

PrEP and Risk of Drug Resistance

FACT SHEET FOR HEALTH CARE WORKERS

Why Is PrEP and Drug Resistance a Concern?

We know that Pre-Exposure Prophylaxis (PrEP) works very well to prevent HIV infection when taken correctly and consistently. However, there is a chance that someone may start PrEP before they know they are HIV infected, or they can become infected with HIV while using PrEP. If this happens, the virus in their body could change, or mutate, and become resistant to these ARV drugs. This does not mean, however, that the virus is resistant to all types of ARV drugs.

People who have HIV typically need to take 3 ARV drugs to stop the virus from making copies of itself (also called replicating). When drug resistance occurs, some ARVs are no longer able to stop HIV from replicating and the person would need to start taking a different combination of ARV drugs. Ultimately, this means that the PrEP user may have fewer choices of the ARV drugs that they can use for treatment.

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

We do not know yet. The Global Evaluation of Microbicide Sensitivity (GEMS) project is collecting samples and analyzing these data to better understand whether resistance will be a problem. We do know that the risk of drug resistance was low in completed clinical trials where study participants were assigned to take a daily pill containing tenofovir or Truvada. But the risk of drug resistance in the “real world” may differ because:

- In clinical trials, study 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 may occur quarterly or at different intervals
- We do not know how well PrEP users will take their medication; when PrEP is not taken consistently, risk of HIV infection is greater
- There is the possibility that PrEP could be started in clients who are newly infected with HIV, but current rapid HIV tests did not detect their infection.

What Should Happen if a PrEP User has a Positive HIV Test?

- **Stop Using PrEP:** stop taking PrEP immediately after the first positive HIV rapid test; if HIV infection is confirmed, they should never start using PrEP again.
- **Refer for Antiretroviral Treatment (ART):** PrEP users who acquire HIV should be referred for HIV treatment according to WHO and country HIV treatment guidelines.
- **Conduct a Drug Resistance Test:** conduct a drug resistance test if recommended by country guidelines; the absence of a drug resistance test should not prevent the individual from accessing antiretroviral treatment.



Avoiding Drug Resistance: Counseling Messages for PrEP Clients

There are three ways to avoid resistance while taking PrEP:

1. **Avoid Getting HIV:** Clients should use PrEP consistently and correctly, as part of their individual comprehensive HIV prevention package. Resistance to ARV drugs cannot occur in a person who does not have HIV.
2. **Attend Clinic Visits:** Clients should attend clinic visits as recommended, to have their health checked and get an HIV test. If they miss visits, they may not know their HIV status. This is important because an HIV infected person that keeps taking PrEP may develop drug resistance.
3. **Do Not Share PrEP:** Sharing PrEP with other people, even with a partner, could be harmful. They could have HIV, and not know it. If HIV infected individuals use PrEP, they could develop resistance to ARV drugs.

Visit the GEMS website for more information about PrEP and drug resistance: <http://gems.pitt.edu>

JUNE 2017