



# HIV/AIDS Today

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## Microbicides

This week’s edition of HIV/AIDS Today describes research into microbicides, a potential tool for primary prevention of sexual transmission of HIV.

### WHAT IS A MICROBICIDE?

Microbicides are topical products that could prevent transmission of HIV or other sexually transmitted infections (STIs). No microbicide for HIV has yet been successfully developed.<sup>i</sup>

A successful microbicide for HIV could be formulated as a gel, film, sponge, lubricant, or time-release suppository or ring. The ideal microbicide would prevent both female and male partners from infection. An effective microbicide could provide women with greater control over their own health because, unlike male condoms, use of the microbicide would not require active male participation.<sup>ii</sup>

### RESEARCH PIPELINE

Once a drug or treatment is ready for testing in humans, there are three clinical trial phases to determine the safety and efficacy of the drug. A Phase I trial tests

the safety of a drug treatment in humans and generally has a small number of participants. Phase II trials look at safety in a larger sample population, while the Phase IIB or III trials test efficacy on a larger scale.<sup>iii</sup>

No safe and effective microbicide against HIV is currently available to the public. In the past year, some of the earliest candidates had disappointing trial results. However a number of new products are moving rapidly through the product pipeline. As of June 2008, four products are currently in effectiveness testing (Phase IIB or III), and several more products are in the safety testing phase.<sup>iv</sup>

### MECHANISMS OF ACTION

Researchers believe that microbicides could reduce the risk of HIV transmission in a number of ways. Some microbicides could be specific to HIV by blocking the replication of the virus or stopping the virus from fus-

### ONGOING CLINICAL TRIALS AS OF JUNE 2008<sup>v</sup>

Phase	Candidate Name	Sponsor	Sites by Country
III	PRO 2000/5 gel	Indevus, MRC, DFID (Funder)	South Africa, Tanzania, Uganda, Zambia
IIB	Tenofovir gel	CAPRISA, USAID, LIFELab, Gilead, FHI, CONRAD	South Africa
II/IIB	PRO 2000/5 gel (P) and BufferGel®	NIAID, Indevus, ReProtect	Malawi, South Africa, United States, Zambia, Zimbabwe
I	Dapivirine (TMC120) gel	IPM	Belgium
	Ethanol in Emollient Gel	NIAID	Kenya
	HEC/CS/N-9	CONRAD/USAID	United States
	Tenofovir/PMPA gel	CONRAD, IPM/USAID	Dominican Republic, United States
	UC-781 gel	NIAID, CONRAD	United States
	UC-781 gel	UCLA, NIAID, CONRAD	United States
	UC-781 gel	CDC, Thailand Ministry of Health, CONRAD	Thailand
	UC-781 gel	CONRAD	United States
	UC-781 gel	CONRAD, CDC, Emory University	United States
VivaGel™ (SPL7013 gel)	DAIDS/NIAID, NICHD, Starpharma	Puerto Rico, United States	

ing with healthy cells. Other microbicides could block HIV and possibly other STIs by boosting the body's natural defenses or blocking the virus from binding to healthy cells. The latter could also provide dual protection against disease transmission and pregnancy.<sup>vi</sup>

According to the National Institutes of Health, the ideal microbicide would be "unnoticeable, fast-acting against HIV and a broad range of other sexually transmitted pathogens, inexpensive, safe for use at least one to two times daily, and easy to store."<sup>vii</sup>

## PREVENTION POTENTIAL

Globally, more than 50% of new HIV infections occur among women. Researchers estimate that a 60% effective microbicide could have a significant impact on the HIV/AIDS epidemic if introduced in the world's 73 lowest-income countries. If 20% of women already accessing health services in these countries were to use such a product, an estimated 2.5 million new infections could be averted among women and indirectly among men and children, in three years.<sup>viii</sup>

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## ENDNOTES

<sup>i</sup> National Institutes of Health, National Institute of Allergy and Infectious Diseases, NIAID Division of AIDS, *Topical Microbicides* (online at <http://www3.niaid.nih.gov/research/topics/HIV/prevention/research/Microbicides>).

<sup>ii</sup> Global Coalition on Women and AIDS, *Microbicides, Women and AIDS* (online at [http://data.unaids.org/GCWA/GCWA\\_BG\\_Microbicides\\_en.pdf](http://data.unaids.org/GCWA/GCWA_BG_Microbicides_en.pdf)).

<sup>iii</sup> Alliance for Microbicide Development (June 10, 2008) (online at [http://www.microbicide.org/cs/drug\\_development\\_process](http://www.microbicide.org/cs/drug_development_process)).

<sup>iv</sup> Global Campaign for Microbicides. *Trial Results and Updates* (online at <http://www.global-campaign.org/trial-updates.htm>); Alliance for Microbicides Development (June 10, 2008) (online <http://www.microbicide.org/cs/clinical>).

<sup>v</sup> *Supra* note iii.

<sup>vi</sup> Global Campaign for Microbicides. *Module 3, How Would Microbicides Work?* (2008) (online at <http://www.hivpreventionresearch.org>).

<sup>vii</sup> National Institutes of Health, National Institute of Allergy and Infectious Diseases, *Sexually Transmitted Infections* (online at [http://www3.niaid.nih.gov/about/overview/profile/fy2005/pdf/research\\_sti.pdf](http://www3.niaid.nih.gov/about/overview/profile/fy2005/pdf/research_sti.pdf)).

<sup>viii</sup> Public Health Working Group of the Microbicide Initiative. *The Public Health Benefits of Microbicides in Lower-Income Countries Model Projections*, funded by The Rockefeller Foundation (accessed on June 12, 2008) (online at [http://www.global-campaign.org/clientfiles/rep7\\_publichealth.pdf](http://www.global-campaign.org/clientfiles/rep7_publichealth.pdf)).