D3) over 6 months; control arm women (n = 63) received matching placebo. BV status was assessed via Nugent scoring at three follow-up visits over six months. The primary analysis will be intention-to-treat using extended Cox proportional hazard models.

Results Participants' median age was 26. Three-quarters (75%) of women were black and 25% were white. All reported a lifetime history of sex with men, and 29% also had a lifetime history of sex with women. At baseline, median serum vitamin D levels (measured as 25-hydroxy vitamin D) were the same for intervention and control women at 15.85 ng/mL (interquartile range (IQR): 12.1–21.4 ng/mL); levels < 20 ng/mL are considered insufficient. Eight-one percent of participants returned for one or more follow-up visits. At trial completion, median vitamin D level among intervention women was 30.5 ng/mL (IQR 24.4–37.7 ng/mL), vs. 17.8 ng/mL among control women (IQR: 11.7–27.1 ng/mL). Nugent scoring is ongoing with primary results available in early spring 2013.

Conclusion Immunologic mechanisms regulated by vitamin D may play a role in BV recurrence, but no previous study has examined whether supplementing women with vitamin D will impact subsequent development of BV. If effective against BV, vitamin D supplementation can have worldwide impact as a safe, simple intervention.

006.3 MACROLIDE RESISTANCE OF MYCOPLASMA GENITALIUM IN FRANCE DIRECTLY DETECTED IN CLINICAL SPECIMENS BY REAL-TIME PCR AND MELTING CURVE ANALYSIS

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[1,2]**A Touati**, [1,2,3]O Peuchant, [4]J Skov-Jensen, [1,2,3]C Bébéar, [1,2,3]S Pereyre. *[1]University of Bordeaux, Bordeaux, France; [2]Institut National de la Recherche Agronomique, Bordeaux, France; [3]Centre Hospitalier Universitaire de Bordeaux, Bordeaux, France; [4]Statens Serum Institute, Copenhagen, Denmark*

Objectives *Mycoplasma genitalium* (MG) is a sexually transmitted organism associated with non-gonococcal urethritis in men and several inflammatory reproductive tract syndromes in women. These infections are commonly treated with azithromycin. However macrolide resistance has been reported and is associated with point mutations in domain V of the 23S rRNA gene. In order to evaluate the prevalence of macrolide resistance in MG in French clinical specimens, we first used a recently published High Resolution Melting (HRM) assay. Because wild-type and mutated MG were hardly discriminated in MG-positive clinical specimens, we developed a new molecular assay for the rapid detection of macrolide resistance.

Methods Between January 2011 and September 2012, 207 urogenital MG-positive clinical specimens were collected from 185 patients. For the detection of macrolide resistance-associated mutations, we designed a real-time PCR based on fluorescence resonance energy transfer (FRET) coupled with melting curve analysis. The assay was first validated on macrolide-resistant MG isolates with characterised A2058G/C and A2059G mutations (*Escherichia coli* numbering), then optimised to be applied directly on clinical specimens. Resistant genotypes were confirmed by 23S rRNA gene sequencing.

Results Among 207 MG-positive clinical specimens, 136 from 119 patients were amplified with our assay, showing a sensitivity of 65.7% (136/207). A substitution in the 23S rRNA gene was found in 14.2% (17/119) of the patients, with a rate of 14.5% in 2011 and 14% in 2012. Nine and eight clinical specimens harboured the A2059G and A2058G mutations, respectively. In four cases, a mixed population of wild-type and mutated MG was observed.

Conclusion Macrolide resistance prevalence of MG is 14.2% in France. Our FRET PCR assay is able to discriminate wild-type from resistant genotype in one reaction directly in clinical specimen. It will allow clinicians to shorten the time to initiate effective treatment and contribute to reduce transmission of resistant strains.

006.4 USING SMS TEXT REMINDERS TO REDUCE 'DID NOT ATTEND' (DNA) RATES IN SEXUAL HEALTH AND HIV APPOINTMENT CLINICS

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G Brook, T Farmer, S Murphy, J McSorley. *Central Middlesex Hospital, London, UK*

Background DNA rates in sexual health and HIV clinics have historically been high and this can reduce the ability of the clinic to see patients within the UK national target of two working days. The availability of technology such as SMS texting allows appointment reminders to be readily sent just prior to the appointment.

