



INTERNATIONAL
PARTNERSHIP FOR
MICROBICIDES

HIV/AIDS AND THE MILLENNIUM DEVELOPMENT GOALS:

MICROBICIDES *and* THE NEED FOR LONG-TERM PREVENTION



IPM MISSION: To prevent HIV transmission by supporting the development and availability of safe and effective microbicides for use by women in developing countries.

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Introduction

The HIV/AIDS epidemic remains a global health challenge of unprecedented dimensions and a monumental threat to development progress.¹ To date, more than 25 million people worldwide have died from HIV-related complications. The number of people living with HIV worldwide continues to grow and reached an estimated 33.4 million in 2008.²

The spread of the epidemic continues to outpace the world's response to it, even with a 10-fold increase in antiretroviral (ARV) treatment made available in low- and middle-income countries from 2003–2008.³ For every two people placed on ARV therapy, five more individuals become infected with the virus.⁴

Sub-Saharan Africa continues to disproportionately bear the global HIV/AIDS burden. Two-thirds of all people newly infected with HIV live in that region, and 72 percent of all AIDS deaths in 2008 occurred there.⁵



HIV/AIDS has also become one of the greatest threats to women's health. HIV/AIDS is the leading cause of death globally in women ages 15–44, and exacts a particularly high toll in sub-Saharan Africa where the epidemic has hit hardest, according to the latest comprehensive data from the World Health Organization. Women account for 60 percent of those living with the disease in sub-Saharan Africa.⁶

These harsh realities threaten progress toward the UN Millennium Development Goals (MDGs), which 189 United Nations member states adopted in 2000 with the objective of meeting them by 2015. The eight goals create a universal framework for development that envisions a better future for all people.

MDGs: Progress, Challenge and the Hope of Microbicides

Despite the challenges, the world is committed to fulfilling the MDG promises. The MDGs represent commitments from both developed and developing countries, and define progress through quantifiable development targets. Nations acknowledge the overriding importance of strengthening the response to HIV/AIDS in Goal 6, which aims to halt and begin to reverse the HIV pandemic by 2015. This was reinforced during the first Special Session on HIV/AIDS of the United Nations General Assembly (UNGASS) in 2001, where member nations endorsed the Declaration of Commitment on HIV/AIDS. The Declaration acknowledged that gender equality and women's empowerment could reduce women's and girls' vulnerability to HIV.

In 2008, UNAIDS noted that although some countries are on course to meet the targets outlined in the Declaration of Commitment, others are not.⁷ The reasons for slow progress are complex and often linked, though HIV/AIDS is a significant factor.⁸ These or similar targets will continue to guide development efforts well beyond 2015.

Achieving the MDG goals will require that key stakeholders:

- ▶ build political will and leadership
- ▶ improve public policies
- ▶ intensify and scale up programs that work
- ▶ invest in the development of new global public health strategies such as effective prevention technologies

One such promising prevention technology is ARV-based microbicides — medical products being developed to prevent HIV transmission to women during sex with an infected male partner. These HIV prevention products contain the same types of ARV drugs currently being used to successfully treat HIV/AIDS.

Clinical trial results announced in July 2010 offer great reason for optimism. The trial, called CAPRISA 004, showed “proof-of-concept” that an ARV-based microbicide vaginal gel can prevent HIV infection in women. Such ARV-based microbicides are currently in clinical development by the International Partnership for Microbicides (IPM) and other nonprofit organizations. Because they are user-initiated, microbicides could put the power of prevention into women’s hands.

