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Partners in Prevention Research Advocacy

Fact Sheet: Pre-Exposure Prophylaxis for HIV Prevention - August 2006

Background

Finding new HIV prevention strategies is important to people everywhere. After years of messages about partner reduction, condom use and monogamy, we know that the epidemic rages on. A new prevention strategy like Pre-exposure prophylaxis, or PrEP, would not solve everything. But it would be an important addition to a comprehensive response to the epidemic. Experience from other fields suggests that introduction of a new prevention strategy will also increase overall use of other prevention strategies.

What is PrEP?

Pre-exposure Prophylaxis or “PrEP” refers to an experimental HIV prevention strategy that would use antiretrovirals to protect HIV-uninfected people from HIV infection. PrEP is not proven to work. In the strategies that are currently being tested, HIV-uninfected people would take a daily dose of a single drug or a combination of drugs¹. PrEP has some similarity to the strategy of giving newborns antiretroviral drugs to help prevent transmission of HIV from mother to child through breastfeeding. PrEP can also be compared to birth control pills; whereas a contraceptive pill is taken once daily to prevent pregnancy, a PrEP pill could be taken once daily to prevent HIV infection in case of exposure. Despite the similarities, it is important to remember that PrEP is a novel and as-yet-unproven prevention strategy.

Current Research

There are now five ongoing human clinical trials of PrEP in Ghana (women), Thailand (men and women), Botswana (men and women), the United States (MSM), and Peru (MSM). These studies are testing a PrEP strategy using either tenofovir or Truvada™, both of which are antiretroviral drugs currently used as treatment for HIV infection. In addition to these ongoing trials, there were trials stopped or cancelled in Malawi, Nigeria, Cameroon and Cambodia. These trials were halted for different reasons. There have been several reports on and consultations about the issues raised by these trials, discussing the specifics of the concerns and the steps that have been proposed to address them. For scientific background, information on research ethics, and a table of current planned and ongoing trials, please visit www.prepwatch.org.

Challenges and Next Steps

- PrEP is still an unproven strategy that must be tested to see if it is effective through clinical trials.
- The ongoing trials do not have sufficient statistical “power” to provide definite answers about whether PrEP works in all populations and against various modes of transmission. Thus, additional trials may be needed.
- Awareness needs to be raised about the need for developing and testing PrEP strategies among all the populations who could benefit from a new HIV prevention intervention.
- Work needs to be done in communities where research is planned or is being conducted in order to increase their understanding of clinical research, including how prevention trials are designed. Also, more efforts are needed to ensure that these studies are scientifically sound, meet the highest ethical standards, and are conducted with full community participation.
- Industry and research partners need to understand and develop an agenda for testing PrEP strategies, and for making decisions about which strategies to move forward (such as particular drugs or combinations of drugs, or different dosing strategies).

¹ The people participating in these trials receive counseling and information about using proven risk reduction strategies such as condoms and clean needles throughout the trial. They are not asked to rely on PrEP (which is unproven) as their sole means of protection. The design and conduct of HIV prevention trials, including provision of risk reduction counseling, is a broad topic. For more information on this topic, see “*Finding Your Way: A guide to understanding ethical issues related to participation in clinical trials for preventive AIDS vaccines*” available at <http://avac.org/publications/ethics.htm>