A proprietary microbicide gel developed by the Population Council has been found in animal studies to prevent the transmission of HIV, herpes simplex virus 2, and human papillomavirus.
Preclinical Study Shows Microbicide Gel’s Effectiveness Against HIV and Other Viruses

Results of a recent animal study offer new optimism for microbicides, biomedical products being developed to protect people against sexually transmitted infections (STIs), including HIV. Population Council scientists and their partners have found that a proprietary microbicide gel developed by the Council is safe, stable, and can prevent the transmission of HIV, herpes simplex virus 2 (HSV-2), and human papillomavirus (HPV), in both the vagina and rectum in animals. It has a window of efficacy in the vagina against all three viruses of at least eight hours prior to exposure. An in vitro study also provides the first data that the gel is effective against multiple strains of HIV.

The gel, known as MZC, contains MIV-150, zinc acetate, and carrageenan. MIV-150 and zinc acetate are potent antiviral agents that inhibit HIV via different mechanisms of action. MIV-150 is an enzyme inhibitor that blocks an early step of HIV replication in target cells, and zinc acetate is an antiviral agent with demonstrated activity against HIV and HSV-2. These compounds are mixed in a water-based solution of carrageenan, a compound derived from seaweed that has been shown to have potent activity against HPV infection. Researchers believe that microbicides that target HIV, HSV-2, and HPV may more effectively limit HIV transmission than those that target HIV alone.

In this study, Council scientists and their partners used macaque and mouse models to examine whether MZC gel could prevent vaginal and rectal transmission of SHIV-RT (a virus combining genes from HIV and SIV, the monkey version of HIV), HSV-2, and HPV. They found that MZC:

- protected macaques against rectal SHIV-RT infection when used close to the time of viral challenge
- protected mice against HSV-2 infection when applied vaginally or anally/rectally just before a high dose of virus
- protected mice against HSV-2 when applied between 8 hours before and 2 hours after vaginal challenge with a low dose of HSV-2
- protected mice against HPV when applied up to 24 hours before and 2 hours after vaginal challenge and also if applied 2 hours before or after HPV inoculation of the anus/rectum.

Researchers involved in developing MZC described the results of the preclinical study as particularly encouraging because of the product’s broad spectrum of activity. According to José A. Fernández-Romero, a scientist at the Population Council and corresponding author of the paper, “It is the versatility of MZC that makes it a desirable microbicide candidate. It is effective against multiple viruses, can be used in both the vagina and the rectum, and retains its efficacy in the vagina over an extended period of time.”

Some microbicides are being designed as vaginal products for women, and others as rectal products for either men or women. Several candidate microbicides have been developed and tested over the past two decades. Turning the concept into reality has proved difficult, however. To date, no product has advanced beyond clinical trials in humans to regulatory approval.

The study was designed to establish proof of concept in monkeys and mice before taking steps to test in humans. Preclinical testing in animals is required by the FDA and is important to ensure the highest level of safety and to build the evidence base for potential efficacy in humans. Phase 1 safety trials of the gel in humans are now underway.

“In addition to the gel,” said Fernández-Romero, “we are exploring sustained-release intravaginal rings and on-demand nanofiber-based delivery systems for MZC.” He stressed that developing different delivery systems for effective medications is an important step in ensuring the ultimate success of any microbicide, adding, “There is a growing demand for microbicides that prevent multiple STIs, and we are committed to ensuring that women and men have options when choosing what works most effectively for their own protection.”

SOURCE

FUNDING
US Agency for International Development (USAID)
Ensuring that Family Planning Programs Respect, Protect, and Fulfill Women’s Rights

In the developing world, 222 million women would like to delay or avoid pregnancy but are not using modern contraceptives. At the 2012 London Summit on Family Planning, the international community made a commitment to reduce this unmet need by reaching 120 million women and girls from the world’s poorest countries with voluntary access to family planning information, contraceptives, and services by 2020, an agreement known as FP2020.

