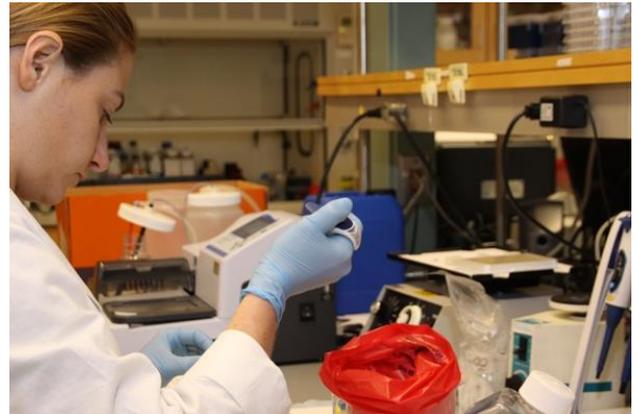


# THE POPULATION COUNCIL: PIONEERING NEW TOOLS TO PREVENT HIV, STIS, AND UNINTENDED PREGNANCY

Population Council researchers are pioneering bold approaches to reducing sexually transmitted infections (STIs) and unintended pregnancy by developing a new generation of products, called multi-purpose prevention technologies (MPTs).

These MPTs are designed to prevent HIV, other STIs, and/or unintended pregnancy simultaneously, allowing women and men to lead healthy sexual and reproductive lives.

- More than 1 million people contract an STI every day. Incurable viral STIs such as HIV, herpes simplex virus (HSV), and human papillomavirus (HPV) cause life-threatening illness and drain health systems' resources.
- Unintended pregnancy adds yet another burden on the lives of individuals, particularly women.
  - Forty percent of all pregnancies—85 million pregnancies a year—are unintended.
  - It is estimated that up to 100,000 maternal deaths could be avoided each year if women who did not want children used effective contraception.
- New tools to prevent multiple STIs, including HIV, and unintended pregnancy are urgently needed. To make a global impact, these new tools should:
  - provide women and men with a range of products that fit their needs
  - be safe and effective
  - be affordable, accessible, and easy to use
  - not inhibit or interfere with sexual activity



**STIs are a global health crisis:** the incurable viral infections caused by HIV, HSV, and HPV result in serious illnesses, increase susceptibility to other serious diseases including HIV, and create a huge burden on health systems, especially in low-income countries.

- According to UNAIDS, 2.1 million people became newly infected with HIV in 2015 and 1.1 million people died from AIDS-related illnesses.
- According to WHO, more than 500 million people are estimated to have a genital infection with HSV.
- HSV can cause significant reproductive health problems, including miscarriage and transmission of HSV infection from mother to infant during childbirth.
- More than 290 million women have an HPV infection; nearly all cervical cancer cases are caused by HPV.
- HPV infection causes 528,000 cases of cervical cancer and 266,000 cervical cancer deaths each year.

**More than 40% of all pregnancies—85 million pregnancies a year—are unintended.**

- Young women experience the highest rate of unintended pregnancy. Most of the 16 million pregnancies each year in young women are unintended.
- Complications in pregnancy and childbirth are a leading cause of death among adolescent girls in developing countries.
- Nearly half (48%) of unintended pregnancies end in abortion. Unsafe abortion can cause serious medical complications, including death.

**Currently available STI and pregnancy prevention approaches miss the mark.**

- Condoms are not 100% effective. They are frequently used incorrectly or inconsistently, in part because they are perceived by many to interfere with sexual pleasure. Women, and particularly adolescent girls, are often unable to successfully negotiate condom use by their male partners.
- HPV vaccines protect against some of the subtypes that increase HIV risk and cause anogenital cancers. An MPT would complement vaccines, focusing protection against additional HPV subtypes that cause cervical and anal cancer as well as protection against HIV and HSV.
- A product that reduces the risk of STIs and unintended pregnancy simultaneously could improve adherence and increase the effectiveness of a product.

**The Population Council is a global leader in contraceptive and MPT development**, with decades of experience in developing new products and strategies to protect women's and men's sexual and reproductive health.

- Council efforts include research to understand how women and men may use products, regulatory and intellectual property planning, and strategies to support strategic and systematic introduction and scale-up of effective technologies once available.
- The Council leads research, collaborates with major universities and research organizations, and conducts programs to support sexual and reproductive health in more than 50 countries.
- 170 million women worldwide are using contraceptive products developed by the Council or based on our technology.

**The Population Council is developing MPT gels, fast-dissolving inserts (FDIs), and intravaginal rings (IVRs) and FDIs designed to prevent HIV, HSV, and HPV simultaneously, in women and men.**

PC-1005 Gel

PC-1005 gel is the only candidate MPT designed for both vaginal and rectal use and to prevent HIV, HSV, and HPV simultaneously. Based on recent Phase 1 study data, PC-1005 is safe for vaginal use. PC-1005 will undergo additional Phase 1 vaginal and rectal testing in 2017–18.

PC-1005 contains a combination of MIV-150, zinc acetate, and carrageenan that provides broad-spectrum antiviral activity, with no sign of HIV resistance.

- MIV-150, a highly potent antiretroviral drug that is effective against HIV.
- Zinc acetate, an antiviral that protects against HIV and HSV.
- Carrageenan, a seaweed-derived compound with highly potent activity against different types of HPV. Carrageenan also strengthens zinc's activity against HSV.
- Innovative delivery systems for the drug combinations in PC-1005 may include sustained-release intravaginal rings, or combining PC-1005 with a SILCS diaphragm.

PC-9500 FDI

The Population Council is collaborating with PATH to develop PC-9500, a candidate MPT designed for on-demand vaginal, and possibly rectal, use to prevent HIV, HSV, and HPV simultaneously. PC-9500 contains a combination of griffithsin (GRFT) and carrageenan, providing broad-spectrum antiviral activity.

- GRFT is a naturally occurring algae-derived protein that inhibits HIV and other pathogens, including HSV.
- GRFT is the most potent anti-HIV agent described in the literature.
- GRFT could eliminate the risk of HIV drug cross-resistance, because no other antiretroviral with similar mode of action is used in treatment.
- When combined with carrageenan, GRFT also inhibits HPV.

Council researchers are also developing an IVR to provide sustained-release protection from HIV, HSV, and HPV for up to 90 days. FDI and IVR development will be supported by a Phase 1 safety and PK study of a GRFT gel, which is planned for 2016–17. This will be the first in-human study of a GRFT MPT.