

# THE POPULATION COUNCIL, HIV AND AIDS, AND MICROBICIDES

## **What does the Population Council do?**

- The Population Council is an international, not-for-profit, nongovernmental organization that conducts biomedical, social science, and public health research on global issues, including HIV and AIDS; poverty, gender, and youth; and reproductive health.
- Founded in 1952 and headquartered in New York, the Population Council employs more than 500 people, has offices in 18 developing countries in Africa, Asia, and the Americas, and conducts research in more than 50 countries.

## **The pandemic of HIV and AIDS**

- The number of people living with HIV is now higher than ever: Approximately 39.5 million people worldwide are HIV-positive. In 2008, more than 2.7 million were newly infected, and the epidemic claimed an estimated 2 million lives.
- Gender-based power imbalances fuel the feminization of AIDS.
- Women are mobilizing to fight HIV and care for those affected by AIDS on every continent. Women are leading efforts to improve women's social and economic status.

## **HIV and AIDS in sub-Saharan Africa**

- Over two-thirds of all people living with HIV reside in sub-Saharan Africa.
- An estimated 1.9 million people in sub-Saharan Africa became infected with HIV in 2008, more than in all other regions of the world combined.
- The latest survey data underscore the disproportionate impact of the AIDS epidemic on women and girls in sub-Saharan Africa. They are more likely to be living with HIV and more likely to be caregivers for other HIV-positive people.
- Sixty percent of people living with HIV in sub-Saharan Africa are women, who are at greater risk of HIV infection than men for a range of biological and sociocultural reasons.
- Young women between the ages of 15 and 19 are particularly vulnerable to HIV. In Kenya, young women are three times more likely to become infected than their male counterparts. In Tanzania, females in this age group are four times more likely than males to be living with HIV.
- In 2008, more than 14 million children in sub-Saharan Africa had lost one or both parents to AIDS.
- Southern Africa remains the area most heavily affected by the pandemic. The nine countries with the highest HIV prevalence worldwide are all located in the subregion, with each of these countries experiencing adult HIV prevalence greater than 10 percent.
- With an estimated adult HIV prevalence of 26 percent in 2007, Swaziland has the most severe level of infection in the world.
- South Africa is home to the world's largest population of people living with HIV (5.7 million).

### **The Population Council and HIV and AIDS**

- The Population Council has a comprehensive approach to HIV prevention, support, and treatment. In high-prevalence areas, Council researchers work to understand the individual, social, and economic circumstances that influence whether people engage in safe sex, learn their HIV status, and seek care. Major biomedical initiatives include studying the role of the immune system in the spread of HIV, which may lay the groundwork for a vaccine, and developing microbicides to prevent sexual transmission of infection. The Council also seeks to reduce the consequences of the pandemic, strengthen health systems, and inform policy decisions. For more information, visit [www.popcouncil.org/hivaids](http://www.popcouncil.org/hivaids).
- The organization is committed to combating the underlying causes of the AIDS pandemic, such as gender inequity, poverty, and low-quality, hard-to-access health services.
- More than 32 percent of the Population Council's direct program expenditures focus on HIV and AIDS prevention, treatment, and care activities.

### **The Population Council in South Africa**

- The Population Council has been working in Africa since the 1960s and in South Africa for nearly a decade. The organization has offices in Johannesburg and ten other African cities. During the past decade, the Council has worked on projects in 25 African countries.
- Population Council programs in South Africa include providing social science research training, encouraging men's participation in the health and welfare of their partners and children, strengthening the quality of services for rape victims, reducing nursing staff turnover at public health facilities, and assessing the value of youth centers as a means of providing reproductive health services. Visit our South Africa pages for an overview of the organization's work there ([www.popcouncil.org/africa/southafrica.html](http://www.popcouncil.org/africa/southafrica.html)).
- The Council's South African collaborators have included Nelson Mandela's Children's Fund's Goelama Project; the departments of Education, Health, and Social Development & Welfare; Eskom; mothers2mothers, the Salvation Army; Save the Children; Development Research Africa; and many others ([www.popcouncil.org/africa/southafricacollab.html](http://www.popcouncil.org/africa/southafricacollab.html)).

### **The Population Council and microbicides development**

- Vaginal microbicides are being developed as a female-initiated method for reducing male-to-female transmission of HIV, and possibly other sexually transmitted infections (STIs), when used during sex. They would most likely be formulated as vaginal gels, creams, foam, or rings.
- Women urgently need more HIV prevention options because the current strategies—abstinence, being faithful, condoms, and STI treatment—often are not feasible.
- The first microbicide on the market probably will not work as well as condoms, which are highly effective (80%–95%) for preventing sexual transmission of HIV when used consistently and correctly. Even a partially effective microbicide, however, could have a substantial impact on the AIDS pandemic, particularly for women for whom condom use is not always possible.
- The Population Council's first-generation candidate microbicide was Carraguard®, an odorless, colorless, tasteless, carrageenan-based vaginal gel. It was the first Phase 3 trial of a candidate microbicide to be completed without any safety concerns.
- Research by the Population Council and independent testing facilities demonstrated that Carraguard is effective in blocking HIV transmission in laboratory studies.

