020.2 ERTAPENEM IS NON-INFERIOR TO CEFTRIAXONE FOR THE TREATMENT OF ANOGENITAL GONORRHEA: THE NABOGO RANDOMIZED DOUBLE BLIND NON-INFERIORITY TRIAL

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Background *Neisseria gonorrhoeae* (Ng) is a common sexually transmitted infection (STI). Emerging strains resistant to first-line ceftriaxone threaten Ng management. Hence, alternative treatments are needed. We evaluated the efficacy of ertapenem, gentamicin and fosfomycin as alternatives for Ng.

Approach We included adults 18 years or older, with anorectal or urogenital gonorrhea in a randomized controlled, double-blind, non-inferiority trial (three experimental- and one control-arm). Participants were randomized (1:1:1:1) to receive: intramuscular (IM) 500mg ceftriaxone, IM 1000mg ertapenem, IM 5mg/kg gentamicin (maximum 400mg), or 6g fosfomycin orally. The primary outcome was the proportion of participants with a negative nucleic acid amplification test of the primary infected site, 7–14 days after treatment. Non-inferiority was established if the lower Hochberg-corrected 95% confidence interval for difference between experimental and control arms was greater than -10%.

Outcomes Between 18 September 2017 and 5 June 2020, we assigned 346 participants to ceftriaxone (n=103), ertapenem (n=103), gentamicin (n=102), and fosfomycin (n=38). The fosfomycin arm was terminated early after interim analysis revealed <60% efficacy. In the primary modified intent-to-treat (mITT) analysis, all patients (93/93) in the ceftriaxone, 99% (86/87) in the ertapenem, 93% (79/85) in the gentamicin, and 12% (4/33) in the fosfomycin arm cleared Ng [risk difference, ertapenem versus ceftriaxone, -0.01(95% CI: -0.06,0.03); gentamicin versus ceftriaxone -0.07(95%CI: -0.16,-0.005)]. Both the secondary mITT analysis (clearance within 7–28 days), and the per-protocol analyses were consistent with the primary mITT analysis.

Significance Single-dose 1000mg ertapenem is non-inferior to single-dose 500mg ceftriaxone in gonorrhea treatment. Given that ertapenem, an already registered antibiotic, is non-inferior to the standard of care, it may currently provide an alternative treatment option for gonorrhea if resistance against ceftriaxone becomes more widespread.

020.3 QUANTITATIVE CHLAMYDIA TRACHOMATIS PGP3 SEROPOSITIVITY AND REPRODUCTIVE SEQUELAE AMONG WOMEN, NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY, UNITED STATES, 2013–2016

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Background Chlamydia trachomatis infection causes reproductive sequelae of pelvic inflammatory disease (PID) and tubal

infertility. Previous studies have demonstrated a relationship between levels of chlamydia antibody and these sequelae. We investigated associations of high chlamydial seropositivity with PID and infertility using a Pgp3 antibody (Pgp3Ab) multiplex bead array (Pgp3AbMBA).

Methods We performed chlamydia Pgp3AbMBA on sera from women 18–39 years old participating in the 2013–2016 National Health and Nutrition Examination Survey with urine chlamydia nucleic acid amplification test results. High chlamydial seropositivity was defined as a median fluorescence intensity (MFI) $\geq 50,000$; low-positive was $551 < \text{MFI} < 50,000$; negative was < 551 . Weighted US population high-positive, low-positive, and negative Pgp3Ab chlamydia seroprevalence and 95% confidence intervals (CI) were calculated for women with chlamydia, PID and infertility.

Results Sera were available from 1,725 (73.7%) of 2,339 women aged 18–39 years; 1,425 were sexually experienced. Overall, 104 women had high-positive Pgp3Ab (5.4% [95% CI 4.0–7.0] of US women); 407 had low-positive Pgp3Ab (25.1% [95% CI 21.5–29.0]), and 914 were negative (69.5% [95% CI 65.5–73.4]). The prevalence of current chlamydia among women with high seropositivity (10.7% [95% CI 5.4–18.6]) was higher than the prevalence of current chlamydia among seronegative women (0.4% [95% CI 0.1–1.3]).

Among women with high-positive Pgp3Ab, infertility prevalence was 2.0 (95% CI 1.1–3.7) times that among Pgp3Ab-negative women (19.6% [95% CI 10.5–31.7] versus 9.9% [95% CI 7.7–12.4]). For women with low-positive Pgp3Ab, PID prevalence was 7.9% (95% CI 4.6–12.6) compared to 2.3% (95% CI 1.4–3.6) in those with negative Pgp3Ab.

Conclusions High chlamydial Pgp3Ab seropositivity was associated with infertility. Small sample size limited evaluation of an association of high seropositivity with PID. In infertile women, Pgp3Ab may be a marker of prior chlamydia.

020.4 EVALUATION OF GLOBAL TREPONEMA PALLIDUM GENETIC DIVERSITY USING REPRESENTATIVE SAMPLING AND HIGH-THROUGHPUT GENOMIC ANALYSIS

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Background Large-scale genomic analyses of *Treponema pallidum* (Tp) are now possible using enrichment methods that enable sequencing without in vivo cultivation in rabbits. Using capture and amplification enrichment approaches, we are generating complete genomes from diverse clinical samples collected as part of a multi-site syphilis vaccine development project. Analysis of these and a growing number of publicly available genomes provides new insights into the global diversity and evolution of Tp.

