The Population Council is working to help women and men worldwide avoid HIV, other sexually transmitted infections (STIs), and unintended pregnancy.

- According to UNAIDS, 2.1 million people were newly infected with HIV in 2013. Although life-saving treatment is increasingly available, HIV remains a debilitating and often deadly condition for millions of people infected with the virus.

- The World Health Organization estimates that more than one million people contract sexually transmitted infections (STIs) each day. STIs endanger individual health and may increase the risk of contracting HIV or other infections. Existing prevention strategies, including behavior change, condom promotion, and treatment have not reduced global STI rates.

- In 2012, 40 percent of all pregnancies worldwide—or 85 million—were unintended, according to the Guttmacher Institute.

Council researchers are developing multipurpose prevention technologies (MPTs), designed to make prevention safer, easier, and more accessible.

Building on decades of research to improve global sexual and reproductive health, the Population Council is at the forefront of MPT research and development.

<table>
<thead>
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<th>ALL-IN-ONE TOOLS</th>
<th>USER-CONTROLLED</th>
<th>MULTIPLE FORMULATIONS</th>
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<tr>
<td>Multipurpose prevention technologies (MPTs) are new, all-in-one tools being developed to protect against HIV, other STIs, and in some cases, unintended pregnancy, with a single product.</td>
<td>MPTs are user-controlled prevention methods for women and men. MPTs place prevention in the hands of the individual who needs it.</td>
<td>MPTs may be formulated as gels that individuals can apply to the vagina or rectum, intravaginal rings (IVRs) that can be inserted into the vagina, or other user-controlled delivery systems.</td>
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The Population Council is developing both ARV- and non-ARV-based MPTs.

Council researchers are pursuing several different approaches to preventing HIV, other STIs, and unintended pregnancy. The Council is developing MPTs that contain antiretroviral drugs (ARVs) as well as other agents shown to be effective in inhibiting HIV and/or STIs and pregnancy.

### ARV-based MPT: MZC

MZC CONTAINS:
- **MIV-150**, an HIV enzyme inhibitor that prevents HIV-infected cells from producing new virus
- **Zinc acetate**, an antiviral agent with activity against HIV and HSV-2
- **Carrageenan**, a seaweed-based compound with potent anti-HPV activity

MZC is a combination of ingredients designed to provide broad-spectrum activity against HIV and two common STIs: human papillomavirus (HPV) and herpes simplex virus (HSV-2).

The compounds in MZC enhance each other’s properties, providing increased antiviral activity at lower doses and decreasing the likelihood of drug resistance. In general, lower doses can improve the safety profile of a drug and potentially reduce product cost.

The Council is also developing the MZCL intravaginal ring (IVR), which adds a highly effective progestin, levonorgestrel, to the MZC combination to provide sustained protection against unintended pregnancy as well as HIV, HPV, and HSV-2.

**STUDIES TO DATE**

In preclinical studies:
- MZC blocked vaginal and rectal infection in monkeys challenged with SHIV-RT (a virus combining genes from HIV and SIV, the monkey version of HIV) for up to 8 hours after the gel was applied.
- MZC effectively blocked vaginal and rectal infection with HSV-2 and HPV in mice.

**NEXT STEPS**

Council researchers are testing MZC gel in a Phase 1 placebo-controlled clinical trial in 30 women. The trial will determine the safety and acceptability of the gel after vaginal administration and the levels of MIV-150 in the blood of trial participants after they use the gel. These findings will inform the Council’s development of MZCL IVRs, which are intended for 90 days of continuous use.

### Non-ARV-based MPT: Griffithsin

Griffithsin is a naturally occurring algae protein that inhibits HIV and other pathogens including HSV-2. Griffithsin is the most potent anti-HIV agent described in the literature to date and can be produced relatively easily and inexpensively in tobacco plants.

Griffithsin’s mode of action and the fact that it is not used in HIV treatment means there is no risk that users of a griffithsin prevention product could develop cross-resistance to ARVs that are used for treatment. This may increase the possibility that a griffithsin microbicide could become an over-the-counter product and increase access for people in high-demand, low-resource settings.

**STUDIES TO DATE**

Griffithsin has been found safe and effective when tested against the HIV and HSV-2 viruses in the laboratory.

**NEXT STEPS**

Council scientists are pursuing multiple delivery systems for griffithsin including an intravaginal ring to provide protection for up to 90 days and a nanofiber delivery system (a film-like formulation) to provide immediate protection. Additional delivery systems may be developed in the future. The first human studies of griffithsin vaginal gel are expected to begin in 2016.
Population Council experts are improving how HIV prevention trials are conducted and preparing the field for product introduction.

The Council’s comprehensive approach to product development includes important behavioral research to improve how HIV prevention trials are conducted and to inform product development. Council researchers are working to:

- Identify more effective methods for recruiting appropriate study populations.
- Improve the informed consent process.
- Increase adherence to prevention products.
- Improve the reporting and measurement of adherence and other sensitive behaviors that impact study outcomes.

Because effective technologies only have impact if they are introduced strategically and scaled up carefully, Council experts are designing and sharing readiness-assessment tools and processes, and developing and implementing a social science and operations research agenda for the introduction of new products. The Council has also developed a map of the critical path from innovation to commercial product, which defines pathways for regulatory approval and rollout of new prevention products once they are proven effective. This work is particularly useful for MPTs, which represent a new and complex class of products that require advanced thinking and problem-solving around regulatory pathways.
The Population Council’s comprehensive approach covers the entire product development lifecycle.

**Basic science research**
To understand the biology of HIV transmission and reproduction and investigate novel ways to stop HIV, other STIs, and unintended pregnancy.

**Clinical testing**
Of the safety and efficacy of promising new prevention products.

The development of strong **regulatory and intellectual property strategies** to simplify and streamline processes for regulatory review, speed access to new technologies, and ensure that products are available in low-resource settings.

**Formulation of MPTs and contraceptives**
As gels, rings, or other novel products that are safe, effective, and affordable.

**Behavioral research**
To understand how women and men may use these products, and to better understand their prevention preferences, choices, and needs.

**Education**
To help individuals who need these products to use them safely and effectively.