Objectives To measure the impact of the SMS text appointment reminders on the DNA rates in a clinic providing sexual health and HIV appointments.

Methods DNA rates were measured for two 2-month periods before (2009) and after (2012) the introduction of routine SMS text reminders being sent to patients who have pre-booked appointments. Texts were sent two working days before the booked appointments.

Results Overall, after the introduction of SMS text appointment reminders, the DNA rates fell by 35% from 203/768 (26%) to 119/699 (17%), P < 0.0001. The fall was especially large for male sexual health appointments: 56/200(28%) vs 24/165 (15%), P < 0.004 a fall of 46%. Female sexual health DNA rates also fell: 69/302(23%) vs 43/273(16%), P < 0.02, a fall of 30%, as did DNA rates for HIV clinics: 78/266(29%) vs 52/261(20%), P < 0.001, a fall of 31%

Conclusions SMS texts sent to patients two days before a booked appointment reduced the DNA rate by an average of one in three. The decrease was especially large for male patient appointments. Routine text reminders for appointments are an effective way of ensuring that the clinic runs efficiently.

006.5 AN EXPLORATORY EVALUATION OF UNIVERSAL OPT-OUT CHLAMYDIA TESTING DURING CLINICAL ENCOUNTERS FOR YOUNG WOMEN IN THE UNITED STATES

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K Owusu-Edusei, K W Hoover, G D Hart-Cooper, T L Gift. *Centers for Disease Control and Prevention, Atlanta, GA, United States*

Background Chlamydia testing rates are low, with only about a third of sexually active young women tested at clinical encounters. Even fewer sexually active female adolescents are tested. Interventions

to increase testing coverage have been moderately successful. In this study, we assessed the relative health and economic outcomes of patient-directed, universal, opt-out testing for women aged 15–24 years in the United States who have at least one clinical encounter each year when compared with current testing (30% coverage).

Methods We used a basic dynamic compartmental model that included two groups based on their self-reported sexual activity in the past 12 months, with 72% being sexually active and 28% inactive. For our base case analysis, we assumed a 75% uptake of the intervention by sexually active women and 5% by sexually inactive women. All model parameters were obtained from the literature. The model was calibrated to produce a pre-intervention prevalence close to the national burden for those aged 15–24 years in the United States (≈2.5%). Health outcomes were measured in quality-adjusted life years (QALYs).

Results Based on our model (including health insurance coverage and utilisation rates), the estimated effective annual testing rate increased to approximately 52%, and overall chlamydia prevalence decreased by 60% to ≈1% over a three-year period. The estimated cost per QALY gained was $1372. When we assumed an uptake rate ≥ 85%, the overall prevalence decreased to zero.

Conclusion The universal, opt-out testing intervention was cost-effective because it did not require additional costs over and above testing and treatment. Our exploratory analyses suggest that implementation of opt-out testing of young women during clinical encounters might substantially increase testing coverage of sexually active young women. However, even with a higher uptake, testing gaps would remain because many women might not have health insurance coverage, or not utilise healthcare.

006.6 A RANDOMISED, DOUBLE-BLIND, CONTROLLED STUDY TO ASSESS THE EFFICACY AND SAFETY OF NIFURATEL IN THE TREATMENT OF TRICHOMONIASIS

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[1]**W Mendling**, [2]M Caserini, [2]R Palmieri. *[1]German Center for Infections in Obstetrics and Gynecology, Wuppertal, Germany; [2]Polichem SA, Lugano, Switzerland*

Background Trichomoniasis is the most prevalent non-viral sexually transmitted disease and there is a clear need for identifying oral therapies that are effective against 5-nitroimidazole-resistant *T. vaginalis* (TV) infections. A randomised, double-blind, double-dummy, parallel group pivotal study was carried out to assess the efficacy and safety of a 7-day oral treatment course with nifuratel in comparison with metronidazole in women with trichomoniasis infection.

Methods Four-hundred-thirty-one patients, aged ≥ 18 years, were enrolled after providing their written informed consent. Women with a positive TV wet-mount microscopy were randomised and the diagnosis was confirmed by the InPouch™ TV culture method 3 days after. They received one tablet of nifuratel 200mg or metronidazole 250mg and one tablet of the corresponding placebo of the comparator three times daily after meals for 7 days. The TV eradication rate was assessed on day 21 ± 3 after the first drug intake. The concomitant infection by candidosis and the vulvovaginal signs and symptoms were also evaluated.