During the 2010 UN review of the MDGs, member states revived efforts to achieve the goals within the next five years and announced major new commitments for women’s and children’s health. Their global action plan promised to accelerate progress to achieve MDG 6 (combating HIV/AIDS, malaria and other diseases) through significantly intensifying HIV prevention efforts, and advance research and development into new prevention tools, including microbicides.⁹

Millennium Development Goals

Goal 1: Eradicate extreme poverty and hunger

Goal 2: Achieve universal primary education

Goal 3: Promote gender equality and empower women

Goal 4: Reduce child mortality

Goal 5: Improve maternal health

Goal 6: Combat HIV/AIDS, malaria and other diseases

Goal 7: Ensure environmental sustainability

Goal 8: Develop a global partnership for development

At the review Summit, IPM pledged to support the Global Strategy on Women’s and Children’s Health by continuing to progress microbicide research and product delivery, and to provide women worldwide with new tools to safeguard their health — and their families’. Inspired by women’s urgent need for new prevention tools and supported by landmark data from the CAPRISA trial showing proof-of-concept for ARV-based microbicides, IPM is committed to turning this hope into a scientific reality.

Ensuring that new HIV prevention technologies such as microbicides are accessible to those who need them most requires coordination from all levels of the international community. To help guarantee success, Goal 8 calls for creating a global partnership for development. This goal is particularly relevant for making certain that, once available, female-initiated microbicides could quickly be approved for use and distributed to those women most in need.

Feminization of HIV

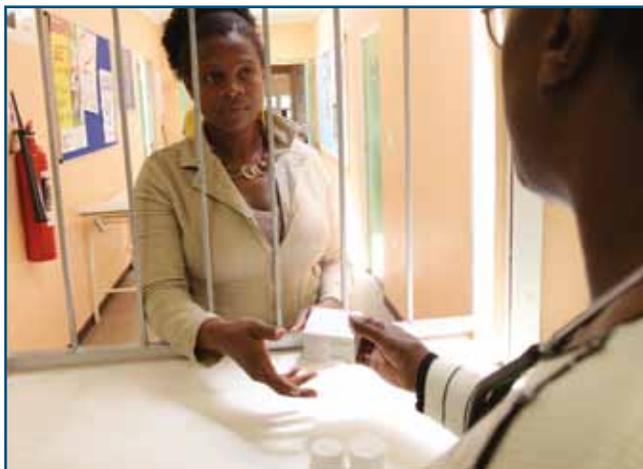
Although the epidemic varies from country to country in sub-Saharan Africa, women are disproportionately affected compared with men — a disparity far greater among young women and men. In some countries, HIV prevalence is three times higher among women ages 15 to 24 than it is among men of the same age.¹⁰ As noted in the Report of the Secretary-General on the Declaration of Commitment

on HIV/AIDS and Political Declaration on HIV/AIDS in 2008: Gender inequities fuel the continued spread of HIV, reducing women's ability to protect themselves from sexual transmission, increasing their vulnerability to sexual violence and placing them in circumstances where their risk of acquiring HIV is greater.¹¹

Heterosexual intercourse remains the primary method of HIV transmission in sub-Saharan Africa.¹² Power imbalances between men and women as well as gender stereotypes contribute to the "feminization" of the HIV epidemic.¹³ If women want to use condoms or abstain from sex, they often lack the ability to do so.¹⁴ These complex social issues are further complicated by women's greater biological vulnerability to the virus. For these reasons, HIV prevention strategies must be targeted to women. Combination prevention approaches based on sound evidence that include system changes, behavioral approaches and medical strategies — such as microbicides — are necessary to end the feminization of the disease.

HIV Prevention for Women: Impact on the MDGs

Reducing HIV infection in women and girls is critical to Goal 1, breaking the cycle of poverty and hunger. Rural women in particular are responsible for producing half of the world's food — in most developing countries, women



"Successful prevention means continuing to invest in prevention research and development — particularly for microbicides, vaccines and pre-exposure prophylaxis — as we continue to work towards a cure. It means forging a prevention movement."

Michel Sidibé, UNAIDS Director
2009 UNAIDS Programme Coordinating Board Meeting
Geneva

produce between 60 percent and 80 percent of food.¹⁵ Production suffers when women fall ill from HIV-related complications or must look after sick family members. In the hardest hit countries, women and girls continue to bear the burden of caring for people living with HIV.¹⁶ These female caregivers have little time to earn income, produce food, go to school or support their families.