The goals of the London Summit and FP2020 have been greeted positively by most organizations and individuals involved in family planning. However, concerns have been raised about certain aspects of the agreement, particularly the numeric goal setting. For example, some observers have said that setting such goals would lead to efforts focusing on the populations who are easiest to reach, in particular women and girls in urban areas who already have access to some services, rather than those who are harder and more costly to reach. These individuals, such as women and girls who are illiterate, undereducated, or live in rural areas, could be largely ignored.

Such concerns were cited by several leading family planning experts who developed a new “Framework for Voluntary Family Planning Programs that Respect, Protect, and Fulfill Human Rights.” This framework, featured in the Population Council’s journal Studies in Family Planning in March 2014, is predicated on the notion that all women and girls, regardless of where they live or how difficult they are to reach and support, have the right to comprehensive family planning information and services.

The framework offers a practical approach to incorporating human rights into the development, implementation, monitoring, and evaluation of voluntary family planning programs. The approach is based on research and analysis indicating that transparent, accountable family planning programs that are grounded in human rights are the most successful in meeting the needs of women and girls.

The framework defines a human rights-based approach to voluntary family planning as requiring the following:

- Carefully analyzing and considering existing inequities in family planning and reproductive health programs, and in the laws and policies that govern these programs
- Ensuring that policies and programs are anchored in a system of rights by integrating core principles such as accountability, empowerment, equitable service delivery, and non-discrimination
- Focusing on availability, accessibility, acceptability, and quality when defining service standards
- Empowering all individuals—especially those in the most marginalized populations—to play a central role in the development of policies and hold stakeholders accountable for demonstrating meaningful change

Programs that are grounded in human rights will help women and adolescent girls access the information and services they need, when they need them. A renewed global commitment to provide support for family planning opens an opportunity to transform family planning programs and reach those most vulnerable and in need of these life-changing services.

The framework was developed by researchers at The Futures Group and EngenderHealth, with support from the Bill & Melinda Gates Foundation. The lead author, Karen Hardee, is now a Population Council senior associate and director of the Council’s USAID-funded Evidence Project.

“Human rights treaties and conventions that uphold reproductive rights have the status of international law. Countries throughout the world are signatories to these human rights treaties and conventions,” said Hardee. “Family planning programming to meet FP2020 goals must have human rights values and norms at their core. The global commitment to provide support for family planning that was galvanized at the 2012 London FP Summit offers the opportunity to transform family planning programs and reach all of those in need of services.”

SOURCE

FUNDING
The Bill & Melinda Gates Foundation
The Influence of Rural Women’s Autonomy on Marital Violence in Four Indian States

There is evidence that women in India who have more education than their husbands, who earn more, or who are the sole earners in their families have a higher likelihood of experiencing intimate partner violence (IPV) than women who are not employed or who are less educated than their spouse. However, recent Population Council research found women’s autonomy to be correlated with less IPV in some regions.

Three researchers at the Population Council in India, Shagun Sabarwal, K. G. Santhya, and Shireen J. Jejeebhoy, investigated the relationship between rural women’s autonomy and their experience of IPV in four Indian states (Bihar and Jharkhand in the north and Maharashtra and Tamil Nadu in the south). The study is believed to be the first to prospectively examine this relationship in regions characterized by varying levels of gender equity. Bihar and Jharkhand are more conservative and patriarchal; Maharashtra and Tamil Nadu are more egalitarian. The study also examined the relationship between changes in women’s autonomy over time and their experiences of IPV. (Past studies have used cross-sectional data, which cannot evaluate such changes over time.)

For this study, Council researchers reviewed data from two linked studies: the National Family Health Survey-2 (NFHS-2), a nationally representative population-based survey conducted during 1998-1999, and a follow-up study of women interviewed in NFHS-2 in Bihar, Jharkhand, Maharashtra, and Tamil Nadu carried out during 2002-2003.

The researchers focused on three dimensions of autonomy: financial autonomy, freedom of movement, and household decision-making among a sample of 4,904 rural women. A similar set of questions was used to assess the extent of women’s autonomy at baseline and at follow-up, including the following:

- For freedom of movement, two items were measured: whether women needed permission to (a) go to the market and (b) visit friends or relatives.
- For household decision-making autonomy, three items were considered: whether women made decisions on the following (a) seeking health care for themselves, (b) the purchase of jewelry, and (c) visiting relatives/friends. Women who reported independent say in decisions related to at least one of the three topics were considered to have decision-making autonomy.