The non-inferiority of nifuratel compared to metronidazole at the pre-specified margin of Δ-10% was defined as the clinically acceptable difference between the two active treatments.

Results The TV eradication was achieved by the 95.9% of patients in the per protocol data set: 95.2% and 96.5% in the nifuratel and metronidazole group, respectively (p = 0.0062). The eradication rate of vulvovaginal candidosis after treatment with nifuratel or metronidazole was 53.6% vs. 45.8%. A similar decrease in vaginal signs and symptoms, such as edoema, erythema, colpitis, cervicitis, itching, burning and dysuria, was detected in both groups. The treatments were also well tolerated with a comparable safety profile.

Conclusion The trial proved that nifuratel 600 mg/day, minimum recommended daily dosage, is effective as metronidazole 750mg/day, average dosage recommended, in the treatment of trichomoniasis infection and suggests that nifuratel could still be an efficient alternative to metronidazole as first-line treatment.

O.07 - Sexually transmitted infections: social and behavioural determinants and consequences

007.1 SEXUAL RELATIONSHIP IMPORTANCE AND CONDOM USE AMONG MEN ATTENDING STD CLINICS IN TWO SOUTHERN CITIES IN THE UNITED STATES

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[1]**P Kissinger**, [1]S White, [1]N Schmidt, [2]S N Taylor, [3]L Mena, [2]R Lillis, [1]S Some, [1]K Defayette, [1]A Adamski, [4]S L Rosenthal. *[1]Tulane University SPHTM, New Orleans, LA, United States; [2]Louisiana State University Health Sciences Center, New Orleans, LA, United States; [3]University of Mississippi – Department of Medicine, Jackson, MS, United States; [4]Columbia University, New York, NY, United States*

Background Relationship type and perception of importance of the relationship may be predictors of condom use.

Methods Men who presented at STD clinics in New Orleans, LA and Jackson, MS with NGU, tested positive for Chlamydia trachomatis (Ct), or were contacts of women with Ct underwent computer-assisted/self-administered interviews and were asked to report information on up to 4 sexual partners in the last two months. Importance of relationship was determined using 4 variables: having history together, shared feelings, commitment to each other, and physical passion.

Results 1065 men reported information on 1924 partnerships; 98.9% of which were with women, 47% were considered main, but only 30% of the men lived with and 6% were married to main partners. Relationships were described as: girlfriend/boyfriend (32%), mother-of-child (6.8%), friend-with-benefit (26.4%), sex with but not friend (6.2%), ex-girlfriend/boyfriend (9.1%), someone I want to have relationship with (5.8%), one night stand (12.3%), paid for sex (1.4%). Most (82.1%) had sex in a home, while 11.3% in hotel, and 6.6% in public place/other. Importance of relationship variables by relationship (most important to least 1–8) were: girlfriend/boyfriend (1.1) and mother-of-child (1.7), and someone I might want to have a relationship (2.6), ex-girlfriend/boyfriend (3.7), friend-with-benefit (5.3), sex but not friend (6.8), paid for sex (7.1) and one night stand (7.2). The less important the relationship was, the more likely they were to be using a condom O.R. 1.13 (95% C.I. 1.08–1.18). Condom use at last sex act was least likely with the mother of child (34.5%) and most likely with paid to have sex (91.7%). Condom use was between 51% - 78% for the other categories.

Conclusion In general, condoms were used more frequently with partners whose relationships were perceived as less important, but this was not universal.

007.2 THE CHANGING RELATIONSHIP BETWEEN MIGRATION AND HIV OVER THE LIFE COURSE OF AFFECTED HOUSEHOLDS IN NORTH INDIA

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[1]**T Rai**, [2]H S Lambert, [3]P Piot, [4]K S Agarwal, [1]H Ward. *[1]Imperial College London, London, UK; [2]University of Bristol, Bristol, UK; [3]London School of Hygiene and Tropical Medicine, London, UK; [4]Kamala Nehru Memorial Hospital, Allahabad, India*

Background Much research explores the relationship between migration and HIV risk; elsewhere the focus is on how HIV affects household structure and viability. In India, rural-to-urban, circular migrants are targeted with prevention campaigns but little is known about the impact of HIV on livelihoods.