Along with their families, these caregivers are more likely to be malnourished, in poor health or economically destitute — all factors that further increase their risk for HIV infection.

Keeping girls in school

Reducing the spread of HIV is therefore critical to keeping girls in school and achieving Goal 2, establishing universal primary education. HIV-related death and illness cause shortages in teaching staff. The illness of a parent or family member often means that girls are withdrawn from school to care for that parent and younger siblings. When a parent dies, girls are also more likely than boys to leave school to take over agricultural and income support roles that will sustain their families.¹⁷

Enhancing gender equality

Goals 3 and 5 both seek to enhance gender equality and women's health. HIV rates among women have been linked to women's political, social and economic

disempowerment, and evidence shows that sexual and reproductive health and rights are central to a woman's ability to build on her capabilities and control her future.¹⁸

Improving maternal health

Maternal health and the HIV/AIDS epidemic intersect all too often, especially in high-burden countries such as South Africa and Zimbabwe, where HIV is the leading cause of maternal mortality.¹⁹

Efforts to improve maternal health and meet Goal 5 are moving ahead, but the HIV epidemic has had an adverse effect on efforts to reduce maternal mortality rates. Pregnant, HIV-positive women may actually see the progression of the disease worsen during their pregnancies.²⁰ HIV is a leading indirect cause of maternal mortality in regions with high incidence of HIV/AIDS.²¹ In fact, without HIV there would have been 60,000 fewer maternal deaths in 2008.²²

Reducing childhood mortality

Reducing HIV infection rates in women will reduce the number of children born with HIV and help achieve Goal 4 by reducing child mortality. Globally, AIDS is responsible for about 3 percent of child deaths.²³ Although new infections in children are declining, an estimated 90 percent of children living with HIV acquired the virus during birth or breastfeeding, or when their mothers were pregnant.²⁴ Women who can protect themselves against HIV infection can preserve their families, which will reduce the number of orphaned children.

Current Methods Fail to Meet Women's Needs

Although a range of prevention strategies exists, current methods have not significantly lowered the rate of new infections — particularly among women.

Women's vulnerability to HIV directly affects progress towards Goals 1, 2 and 4:

Goal 1: Eradicate extreme poverty and hunger

Goal 2: Achieve universal primary education

Goal 4: Reduce child mortality

Three of the eight MDGs are directly related to the health and rights of women:

Goal 3: Promote gender equality and empower women

Goal 5: Improve maternal health

Goal 6: Combat HIV/AIDS, malaria and other diseases

When women and girls have little control over the conditions under which sexual intercourse takes place, prevention approaches such as using condoms, behavior change and mutual monogamy are unrealistic. The efficacy of male circumcision in reducing female-to-male HIV transmission has been proven, but it does not provide complete protection.²⁵ Nor is it known whether male circumcision reduces HIV transmission from men to women. An HIV/AIDS vaccine, and oral prevention pills or injections (also known as "PrEP" or pre-exposure prophylaxis) have the potential to provide additional prevention options in the future, and are in development.

There is an urgent need for female-initiated HIV prevention strategies, such as microbicides, that do not interfere with intimate relations and are not necessarily contraceptive.

The Potential of Safe and Effective Microbicides

Vaginal microbicides would complement existing prevention methods and others being developed, and would serve as a prevention tool for women who are unable to access or use other methods. Most important, these products would address one of the central gaps

in the existing continuum of HIV prevention options by offering a discreet method that women could use to protect themselves.

The first microbicides to be studied were compounds that did not specifically target HIV. Several of these early-generation products were tested in large-scale efficacy trials, typically in the form of vaginal gels, but none were shown to be effective tools for HIV prevention.

In the last few years, researchers have made progress in developing a new class of microbicides based on the same types of antiretroviral compounds being used successfully to treat millions of people who are already infected with the virus and to prevent mother-to-child transmission of HIV. As noted earlier, the recent findings from CAPRISA study, the first clinical trial of an ARV-based

The global HIV epidemic cannot be reversed without effective and tailored HIV prevention strategies.

microbicide, demonstrated proof-of-concept that an ARV-based vaginal gel can offer women protection against HIV.