Methods Clinical samples were collected from subjects presenting with primary and secondary syphilis in the US, Columbia, Malawi, China, and Czech Republic. DNA extracted from

ulcer swabs, skin biopsies, and rabbit-passaged clinical isolates was enriched for Tp using pooled, parallel whole-genome amplification and/or RNA baits before Illumina short-read sequencing. We adopted hybrid comparative genome assembly analysis that involved de novo and reference-based assembly strategies to generate whole-genome consensus sequences. Repetitive and paralogous loci are being finished using Oxford Nanopore Technologies long-read sequencing and outer membrane protein (OMP) variability assessed using three-dimensional structural modelling.

Results We whole-genome sequenced 20 newly collected strains and analyzed publicly available sequencing data from 605 Tp samples. We observed a higher proportion of Nichols-like strains (6 of 20 [30%]) than expected in newly sequenced samples. Macrolide resistance-associated 23S rRNA alleles were not observed in samples from Columbia or Malawi. Initial analysis of bamA, lptD, and fadL-like loci suggests a spectrum of OMP variability that supersedes clade assignment. Analyses of newly collected samples and publicly available genomes is ongoing.

Conclusion Sampling from geographically diverse sites suggests that Tp strains are more genetically diverse than previously appreciated. Nichols and SS-14 clades were well represented, and macrolide susceptibility was maintained in some localities. Representative sampling complemented by analysis of robust clinical data and paired biological samples is critical to the development of a globally effective syphilis vaccine.

020.5 LOVE IN LOCKDOWN: RELATIONSHIP STRESS, DATING VIOLENCE AND STI RISK IN ADOLESCENT AND YOUNG ADULT RELATIONSHIPS DURING THE COVID-19 PANDEMIC

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Background Adolescents and young adults (AYA) who experience dating violence (DV) are at increased STI risk. Social restrictions during the COVID-19 pandemic have stressed AYA relationships and may cut them off from sources of support. AYA have been shown to respond to relationship stressors with behaviors that increase STI risk. This work examines whether relationship stressors (jealousy and worry about the relationship) exacerbate violence and STI risk among urban AYA during the COVID-19 pandemic.

Methods Participants from four sexual and reproductive health studies in Baltimore, Maryland (USA) were invited to complete a cross-sectional telephone survey on relationship experiences/sexual behavior during the pandemic. March 16, 2020 'stay-at-home' order was used to define the pandemic period. Partner support, jealousy, worry about the relationship making it through the pandemic, current DV, change in DV during pandemic, and condom use at last sex were evaluated using regression analyses. Data collection is still underway in 2021.

Results Of 194 participants surveyed, mean (sd) age 22.7 (2.8) years, 61% were in a romantic/sexual relationship. Of these, 14% reported current TDV, 6% experienced an increase in DV, 66% did not use a condom at last sex. AYA who worried

their relationship would not make it through the pandemic were more likely to experience DV (OR: 5.64, 95%CI: 1.69, 18.9). AYA who felt jealous of other people their partner was talking to/hanging out with during the pandemic were more likely to experience DV (OR: 4.51, 95%CI: 1.39, 14.6). Greater partner support was associated with experiencing less DV (OR: 0.71, 95%CI: 0.56, 0.90). Relationship stressors were not associated with condom use.

Conclusions Relationship insecurity exacerbated by the COVID-19 pandemic may increase risk for DV among AYA. As DV and STI are interconnected, romantic relationship context must be a key focus of STI prevention strategies during and after the pandemic.

020.6 CHLAMYDIA TRACHOMATIS VIABLE LOAD AT SIX DIFFERENT ANATOMICAL SAMPLE SITES IN WOMEN (CHLAMOUR)

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Background Nucleic acid amplification tests (NAATs) have revolutionized our ability to diagnose Chlamydia trachomatis (CT). Sometimes, in addition, assessment of CT viability would help to gain more insight in the clinical impact of a positive NAAT. Methods to assess the CT viability have become available in research settings (e.g. viability-PCR; V-PCR). Here we assess viability in six different anatomic sites in women.

Methods Immediately prior to treatment (STI clinic South Limburg), 28 vaginal NAAT-CT-positive (COBAS4800 CT/NG) adult women, were included in the 'CHLAMOUR' study. We used V-PCR to assess CT viable load (log₁₀ CT/ml) in same clinician taken standardized samples from the cervix, vagina, perineum, anus, optional rectum, and pharynx. Mean loads were compared using t-tests.

Results Twenty-eight women were included of whom 68% (19/28) consented to proctoscopic examination (rectal). NAAT-CT-positive rate was 75% for cervix, 79% vagina, 64% perineum, 64% anus, 74% rectum, and 21% for pharynx. Viable load was detected in 90% (19/21) CT positive cervix, 77% (17/22) vagina, 11% (2/18) perineum, 61% (11/18) anal, 93% (13/14) rectal, and 0% (0/6) pharynx samples. The mean viable load was marginally higher in cervical compared to vaginal samples (4.37 [SD:1.35] vs. 3.45 [SD:1.05], p=0.055). Mean viable load was higher in rectal compared to anal samples (3.51 [SD:0.51] vs. 2.70 [SD:0.42], p=0.01). Viable load was 2.72 [SD:1.69] CT positive perineum samples.

Conclusions The amount of viable CT varied by anatomic site, and were highest 'upward in the body', which is thus likely to represent actual site of infection. Still, the vaginal and anal sites (that are usually self-sampled) had high concordance with the cervical and rectal sites. CT at the perineum may indicate