

INCREASE WOMEN'S CONTROL OVER HIV PREVENTION FIGHT AIDS



A UNAIDS Initiative

**The Global Coalition
on Women and AIDS**

WHAT'S REAL

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Women account for nearly half of HIV infections worldwide and almost two-thirds of those among young people, with female infections rising in almost every region. Yet twenty-five years into the global AIDS epidemic, there is still no widely available technology that women can both initiate and

be able to provide for all those in need, particularly given the cost of sustaining treatment over time.³ Comprehensive prevention remains the first line of defense against HIV and must go hand-in-hand with treatment, care, and support for those living with HIV.



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control to protect themselves from HIV. Due to gender norms and inequalities, many women and girls lack the social and economic power to control key aspects of their lives, particularly sexual matters. As a result, women are in a difficult, and often impossible, situation when it comes to negotiating with their partners over abstinence, fidelity, or condom use.

"The women of Africa need new prevention options...Microbicides will put HIV-prevention into their hands."

Mrs. Graça Machel, President, Foundation for Community Development & Member, Board of Trustees, Nelson Mandela Foundation.

Globally, the vast majority of HIV infections are transmitted through heterosexual sex. Research from around the world shows that social, cultural, and economic factors – linked to sexual violence and coercion, as well as unequal access

to education, economic options, and legal protection – increase women's vulnerability to HIV.

Given the AIDS epidemic's disproportionate impact on women, there is a critical need to develop prevention options that women can use with, or when necessary without, their partner's knowledge. Unless women gain greater access to effective prevention tools that they can control, global and national efforts to halt the spread of AIDS cannot succeed. Improving prevention options for women requires both broadening current prevention strategies and developing new technologies that enhance women's ability to protect themselves.

That is why the UNAIDS-led Global Coalition on Women and AIDS has made female-controlled prevention a top priority.¹

Current Prevention Options for Women Are Not Enough

While access to HIV treatment has tripled in the last two years, now reaching 1.3 million people,² new infections continue to vastly outpace available treatment. Even as access to treatment rapidly expands, these programs will not

Consequently, current prevention strategies – often summed up by the "ABC" approach, Abstain, Be mutually faithful and use Condoms – do not enable women to adequately protect themselves from HIV. Among young women surveyed in Harare (Zimbabwe), Durban and Soweto (South Africa), 66% reported having one lifetime partner, and 79% had abstained from sex at least until the age of 17. Yet, 40% of these young women were also HIV-positive, and most had been infected despite staying faithful to one partner.⁴ Similar trends are seen in Asia; in India, for example, the majority of women are getting infected within monogamous relationships,⁵ and many have been infected by their husbands.

To reverse these trends, HIV prevention strategies must be broadened so that they better respond to the challenging contexts of women's lives. This means moving beyond only "ABC" to address the underlying vulnerabilities faced by women, including by expanding affordable access to prevention options that women can initiate and control.

New HIV Prevention Options for Women are Key

Microbicides

Microbicides are products being developed and tested that women could apply topically to the vagina to reduce the transmission of HIV during sexual intercourse. Microbicides could take the form of a gel, cream, film, suppository, sponge, or vaginal ring that releases the active ingredient gradually. Microbicides would block or disable the HIV virus from the moment it enters the body, before it spreads.⁶ With increased investment in scientific research, a safe and effective microbicide could be developed within five to seven years.⁷

The first generation of microbicides is likely to reduce the risk of transmission by 40-60%.⁸ Yet even a partially effective microbicide could provide substantial protection from HIV, especially if used consistently. According to modeling done by the London School of Hygiene and Tropical Medicine, a 60% effective microbicide would avert 2.5 million HIV infections over three years.⁹ Given the high rate of new HIV infections, a dual push is needed both to get an effective microbicide on the market as soon as possible, and to continue research that improves their overall effectiveness. In addition, both contraceptive and non-contraceptive microbicides are under development, which would allow women the option of becoming pregnant while remaining protected against HIV.

Microbicides are intended as part of a broader package of prevention options. They would complement – not replace – options such as abstinence, faithfulness, and condom use, and yet would address a glaring gap in current prevention packages – female control. Just as effective HIV treatment requires a combination of interventions, so too does HIV prevention, particularly for women. Together, these options would comprise a truly comprehensive HIV prevention package, eventually including HIV vaccines as well.

