Women and the Need for Microbicides



Current HIV prevention options are not slowing the epidemic. The spread of HIV/AIDS continues to outpace the world's response to it. Women and girls continue to bear the burden of the epidemic, with 15.9 million women living with the disease across the globe.ⁱ HIV/AIDS is the leading cause of death globally among women ages 15-44, and exacts an especially high toll in sub-Saharan Africa where approximately six in 10 HIV-infected adults are women.^{ii,iii} In fact, in some countries, HIV prevalence is three to eight times higher among women ages 15-24 than it is among men in the same age group.^{iv} Current prevention strategies are not enough to stop the spread of HIV — particularly among women. Many women are unable to negotiate successfully with their male partners to use condoms or to be faithful. Abstinence is not realistic for women who are married, who want children or who are at risk of violence.

New female-initiated prevention options like microbicides are urgently needed. Microbicides are antiretroviral (ARV)-based products being developed to reduce the transmission of HIV to women during sex with an HIV-positive male partner. The active ingredients in the products are based on the same types of ARV drugs used successfully to prolong the lives of HIV-positive individuals and to prevent mother-to-child transmission of the virus. Microbicides would give women a new way to prevent HIV — one that would empower them to protect their own health.

Microbicides are being developed in several forms, including products that would be used around the time of sex and those that could be used independently of the time of sex by gradually releasing the active ingredient over time. They could potentially come in forms such as once-daily gels, films and tablets, as well as monthly vaginal rings that would provide longer term protection against HIV. Microbicides potentially could attack the virus at multiple points during its life cycle, from the moment the virus enters the vagina during intercourse.

Microbicide development has entered a new and promising chapter. Decades of research into microbicides have resulted in <u>proof-of-concept</u> that ARV-based microbicides can offer women protection against HIV infection and potentially save millions of lives. In July 2010, the results announced from CAPRISA 004, a Phase IIb efficacy trial, showed that a vaginal microbicide gel containing the ARV 1% tenofovir used around the time of sex could offer protection against HIV. Confirmatory/complementary trials are being planned for 2011. Regulatory approvals could possibly begin in 2014 if the results of these trials support product licensure.

Microbicides would be a vital part of a comprehensive HIV prevention strategy. Microbicides would complement other prevention methods such as behavior change, abstinence, male and female condoms, and male circumcision. They would also expand the toolkit for other future drug-based prevention approaches, including oral or injected products (also known as "PrEP" or pre-exposure prophylaxis), and HIV vaccines.

Capturing the promise of microbicides requires continued support. In 2009, total global investment in microbicide research decreased by 3 percent, representing the first year-to-year decline since 2000.^v Funding levels for microbicide research — \$236 million in 2009 — are well below the annual \$300 million amount recommended by experts to ensure an optimal research effort. As a result, promising microbicide research avenues are at risk of moving at a much slower pace than is warranted by the seriousness of the epidemic. Lessons learned through years of scientific inquiry have brought the world in 2011 to a milestone in HIV/AIDS research: proof that a topical microbicide can prevent heterosexual transmission of HIV. Continued, even stronger support will be required to capitalize on the promise of safe and effective microbicides to empower women to protect themselves from HIV/AIDS.

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UNAIDS/WHO, "Report on the Global AIDS Epidemic," 2010

WHO, "The Global Burden of Disease, 2004 Update," 2008

^{iv} Ibid.

^v Advancing the Science in a Time of Fiscal Constraint: Funding for HIV Prevention Technologies in 2009, HIV Vaccines and Microbicides Resource Tracking Working Group, 2010

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[&]quot; UNAIDS/WHO, "Report on the Global AIDS Epidemic," 2010