- In five studies prior to the Phase 3 trial, Carraguard and similar carrageenan formulations were found to be safe for vaginal use and acceptable to both HIV-negative and HIV-positive women and men. More than 850 people participated in those studies, which were conducted on six continents including in Australia, Chile, the Dominican Republic, Finland, South Africa, Thailand, and the United States.

#### **Carraguard Phase 3 clinical trial: Background**

- The Population Council sponsored the Carraguard Phase 3 trial to evaluate Carraguard's safety when used during a two-year period and its efficacy for preventing male-to-female transmission of HIV.
- The Phase 3 Carraguard trial was conducted in South Africa because vaginal microbicide efficacy trials must be conducted where there are high rates of HIV infection and where HIV is spread primarily through heterosexual sex, so that scientists can determine whether or not the product prevents infection.
- The 6,202 women who participated in the trial were randomly assigned to a study group: half received Carraguard and the other half received a placebo. Neither the volunteers nor the study staff knew who was using which gel.
- As part of ongoing HIV risk-reduction counseling, women were given condoms and counseled to use them with the study gel each time they had (vaginal) sex because (1) condoms currently are the best-known method of preventing HIV transmission during sex; (2) it was not known whether Carraguard prevents HIV transmission; and (3) half of the women received a "comparison gel" or placebo, which has not been shown to prevent transmission of HIV.
- The Phase 3 study was reviewed and approved by the ethics committees (groups making sure that participants are treated properly in research) at each collaborating institution: the Population Council Institutional Review Board, the University of KwaZulu-Natal Biomedical Research Ethics Committee, the University of Cape Town Research Ethics Committee, and the University of Limpopo Research Ethics and Publications Committee (REPC). The trial also was reviewed and approved by the Medicines Control Council (MCC), the regulatory agency in South Africa, and was submitted to the US Food and Drug Administration.
- An external, independent panel of experts called a Data Safety Monitoring Board reviewed study data three times during the trial and judged that there were no significant safety risks to study participants, so the trial continued to its scheduled completion.
- All trial volunteers took part in an extensive informed consent process, which included a video and other educational materials. The importance of condom use, the unknown efficacy of the gel, and the fact that half of the women had a placebo were emphasized in all materials, which were available in three local languages in addition to English: Zulu at the Durban site, Xhosa at the Cape Town site, and Setswana at the Medunsa site.
- In collaboration with Community Advisory Groups, informed consent procedures were developed that allowed women interested in the trial to make truly informed decisions about whether or not to join. Community feedback was incorporated into trial outreach materials, informed consent forms, study booklets, and a video. Regular community meetings during the trial provided a forum for discussions, where concerns could be aired and discussed.
- Women who tested HIV-positive at screening and women who became infected while participating in the trial were referred to medical, psychological, and supportive services in the community. Some sites offered CD4 count, nutritional counseling, physician check-ups, and support groups.

- The Population Council provided funding to the trial sites to help support medical and psychological referral services for HIV-positive women.

#### **Carraguard Phase 3 clinical trial: Study results**

- The Carraguard Phase 3 trial is a milestone for microbicides development; it is the first Phase 3 trial of a novel candidate microbicide to be conducted among a general population of women and completed as planned without any safety concerns.
- The Phase 3 clinical trial of the Population Council's candidate microbicide Carraguard did not show that Carraguard is effective in preventing HIV transmission during vaginal sex.
- Carraguard was found to be safe when used approximately once per week, on average, for up to two years, confirming results of previous safety trials.
- Carraguard's favorable safety profile and physical properties make it a potentially useful vehicle for future-generation microbicides.
- The safety of the participants in the Carraguard trial was the top priority of researchers and donors. More than 6,000 trial participants received high-quality sexual and reproductive health care and education free of charge, as well as regular testing and treatment for curable sexually transmitted infections (STIs), safer-sex counseling, HIV testing, and pelvic exams, all of which contribute to reduced risk of HIV infection.

#### **The Population Council's current microbicide development**

- Population Council research on future candidate microbicides now comprises a range of vaginal and rectal products, including gels for daily application and vaginal rings for continuous use.
- The Council is formulating microbicides both with and without an anti-retroviral compound.
- We anticipate the first clinical testing of a gel and a ring in 2011.
- The Council will continue microbicide development as part of an overall effort to achieve our mission of improving the well-being and reproductive health of current and future generations around the world.

#### **Sources**

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