Female Condoms

Since an effective microbicide is still in development, the female condom is the closest to a female-initiated HIV prevention product that women now have. Although detectable during use, and still requiring partner negotiation and consent, when used correctly and consistently the female condom dramatically reduces the risk of HIV transmission. As such, female condoms offer women a valuable alternative, especially for those whose partners refuse to use male condoms.

The female condom is a soft polyurethane sheath that covers the vagina, cervix, and external genitalia, and is inserted before intercourse. Numerous laboratory studies have shown that the female condom is extremely effective in blocking the passage of micro-organisms, including HIV.¹⁰ Given its effectiveness, and its unique ability to place greater control over HIV prevention in women's hands, female condoms should be an integral part of HIV prevention, treatment, and care strategies and programs worldwide.

Despite these considerable benefits, a number of barriers remain to broader acceptance and use of female condoms. The current cost of a female condom (approximately \$0.70) is at least ten times that of most male condoms.¹¹ In addition, female condoms have not been extensively marketed, thus adequate awareness, availability, and necessary information about the female condom is still lacking in most countries and communities, severely limiting its potential use.

This highlights the critical need to promote the availability of female condoms, as well as to provide more information and training to women on its use. The hope is that with greater access to and promotion of female condoms, coupled with improved and more cost-effective product designs, consumer demand will rise, and its cost will continue to decrease. New versions of the female condom, currently in various stages of development and approval processes, should help to address many of the design and cost barriers.

Promising Developments

- Over the last decade, there have been major strides toward developing an effective microbicide. Increasing financial commitments from the public sector, led by the U.S. Government, and the philanthropic sector, led by the Bill and Melinda Gates Foundation,¹² have pushed numerous microbicides candidates into advanced stages of development and testing. With greater support from these donors, a broad range of developers – including non-governmental organizations, biotechnology companies, and public-private partnerships – are conducting research on microbicides.
- Five “first generation” candidate microbicides are currently being tested in large-scale efficacy trials throughout Africa and Asia, with over 23,000 women participating in total.¹³ If any of these trials prove successful, it is possible that a microbicide could be ready for initial distribution in as early as five years.¹⁴ All five of these products have been shown to be safe for human use, and the trials are determining their level of effectiveness against HIV.
- At least four pharmaceutical companies: Bristol-Myers Squibb, Merck & Co.,¹⁵ Cellegy,¹⁶ and Tibotec Pharmaceuticals Ltd. (a subsidiary of Johnson & Johnson)¹⁷ have granted licenses to non-profit organizations to research and develop some of their candidate microbicides.
- As “first generation” trials progress, researchers are already developing the next generation of microbicides based on anti-retroviral compounds, as well as microbicides formulated in combinations. This “second generation” research may produce microbicides with increased efficacy rates.

WHAT'S NEEDED

In endorsing the Millennium Development Goals, the U.N. Declaration of Commitment on HIV/AIDS, and other international development agreements, world leaders have committed to a series of critical steps needed to stop the spread of HIV. Prominent among these steps is the need to reduce the vulnerability of women and girls to HIV. World leaders have recognized that, unless the rising tide of new infections among women and girls is addressed, the realization of global and national efforts to curb the spread of HIV and to make progress toward other key development goals will be impossible. Ultimately, significantly reducing female HIV infections will require the development and improvement of female-initiated and controlled prevention options. As part of a comprehensive prevention package, microbicides and expanded access to improved female condoms would dramatically enhance women's ability to protect themselves from HIV and, in turn, would go a long way to stop the global spread of HIV.

"According to modeling done by the London School of Hygiene and Tropical Medicine, a 60% effective microbicide would avert 2.5 million HIV infections over three years."

Actions for National Governments

- Increase political support for microbicide research and development by funding and collaborating with product developers and local research institutions to undertake ethical and open clinical trials, both in developing and developed countries.
- Use available national mechanisms to promote awareness of microbicides among women and men, and to expand community engagement with microbicide clinical trials at the country level.
- Build capacity within national regulatory agencies and research institutions to better define regulatory pathways for microbicides, and collaborate with key partners to build the national and local capacity that will be needed to introduce microbicides widely once they become available.
- Develop political and social support among stakeholders – including donors, clients, service providers, researchers, and policymakers – to increase public awareness, acceptance, and supply of female condoms. Outreach and education should include women's groups, networks of women living with HIV, and other civil society organizations, and specific efforts should be undertaken to increase understanding and acceptance of female condoms among men.
- Integrate female condoms into the core service package of existing HIV prevention and reproductive health programs, including through national health ministry procurements of condoms for clinics, hospital, etc., thereby expanding their public availability.

