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**Background:** Prevention of bacterial STIs with post-exposure doxycycline (Doxy-PEP) in MSM raised concerns regarding antimicrobial resistance (AMR). We studied the impact of Doxy-PEP on *Neisseria gonorrhoeae* AMR in the ANRS DOXYVAC trial.
**Methods:** 545 MSM on HIV PrEP were randomized to Doxy-PEP (n = 362) or No-PEP (n = 183) and followed for a median of 14 months. Participants were tested at baseline and every 3 months by nucleic acid amplification technic (NAAT) using the Cobas 6800 (Roche) and culture for GC detection in urine, oro-pharyngeal and anal samples. Etest (Biomerieux) determined MICs and EUCAST guidelines were used for interpretation. Molecular analysis was performed by Whole Genome Sequencing on GC isolates and on NAAT-positive samples in search of molecular determinants of resistance (*tetM* gene, V57M substitution in S10 protein, MtrR and its promotor modification, mutations in the genes coding for 23S rRNA, S91F substitution in GyrA protein, *penA* mosaic gene). P-values were calculated using Fisher's exact test.
**Results:** From January 2021 to February 2023, 450 samples (278 patients) were GC-positive by NAAT. Seventy-eight GC obtained in cultures (7 at baseline, 40 No-PEP group, 31 Doxy-PEP group) and 231 GC-NAAT-positive samples (38 at baseline, 99 No-PEP group, 94 Doxy-PEP group) were retained for molecular testing.
MICs of ceftriaxone, fluoroquinolones and aminoglycosides were similar in the Doxy-PEP and No-PEP groups and no significant change in genetic determinants for these antibiotics was found. Only TEM-1 genes associated with penicillin resistance were more frequently observed in the doxyPEP group than in the no-PEP group (40.4% *vs* 17.5% of cases respectively, p = 0.04).
All GC isolates were resistant to tetracycline, with a significant increase in rate of high-level tetracycline resistance in the Doxy-PEP *vs.* No-PEP group (35.5 vs 12.5%, respectively p = 0.04). In addition, the genetic determinant *tetM* was significantly more frequent in the Doxy-PEP group as compared to the No-PEP group (55/94 = 59.1% *vs* 23/99 = 23.7%), respectively (p<0.0001). No mutation in the gene encoding 23S rRNA was observed.
**Conclusions:** All GC were resistant to tetracycline but rate of high-level resistance mediated by the *tetM* gene were higher with Doxy-PEP. No impact of Doxy-PEP on Ceftriaxone susceptibility was found.

## SS0405LB

### Tenofovir-diphosphate concentrations and viral suppression following monthly point-of-care urine tenofovir testing among adults initiating antiretroviral therapy: primary outcome of the randomised controlled STREAM HIV trial

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**Background:** Point-of-care urine tenofovir (TFV) tests may improve HIV treatment outcomes and need to be assessed in randomized trials. The STREAM HIV trial evaluated whether monthly urine TFV testing among people with HIV (PWH) initiating dolutegravir-based antiretroviral therapy (ART) improved adherence.
**Methods:** We recruited PWH initiating first-line ART at three public clinics in South Africa and randomised participants 1:1 to the intervention (monthly point-of-care urine TFV testing [UCSF/Abbott] with adherence counselling) or control arm (monthly adherence counselling without urine TFV testing). The primary outcome was adherence at 24 weeks, assessed by intracellular TFV-diphosphate concentrations in dried blood spots using mass spectrometry. Secondary outcomes were retention-in-care and viral suppression (VS <200 copies/ml). We compared $\log_{10}$ TFV-diphosphate concentrations using t-tests and estimated risk ratios (RR) using modified Poisson regression.
**Results:** 539 participants (58% female, mean age 33 years, CD4 count 393 cells/μl, median viral load 38,163 copies/ml, 5.8% active TB) were initiated on ART between 02/2021-06/2023. At 24 weeks, 242/270 intervention and 234/269 control arm participants had TFV-diphosphate results for analyses. Geometric mean TFV-diphosphate concentrations were similar among intervention and control participants (1,253 versus 1,198 fmol/punch, p = 0.510). However, the proportion with detectable TFV-diphosphate (≥200 fmol/punch) was higher in the intervention than control arm (98.8% versus 92.7%, RR = 1.06, 95%CI 1.02-1.11, p = 0.001), Figure 1. Retention-in-care (88.5% versus 86.2%, RR = 1.03, 0.96-1.09), VS (93.8% versus 91.4%, RR = 1.03, 0.97-1.08) and Retained+VS (82.2% versus 78.8%, RR = 1.04, 0.96-1.13) were slightly higher in the intervention than control arm, but not significantly different.
**Conclusions:** In this South African cohort initiating dolutegravir-based ART, overall adherence and VS were high at 24 weeks. Monthly point-of-care urine TFV testing led to more participants achieving detectable TFV-diphosphate concentrations, but did not produce higher drug concentrations or more VS. The impact of urine TFV testing in combination with point-of-care viral load testing will be assessed at 72 weeks.