These highly potent next-generation products specifically target HIV from the moment the virus enters the vagina during intercourse. ARV-based microbicides are being developed to work in a variety of ways by either preventing the HIV virus from attaching to or entering a healthy human cell, or by preventing the virus from making copies of itself once it is inside a cell. Tenofovir gel, the ARV-based microbicide tested in the CAPRISA trial, prevents HIV from copying its genetic material inside healthy cells.

ARV-based microbicides would come in a variety of formulations that could be used around the time of sex or longer-acting products that would be used independent

“Women in their productive years bear the brunt of HIV more than any other group in the population but the methods we have so far – condoms, male circumcision – only work if the man is prepared to accept them. Young women with [microbicides] will be able to take their health into their own hands.”

Aaron Motsoaledi, SA Minister of Health
AIDS Map, July 20, 2010

of the time of sexual activity, such as once-daily vaginal gels, films, tablets and vaginal rings that would provide a month’s protection from HIV.

Researchers are testing single and combination products, and conducting acceptability studies in several countries to help determine the types of products women and their partners would really want and use. Developing microbicides in a variety of forms would help ensure their wide acceptability and use.

Investment in Microbicides and Women Who Need Them

If a second, multi-center clinical trial confirms the CAPRISA trial’s findings for tenofovir and the global community adequately funds microbicide research, the first microbicide product might be registered as early as 2013.

In 2009, total global investment in microbicide research was US \$236 million, which is a 3 percent decrease since 2008 and the first year-to-year decline since 2000.²⁶

A number of pharmaceutical companies have contributed to microbicide development by granting royalty-free licenses to use their ARV compounds for research. Since its inception in 2002, IPM has obtained non-exclusive, royalty-free licenses from five pharmaceutical companies to develop a number of ARV-based compounds as microbicides: Bristol-Myers Squibb, Gilead Sciences, Merck, Pfizer and Tibotec Pharmaceuticals.

These partnerships and licensing agreements ensure that when IPM develops an effective microbicide, it will be accessible to women in developing countries at low or no cost. IPM's other partners include host country governments, universities, scientific communities that assist in research, global health leaders whose support furthers research and donors who continue to support microbicide research and development. IPM also partners with a variety of nongovernmental organizations in Africa and elsewhere, working together on a variety of issues related to women's health and rights, and HIV prevention.



Long-term Prevention: A Call to Action

The response to HIV has focused on addressing its devastating impact on people. Indeed, HIV is a humanitarian issue.

The epidemic also has fundamentally affected many countries' development performance, which makes it difficult for many resource-poor countries to reach MDG targets before 2015 or even in the more distant future.

The global HIV epidemic cannot be reversed without effective and tailored HIV prevention strategies. It is reassuring that global leaders recognize the need to support comprehensive prevention strategies that can protect a wide range of populations from HIV infection and the urgent need for a HIV prevention tool that women can use to protect their own health, especially given women's greater vulnerability to HIV infection.

The results of the CAPRISA 004 clinical trial are very encouraging and also indicate the potential and the need for products with even higher efficacy. Increased investment in a wide range of new prevention technologies, including ARV-based microbicide products, is needed to stem the spread of the HIV/AIDS epidemic.

IPM is a nonprofit product development partnership (PDP) that brings together private sector technologies and public sector resources to fulfill its mission to develop microbicides for women in urgent need of HIV prevention options.

PDPs work closely with researchers in developing countries to create affordable medical products for use there, and help to build these countries' capacities and infrastructure. PDPs received high marks for their impact on improving public health in developing countries, as noted in the World Health Organization 2010 Expert Working Group Report on Research and Development Financing and Coordination.²⁷

The PDP model is built on successful partnerships with a variety of public and private actors:

- ▶ public and private donors
- ▶ pharmaceutical companies
- ▶ scientific research organizations
- ▶ global policymakers and multilateral organizations
- ▶ nongovernmental organizations

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