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Determinants of the use of the fixed dose combination emtricitabine/rilpivirine/tenofovir (Eviplera) in the Icona Foundation Study

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Background: Emtricitabine/rilpivirine/tenofovir (Eviplera) is a fixed dose combination of antiretroviral approved by the Food and Drug Administration in August 2011, by the European Medicines Agency in November 2011 and introduced in care in Italy in February 2013 for patients who have not previously been treated for HIV. It is available as a once-a-day single tablet and In the European Union is licensed for use only in patients with a viral load less than or equal to 100,000 copies/ml.

Objective: To identify factors that may be associated with the use of EVP as first-line regimen in HIVinfected individuals starting cART from ART-naïve in Italy. **Methods:** Clinical sites in Icona Foundation Study in which ≥ 1 patient had started EVP were selected for this analysis. From these sites we included all patients who started an EVP-based cART regimen as well as those starting other cART regimens after the date of first introduction of EVP at the site (after February 2013 in any case) and with a viral load $\leq 100,000$ copies/ml from ART-naïve. Characteristics at the time of starting cART were compared using chi-square test and unadjusted and adjusted logistic regression analysis. Factors showing unadjusted associations with a pvalue of 10% or smaller, were retained in the multivariable model.

Results: We identified 106 patients starting EVP and 111 starting a concurrent control regimen from ARTnaïve from 23 sites. The number of patients starting EVP included at each site ranged from 1 to 12 and the number of those starting concurrent regimen was similar. The most frequently used drugs in the concurrent group were: tenofovir (71%), emtricitabine (70%), darunavir (35%), atazanavir (29%), lopinavir (11%), efavirenz (20%) and raltegravir (11%). Percentages in EVP vs. concurrent were as follows: heterosexuals (37% vs. 48%, $p=0.27$), university level of education (10% vs. 19%, $p=0.06$) and students (8% vs. 2%, $p=0.24$). There were imbalances between the two groups in median CD4 count (404 vs. 301 cells/mm³, $p=0.001$) and time from HIV diagnosis to starting cART (17 vs. 3 months, $p=0.001$). No larger differences were observed for other factors examined. The table shows all these factors investigated and the estimates of the odds ratios (OR) from fitting a logistic regression model.

Conclusions: In a subset of sites of our cohort with documented use of EVP, no large differences in the characteristics of patients starting EVP or concurrent regimens were observed, with the exception of level of education (lower in the EVP), prevalence of students (higher in the EVP group), time from HIV diagnosis and CD4 count (EVP was started in those who have been diagnosed with HIV for longer and had higher count). Guidelines suggest avoiding initiation of EVP in people with high viral load and this might have led to the observed difference in CD4 count. It also appears that EVP is preferably given to people with lower education or perceived to have a slow progressing disease.