Microbicides: New HIV Protection for Women
Global Diseases: Voices from the Vanguard

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Increasingly female, young

- In Sub-Saharan Africa, 74% of young adults (aged 15-24 years) living with HIV are female
- In South Africa: 1 in 4 women infected by age 22
- HIV infections also on the rise in women and girls in Eastern Europe, Asia, Latin America and the Caribbean

Married, monogamous

- In India: 22% of cases in housewives with single partner

Mothers

- In Swaziland: 56% of pregnant women from ages 25 to 29 are HIV positive – highest prevalence in 5 years
Women’s susceptibility to HIV infection results from a combination of biological, economic and socio-cultural factors:

- Male-to-female transmission higher
- Young women at even higher risk
- Financial dependence on male partners
- Inequality of women (exploitation and violence)
- Cultural practices such as early marriages, intergenerational sex and marital infidelity
Marriage and women’s own fidelity not enough to protect them against HIV infection

Many women infected despite staying faithful to one partner – 66% of women surveyed in Zimbabwe and South Africa reported one lifetime partner and 40% were HIV positive

UN report 2006: 56% of pregnant women between 25 and 29 in Swaziland HIV positive – the highest prevalence in five years
The Need for Women-Initiated HIV Prevention

- Most HIV infections are spread by unprotected sex
- Current methods are male-initiated and contraceptive
- Women have no means to protect themselves if their partners do not use male condoms or allow female condoms to be used
- Abstinence and being faithful are not likely to protect married women or those who are sexually abused
What is a Microbicide?

- Vaginally applied substance that prevents or reduces transmission of HIV

- Could potentially be delivered in many forms:
  - gel or cream
  - sponge
  - film, tablet
  - suppository
  - diaphragm
  - intravaginal ring

- Ideally, safe, effective, low cost and user-friendly
Microbicides: A Human Rights Issue for Women

- Microbicides would provide women with a prevention tool consistent with their right to self-protection and personal autonomy.

- Over time, microbicides could be developed with both contraceptive and non-contraceptive properties.
We want to call on everyone … to help speed up what we hope will be the next big breakthrough on the fight against AIDS - the discovery of a microbicide or an oral prevention drug ... – Bill Gates

We believe the most promising breakthrough that could be available soon is an effective microbicide or oral prevention drug – Melinda Gates

The growing excitement around a microbicide is entirely warranted. This is a preventive technology whose time has come... it would appear that where preventive technologies are concerned, the microbicide is first in line – Stephen Lewis

Our foundation is now partnering with the International Partnership for Microbicides to help accelerate their work by guaranteeing proper care and treatment for all the participants in the test trials – Bill Clinton

We are so close (to a microbicide) at this point that the question everybody is asking is no longer if, but when ... and the moment can't come too soon – Sen. Barack Obama
Microbicides would offer a woman-initiated method to reduce HIV transmission.

### Comprehensive Approaches to HIV/AIDS

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Drug Development Process

- Basic research
- Discovery
- Pre-clinical
- Clinical trials
- Launch & access
Realistic Expectations

- First generation of microbicides may be ineffective
- Microbicide development path similar to that of AIDS therapeutics
- IPM hopes to condense the development process and expedite access

- 1981: First AIDS case reported in the US
- 1983: HIV virus identified
- 1987: AZT mono-therapy approved for use
- 1995: Two-drug therapy becomes available
- 1997: Three-drug therapy: HAART
- 1997: Brazil offers free universal access to treatment
- 2002: Global Fund established
- 2003: Drug combinations/reducing pill burden
- 2006: "3 by 5" initiative
- 2006: 26 FDA-approved drugs and research continues
IPM is a non-profit product development partnership (PDP) established in 2002 whose mission is to prevent HIV transmission by accelerating the development and availability of safe and effective microbicides for use by women in developing countries.

**Donors:**

World Bank, Belgium, Canada, Denmark, France, Germany, Ireland, Norway, Netherlands, Sweden, United Kingdom, United States, European Commission, Rockefeller Foundation, Gates Foundation
Opportunities For Action

1. Assess and fund across the microbicide portfolio

2. Help develop the “next generation” of microbicides

3. Provide common capabilities or supports for the field

4. Optimize clinical trial capacity

Basic research → Discovery → Pre-clinical → Clinical trials → Launch & Access

- Multiple mechanisms/targets/products
- Formulation capacity
  - In vitro and in vivo models
  - Regulatory
  - Manufacturing
IPM’s basic strategy involves licensing of active compounds from commercial pharmaceutical companies for development as microbicides.

Announced Licenses:
- Johnson & Johnson (Tibotec)
- Merck
- Bristol Myers-Squibb
- Gilead
Current License Structure

1. IPM is the non-exclusive developer

2. IPM receives a license that is:
   - Royalty Free
   - For Distribution on an Affordable Basis
   - In Resource Poor Countries
Delivery: GMP Manufacture of Semi-Solid Formulations

IPM CTS Facility

Applicator Filling Line
Site Development

- At least 10 sites needed for pivotal phase III trials
- Identify promising new sites (dependent on incidence)
- Build research capacity
- Establish links for community-based HIV/AIDS care and support services
- Conduct site preparedness studies
- Community participation and advisory process
IPM Approach to Site Development

Non SA:
8 countries
11 sites

SA:
12 sites