

PrEP and Risk of Drug Resistance

FACT SHEET FOR POLICY MAKERS

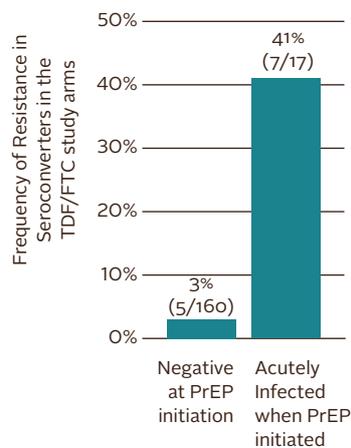
Why Is PrEP and Drug Resistance a Concern?

We know that TDF-based PrEP (either tenofovir or Truvada, which contains the antiretroviral (ARV) drug emtricitabine in addition to tenofovir) works well to prevent HIV infection when taken correctly and consistently. However, PrEP does not eliminate HIV risk completely. If a person becomes infected with HIV while taking PrEP, the virus in their body could become resistant to these ARV drugs; potentially limiting long-term ARV treatment options for the HIV infected individual. On a larger scale, if exposure to PrEP leads to an increased rate of drug resistance in the community, this will impact the effectiveness of ARV drug regimens for both prevention and treatment.

What Do We Currently Know About Drug Resistance and PrEP?

The current understanding about the frequency of drug resistance is from the 5 completed placebo-controlled TDF/FTC PrEP clinical trials (FEM-PrEP, iPrEX, TDF2, Partners PrEP, VOICE)¹:

- Among the 160 study participants that seroconverted while on PrEP, only 5 (3%) developed resistance to emtricitabine
- Among the 17 study participants that initiated PrEP while they were in the acute seroconversion phase, 7 (41%) developed drug resistance: 6 had emtricitabine resistance only, and 1 had both tenofovir and emtricitabine resistance



Will Drug Resistance be a Problem when PrEP is Rolled Out on a Larger Scale?

We do not know yet. The risk was low among clinical trial participants overall; however, it was higher among those who initiated PrEP while they were in the acute seroconversion phase. The risk of drug resistance when PrEP is implemented on a large scale may differ from clinical trials because:

- In clinical trials, participants received monthly HIV testing which allowed research clinicians to immediately stop PrEP use once infection was identified; in large scale PrEP programs, HIV testing will occur quarterly or at different intervals
- We do not know how adherent individuals will be while taking their PrEP medication
- We cannot rule out the possibility that an individual will initiate PrEP during acute infection; however newer HIV tests that confirm infection within a shorter window period, and a thorough assessment of acute seroconversion symptoms, could help reduce this possibility

How Can Countries Evaluate the Risk of Drug Resistance?

Policy makers should consider monitoring PrEP users for drug resistance to better inform the effectiveness of the PrEP program. This can be done by collecting a blood sample on seroconverters at the time of HIV infection, and conducting a drug resistance laboratory test. For information on ongoing assessments of PrEP and drug resistance, and to review toolkit materials that support a drug resistance monitoring program, visit:

<http://gems.pitt.edu>.

¹ Parikh UM, Mellors JW. Should we fear resistance from tenofovir/emtricitabine preexposure prophylaxis? *Curr Opin HIV AIDS* 2016 Jan; 11(1):49-55.