Research news in clinical context – Perspectives Issue September

Authors and affiliations:

[1]Miguel Fernandez-Huerta. Microbiology Department, Bellvitge University Hospital, University of Barcelona, Barcelona, Spain

[2]Danielle Solomon. Institute for Global Health, University College London, London, United Kingdom

[3]Rayner Kay Jin Tan. Saw Swee Hock School of Public Health, National University of Singapore, Singapore

High efficacy of ceftriaxone monotherapy for treating extragenital gonorrhoea

Ceftriaxone is a well-established monotherapy for gonococcal urethritis, but efficacy data is limited for its use in treating extragenital *Neisseria gonorrhoeae* (NG) infections. A prospective single-centre study, conducted in Japan between 2017 and 2020 among HIV-negative MSM with extragenital infections, compared the efficacy of 1 g ceftriaxone IV monotherapy with dual therapy adding a single dose of oral azithromycin (1 g) or doxycycline (100 mg twice daily, for 7 days) in those with concomitant chlamydia infection. The total efficacy of ceftriaxone alone and dual therapy were 98.1% and 95.5%, respectively (p=0.29); with no significant difference in efficacy between pharyngeal and rectal NG infections. Despite the high efficacy of ceftriaxone demonstrated in this real-world setting, additional trials need to assess the use of monotherapy for extragenital gonorrhoea in areas where ceftriaxone resistance is a major concern.

Word count: 135

Aoki T, Mizushima D, Takano M, et al. Efficacy of 1g ceftriaxone monotherapy compared to dual therapy with azithromycin or doxycycline for treating extragenital gonorrhea among men who have sex with men. *Clin Infect Dis*. 2021 May 17:ciab455.

Published in STI – The Editor´s Choice: *Neisseria gonorrhoeae* is associated with poor pregnancy outcomes: evidence from a systematic review and meta-analysis

Many bacterial sexually transmitted infections have been associated with adverse pregnancy and birth outcomes (1); however, this risk has not been systematically assessed for *Neisseria gonorrhoeae* (NG). In this systematic review and meta-analysis of 30 studies, NG infections during pregnancy were associated with preterm birth (PTB) (adjusted OR 1.9 [95% CI, 1.1-3.2]) and low birth weight (aOR 1.5 [95% CI, 0.8-2.8]), particularly in low and middle-income countries. Additionally, results suggest that NG infection may be associated with premature rupture of membranes, perinatal mortality, and ophthalmia neonatorum, although estimates in most studies did not control for confounders. The presumptive role of NG in these adverse conditions suggests the need to strengthen preventative interventions for perinatal mortality, especially in low and middle-income countries.

Word count: 121

Vallely LM, Egli-Gany D, Wand H, et al. Adverse pregnancy and neonatal outcomes associated with *Neisseria gonorrhoeae*: systematic review and meta-analysis. *Sex Transm Infect*. 2021 Mar 97(2):104-111.

High accuracy rates found for a point-of-care STI testing system

Point-of care (POC) STI testing is an intervention that could improve treatment rates and optimise antibiotic stewardship. This study investigated the performance of the Visby Medical Sexual Health Test, a POC PCR device for rapid (30 minute) *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Trichomonas vaginalis* (TV) testing. An analysis of self-collected vaginal samples from 1535 cisgender women who attended 10 clinics in seven US states over an 11-month period was undertaken. Results were compared with clinician-collected samples that were tested using three validated nucleic acid amplification tests (NAATs). The device was found to have a specificity of 98.3% (95% CI, 97.5-98.9) and a sensitivity of 97.4% (95% CI, 86.5-99.5) for CT, 97.4% (95% CI, 86.5-99.5) and 99.4% (95% CI, 98.9-99.7) for NG, and 99.2% (95% CI, 95.5-99.9) and 96.9% (95% CI, 95.8-97.7) for TV, respectively. These results indicate the potential utility of this easy-to-use POC test in clinical practice.

Word count: 150

Morris SR, Bristow CC, Wierzbicki MR, et al. Performance of a single-use, rapid, point-of-care PCR device for the detection of *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *Trichomonas vaginalis*: a cross-sectional study. *Lancet Infect Dis*. 2021 May 21(5):668-676.

