

NEWS RELEASE

Trial Shows Anti-HIV Microbicide Is Safe, but Does Not Prove It Effective *Research Advances HIV Prevention Field*

JOHANNESBURG, SOUTH AFRICA and NEW YORK, NY (18 February 2008) — The Phase 3 clinical trial of the Population Council's candidate microbicide Carraguard® found the product to be safe for vaginal use. The trial did not demonstrate that Carraguard is effective in preventing male-to-female HIV transmission during vaginal intercourse.

There were 134 new infections in the Carraguard group (an incidence of 3.3 infections per 100 woman-years) and 151 new infections in a placebo group (an incidence of 3.7 per 100 woman-years). The difference between the two groups is not statistically significant.

Carraguard is the first product developed as a microbicide to complete the final phase of product testing. "We are disappointed that this trial did not show Carraguard to be effective; nonetheless the completion of this trial is a milestone in HIV prevention research," said Population Council president Peter Donaldson. "The trial has contributed significantly to the field's body of knowledge regarding product development, trial design, and women's and their partners' willingness to use a vaginal gel consistently. The data from the trial will be used by the Population Council and others working on microbicides to improve future products and trials."

The Carraguard trial, which began in March 2004 and ended in March 2007, enrolled 6,202 women and was conducted at three sites in South Africa: the Setshaba Research Centre, through the University of Limpopo/Medunsa campus; the Empilisweni Centre for Wellness Studies, through the University of Cape Town; and the Isipingo Clinic, through the Medical Research Council of South Africa. These sites are located in areas where the HIV epidemic is acute.

Carraguard is made of carrageenan, a seaweed derivative that is on the US Food and Drug Administration's list of products "Generally Recognized As Safe" for consumption and topical application. Laboratory research has shown Carraguard to be effective in blocking cells from becoming infected by HIV and in protecting mice from some other sexually transmitted infections. Carraguard and similar carrageenan formulations had undergone extensive safety testing involving more than 850 women and men in earlier clinical trials in Australia, Chile, the Dominican Republic, Finland, South Africa, Thailand, and the United States.

Half of the women enrolled in the Phase 3 study were given Carraguard gel and condoms, and the other half received a placebo gel and condoms. Participants received HIV education, gynecological exams, risk-reduction and safer-sex counseling, and testing and treatment for curable sexually transmitted infections. The Population Council funded medical and psychological services for women who were HIV-positive at screening or became HIV-positive during the course of the trial.

The randomized, double-blind study found that there were no safety-related differences between women using Carraguard and women using the placebo, and that gel-related side effects were minor and infrequent. This finding is important because Carraguard is a key component of next-generation microbicide candidates being developed at the Population Council. Several of these candidates combine Carraguard with one or more ingredients that have been shown to be effective in preventing virus transmission in laboratory settings.

“The Population Council will use these trial results to accelerate the development of effective means for women to protect themselves against HIV,” said Naomi Rutenberg, director of the Population Council’s HIV and AIDS program.

The trial was funded by the US Agency for International Development (USAID) and the Bill & Melinda Gates Foundation. Jeff Spieler, senior science advisor in population and reproductive health at USAID, said, “We have always known that the path to developing a successful microbicide would be a long one. The Population Council has done groundbreaking work in completing this trial, even though we are terribly disappointed that the product was not shown to be effective. Now we all have to redouble our efforts to develop a microbicide that women can use to protect themselves.”

More information about the Population Council’s microbicides program is available at www.popcouncil.org/microbicides.

About the Population Council

The Population Council is an international, nonprofit, nongovernmental research organization that seeks to improve the well-being and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources. The Council conducts biomedical, social science, and public health research and helps build research capacities in developing countries. Established in 1952, the Population Council has been working in Africa since the 1960s and in South Africa for nearly a decade. It has a global network of regional and country offices, including one in Johannesburg, South Africa, and ten others in Africa. During the past decade, the Council has worked on projects in 25 African countries.

About microbicides

Vaginal microbicides are being developed as female-initiated methods for reducing male-to-female transmission of HIV and possibly other sexually transmitted infections when used during sex. Women need more options to protect themselves from infection because current prevention strategies are not always feasible. While no effective microbicides yet exist, they would most likely be formulated as gels, creams, foams, or vaginal rings. More information about the field is available at <http://www.global-campaign.org> and <http://www.microbicide.org>.

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