The researchers controlled for a number of background variables, including religion, educational level, wealth status at baseline, and change in wealth status from baseline to follow-up—as well as variables specific to the Indian context, such as caste.

Key Findings

The researchers’ analysis revealed that the effects of women’s autonomy on their experience of violence varied according to region of residence. For example, for respondents residing in Maharashtra and Tamil Nadu, in the southern region of India, where gender relations are less hierarchical and more egalitarian, researchers found a strong protective relationship between women’s financial autonomy and marital violence. No such effects were seen among sample subjects residing in Bihar and Jharkand, in the northern part of the country, which is characterized by greater gender inequality.

The study’s authors posit that in comparison with the southern states, even financially autonomous women in those northern states have limited capacity to (a) challenge the acceptability of partner violence, (b) expect or receive better treatment from partners, or (c) find social support that can potentially prevent violence from their partner.

The authors strongly recommend implementing strategies and interventions to protect women, such as providing shelters and support groups and making legal and psychological counseling more widely available. They recognize and support the importance of further enhancing the conditions for women to attain greater autonomy and to change norms and laws that keep them at risk for violence at the hands of their partners.

“More focused efforts are needed to enhance married women’s agency, mitigate their social disadvantage, and encourage savings among women,” said Santhya. “Equally important are efforts to raise awareness among women about their rights and enhance their ability to challenge existing gender norms.”

SOURCE
In Zambia, Population Council researchers are implementing and evaluating the Adolescent Girls Empowerment Program (AGEP) using a randomized control trial, in order to provide strong evidence of the intervention’s impact. AGEP will enroll 10,000 poor adolescent girls and address their social isolation, economic vulnerability, and lack of access to vital health services.

**Three Components**

AGEP has three main components: safe spaces meetings, health vouchers, and savings accounts:

- **Safe spaces**: During weekly meetings, 20–30 girls gather with a local mentor in a safe place, such as a community center. There, they develop supportive social networks and receive training on health, life skills, and money management.

- **Health vouchers**: Girls are given vouchers for health services that they can redeem at partner public and private health providers.

- **Savings accounts**: Girls can open a “Girls Dream” savings account at a nearby bank that has partnered with the program.

The randomized control trial has three arms, so that researchers can assess the added effect of each component. In group 1, girls will attend safe spaces meetings. In group 2, girls will attend safe spaces meetings and receive a health voucher. In group 3, girls will attend safe spaces meetings, receive a health voucher, and have access to a savings account.

The study will document how each activity affects the participants and whether there are added benefits of a health voucher and a savings account. Researchers will focus on primary impact indicators of school attainment, HIV prevalence, HSV-2 prevalence, age at marriage, age of sexual initiation, age of first birth, and experience of sexual violence. The data will also reveal effects on self-esteem, agency, gender norms, savings activity, income generation, health service seeking, and nutritional status. Finally, the study will determine the cost of delivering each program component and the cost of achieving each additional benefit. Such information is crucial in places where resources are scarce.

**Pilot Phase**

This research started with a pilot phase during which the researchers collected evidence to help them fine-tune the three program components. This assessment suggested a number of specific adjustments to each component to allow successful program scale-up. Some examples include:

- outlining attendance requirements for mentors in their contracts to make clear that the monthly stipend is dependent upon attendance;
- bringing the girls to the bank as a group to open their savings accounts; and
- ensuring that materials about the health voucher are available for girls with low or no literacy.

These and other important lessons will help guide the program as it expands to sites across rural and urban Zambia, ultimately reaching more than 10,000 girls aged 10 to 19. The evaluation of the program’s randomized control trial will take place in 2017.

**SOURCES**


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UK Department for International Development
HIV AND AIDS


POVERTY, GENDER, AND YOUTH


REPRODUCTIVE HEALTH


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OTHER


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