PrEP use decreased HIV incidence and did not increase risk behaviours among MSM in West Africa

CohMSM-PrEP is a clinic-based prospective cohort study investigating PrEP delivery in Côte D'Ivoire, Mali, Togo, and Burkina Faso. It is an extension of CohMSM, a prevention study that did not include PrEP. Five hundred ninety-eight MSM were followed-up for 743.6 person years after starting PrEP, with 27% lost to follow-up. Seventy-four percent of participants chose event-driven PrEP, and 21% changed PrEP regimen at least once ($p<0.001$). Adherence was optimal in 71% of those taking daily PrEP, and only 41% of those using event-driven PrEP ($p<0.001$). Incidence of HIV was 2.3 per 100 person-years (95% CI, 1.3-3.7), which was lower than that seen in the CohMSM cohort (adjusted IRR 0.21 [95% CI, 0.12-0.36]). Condomless anal sex did not significantly change during the follow-up period ($p=0.99$). These results highlight the utility of PrEP as a prevention tool for MSM in West Africa, and the importance of offering tailored PrEP regimens to this group.

Word count: 151

Laurent C, Dembélé Keita B, Yaya I, et al. HIV pre-exposure prophylaxis for men who have sex with men in West Africa: a multicountry demonstration study. *Lancet HIV*. 2021 May 25:S2352-3018(21)00005-9.

Reducing time to viral suppression through rapid acute HIV Infection testing and immediate treatment among MSM

Targeted screening for acute HIV infection (AHI) may substantially decrease HIV incidence among MSM. This study analyzed data from the Amsterdam STI clinic between 2008 and 2017 from 19728 MSM, of whom 1013 were diagnosed with HIV. A standard strategy involving HIV

diagnosis confirmation in <1 week and combination antiretroviral therapy (cART) initiation in <1 month was utilized from 2008-2014, while an AHI strategy involving same-visit diagnosis and immediate cART initiation was implemented since 2015. Median time to viral suppression dropped from an average of 584 days in 2008-2011 (IQR, 267-1065) to 95 days in 2015-2017 (IQR, 63-136) when universal cART was initiated, but was further reduced to 55 days (IQR, 31-72) for MSM who benefitted from the AHI strategy (2015-2017). Early diagnosis of AHI and immediate cART should be considered in public health responses.

Word count: 135

Dijkstra M, van Rooijen MS, Hillebregt MM, et al. Decreased time to viral suppression after implementation of targeted testing and immediate initiation of treatment of acute Human Immunodeficiency Virus infection among men who have sex with men in Amsterdam. *Clin Infect Dis*. 2021 Jun 72(11):1952-1960.

9-Valent HPV vaccine in pregnancy is not associated with spontaneous abortion and adverse birth outcomes

Data on 9-valent HPV (9vHPV) vaccine exposures during pregnancy are limited. A multisite cohort study comprised 1493 pregnancies between 2015 and 2018 in the US; 445 (29.8%) had vaccine exposures during pregnancy, 496 (33.2%) had peri-pregnancy exposures (within 42 days before last menstrual period [LMP]), and 552 (37.0%) had distal exposures (22 to 16 weeks pre-LMP). Compared with distal-exposures, exposures during-pregnancy or peri-pregnancy were not associated with spontaneous abortion (HR 1.12; 95% CI, 0.66-1.93 and RR 0.72; 95% CI, 0.42-1.24, respectively), preterm birth (RR 0.73; 95% CI, 0.44-1.20 and RR 0.72; 0.45-1.17, respectively), or small-for-gestational-age births (RR 1.31; 95% CI, 0.78-2.20 and RR 1.10; 95% CI 0.65-1.88, respectively) among live births. This findings can inform counselling for patients after inadvertent 9vHPV vaccine exposures.

Word count: 123

Kharbanda EO, Vazquez-Benitez G, DeSilva MB, et al. Association of inadvertent 9-valent Human Papillomavirus vaccine in pregnancy with spontaneous abortion and adverse birth Outcomes. *JAMA Netw Open*. 2021 Apr 4(4):e214340.

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