

PREP TRIAL RESULTS AT CROI

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Overview

New scientific data on the use of pre-exposure prophylaxis (PrEP) and a microbicide gel are among the results being presented at the 2015 Conference on Retroviruses and Opportunistic Infections (CROI), which is taking place from 23 to 26 February 2015.

The data are likely to attract wide interest from the media, countries, donors, civil society and other partners working on the global response to HIV.

UNAIDS will be releasing a press statement directly after the results are presented. A Q&A is detailed below.

Q&A

What are the new results?

- New results presented at the 2015 Conference on Retroviruses and Opportunistic Infections (CROI) have shown that two studies demonstrate that the antiretroviral medicines tenofovir and emtricitabine, when used as pre-exposure prophylaxis (PrEP), are 86% effective in preventing new HIV infections among men who have sex with men.
- A third study found PrEP for HIV-negative partners, combined with antiretroviral therapy for HIV-positive partners in serodiscordant couples, to be up to 96% effective in preventing HIV infection.
- A further study in South Africa showed that the use of tenofovir as a vaginal gel was not effective in preventing new HIV infections among young women.

What are the details of the studies?

- The **PROUD** study in the United Kingdom enrolled 545 men who have sex with men at higher risk of HIV infection. Half of the participants were given a daily pill of tenofovir and emtricitabine, the other half were deferred and only received PrEP after one year.
- According to the results presented at CROI, there were a total of 22 new HIV infections among people in the study—19 were among people in the group that was not initially offered the active medicine and three were among the people who took tenofovir and emtricitabine daily. The PROUD results showed that people taking a daily pill of tenofovir and emtricitabine were 86% less likely to become infected with HIV.

- Results presented by the organizers of the Franco-Canadian **IPERGAY** study have also showed the significant efficacy of PrEP. In the **IPERGAY** study, 445 men who have sex with men at higher risk of HIV infection were enrolled in a trial in which half were asked to take four tablets of tenofovir and emtricitabine, two before and two after sexual intercourse; the other half were given a placebo.
- According to the results presented, there were a total of 16 new HIV infections in the **IPERGAY** study, 14 among people taking the placebo and two among people in the group taking tenofovir and emtricitabine. The **IPERGAY** results showed that people in the group taking the active pill before and after sex were 86% less likely to become infected with HIV.
- In both the studies, the trials were modified to offer active medicines to all participants after interim analysis of the data showed such a positive effect.
- In a further study, the **Partners PrEP Demonstration Project**, more than 1000 serodiscordant couples (where one partner is living with HIV and the other is not) in Uganda and Kenya were enrolled. The HIV-positive partner in each serodiscordant couple was offered antiretroviral therapy and the HIV-negative partner was offered PrEP.
- A computer simulation model calculated efficacy of PrEP combined with early treatment to be up to 96% among serodiscordant couples.

How significant does UNAIDS think these studies are?

- UNAIDS strongly welcomes the results of the scientific trials presented at CROI.
- The two studies demonstrating that the antiretroviral medicines tenofovir and emtricitabine, when used as PrEP, are effective in preventing new HIV infections among men who have sex with men are a significant breakthrough in advancing efforts to provide effective HIV prevention options to men who have sex with men.
 - New HIV infections among men who have sex with men are continuing to rise in many settings.
 - These new scientific advances, combined with other proven HIV prevention options, could give men who have sex with men the additional HIV prevention options they need to protect themselves against HIV infection.
- The Partners PrEP Demonstration Project is significant in that it is an effective demonstration that PrEP combined with antiretroviral therapy is extremely effective in preventing HIV among serodiscordant couples and could significantly reduce the rate of new HIV infections among serodiscordant couples.

Does UNAIDS recommend the use of PrEP for men who have sex with men and serodiscordant couples?

- Yes. Both of these uses of PrEP are included within existing WHO recommendations. What is more challenging is to develop appropriate delivery systems that fit within country prevention programmes.

What are the next steps for implementation?

- UNAIDS and WHO are convening a series of meetings next month in Geneva to move forward with guidance on implementation for men who have sex with men, to define the possible scope of recommendations on PrEP for women and to garner consensus on the position of PrEP within the overall HIV prevention agenda for the coming years.

Do the results from FACTS 001 show that a microbicide gel is not effective?

- The results from the South African FACTS 001 trial were disappointing as they showed that the use of tenofovir as a vaginal gel was not effective in preventing new HIV infections among young women.
- However, it does give valuable information about the ongoing need for effective prevention in this group of women. The study was well conducted and had excellent retention, so the result is clear-cut. Results of ongoing studies, in particular of other antiretroviral-based products within vaginal rings worn for one month at a time, will be reported next year.

Is PrEP the magic bullet for HIV prevention?

- UNAIDS stresses that despite the recent scientific advances there is still no single method that is fully protective against HIV. To advance efforts to end the AIDS epidemic by 2030, UNAIDS strongly recommends a combination of HIV prevention options. These include timely access to antiretroviral medicines for people living with HIV and as HIV prevention for people at higher risk of exposure to HIV, correct and consistent use of male and female condoms, waiting longer before having sex for the first time, having fewer sexual partners, medical male circumcision as well as other biomedical, behaviour change and structural approaches. PrEP is an additional approach, which when added to the existing package clearly reduces HIV infection among higher risk men who have sex with men and among serodiscordant couples.