

BENEFITS

of the Population Council's Microbicides Program and Phase 3 Carraguard® Trial

The Population Council's Phase 3 clinical trial of Carraguard has contributed vital knowledge, systems, and processes to the microbicides community that will facilitate and enhance future product development and testing. The nation of South Africa has gained in its capacity to host and conduct scientific research through the training and experience of researchers and health care workers, and through new and improved research facilities. The people of the trial communities have learned more about HIV and AIDS and safer-sex practices, while contributing to groundbreaking HIV-prevention research.

Trial Benefits for the Microbicides and HIV-Prevention Fields

In collaboration with Community Advisory Groups, informed consent procedures were developed that allowed women interested in the trial to make truly voluntary decisions about whether or not to join. Community feedback was incorporated into trial outreach materials, informed consent forms, study booklets, and video.

A biomarker was developed to determine how frequently participants were using the study gels. Accurate information about product use is vital to understanding study results.

For the first time in microbicides trials, bar codes were printed on product applicators to track each individual applicator in circulation during the trial, creating accountability and accuracy to a degree not possible with counting by hand.

During the past 18 years, as the Population Council has been developing and testing microbicides, many international ethical and regulatory review entities have been educated in the concept and realities of microbicides.

Research among Phase 3 trial participants, their partners, and study staff members advanced knowledge of:

- how sexual norms and practices, partner relationships, and the importance of covert product use affect acceptability of and consistency in using a microbicide
- how relationships between staff health care providers and trial participants may affect participants' perceptions, experiences, and willingness to use a microbicide
- whether referral services for HIV and AIDS were meeting the needs of HIV-positive women
- whether the video improved comprehension among women considering trial enrollment

Trial Benefits for South Africa

Clinical and laboratory facilities were refurbished and/or redesigned at each location to a level appropriate for a clinical trial. These well-equipped sites are now being used for other HIV-

prevention product studies. Motor vehicles used during the trial have been donated to Family Health International, another NGO, to use during its HIV-prevention clinical trial at these facilities.

Dozens of South African clinicians, nurses, and counselors received training that enhanced their ability to conduct high-quality scientific clinical studies.

Local journalists were provided with background materials, expert resources, and educational workshops, enhancing their—and thus their current and future audiences'—understanding of public health issues.

Trial Benefits for Participants and Communities

More than 9,500 women learned their HIV status as a result of the Carraguard trial. Participants reported that one of the incentives to join the trial was to be tested for HIV in a professional setting that included counseling.

More than 6,000 trial participants received high-quality sexual and reproductive health care, free of charge, as well as regular STI testing and treatment, safer-sex counseling, and HIV testing, all of which contribute to reduced risk of HIV infection.

Women who tested positive for HIV at screening or during the trial were referred to medical, psychological, and support services in the community. One site also offered CD4 count testing, nutritional counseling, physician check-ups, and support groups.

After the trial, all women who seroconverted were offered an additional, on-site monitoring visit including tests for CD4 count and viral load, a Pap smear, a physical exam, and direct referrals to antiretroviral programs for women who were eligible.

Women who volunteered for but did not participate in the trial were eligible for services at screening, including testing and treatment for sexually transmitted infections; pre- and post-test counseling for HIV; screening and referrals for gynecological conditions; free condoms; and risk-reduction counseling.

The women who enrolled in the trial had access to comprehensive family planning services.

Women in the study were entitled to bring their male partners in for free counseling, information, and STI treatment.

Evaluations continue to identify specific areas of need in the clinics to which HIV-positive women were referred—an important step in the development of higher-quality services for people living with HIV and AIDS in the trial communities.

For more information about the Population Council's microbicides program, visit
www.popcouncil.org/microbicides/Resources