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Virological efficacy of first-line regimens, resistance profile and factors influencing adherence to ART in clinical practice in Ukraine

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Background: Integrase inhibitors (INI) have recently been recommended for first line therapy (FLT) in Ukraine, but non-nucleoside reverse transcriptase inhibitors (NNRTI) based regimens present a majority of FLT cases, even though testing for NNRTI mutation has not been routinely performed. Data regarding virological efficacy of ART and prevalence of drug resistance mutations in Ukraine is scarce. We evaluated the virological response, resistance profile, factors influencing adherence to treatment in patients starting a first-line regimen in clinical settings in Ukraine.

Materials and methods: We conducted a retrospective cohort study in Poltava region, Central Ukraine of 2813 newly diagnosed HIV-patients >18 years old who entered care and started ART from 2004 to 2018 and followed at least 6 months. The presence of major resistance mutation to NRTIs, NNRTIs, PIs was evaluated at virological failure (VF, defined as an HIV-RNA, VL > 1,000 copies/mL after week 24 for treatment experienced). The RNA isolation, amplification and sequencing were performed using ViroSeq HIV-1 Genotyping Kit (Celera), for the data interpretation Stanford HIV DR Database was used. Potential risk factors associated with bad adherence and treatment discontinuing have been identified by using multivariate logistic regression models.

Results: Among our cohort of 2813 HIV-patients receiving ART, heterosexual route of HIV transmission made up 62% (n = 1730). Median enrolment age was 42 years (IQR 42 - 62), 1431 (51%) were men. Late stages of HIV-infection (III, IV) were diagnosed in 66 % (n = 1849) patients. During observation period, 1617 (57.5%) patients continued initial first-line regimen ART, 891 (31.7%) had at least one switch of ART in same drug class, and 130 (4.6%) patients developed virological failure and have been switch to second-line regimen of ART. Among

patients continued initial first-line ART during the study period, EFV-based regimens were reported in 69.2% (n = 1118), DTG - in 21.7 % (n=352), LPV/rtv in 5.8% (n = 95) patients. Twenty patients (15.3%) had an available genotypic resistance test at virological failure. The most frequent mutation were: NRTI class – K65R (11/20, 55%), M184V (8/20, 40%), Y115F (3/20, 15%), L74V, D67V, A62V, K219E – 2/20, 10%, NNRTI class - G190S (17/20, 85%), Y181C (15/20, 75%), K101E (13/20, 65%), PI class - M46IM (3/20, 15%), L10I (1/20, 5%). High adherence to care during ART was best predicted by social support (OR=1.4, 95%CI 1.0- 2.1), attending clinic of integrated services with access to opioid replacement therapy (ORT) (OR=1.1, 95% CI 1.0-1.1). Bad adherence to care was significantly higher in HIV-infected patients who injected drugs and women who diagnosed during the pregnancy (OR=1.6, 95% CI 1.1- 1.8; OR=1.9, 95% CI 1.5-2.3).

Conclusion. In clinical practice, patients receiving first-line ART achieve and maintain high rates of virological suppression. NNRTI - based regimens had the most frequent rate of administration in first-line ART and high prevalence of mutation. The main factors associated with high adherence during ART were social support, good access to integrated services clinics with ORT.