Actions for International Partners

- Increase funding for microbicide research, development, and large-scale clinical trials through funding mechanisms such as the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the European Commission, and others. To fully fund these efforts, and to significantly accelerate microbicide research and development, total global investment will need to increase from US\$140 million in 2004 to US\$280 million per year for each of the next five to ten years.
- Encourage private pharmaceutical companies, through incentives arrangements and other mechanisms, to increase support for microbicide research and development and to enrich the product pipeline.
- Promote international leadership by supporting and financing a comprehensive approach to HIV prevention for women that includes microbicides and the female condom. Provide technical assistance to strengthen regulatory systems in developing countries, as well as the advocacy and policy research that underpins such efforts.
- Support efforts to build and enhance the capacity of delivery systems, especially in developing countries, so that once an effective microbicide is developed, it can be distributed widely and efficiently to women worldwide.
- Promote public and private sector investment in female condoms, and increase financial and technical support for female condom programs.
- Document and disseminate lessons learned and best practices on the effective distribution and impact of female condoms, focusing on experiences from countries and communities where female condoms have gained greater acceptance and attracted wider use, in order to facilitate their successful introduction elsewhere.

- ¹ The Global Coalition on Women and AIDS is a worldwide alliance of civil society groups, networks of women living with HIV, governments, and UN organizations supporting AIDS strategies that work for women and girls. This brief is the fourth in a series that will explore a range of key issues particularly affecting women and girls in the global fight against AIDS. All the briefings can be found at: <http://womenandaids.unaids.org>.
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- ³ Global HIV Prevention Working Group, "HIV Prevention in the Era of Expanded Treatment Access," June 2004.
- ⁴ Joint United Nations Programme on HIV/AIDS, "2005 AIDS Epidemic Update," p 9.
- ⁵ UNAIDS India fact sheet, "Women, Girls and HIV/AIDS in India," 2005.
- ⁶ IPM, "R & D Debriefing on Microbicides," June 2004, p. 2.
- ⁷ IPM Press Release, "Nearly US\$30 Million Committed to Microbicide Development, IPM Lauds Significant Support from European Nations for HIV Prevention," Dec. 1. 2005 (http://www.ipm-microbicides.org/news_room/english/press_releases/2005/2005_1201_30_million.htm).
- ⁸ Global Campaign for Microbicides, Fact Sheet #19, p. 3, March 2006. (<http://www.global-campaign.org/clientfiles/FS19-ManagingExpectations/Mar06.pdf>).
- ⁹ The Microbicide Initiative, funded by the Rockefeller Foundation report: "Mobilization for Microbicides: The Decisive Decade," page 11.
- ¹⁰ See for example: Voeller, B, Coulter SL, Mayhan KG. [Letter]. Gas, dye, and viral transport through polyurethane condoms. JAMA. 1991. 266 (21); Drew WL, Blair M, Miner RC, Conant M. Evaluation of the virus permeability of a new condom for women. Sexually Transmitted Diseases, 1990. 17: 110-112; and Study of the permeability of the female condom (femdom) to herpes simplex virus type 1. Data on file, The Female Health Company.
- ¹¹ Global Campaign for Microbicides and The Global Coalition on Women and AIDS, "Observations and Outcomes from the Experts' Meeting on Female Condom," December 10, 2004.
- ¹² HIV Vaccines and Microbicides Tracking Working Group, "Tracking Funding for Microbicide Research and Development: Estimates of Annual Investments 2000 to 2005," August 2005, p. 7 and 10.
- ¹³ Alliance for Microbicide Development, "Ongoing Microbicides Trials (By Phase)," p. 3-4, <http://secure.microbicide.org/NetReports/ClinicalTrialsOngoingByPhase.aspx>.
- ¹⁴ Alliance for Microbicide Development, "Microbicide Clinical Trial Summary Table," March 2006 (www.microbicide.org).
- ¹⁵ The Wall Street Journal, "Non-profit Is Given Licenses to Make AIDS Compounds," Nov. 1, 2005.
- ¹⁶ Press Release, Cellegy Pharmaceuticals Inc., "Cellegy Announces Licensing Agreement with CONRAD and Other Events," Feb. 1, 2006 (<http://www.cellegy.com/newsroom/press/01feb06.html>).
- ¹⁷ Financial Times, "J&J Gives Away HIV Drug Rights," March 29, 2004.



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