



## **Trial of Microbicide for HIV Prevention Finds Tenofovir Gel Safe and Readily Accepted by Women**

A vaginal microbicide that incorporates an antiretroviral (ARV) drug normally used to treat people with HIV is safe for sexually active HIV-negative women to use every day over an extended period, suggest results of a multi-institutional clinical trial of tenofovir topical gel. Moreover, most of the women who participated in the study conducted in India and the United States said they would be willing to apply gel, including daily, if it could help prevent getting HIV from their sexual partners. These findings by the Microbicide Trials Network (MTN), a National Institutes of Health (NIH)-funded clinical trials network which conducts studies through a consortium of institutions that includes the Mailman School of Public Health, were reported at an international meeting of microbicide researchers, Feb. 24-26, in New Delhi, India.

Microbicides are substances designed to prevent the sexual transmission of HIV when applied in the vagina or rectum. Tenofovir gel is among a newer group of candidate microbicides that differ from the early types because they have specific action against HIV. In addition, because tenofovir gel and similar substances are longer acting, their use may not be required before each act of sex, which is not always practical or desirable for some women.

Findings from the MTN trial are a significant boost to HIV prevention efforts focused on the potential of “next-generation” microbicides to curb infection rates in women who are more than twice as likely as men to contract HIV through sexual intercourse. In this Phase II study, called HPTN 059, researchers wanted to understand if tenofovir was safe to use every day for six months compared to its use prior to sex. Researchers also wanted to find out whether women would readily use tenofovir gel on a daily basis. The study showed that use of tenofovir gel was equally safe, when used every day or before sex. Women who participated in the study were similarly able to adhere to the prescribed daily application schedule.

“These findings represent an important step towards developing an effective microbicide that women can use on a daily basis to protect themselves from HIV,” said Wafaa El-Sadr, MD, professor of Epidemiology and Medicine, director of the International Center for AIDS Care and Treatment Programs (ICAP), and principal investigator of the Mailman School’s Centers for Innovative Research to Control AIDS (CIRCA), an NIH-funded prevention research unit which helped design and implement the HPTN 059 study. “We are especially encouraged by the nearly unanimous willingness of the study participants to use the gel if it were found to help prevent people from getting HIV.”

Jessica Justman, MD, assistant professor of clinical Epidemiology, who also helped design and implement the tenofovir microbicide study, served as the lead investigator of the clinical trial at Bronx Lebanon Hospital in New York City, one of the sites affiliated with CIRCA. Two other sites at the University of Alabama at Birmingham and the National AIDS Research Institute in Pune, India, also served as trial sites for the microbicide.

In its pill form, tenofovir is a mainstay of one of the most widely used regimens for treating HIV. The active ingredient in tenofovir gel belongs to a class of ARV drugs called nucleotide reverse transcriptase inhibitors, which act against HIV by targeting a key enzyme that HIV needs to copy itself before taking over a host cell.

Additional studies are planned to further evaluate the safety of tenofovir gel, its effectiveness for preventing HIV, and the adherence profile among women. Other microbicide products have been or are currently being tested in clinical trials, although none is yet approved or available for use by women.

HPTN 059 was conducted by the Microbicide Trials Network clinical trials network established in 2006 by the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The MTN brings together international investigators, community and industry partners who are devoted to reducing the sexual transmission of HIV through the development and evaluation of microbicides, working within a unique infrastructure specifically designed to facilitate research required to support licensure of topical microbicide products for widespread use. The Microbicide Trials Network is based at the University of Pittsburgh.