Microbicides: A Vaginal Gel That Could Prevent HIV

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I am a study manager of the Population Council's microbicides program and on January 19th I kicked off this winter's SMART University by discussing the Council's research on HIV prevention and, specifically, microbicide development.

Globally, women's rates of HIV infection are rising higher and faster than men's, and the existing strategies for prevention—abstinence, condom use, and mutual monogamy between HIV-negative partners—are not practical for the majority of women, particularly those in developing countries.

In March 2004, the Population Council began a large clinical trial of a potential microbicide—a vaginal gel called Carraguard® —that may be able to protect women from becoming infected with HIV. If proven effective, this colorless, odorless gel will offer a powerful new tool against AIDS.

Because of the urgent need for a female-controlled product useful to all women, the Council's first candidate for a microbicide, Carraguard, was designed so that it does not prevent pregnancy. However, additional microbicide products the Council is developing do include a contraceptive option.

Before the current study was begun, five safety studies of Carraguard were performed on seven different continents, with HIV-negative as well as HIV-positive women and men. It was important to make sure the gel was safe for HIV-positive people, since many women may want to use it to prevent re-infection with a different strain of HIV and because, should the gel prove effective, many infected people may use it without knowing their own HIV status.

The current Carraguard study is being conducted at three clinic sites in South Africa in collaboration with the Medical University of Southern Africa, the University of Cape Town, and the Medical Research Council. Altogether, 6,203 HIV-negative, non-pregnant volunteers who were able to commit two years to the study were enrolled and randomly and anonymously assigned to one of two study groups. Not even the researchers know who is in which group, to ensure they do not accidentally cue participants and affect their behavior.

One group is using the Carraguard gel, the other a placebo that smell, tastes, and feels like Carraguard but contains no active ingredients. Each group is instructed to use both a condom—the surest known way to protect against HIV/AIDS—and a gel during intercourse. Women in both groups receive benefits, including free pap smears, condoms, counseling, and testing for sexually transmitted infections (STIs) and HIV and AIDS. Participants with curable STIs are treated, and HIV-positive women are given additional counseling sessions and referred to hospital programs.

The study will end on March 31, 2007. After that, the data will be analyzed and will reveal to what extent Carraguard protects women from HIV infection. The gel is not expected to provide 100 percent protection, but even if it is 50 percent effective, it could

mean hundreds of thousands, perhaps millions, of HIV infections avoided and lives saved.

In addition to the Carraguard study, the Council is carrying out several other studies in the three South African clinics: researching the acceptability of the gel, testing informed-consent procedures within the trial, and evaluating the HIV and AIDS services of the local health care system.

Funding from a dozen major grant-making institutions—in particular the United States Agency for International Development (USAID), the Bill and Melinda Gates Foundation, and the International Partnership for Microbicides—supports the work described above. For more information on the Population Council, you can visit the website www.popcouncil.org/microbicides.

This spring, The Microbicide Development Act will be introduced in both the House and Senate. The goal of the bill will be to achieve better coordination and expanded resources for microbicide research and development in the major US government agencies—the National Institute of Health, the Centers for Disease Control and Prevention, and USAID. For more information on how you can support microbicides development and this bill in particular, you can visit: www.global-campaign.org.